

MATERIAL RELIED UPON

- A. Federal Register, Volume 78, Number. 6, January 9, 2013, pages 2071-2075.
- B. Animal Health Branch district office map.
- C. CA brucellosis vaccination tag sample.
- D. CA Electronic Identification Device sample.
- E. United States Bovine Brucellosis Affected Herd Investigations and Designated Surveillance Areas map, September, 2015.
- F. Cattle Health Advisory Task Force Meeting Minutes dated April 22, 2015.
- G. California Cattlemen's Association petition letter dated December 16, 2013 and Notice of Decision on Petition for Rulemaking, California Regulatory Notice Register 2014, Volume No. 5-Z, pages 209-210.
- H. California Cattlemen's Association petition letter dated January 16, 2015 and Notice of Decision on Petition for Rulemaking, California Regulatory Notice Register 2015, Volume No. 10-Z, pages 411-413.
- I. WA Department of Agriculture – tag order form, trichomonosis tag sample and Bovine Trichomonosis in Washington State brochure.
- J. California Animal Health and Food Safety laboratory system Trichomonas Submission Form and Trichomonas/*Tritrichomonas foetus* testing protocol.
- K. USDA Process Verified Program, GVD 1001 Procedure, October 26, 2015.
- L. USDA Quality Systems Verification Program GVD 1002, March 4, 2004.
- M. USDA, Animal Disease Traceability, General Standards, January 2, 2015, Version 2.4.
- N. USDA, APHIS, Regulatory Impact Analysis & Final Regulatory Flexibility Analysis, July 2012.
- O. UC Davis, Veterinary Medicine, California Animal Health and Food Safety Laboratory System, Select List of Tests Performed on Beef Cattle at CAHFS.
- P. 2012 Census of Agriculture – State Data, USDA, National Agricultural Statistics Service.

■ a. In paragraphs (a) and (b), by adding the word “further” after the word “without” each time it occurs.

■ b. In paragraphs (d)(1), (d)(2), (d)(3), and (d)(4), by removing the words “a certificate” and adding the words “an ICVI” in their place each time they occur.

■ 37. A new part 86 is added to subchapter C to read as follows:

PART 86—ANIMAL DISEASE TRACEABILITY

Sec.

86.1 Definitions.

86.2 General requirements for traceability.

86.3 Recordkeeping requirements.

86.4 Official identification.

86.5 Documentation requirements for interstate movement of covered livestock.

86.6 [Reserved]

86.7 [Reserved]

86.8 Preemption.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 86.1 Definitions.

Animal identification number (AIN).

A numbering system for the official identification of individual animals in the United States that provides a nationally unique identification number for each animal. The AIN consists of 15 digits, with the first 3 being the country code (840 for the United States or a unique country code for any U.S. territory that has such a code and elects to use it in place of the 840 code). The alpha characters USA or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording may be used as an alternative to the 840 or other prefix representing a U.S. territory; however, only the AIN beginning with the 840 or other prefix representing a U.S. territory will be recognized as official for use on AIN tags applied to animals on or after March 11, 2015. The AIN beginning with the 840 prefix may not be applied to animals known to have been born outside the United States.

Approved livestock facility. A stockyard, livestock market, buying station, concentration point, or any other premises under State or Federal veterinary inspection where livestock are assembled and that has been approved under § 71.20 of this chapter.

Approved tagging site. A premises, 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.

Commuter herd. A herd of cattle or bison moved interstate during the course of normal livestock management operations and without change of ownership directly between two premises, as provided in a commuter herd agreement.

Commuter herd agreement. 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 from one premises to another in the course of normal livestock management operations and specifying the time period, up to 1 year, that the agreement is effective. A commuter herd agreement may be renewed annually.

Covered livestock. Cattle and bison, horses and other equine species, poultry, sheep and goats, swine, and captive cervids.

