SUPPORTING STATEMENT - OMB NO. 0579-xxxx

Traceability for Livestock Moving Interstate

August 2011

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act of 2002 (7 U.S.C. 8301–8317) is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the Animal and Plant Health Inspection Service's (APHIS) Veterinary Services' (VS) ability to compete in the world market of animal and animal product trade.

VS safeguards U.S. animal health through a variety of activities, including disease control. One important part of disease control is animal disease traceability. Animal disease traceability means being able to document the movement history of an animal throughout its life. Knowing where diseased and at-risk animals have been and are located, as well as when they have been there, is indispensable during an emergency response and important for ongoing disease programs. Epidemiologists use this information to determine the potential spread of a disease. Having the ability to plot locations within a radius of an infected premises helps determine the potential magnitude of a contagious disease and the resources needed to contain it.

Furthermore, as diseases are controlled or eradicated, it is important to document areas, States, or regions of the country that are free from disease. Traceability helps us determine those disease-free zones, thus enhancing the marketability of livestock.

APHIS has drafted a proposed rule establishing general traceability regulations for livestock moving interstate. Under this proposed rule, unless specifically exempted, livestock moved interstate would have to be officially identified and accompanied by an interstate certificate of veterinary inspection or other documentation. The proposed regulations specify approved forms of official identification for each species but would allow livestock to be moved between any two States or Tribes with another form of identification as agreed upon by animal health officials in the two jurisdictions. This rule will improve the ability of APHIS to trace livestock if disease is found. These proposed regulations would be added to the *Code of Federal Regulations* at a new 9 CFR part 90.

The new rule will place the greatest information collection burden on the cattle industry, because that sector has the greatest gaps in traceability and the greatest need for new traceability standards. The current regulations for the sheep and goat, swine, and poultry sectors provide

adequate traceability and the burden associated with those disease programs is contained in information collections related to those programs.

APHIS is asking OMB to approve, for 3 years, its use of this information collection activity to facilitate animal disease traceability and support these disease control, eradication, and surveillance activities.

2. Indicate how, by whom, how frequently, 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.

Application for Use of More Than One Official Identification (ID) Device

State animal health official, producer, market, accredited veterinarians, or research facilities may make an informal request to a State, Tribe, or Area Veterinarian in Charge (AVIC) for the purposes of using more than one official ID device. The use of multiple official ID devices or methods with multiple official ID numbers for a single animal could impede efforts to track the animal's movements. A State or Tribal animal health official or an AVIC could approve an application of a second official ID device by a State animal health official, producer, market, accredited veterinarians, or research facility in specific cases when the need to maintain the identity of an animal is intensified. Such needs could arise where an animal is exported to a country that requires multiple forms of ID, or for research field trials (including field trials conducted by nonprofit entities) where the loss of identification would hurt the outcome of the study. Approval would not be given simply for the convenience of individuals testing livestock or certifying them for interstate movement. The approval process is not formal and would be determined at the local level. All 50 States and the territories of Puerto Rico and the Virgin Islands may have a few instances each year that would require permission to apply multiple ID devices. There are no Tribes that currently issue their own eartags, but there may be a few in the future.

Application for and Approval of an Approved Tagging Site

An approved tagging site is a premises, such as a livestock market or other private sale venue, authorized by APHIS, State, or Tribal animal health officials, where livestock may be officially identified on behalf of their owner or the person in possession, care, or control of the animals when they are brought to the premises. Such sites would give producers a safe and convenient alternative, not provided for in the existing regulations, to identifying their animals themselves. The new regulation at 9 CFR 90.4(b)(1)(i)(C) will allow producers to use this alternative when they cannot tag animals at their farm or ranch. For livestock auction markets, tagging site approval will be incorporated into the process for approving livestock facilities outlined at 9 CFR 71.20. Businesses that do not fit the definition of "approved livestock facility" will request an APHIS evaluation by phone or e-mail. APHIS personnel will then conduct an onsite inspection before approving the site.

