**2016 SUPPORTING STATEMENT**

**Mandatory Country of Origin Labeling of Venison under the Authority of the**

**Agricultural Marketing Act of 1946**

**OMB NO. 0581-NEW**

**(Proposed Rule)**

This information collection (0581-NEW) will be merged into the currently approved OMB 0581-0250 once the new information request has been approved.

**A. Justification**

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

The 2014 Farm Bill (P.L. 113-79) amended the Agricultural Marketing Act of 1946 to add venison and ground venison meat to the list of covered commodities for mandatory country of origin labeling. Retailers are required to notify their customers of the country of origin of covered commodities. Suppliers of venison covered commodities to retailers, whether directly or indirectly, are required to convey origin information to subsequent recipients. In addition, suppliers must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of one year from the date of the transaction. Retailers must maintain country of origin information for a period of one year from the date the origin declaration is made at retail.

This is a new information collection requirement for suppliers and retailers of venison meat. The information collection and recordkeeping requirements that are imposed by the COOL regulations (7 CFR part 60 and part 65) for all existing covered commodities have been approved previously under OMB control number 0581-0250 Mandatory Country of Origin Labeling of Covered Commodities (COOL). The most recently approved information collection for COOL was published in the Federal Register (81 FR 10827) on March 2, 2016.

 **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.**

Individuals who supply covered commodities, whether directly to retailers or indirectly through other participants in the marketing chain, are required to establish and maintain country of origin and, if applicable, method of production information for the covered commodities and supply this information to retailers. As a result producers, handlers, manufacturers, wholesalers, importers, and retailers of covered commodities are affected. This public reporting burden is necessary to ensure conveyance and accuracy of country of origin and method of production declarations relied upon at the retail point of sale. The public reporting burden also assures that all parties involved in supplying covered commodities to retail stores maintain and convey accurate information as required.

**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. This collection 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. In addition, the law prohibits the Secretary from requiring the creation of new records.

 **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 information requested from regulated firms to comply with the requirements of the COOL regulation cannot be found by any other means than reporting by individual firms. The information is not requested of these firms by another source.

**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 Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (domestic manufacturers and importers) as those having annual receipts of no more than $7 million.  Under these definitions, all venison producers and the majority of manufacturers and importers that would be affected are considered small entities.  We have estimated that the number of respondents for this collection is 3,856 and we estimated that 2,892 (75%) are small businesses.

Information collection requirements have been reduced to the minimum requirements authorized by the statute and regulation.  The primary sources of information used to complete the required forms are readily available from normal business records maintained by manufacturers and importers.  Such information can be supplied without data processing equipment or outside technical expertise. Thus, the information collection and reporting burden is relatively small, and requires the same reporting elements for all manufacturers and importers. Reporting requirements do not significantly disadvantage any producer, processor, wholesaler, importer, or retailer that is smaller than the corresponding industry average.

**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, and for fish and shellfish covered commodities, method of production 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.

In addition, the 2008 Farm Bill contained a number of amendments to COOL provisions, which further reduces 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**.

As required by 5 CFR 1320.8(d) a 60-day notice for comments was embedded in the proposed rule published in the Federal Register on January 13, 2017, Vol. 82, No. 9, page 4198.

 **- 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, OR 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. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.**

The Agency is in continual contact with the following companies to gain better understanding of how retailers, suppliers, and producers handle and feel about the record requirements.

Food Marketing Institute

2345 Crystal Drive, #800

Arlington, Virginia 22202

(703) 524-8880

National Grocers Association

1005 North Glebe Road, #250

Arlington, Virginia, 22201

(703) 516-0700

North American Deer Farmers Association

4501 Hills & Dales Road NW

Suite C

Canton, OH 44708

(303) 454-3944

**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 OF 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 ITEM 13 OF OMB FORM 83-I.**

This NEW submission reflects 3,856 total record keepers for 1,874 burden hours. 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.**

In general, the supply chain for venison covered commodities includes venison producers, processors and slaughterhouses, 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 annualized cost to affected parties for the paperwork burden incurred by the number and types of firms are listed in Table 1, which follows.

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| Table 1. Estimated Annual Costs Associated with Paperwork Burden |
| *Initial & Set-Up Costs* | ***Firms*** | ***Initial Costs*** | ***Sources*** |
| Venison Producers | 3,144 | $24,287 | NASS 2012 Census of Agriculture; BLS National Compensation Survey, May 2015. Wage rates for bookkeepers, accounting, and auditing clerks. |
| Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering) | 0 | 0 | 2012 Economic Census. |
| Livestock Processing & Slaughtering (non-amenable species) | 577 | $25, 965 | FSIS 2016 Public Health Information System; FDA Label Cost Model. |
| Retailers | 135 | $ 6,075 | AMS PACA Database; FDA Label Cost Model. |
| Total Initial & Set-Up Costs | **3,856** | **$56,327** |  |
|  |  |  |  |
| *Storing & Maintenance Costs* | ***Firms*** | ***Maintenance Costs*** | ***Sources*** |
| Venison Producers | 3,144 | $ 8,063 | NASS 2012 Census of Agriculture; BLS National Compensation Survey, May 2015. Wage rates for bookkeepers, accounting, and auditing clerks. |
| Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering) | 0 | 0 | 2012 Economic Census. |
| Livestock Processing & Slaughtering (non-amenable species) | 577 | $ 1,108 | FSIS 2016 Public Health Information System; BLS National Compensation Survey, May 2015. Wage rate for administrative support occupations. |
| Retailers | 135 | $ 1,562 | AMS PACA Database; BLS National Compensation Survey, May 2015. Wage rate for administrative support occupations. |
| Total Annual Storing & Maintenance Costs | **3,856** | **$10,734** |  |