Dairy cattle. All cattle, regardless of age or sex or current use, that are of a breed(s) used to produce milk or other dairy products for human consumption, including, but not limited to, Ayrshire, Brown Swiss, Holstein, Jersey, Guernsey, Milking Shorthorn, and Red and Whites.

Directly. Moved in a means of conveyance, without stopping to unload while en route, except for stops of less than 24 hours to feed, water, or rest the animals being moved, and with no commingling of animals at such stops.

Flock-based number system. The flock-based number system combines a flock identification number (FIN) with a producer's unique livestock production numbering system to provide a nationally unique identification number for an animal.

Flock identification number (FIN). A nationally unique number assigned by a State, Tribal, or Federal animal health authority to a group of animals that are managed as a unit on one or more premises and are under the same ownership.

Group/lot identification number (GIN). The identification number used to uniquely identify a “unit of animals” of the same species that is managed together as one group throughout the preharvest production chain. When a GIN is used, it is recorded on documents accompanying the animals moving interstate; it is not necessary to have the GIN attached to each animal.

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement.

(a) The ICVI must show the species of animals covered by the ICVI; the

number of animals covered by the ICVI; the purpose for which the animals are to be moved; the address at which the animals were loaded for interstate movement; the address to which the animals are destined; and the names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined. Additionally, unless the species-specific requirements for ICVIs provide an exception, the ICVI must list the official identification number of each animal, except as provided in paragraph (b) of this definition, or group of animals moved that is required to be officially identified, or, if an alternative form of identification has been agreed upon by the sending and receiving States, the ICVI must include a record of that identification. If animals moving under a GIN also have individual official identification, only the GIN must be listed on the ICVI. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (e.g., the cattle and bison do not belong to one of the classes of cattle and bison to which the official identification requirements of this part apply). If the animals are required to be officially identified but the identification number does not have to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified.

(b) As an alternative to typing or writing individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, another document may be used to provide this information, but only under the following conditions:

(1) The document must be a State form or APHIS form that requires individual identification of animals or a printout of official identification numbers generated by computer or other means;

(2) A legible copy of the document must be stapled to the original and each copy of the ICVI;

(3) Each copy of the document must identify each animal to be moved with the ICVI, but any information pertaining to other animals, and any unused space on the document for recording animal identification, must be crossed out in ink; and

(4) The following information must be written in ink in the identification column on the original and each copy of the ICVI and must be circled or boxed, also in ink, so that no additional information can be added:

A

(i) The name of the document; and
 (ii) Either the unique serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who prepared the document and the date the document was signed.

Interstate movement. From one State into or through any other State.

Livestock. All farm-raised animals.

Location-based numbering system. The location-based number system combines a State or Tribal issued location identification (LID) number or a premises identification number (PIN) with a producer's unique livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal.

Location identification (LID) number. A nationally unique number issued by a State, Tribal, and/or Federal animal health authority to a location as determined by the State or Tribe in which it is issued. The LID number may be used in conjunction with a producer's own unique livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal. It may also be used as a component of a group/lot identification number (GIN).

Move. To carry, enter, import, mail, ship, or transport; to aid, abet, cause, or induce carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive in order to carry, enter, import, mail, ship, or transport; or to allow any of these activities.

National Uniform Eartagging System (NUES). A numbering system for the official identification of individual animals in the United States that provides a nationally unique identification number for each animal.

Official eartag. An identification tag approved by APHIS that bears an official identification number for individual animals. Beginning March 11, 2014, all official eartags manufactured must bear an official eartag shield. Beginning March 11, 2015, all official eartags applied to animals must bear an official eartag shield. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

Official eartag shield. The shield-shaped graphic of the U.S. Route Shield with "U.S." or the State postal abbreviation or Tribal alpha code imprinted within the shield.

Official identification device or method. A means approved by the Administrator of applying an official identification number to an animal of a specific species or associating an official identification number with an animal or group of animals of a specific species or otherwise officially identifying an animal or group of animals.