Evaluation of States and Tribes

Because APHIS has not yet finalized the performance standards, it is not presently proposing to add to the regulations a description of the process APHIS will use to evaluate State and Tribal

performance or requirements for conducting such evaluations. APHIS is reserving 9 CFR 90.7 for evaluation requirements. APHIS is considering making evaluation part of the administration of the cooperative agreements used to fund traceability in the States and Tribes. The process would involve examination of actual animal traces for disease program work as well as supplemental test exercises. Traceability plans would also be examined during routine disease program and station reviews conducted periodically by the VS Regions. These evaluations would not involve the producers directly, but would focus on the ability of the State or Tribe to conduct specific traceability activities that serve as indicators of tracing capability. Such activities, under the performance standards currently under consideration, would include:

- Notification of the State or Tribe where the animal was initially identified by the receiving State or Tribe of the official identification of a reference animal.
- Confirmation by the State or Tribe where the animal was initially identified that it was the State or Tribe where the reference animal was officially identified and that it has documentation to that effect. This documentation should contain the contact information for the person who received the identification number.
- Notification by the receiving State or Tribe of the State or Tribe from which the reference animal was moved regarding that animal's official identification number.
- Determination by the State or Tribe from which the reference animal was moved of the address from which the reference animal was shipped.

APHIS will collect information on State and Tribal abilities to carry out these four activities for each species covered by the traceability regulation. This information will help APHIS establish firm measurements for evaluating the performance of States and Tribes.

The "reference animals" are the animals used to evaluate State or Tribal ability to meet the performance standards. APHIS could randomly select reference animals for a test exercise or could select animals included in actual disease traceback investigations. However, animals could be used as reference animals only if they were moved interstate on or after the date they are required to be officially identified and only if they are identified with an official identification number issued on or after the effective date of the final traceability rule. These eligibility criteria would ensure that animals moved interstate before this rulemaking would not be included in the pool of reference animals. States and Tribes would be evaluated on their ability to trace animals moved only in accordance with the new regulation.

Documentation of Completion of Performance Measures

APHIS does not currently have the data necessary to establish performance standards for States and Tribes and is not proposing to add any to the regulations at this time. APHIS is reserving 9 CFR 90.6 for the performance standards. States and Tribes will probably describe their method of documenting completion of performance measures in the workplans they submit for the cooperative agreements that provide funding for traceability. Each workplan will be reviewed and approved by the AVIC and the Regional directors.

Commuter Herd Agreement

A commuter herd agreement is a written agreement between the owner(s) of a herd of cattle or bison and the animal health officials for the States or Tribes of origin and destination specifying

the conditions required for the interstate movement between premises during normal livestock management operations. The agreement is usually effective for 1 year and may be renewed annually. The agreement conditions are determined by the animal health officials of the States or Tribes involved in the movement as well as the producer who requests the movement. A copy of the agreement bearing original signatures must accompany each movement. APHIS has no role in preparing or signing the agreement and does not receive a copy; it only requires that the signed document accompany shipments of animals moving interstate.

Collection of ID Devices at Slaughter

APHIS needs correlation of ID devices with carcasses and/or diagnostic samples collected at harvest facilities to support tracebacks where disease is found in an animal after slaughter. All manmade ID devices affixed to livestock moved interstate must be removed at slaughter and correlated with the carcasses through final inspection. If diagnostic samples are taken, the devices must be packaged with the samples and correlated with the carcasses. Slaughter plant personnel currently handle this activity under the supervision of the Food Safety and Inspection Service (FSIS) under 9 CFR 310.2, but APHIS anticipates more active involvement in the process with the passage of the proposed traceability rule. Handling of devices after final inspection will be determined based on the needs of both APHIS and FSIS.

Obtaining Official Eartags for Cattle not Currently Required to be Identified with Official Eartags

Official eartags are used for official identification of cattle under the existing regulations and will continue to be used under the new traceability regulations. Brands, breed association tattoos, and other forms of identification will no longer be accepted as official ID. Cattle (with some exceptions) will need to be identified with an official eartag. This will initially be limited to breeding animals, dairy breeds, and animals involved in shows, exhibitions, and recreational events. APHIS will make metal eartags available to producers free of charge to facilitate compliance with this requirement. These tags can be ordered through State or Tribal animal health officials in a manner that best fits local needs; State and Tribal animal health officials will process tag orders placed with them and obtain tags for producers. Producers also may obtain official eartags directly from tag manufacturers or distributors; or through accredited veterinarians, livestock market operators, breed associations and livestock production records associations, or other entities. Tag orders may be placed by phone, Internet, fax, or mail.