The affected firms will broadly incur two types of costs. First, newly established firms will incur initial or start-up costs to comply with the rule establishing a record keeping system. Initial costs will be borne by each firm, even though a single firm may operate more than one establishment. Second, firms 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. There are approximately 3,856 firms that may be involved in the marketing chain for venison meat and which would need to establish a record collection system for country of origin information. Since the information collection requirement for the COOL regulations was part of the initial rule, established firms should not have any additional costs associated with establishing a record keeping system.

*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, venison producers do not typically record or pass along country of origin information to subsequent purchasers. Therefore, venison producers 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 venison ranching operations, it is estimated that the incremental costs for producers to supplement existing records with country of origin 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.

Venison producers may use a (generic) affidavit to proclaim where the animals they produce are born and raised. Two factors drive the additional cost to venison producers: the time to create the affidavit and the time to administer and use the affidavit. The Agency estimates it will take each venison producer one half hour to create and sign the initial affidavit used to substantiate country of origin claims and carry out the purposes of this regulation. Venison producers may rely on documents and recordkeeping systems they have previously established for organizing animal records. Not all venison produced ultimately will be sold at retail establishments covered by this rule. According to NASS, in 2012, there were 269,000 deer and elk on 5,241 ranches. Research conducted by Texas A&M University in 2007 revealed that 32% of the ranches are breeding and hunting operations, and 7% of the ranches are hunting-only operations. Relying on the NASS and Texas A&M data, the Agency assumes that 60% of the ranches, or 3,144 producers, raise animals for meat consumption and have established recordkeeping systems sufficient to substantiate country of origin claims.

In estimating initial recordkeeping costs, May 2015 wage rates and benefits published by the Bureau of Labor statistics from the National Compensation Survey are used. For venison producers, it is assumed that the added work needed to generate an affidavit from an existing recordkeeping system for country of origin is primarily a bookkeeping task. This task may be performed by an independent bookkeeper, 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. It is assumed that this wage rate represents the cost for venison producers to hire an independent bookkeeper. In the case of venison 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 2015 wage rate is estimated at $23.23 per hour. For this analysis, an additional 33 percent is added to the wage rate to account for total benefits which includes social security, unemployment insurance, workers compensation, etc. BLS publishes the data used to estimate the additional cost to employers. Initial recordkeeping costs to venison producers are estimated at fifteen minutes (one quarter hour) per firm multiplied by 3,144 producers at a cost of $30.90 per hour, resulting in approximately $24,287 to generate affidavits to substantiate country of origin claims.

The recordkeeping burden on handlers, processors, wholesalers, and retailers is expected to comprise maintaining country of origin information on the venison purchased and subsequently furnishing 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 venison products from purchase to sale. It is believed that most of these operations already maintain necessary records for country of origin verification in their existing systems because they already purchase and sell other COOL covered commodities. Thus, it is assumed that country of origin information for venison 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 is used to estimate the cost of including additional country of origin information to an operation’s records. Virtually all intermediary and retail firms are assumed to already have a recordkeeping system in place for other COOL covered commodities. It is estimated that 1 hour will be required to add venison to the design at a cost of $45 per firm. While the cost will be higher for some firms and lower for others, it is believed that $45 per hour represents a reasonable estimate of average cost for all firms. Based on this calculation, it is estimated that the initial recordkeeping costs for the 577 firms specializing in livestock processing and slaughtering of non-amenable species will be approximately $25,965. Intermediaries such handlers, processors, importers and wholesalers (except livestock processing and slaughtering) are considered to already have sufficient recordkeeping and documentation systems in place to convey COOL information for venison products. Thus, no set-up and maintenance recordkeeping burden is estimated for these entities. Using the same Labor Cost Model, initial recordkeeping costs for 135 retail firms will be approximately $6,075.

The total initial recordkeeping hours are 1,873. Total initial costs for all 3,856 firms affected by this new requirement are estimated to be $56,327.

*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. Again, the marginal cost for venison producers to maintain and store any additional information needed to substantiate country of origin claims is expected to be relatively small.

Cervidae producers already maintain birth and raising records on each animal. These records may include ear tagging, radio frequency identification devices, and other related means of identification on either an animal or a lot basis. These recordkeeping systems already established and maintained by venison producers are sufficient for country of origin information. The only added cost to comply with the requirements of this proposed rule would be to generate and sign a (generic) producer affidavit each year. The producer does not know at the time of birth whether the meat from any individual animal will be used for sale to restaurants, retail, or hunting and game. Accordingly, cervidae producers will need to sign an affidavit necessary for country of origin verification on all animals in the herd. The Agency estimates this proposed rule would affect 3,144 venison producers. Annual maintenance is estimated to take five minutes (0.083 hours) to sign producer affidavits per operation at a cost of $30.90 per hour for total annual costs of $8,063.