Official identification number. A nationally unique number that is permanently associated with an animal or group of animals and that adheres to one of the following systems:

(1) National Uniform Eartagging System (NUES).

(2) Animal identification number (AIN).

(3) Location-based number system.

(4) Flock-based number system.

(5) Any other numbering system approved by the Administrator for the official identification of animals.

Officially identified. Identified by means of an official identification device or method approved by the Administrator.

Owner-shipper statement. A statement signed by the owner or shipper of the livestock being moved stating the location from which the animals are moved interstate; the destination of the animals; the number of animals covered by the statement; the species of animal covered; the name and address of the owner at the time of the movement; the name and address of the shipper; and the identification of each animal, as required by the regulations, unless the regulations specifically provide that the identification does not have to be recorded.

Person. Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other legal entity.

Premises identification number (PIN). A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority a geographically distinct location from other premises. The PIN may be used in conjunction with a producer's own livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal. It may be used as a component of a group/lot identification number (GIN).

Recognized slaughtering establishment. Any slaughtering facility operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or State meat or poultry inspection acts that is

approved in accordance with 9 CFR 71.21.

United States Department of Agriculture (USDA) approved backtag. A backtag issued by APHIS that provides a temporary unique identification for each animal.

§ 86.2 General requirements for traceability.

(a) The regulations in this part apply only to covered livestock, as defined in § 86.1.

(b) No person may move covered livestock interstate or receive such livestock moved interstate unless the livestock meet all applicable requirements of this part.

(c) The regulations in this part will apply to the movement of covered livestock onto and from Tribal lands only when the movement is an interstate movement; i.e., when the movement is across a State line.

(d) In addition to meeting all applicable requirements of this part, all covered livestock moved interstate must be moved in compliance with all applicable provisions of APHIS program disease regulations (subchapter C of this chapter).

(e) The interstate movement requirements in this part do not apply to the movement of covered livestock if:

(1) The movement occurs entirely within Tribal land that straddles a State line and the Tribe has a separate traceability system from the States in which its lands are located; or

(2) The movement is to a custom slaughter facility in accordance with Federal and State regulations for preparation of meat.

§ 86.3 Recordkeeping requirements.

(a) **Official identification device distribution records.** Any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices must maintain for 5 years a record of the names and addresses of anyone to whom the devices were distributed.

(b) **Interstate movement records.** Approved livestock facilities must keep any ICVIs or alternate documentation that is required by this part for the interstate movement of covered livestock that enter the facility on or after March 11, 2013. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equines, 5 years.

§ 86.4 Official identification.

(a) **Official identification devices and methods.** The Administrator has approved the following official

identification devices or methods for the species listed. The Administrator may authorize the use of additional devices or methods for a specific species if he or she determines that such additional devices or methods will provide for adequate traceability.

(1) *Cattle and bison*. Cattle and bison that are required to be officially identified for interstate movement under this part must be identified by means of:

- (i) An official eartag; or
- (ii) Brands registered with a recognized brand inspection authority and accompanied by an official brand inspection certificate, when agreed to by the shipping and receiving State or Tribal animal health authorities; or
- (iii) Tattoos and other identification methods acceptable to a breed association for registration purposes, accompanied by a breed registration certificate, when agreed to by the shipping and receiving State or Tribal animal health authorities; or
- (iv) Group/lot identification when a group/lot identification number (GIN) may be used.

(2) *Horses and other equine species*. Horses and other equine species that are required to be officially identified for interstate movement under this part must be identified by one of the following methods:

- (i) A description sufficient to identify the individual equine including, but not limited to, name, age, breed, color, gender, distinctive markings, and unique and permanent forms of identification when present (e.g., brands, tattoos, scars, cowlicks, blemishes or biometric measurements). When the identity of the equine is in question at the receiving destination, the State or Tribal animal health official in the State or Tribe of destination or APHIS representative may determine if the description provided is sufficient; or
- (ii) Electronic identification that complies with ISO 11784/11785; or
- (iii) Non-ISO electronic identification injected to the equine on or before March 11, 2014; or
- (iv) Digital photographs sufficient to identify the individual equine; or
- (v) For equines being commercially transported to slaughter, a device or method authorized by 88 of this chapter.