Official Identification Device Distribution Records

Although applying eartags will be the producers' responsibility, States and Tribes will be primarily responsible for recording distribution information in a way they can access quickly. Breed and registry associations, accredited veterinarians, and eartag distributors must report to the State or Tribe from which they receive tags the numbers of any tags they issue to livestock operations. States and Tribes must keep the records for a minimum of 5 years, as they are critical in helping APHIS determine the origin of animals that move interstate.

Record of tags issued

Entities that distribute official eartags must keep a record of tags issued to ensure accountability in the distribution system and to ensure that APHIS has the traceability information needed for disease control, eradication, and surveillance efforts. The record may be electronic or paper-

based depending on the volume of tags and the needs of the State or Tribe. States, Tribes, and territories must collect sufficient contact information about where official eartags are distributed to meet their traceability needs. At a minimum, the record must include:

- The name of the person receiving the tags.
- The street address, city, State, and ZIP code where the tags are distributed.
- The identification numbers issued.
- The date the tags were issued.
- The name and contact information of the person issuing the tags.

Record of tags applied

State and Tribal animal health officials and accredited veterinarians using the tags for official disease program work must record sufficient contact information about where official eartags are applied (not just the person to whom they are issued) to meet the traceability needs of the State, Tribe, or territory. Producers will not be required to record or report the application of tags to animals on their livestock operation. At a minimum, the record must include:

- The name of the owner of the livestock operation where the tags are applied.
- The street address, city, State, and ZIP code where the tags are applied.
- The identification numbers applied.
- The date the tags were applied.
- The name and contact information of the person applying the tags.
- If the State, Tribe, or territory uses the Animal Identification Management System (AIMS) to record tag application records, the record must include a premises identification number or State location identifier.

Certificate of Veterinary Inspection and Recordkeeping

Currently, all States require certificates of veterinary inspection (CVIs) for breeding cattle received from other States. The CVI, completed by an accredited veterinarian from information the producer provides, documents that the veterinarian inspected the animals and found them free of communicable disease. The CVI must show the species of animals covered by the certificate; the number of animals covered; the purpose for which the animals are to be moved; the departure address; the destination address; and the names and addresses of the consignor and the consignee (if different from the departure and destination addresses). Additionally, unless the proposed rule's species-specific CVI requirements provide an exception, the CVI must list the official identification number of each animal, or group of animals, moved that must be officially identified. If an alternate form of identification has been agreed on by the sending and receiving States or Tribes, the CVI must include a record of that identification.

The proposed traceability rule establishes the current State practice as a Federal requirement for interstate movement. The rule requires a State representative, or an accredited veterinarian, issuing an CVI to enter all the required information, retain a copy for his or her records, provide a copy to accompany the shipment, and forward a copy of the certificate to the State animal health official in the State of origin within 5 business days. The State of origin will forward a copy to the State of destination within 5 business days. APHIS currently has no role in preparing the CVI and does not receive a copy.

States must retain received CVIs so they can be easily found. The records must be kept for a minimum of 5 years to ensure that information is readily available to facilitate animal disease investigations.

Unauthorized Removal or Loss of Official ID Devices

Removal of official identification devices can impair APHIS' ability to find the source of a disease outbreak or document the absence of disease. Thus, removal needs to be approved except when the animal is presented at slaughter, rendering, diagnostic labs, or other termination points. State animal health officials or the AVIC will approve removal on request and after evaluation of the request at the local level by contacting the requestor by phone, fax, or e-mail.

Reporting Retagging Animal Records – Removed Tags

If an eartag has to be removed, the State, Tribal, or territorial animal health official will record in a manner that meets State, Tribal, or territorial needs the date the device is removed, contact information (address and phone number) for the location at which the device is removed, the official number of the device being removed, device type, reason for removal, the new identification number, and the type of replacement tag. APHIS requires States and Tribes to keep records of replaced removed tags at the local level, although replacement does not need to be reported to APHIS at this time. The record must be maintained for 5 years to ensure that multiple devices issued to a single animal do not result in multiple traces.

