

SUPPORTING STATEMENT

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

OMB NO. 0581-NEW

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 interim final rule includes definitions that can be used by retailers and their suppliers and understood by other market participants. The interim 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. This is a new collection.

- 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 interim 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 interim final rule provides flexibility in allowing market participants to decide how best to implement mandatory COOL in their operations. Market participants other than those retailers defined by the statute may decide to sell products through marketing channels not subject to the interim final rule. Taking into account comments received on the proposed rule, the interim final rule decreases the length of time that records are required to be kept, providing some relief to affected entities both large and small. In addition, the number of products required to be labeled is reduced because the definition of a processed food item has been broadened, thus providing additional regulatory relief.

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 interim 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 interim 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**

- 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 proposed rule was published in the October 30, 2003, Federal Register (68 FR 61944) with a 60-day comment period. On December 22, 2003, AMS published a notice extending the comment period (68 FR 71039) an additional 60 days. The comments received that pertained to recordkeeping were addressed in the interim final rule for fish and shellfish that was published in the October 5, 2004, Federal Register. (69 FR 59708). On June 20, 2007, AMS reopened the comment period for the proposed rule for all covered commodities (72 FR 33917). A summary of the comments received and the Agency responses are included below. In addition, this rule is being issued as an interim final rule 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, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts; Reopening of the Comment Period)

Summary of Comments and Responses

General

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

Agency Response: The Agency agrees that records kept in the normal course of business

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

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

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

Location of Records

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

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

Recordkeeping Retention

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

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

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

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

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

- **DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE**

**OF AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY
OR DATA, FREQUENCY OF COLLECTION, THE CLARITY OF
ELEMENTS TO INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE,
REPORTING FORMAT (IF ANY), AND ON THE DATA
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.
THERE MAY BE CIRCUMSTANCES THAT MAY
PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE
CIRCUMSTANCES SHOULD BE 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.

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**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 DO 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 1,255,591 establishments owned by approximately 1,221,740 firms are

estimated to be either directly or indirectly affected by this rule. As previously discussed in previous sections of this document, several changes have been made in this interim final rule compared to the October 30, 2003, proposed rule. These changes are a result of changes made by the Agency in an effort to reduce the burden on regulated entities as well as changes made by the 2008 Farm Bill.

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

Table 9.--Costs Associated with Paperwork Burden

Type	Firms	Initial Costs	Establishments	Maintenance Costs	Total Costs
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
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
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	1,197,026	93,281,849	1,197,156	171,119,224	264,401,073
Handlers, Processors, & Wholesalers	20,674	27,062,266	22,043	80,319,108	107,381,374
Retailers	4,040	5,288,360	36,392	247,264,534	252,552,894
Grand Total	1,221,740	125,632,475	1,255,591	498,702,866	624,335,341

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

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

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

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

Initial Recordkeeping Costs

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

Producers will need an estimated 4 hours to modify an established system for organizing records to carry out the purposes of this regulation. This additional time would be required to modify existing recordkeeping systems to incorporate any added information needed to substantiate country of origin claims. Although not all farm products ultimately will be sold at retail establishments covered by this rule, it is assumed that virtually all producers will wish to keep their marketing options as flexible as possible. Thus, all producers of covered commodities or livestock (in the case of the covered meat commodities) will modify recordkeeping systems sufficient to substantiate country of origin claims. It is also recognized that some operations will require substantially more than 4 hours modifying their recordkeeping systems. In particular, it is believed that livestock backgrounders, stockers, and feeders will face a greater burden in modifying recordkeeping systems. These types of operations will need to track country of origin information for animals brought into the operation as well as for animals sold from the operation

via records used in the normal course of business, increasing the burden of substantiating country of origin claims. Conversely, operations such as fruit and vegetable farms that produce only United States products likely will require little if any change to their existing recordkeeping systems in order to substantiate country of origin claims. Overall, it is believed that 4 hours represents a reasonable estimate of the average additional time that will be required per year across all types of producers.

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

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

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

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

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

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

Storing 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 claims is expected to be relatively small.

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

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

It is assumed that farm labor will primarily be responsible for maintaining country of origin information at producers' enterprises. NASS data (Ref. 18) are used to estimate average farm wage rates--\$9.80 per hour for livestock workers and \$9.31 per hour for other crops workers. Applying the rate of 27.5 percent to account for benefits results in an hourly rate of

\$12.50 for livestock workers and \$11.87 for other crops workers. Assuming 12 hours of labor per year for livestock operations and 4 hours per year for all other operations, the estimated total annual maintenance costs to producers is \$171 million, which is higher than the initial maintenance costs in the proposed rule. The increase in the estimated maintenance cost is due to the higher estimated wage rates and benefits and the increase in the number of producers due to the inclusion of chickens, goats, ginseng, macadamia nuts, and pecans as covered commodities.

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

With the exception of livestock processing and slaughtering establishments, the maintenance burden hours for country of origin recordkeeping is estimated to be 52 hours per year per establishment. For this part of the supply chain, the recordkeeping activities are ongoing and are estimated to require an additional hour a week. It is expected, however, that livestock processing and slaughtering enterprises will experience a more intensive recordkeeping burden. These enterprises disassemble carcasses into many individual cuts, which must maintain their country of origin identity. In addition, businesses that produce ground beef, lamb, and pork may commingle product from multiple origins, which will require some monitoring and recordkeeping to ensure accurate labeling and to substantiate the country of origin information provided to retailers. Maintenance of the recordkeeping system at these establishments is estimated to total 1,040 hours per establishment, or 20 hours per week.

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

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

The total maintenance recordkeeping costs for all enterprises are thus estimated at

approximately \$499 million. The increase in the total maintenance cost over the initial maintenance cost estimate in the proposed rule is due to the higher wage rates and benefits which were updated with more recent information and the addition of more covered commodities.

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

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 PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE 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
CONTAINING THE INFORMATION COLLECTION, AS**

**RULEMAKING
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 PCUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-I.

This is a new information collection.

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.