(3) *Poultry*. Poultry that are required to be officially identified for interstate movement under this part must be identified by one of the following methods:

- (i) Sealed and numbered leg bands in the manner referenced in the National Poultry Improvement Plan regulations (parts 145 through 147 of this chapter); or

(ii) Group/lot identification when a group/lot identification number (GIN) may be used.

(4) *Sheep and goats*. Sheep and goats that are required to be officially identified for interstate movement under this part must be identified by a device or method authorized by part 79 of this chapter.

(5) *Swine*. Swine that are required to be officially identified for interstate movement under this part must be identified by a device or method authorized by § 71.19 of this chapter.

(6) *Captive cervids*. Captive cervids that are required to be officially identified for interstate movement under this part must be identified by a device or method authorized by part 77 of this chapter.

(b) *Official identification requirements for interstate movement—*
(1) *Cattle and bison*. (i) All cattle and bison listed in paragraphs (b)(1)(iii)(A) through (b)(1)(iii)(D) of this section must be officially identified prior to the interstate movement, using an official identification device or method listed in paragraph (a)(1) of this section unless:

(A) The cattle and bison are moved as a commuter herd with a copy of the commuter herd agreement or other documents as agreed to by the shipping and receiving States or Tribes. If any of the cattle or bison are shipped to a State or Tribe not included in the commuter herd agreement or other documentation, then these cattle or bison must be officially identified and documented to the original State of origin.

(B) The cattle and bison are moved directly from a location in one State through another State to a second location in the original State.

(C) The cattle and bison are moved interstate directly to an approved tagging site and are officially identified before commingling with cattle and bison from other premises or identified by the use of backtags or other methods that will ensure that the identity of the animal is accurately maintained until tagging so that the official eartag can be correlated to the person responsible for shipping the animal to the approved tagging site.

(D) The cattle and bison are moved between shipping and receiving States or Tribes with another form of identification, as agreed upon by animal health officials in the shipping and receiving States or Tribes.

(ii) Cattle and bison may also be moved interstate without official identification if they are moved directly to a recognized slaughtering establishment or directly to no more than one approved livestock facility and then directly to a recognized

slaughtering establishment, where they are harvested within 3 days of arrival; and

(A) They are moved interstate with a USDA-approved backtag; or

(B) A USDA-approved backtag is applied to the cattle or bison at the recognized slaughtering establishment or federally approved livestock facility.

(C) If a determination to hold the cattle or bison for more than 3 days is made after the animals arrive at the slaughter establishment, the animals must be officially identified in accordance with § 86.4(d)(4)(ii).

(iii) Beginning on March 11, 2013, all cattle and bison listed below are subject to the official identification requirements of this section:

(A) All sexually intact cattle and bison 18 months of age or over;

(B) All female dairy cattle of any age and all dairy males born after March 11, 2013;

(C) Cattle and bison of any age used for rodeo or recreational events; and

(D) Cattle and bison of any age used for shows or exhibitions.

(2) *Sheep and goats*. Sheep and goats moved interstate must be officially identified prior to the interstate movement unless they are exempt from official identification requirements under 9 CFR part 79 or are officially identified after the interstate movement, as provided in 9 CFR part 79.

(3) *Swine*. Swine moving interstate must be officially identified in accordance with § 71.19 of this chapter.

(4) *Horses and other equines*. Horses and other equines moving interstate moved interstate must be officially identified prior to the interstate movement, using an official identification device or method listed in paragraph (a)(2) of this section unless:

(i) They are used as the mode of transportation (horseback, horse and buggy) for travel to another location and then return direct to the original location.

(ii) They are moved from the farm or stable for veterinary medical examination or treatment and returned to the same location without change in ownership.