Reporting Retagging Animal Records – Lost, Stolen or Misused Tags and Recordkeeping If an animal loses an official identification device and needs a new one, the person (who could be a producer as well as a State, Tribal, or Federal employee) applying the new official identification device must record the following information: The date the new device is added; the official identification number on the device; and the official identification number on the old device if known. The record must be maintained for 5 years to ensure that multiple devices issued to a single animal do not result in multiple traces. Further, VS personnel, State and Tribal animal health officials and their staffs, and accredited veterinarians who use official eartags for program work must report to the AVIC (using the same information) by phone, fax, or e-mail, the loss, theft, or misuse of eartags. This ensures that no one uses tags fraudulently or irresponsibly so as to prevent the accurate traceability of the animal bearing the tag. Private individuals are encouraged but not required to report misused tags.

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.

Application for Use of More Than One Official ID Device

This will be managed at the local level in a way that best suits the needs of the State or Tribe; therefore, whether it is, or can be, automated, is not determinable at the Federal level.

Application for and Approval of an Approved Tagging Site

There is currently no process for approving tagging sites, automated or otherwise. APHIS anticipates that operators of potential tagging sites will apply by phone, although evaluation and approval may require an onsite inspection of recordkeeping systems. APHIS has a system for evaluating livestock markets to be federally approved livestock facilities, and the approval of a tagging site could become part of that process to consolidate functions and eliminate redundancies. The current market approval system is not automated because it requires onsite inspections.

Evaluation of States and Tribes

We do not currently have an automated system to evaluate State or Tribal traceability plans or adherence to traceability performance standards. As we collect baseline traceability implementation data over the next several years, we expect to have the necessary information to design and implement an electronic evaluation system. At the moment we expect the work to involve onsite review of documents and procedures which would not qualify this task for electronic submission.

Documentation of Completion of Performance Measures

At the moment we expect the work to involve onsite review of documents and procedures which would not qualify this task for electronic submission.

Commuter Herd Agreement

An original copy of the Commuter Herd Agreement must accompany the herds during movement, and is therefore not a candidate for electronic submission.

Collection of ID Devices at Slaughter

The original devices must physically accompany samples to the laboratory for identification purposes. The devices must also be available to collect information in or on the device that could be useful for tracebacks. For instance, a backtag with a barcode might also have attached some of the hair of the animal from which it was removed. The hair sample could help identify the animal and would be lost if only the number of the backtag was recorded. Thus, this activity is not a candidate for complete electronic submission.

Applying and Obtaining Official Eartags for Cattle Not Currently IDed

USDA has provided a Web-based system, the Animal Identification Management System (AIMS), to order official eartags and track the order to the livestock location to which they are issued. We will make this system available to any State or Tribe that wishes to use it, but will not require its use. The AIMS also serves as a record of eartag distribution that can be accessed well beyond the 5 years required by the rule.

Official Identification Device Distribution Records

This will be managed at the local level in a way that best suits the needs of the State or Tribe; therefore, whether it is, or can be, automated, is not determinable at the Federal level.

Certificate of Veterinary Inspection

The CVI bearing original signatures must accompany the shipment of animals and thus is not a candidate for electronic submission.

Unauthorized Removal of Official ID Devices

Approval of removal of official ID devices will be managed at the local level in a way that best suits the needs of the State or Tribe; therefore, whether it is, or can be, automated, is not determinable at the Federal level.

Reporting Retagging Records - Removed and Lost Tags

Records regarding replacement of lost or removed tags are kept at the local level. Recordkeeping does not need to be reported to the Federal level at this time.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information collected in connection with this activity is not available from any other source. APHIS is the only Federal agency responsible for tracing animal disease outbreaks. However, APHIS coordinates with three other USDA agencies (FSIS, the Agricultural Marketing Service, and the Grain Inspection, Packers, and Stockyards Administration) and with Health and Human Services' Food and Drug Administration in certain aspects of this traceability work.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS has developed this rule with the intent of minimizing burden on small businesses, because about most producers that move livestock interstate (the principal respondents under the proposed rule) are small entities. Such entities would not be required to maintain official identification records (other than for retagging of animals, which is expected to occur infrequently) or copies of CVIs. About 80 percent of the entities that would be affected by these requirements are small entities.