Intermediaries are generally assumed to have prior experience with COOL compliance and are expected to have lower costs needed to meet the requirements of this proposed rule than they did when COOL was first implemented. Wholesalers would incur recordkeeping costs, costs associated with supplying country of origin information to retailers, costs associated with segmenting products by country of origin, and additional handling costs. Given that venison is such a small percentage of proteins on the market, it is estimated that few intermediaries handle venison meat for sale to retail. Since the information collection requirement for the COOL regulations was part of the initial rule, established handlers, processors, importers, and wholesalers (except livestock processing & slaughtering) firms should not have any additional costs associated with maintaining a record keeping system. Those that do will likely experience per-pound costs similar to costs faced by beef and pork sector intermediaries, which were estimated at $0.015 per pound in the 2009 final rule (74 FR 2687). USDA’s Economic Research Service supermarket sales data from 2008 through 2012 reports 70,081 pounds of venison sol per year in supermarkets. Assuming that all 70,000 pounds sold at retail passed through an intermediary, total costs for intermediaries are estimated at $1,051 per year. There are 577 livestock processing and slaughtering facilities that handle non-amenable species, as defined by FSIS, which includes venison. 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 2015 BLS wage rate from the National Compensation Survey for administrative support occupations ($17.40 per hour with an additional 33 percent added to cover benefit costs for a total of $23.14 per hour). This occupation category includes stock and inventory clerks and record clerks. Annual maintenance for venison processing and slaughter facilities is estimated to take five minutes (0.083 hours) at a cost of $23.14 per hour, for a total annual cost of $1,108.

The number of retailers selling venison is a small subset of the COOL-regulated retailer population. Retailers choosing to carry venison products would accrue additional recordkeeping costs associated with supplying country of origin information to consumers as well as additional handling costs. There are 4,504 PACA-licensed retail firms subject to COOL. This analysis assumes that 3% of retailers, or 135 firms, will carry venison. The yearly storing and maintenance cost is estimated by using the May 2015 BLS wage rate from the National Compensation Survey for administrative support occupations ($17.40 per hour with an additional 33 percent added to cover benefit costs for a total of $23.14 per hour). Annual maintenance for 135 retail firms which would carry venison is estimated to take one-half (0.5) hour on average at a cost of $23.14 per hour for total annual maintenance costs of $1,562.

The total annual maintenance hours for all 3,856 firms are estimated to be 375. Total annual maintenance costs for all firms affected by this new requirement are estimated to be $10,734.

**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 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.**

The total initial start-up costs to establish country of origin recordkeeping systems for venison products by all firms are estimated at approximately $56,327. The annual maintenance costs of recordkeeping for all enterprises to verify country of origin information on venison products are estimated at approximately $10,734.

**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.**

AMS deployed 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 listed in Table 2 as follows:

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| Table 2. Total Annual Cost of Country of Origin Labeling Compliance and Enforcement |
| Retail Surveillance Reviews |  |
| 900/year x $600/Review | $ 540,000 |
| 2,000/year x $800/Follow-up ReviewsPrimarily paid to States | $1,600,000 |
| Administration-Salary and Benefits |  |
| 12 Staff Years x 108,000 | $1,300,000 |
| Miscellaneous Costs |  |
| Rent/utilities/phonesDept. assessments/travel                         Printing/equipment | $ 525,000 |
| *Total Cost to the Government* | ***$3,965,000*** |

The total annual cost to the Government to maintain this regulation is $3.965 million.

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

This is a new commodity subject to COOL requirements and a NEW information collection under the Paperwork Reduction Act.

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| Table 3. Summary Effects of Program Changes on Recordkeeping Burden Hours |
| Description | Record Keepers | Hours Per Record Keeper | Record Keeping Hours | Type |
| *Initial Set-Up Hours* |  |  |  |  |
| Venison Producers | 3,144 | 0.25 | 786 | New |
| Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering) | 0 | 0.0 | 0 | New |
| Livestock Processing & Slaughtering (non-amenable species only) | 577 | 1.0 | 577 | New |
| Retailers | 135 | 1.0 | 135 | New |
| Subtotal Initial Set-Up  | **3,856** |  | **1,498** | **New** |
|  |  |  |  |  |
| *Storing & Maintenance Hours* |  |  |  |  |
| Producers | 3,144 | 0.083 | 261 | New |
| Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering) | 0 | 0.00 | 0 | New |
| Livestock Processing & Slaughtering (non-amenable species only) | 577 | 0.08 | 46 | New |
| Retailers | 135 | 0.5 | 68 | New |
| Subtotal Storing & Maintenance | **3,856** |  | **376** | **New** |
|  |  |  |  |  |
| TOTAL RECORD KEEPING BURDEN | **7,712** |  | **1,874** | **New** |

**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.