(iii) They are moved directly from a location in one State through another State to a second location in the original State.

(iv) They are moved between shipping and receiving States or Tribes with another form of identification as agreed upon by animal health officials in the shipping and receiving States or Tribes.

(5) *Poultry*. Poultry moving interstate must be officially identified prior to interstate movement unless:

(i) The shipment of poultry is from a hatchery to a distributor or poultry

grower and the person responsible for receiving the shipment maintains a record of the supplier; or

(ii) The shipment is from a redistributor to a poultry grower and the person responsible for receiving the chicks maintains a record of the supplier of the chicks; or

(iii) The poultry are identified as agreed upon by the States or Tribes involved in the movement.

(6) *Captive cervids*. Captive cervids moving interstate must be officially identified prior to interstate movement in accordance with part 77 of this chapter.

(c) *Use of more than one official eartag*. Beginning on March 13, 2013, no more than one official eartag may be applied to an animal, except that:

(1) Another official eartag may be applied providing it bears the same official identification number as an existing one.

(2) In specific cases when the need to maintain the identity of an animal is intensified (e.g., such as for export shipments, quarantined herds, field trials, experiments, or disease surveys), a State or Tribal animal health official or an area veterinarian in charge may approve the application of an additional official eartag to an animal that already has one or more. The person applying the additional official eartag must record the following information about the event and maintain the record for 5 years: The date the additional official eartag is added; the reason for the additional official eartag device; and the official identification numbers of both the new official eartag and the one(s) already attached to the animal.

(3) An eartag with an animal identification number (AIN) beginning with the 840 prefix (either radio frequency identification or visual-only tag) may be applied to an animal that is already officially identified with one or more National Uniform Eartagging System tags and/or an official vaccination eartag used for brucellosis. The person applying the AIN eartag must record the date the AIN tag is added and the official identification numbers of both official eartags and must maintain those records for 5 years.

(4) A brucellosis vaccination eartag with a National Uniform Eartagging System number may be applied in accordance with part 78 of this chapter to an animal that is already officially identified with one or more official eartags under this part. The person applying the vaccination eartag must record the date the tag is added and the official identification numbers of both the existing official eartag(s) and the

vaccination eartag and must maintain those records for 5 years.

(d) *Removal or loss of official identification devices*. (1) Official identification devices are intended to provide permanent identification of livestock and to ensure the ability to find the source of animal disease outbreaks. Removal of these devices, including devices applied to imported animals in their countries of origin and recognized by the Administrator as official, is prohibited except at the time of slaughter, at any other location upon the death of the animal, or as otherwise approved by the State or Tribal animal health official or an area veterinarian in charge when a device needs to be replaced.

(2) All man-made identification devices affixed to covered livestock unloaded at slaughter plants after moving interstate must be removed at the slaughter facility by slaughter-facility personnel with the devices correlated with the animal and its carcass through final inspection or condemnation by means approved by the Food Safety Inspection Service (FSIS). If diagnostic samples are taken, the identification devices must be packaged with the samples and be correlated with the carcasses through final inspection or condemnation by means approved by FSIS. Devices collected at slaughter must be made available to APHIS and FSIS by the slaughter plant.

(3) All official identification devices affixed to covered livestock carcasses moved interstate for rendering must be removed at the rendering facility and made available to APHIS.

(4) If an animal loses an official identification device and needs a new one: (i) A replacement tag with a different official identification number may be applied. The person applying a new official identification device with a different official identification number must record the following information about the event and maintain the record for 5 years: The date the new official identification device was added; the official identification number on the device; and the official identification number on the old device if known.

(ii) Replacement of a temporary identification device with a new official identification device is considered to be a retagging event, and all applicable information must be maintained in accordance with paragraph (d)(4)(i) of this section.

(iii) A duplicate replacement eartag with the official number of the lost tag may be applied in accordance with APHIS' protocol for the administration of such tags.