Moreover, the Federal traceability requirements would not apply in the following instances:

- Movement entirely within Tribal land that straddles a State line, if the Tribe has a separate traceability status from the States in which its lands are located;
- Movement to a custom slaughter facility in accordance with Federal and State regulations for preparation of meat for personal consumption;
- Movement as part of a commuter herd with a copy of the commuter herd agreement;
- Movement directly from one State through another State and back to the original State; or
- Movement to an approved tagging site, if the animals are officially identified there before they are commingled with cattle and bison from other premises.

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.

If the information was collected less frequently or not collected, APHIS' ability to trace and appropriately address the outbreak of disease would be significantly hampered. This could have a tremendous impact on the health of U.S. livestock, and on the viability of industries dependent on U.S. livestock.

- 7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.
 - 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;

The proposed rule requires that the animal health official issuing a CVI forward a copy to the State or Tribe of origin within 5 working days. The State of origin would also be required to forward copies of CVIs they receive to the Destination State within 5 working days. These requirements are based on the speed, frequency, and volume of interstate livestock movements in today's marketing environment and the threat of rapid disease spread that movement poses. APHIS needs information that supports rapid and effective traceability to stop disease outbreaks and prevent recurrences; the 5-day requirement provides it in a timeframe that is workable at the State level.

- 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 three years;

The proposed rule also requires retention of official identification device distribution records and reports of removed, lost, stolen, or misused tags for 5 years. This requirement is based on the fact that livestock animals, especially cattle, typically live to be more than 3 years old. Therefore, traceability information that fully supports disease control, eradication, and surveillance needs to be maintained for longer than 3 years. The 5-year requirement brings consistency throughout our regulations.

- 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 statute 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 other special circumstances and this information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. 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 form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS has engaged in productive consultations with the following individuals concerning the information collection activities associated with this program during 2011:

Dr. Keith Roehr State Veterinarian Division of Animal Industry Colorado Department of Agriculture 700 Kipling Street, Suite 4000 Lakewood, CO 80215 (303) 239-4161 Keith.roehr@ag.state.co.us

Dr. Betsy Brewer-Walker State Veterinarian Animal Industry Division Oklahoma Department of Agriculture P.O. Box 528804 Oklahoma City, OK 73152 (405) 522-6131 Becky.brewer@oda.state.ok.us

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APHIS' proposed rule (09-091-1) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or 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.

This information collection activity will ask no questions of a personal or sensitive nature.

- 12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.
- Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. 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.

See APHIS form 71.

• Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

Respondents are producers; State, Tribal, and territorial animal health officials; accredited veterinarians; livestock production and breed associations; livestock market operators; eartag manufacturers and distributors; and harvest facility operators. APHIS estimates the total

annualized cost to these respondents to be \$16,843,592. APHIS arrived at this figure by multiplying the hours of estimated response time (723,522 hours) by the estimated average hourly wage of the above respondents (\$23.28). Estimated hourly wages for the respondents were determined from the U.S. Department of Labor, Bureau of Labor Statistics May 2010 Report – National Compensation Survey: Occupational Employment and Wages, May 2009. See http://www.bls.gov/oes/#tables.

Farm, ranch, and other agricultural managers - \$31.13
Farmers and ranchers - \$20.53
Agricultural and food science technicians - \$17.72
Veterinarians - \$43.32
Agricultural inspectors - \$20.12
First-line supervisors/managers of production and operating workers - \$26.52
Assemblers and fabricators, all others - \$15.52
Slaughterers and meat packers - \$11.42

13. Provide estimates 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 estimates 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.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS Form 79. The annualized cost to the Federal government is estimated at \$628,178.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a new information collection.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this activity.

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 are no forms associated with this information collection.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

No statistical methods are associated with the information collection activities used in this program.