(e) *Replacement of official identification devices for reasons other than loss*.

(1) Circumstances under which a State or Tribal animal health official or an area veterinarian in charge may authorize replacement of an official identification device include, but are not limited to:

(i) Deterioration of the device such that loss of the device appears likely or the number can no longer be read;

(ii) Infection at the site where the device is attached, necessitating application of a device at another location (e.g., a slightly different location of an eartag in the ear);

(iii) Malfunction of the electronic component of a radio frequency identification (RFID) device; or

(iv) *Incompatibility or inoperability* of the electronic component of an RFID device with the management system or unacceptable functionality of the management system due to use of an RFID device.

(2) Any time an official identification device is replaced, as authorized by the State or Tribal animal health official or area veterinarian in charge, the person replacing the device must record the following information about the event and maintain the record for 5 years:

(i) The date on which the device was removed;

(ii) Contact information for the location where the device was removed;

(iii) The official identification number (to the extent possible) on the device removed;

(iv) The type of device removed (e.g., metal eartag, RFID eartag);

(v) The reason for the removal of the device;

(vi) The new official identification number on the replacement device; and

(vii) The type of replacement device applied.

(f) *Sale or transfer of official identification devices*. Official identification devices are not to be sold or otherwise transferred from the premises to which they were originally issued to another premises without authorization by the Administrator or a State or Tribal animal health official.

§ 86.5 Documentation requirements for interstate movement of covered livestock.

(a) The persons responsible for animals leaving a premises for interstate movement must ensure that the animals are accompanied by an interstate certificate of veterinary inspection (ICVI) or other document required by this part for the interstate movement of animals.

(b)(1) The APHIS representative, State or Tribal representative, or accredited

veterinarian issuing an ICVI or other document required for the interstate movement of animals under this part must forward a copy of the ICVI or other document to the State or Tribal animal health official of the State or Tribe of origin within 7 calendar days from the date on which the ICVI or other document is issued. The State or Tribal animal health official in the State or Tribe of origin must forward a copy of the ICVI or other document to the State or Tribal animal health official the State or Tribe of destination within 7 calendar days from date on which the ICVI or other document is received.

(2) The animal health official or accredited veterinarian issuing or receiving an ICVI or other interstate movement document in accordance with paragraph (b)(1) of this section must keep a copy of the ICVI or alternate documentation. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equines, 5 years.

(c) *Cattle and bison.* Cattle and bison moved interstate must be accompanied by an ICVI unless:

(1) They are moved directly to a recognized slaughtering establishment, or directly to an approved livestock facility and then directly to a recognized slaughtering establishment, and they are accompanied by an owner-shipper statement.

(2) They are moved directly to an approved livestock facility with an owner-shipper statement and do not move interstate from the facility unless accompanied by an ICVI.

(3) They are moved from the farm of origin for veterinary medical examination or treatment and returned to the farm of origin without change in ownership.

(4) They are moved directly from one State through another State and back to the original State.

(5) They are moved as a commuter herd with a copy of the commuter herd agreement or other document as agreed to by the States or Tribes involved in the movement.

(6) Additionally, cattle and bison may be moved between shipping and receiving States or Tribes with documentation other than an ICVI, e.g., a brand inspection certificate, as agreed

upon by animal health officials in the shipping and receiving States or Tribes.

(7) The official identification number of cattle or bison must be recorded on the ICVI or alternate documentation unless:

(i) The cattle or bison are moved from an approved livestock facility directly to a recognized slaughtering establishment; or

(ii) The cattle and bison are sexually intact cattle or bison under 18 months of age or steers or spayed heifers; *Except that:* This exception does not apply to sexually intact dairy cattle of any age or to cattle or bison used for rodeo, exhibition, or recreational purposes.

(d) *Sheep and goats.* Sheep and goats moved interstate must be accompanied by documentation as required by part 79 of this chapter.

(e) *Swine.* Swine moved interstate must be accompanied by documentation in accordance with § 71.19 of this chapter or, if applicable, with part 85.

(f) *Horses and other equines.* Horses and other equines moved interstate must be accompanied by an ICVI unless:

(1) They are used as the mode of transportation (horseback, horse and buggy) for travel to another location and then return direct to the original location.

(2) They are moved from the farm or stable for veterinary medical examination or treatment and returned to the same location without change in ownership.

(3) They are moved directly from a location in one State through another State to a second location in the original State.

(4) Additionally, equines may be moved between shipping and receiving States or Tribes with documentation other than an ICVI, e.g., an equine infectious anemia test chart, as agreed to by the shipping and receiving States or Tribes involved in the movement.

(5) Equines moving commercially to slaughter must be accompanied by documentation in accordance with part 88 of this chapter. Equine infectious anemia reactors moving interstate must be accompanied by documentation as required by part 75 of this chapter.

(g) *Poultry.* Poultry moved interstate must be accompanied by an ICVI unless:

(1) They are from a flock participating in the National Poultry Improvement

Plan (NPIP) and are accompanied by the documentation required under the NPIP regulations (parts 145 through 147 of this chapter) for participation in that program; or

(2) They are moved directly to a recognized slaughtering or rendering establishment; or

(3) They are moved from the farm of origin for veterinary medical examination, treatment, or diagnostic purposes and either returned to the farm of origin without change in ownership or euthanized and disposed of at the veterinary facility; or

(4) They are moved directly from one State through another State and back to the original State; or

(5) They are moved between shipping and receiving States or Tribes with a VS Form 9-3 or documentation other than an ICVI, as agreed upon by animal health officials in the shipping and receiving States or Tribes.

(6) They are moved under permit in accordance with part 82 of this chapter.

(h) *Captive cervids.* Captive cervids moved interstate must be accompanied by documentation as required by part 77 of this chapter.

§ 86.6 [Reserved]

§ 86.7 [Reserved]

§ 86.8 Preemption.

State, Tribal, and local laws and regulations may not specify an official identification device or method that would have to be used if multiple devices or methods may be used under this part for a particular species, nor may the State or Tribe of destination impose requirements that would otherwise cause the State or Tribe from which the shipments originate to have to develop a particular kind of traceability system or change its existing system in order to meet the requirements of the State or Tribe of destination.

Done in Washington, DC, this 19th day of December 2012.

Edward Avalos,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2012-31114 Filed 1-8-13; 8:45 am]

BILLING CODE 3410-34-P

SACRAMENTO HEADQUARTERS

Surveillance, Preparedness and Response Service

Asst. District Director: Larry Rawson
USDA/APHIS/VS
10365 Old Placerville Rd., Suite 210
Sacramento, CA 95827
Telephone: (916) 854-3950
FAX: (916) 363-3919

SACRAMENTO HEADQUARTERS

International Import and Export:

National Import and Export Service Center
Director: David Ewey, DVM, MPVM
USDA/APHIS/VS
10365 Old Placerville Rd., Suite 210
Sacramento, CA 95827
Telephone: (916) 854-3950
FAX: (916) 363-3919

PORT OF LOS ANGELES

Port Director: Francis Okino, DVM
USDA/APHIS/VS
Los Angeles Animal Import Center
USDA/APHIS/VS
222 Kansas St.
El Segundo, CA 90245
Telephone: (310) 955-331
FAX: (310) 955-3347

SAN FRANCISCO

Port Veterinarian: Katharine Starzel, DVM
USDA/APHIS/VS
Port of San Francisco
389 Oyster Point Blvd., Suite 2B
South San Francisco, CA 94080
Telephone: (650) 876-9358
FAX: (650) 876-0915

http://www.aphis.usda.gov/animal_health/



SACRAMENTO HEADQUARTERS

Chief: Kent Fowler, DVM
CDFA-Animal Health Branch
1220 N St.
Sacramento, CA 95814
Telephone: (916) 900-5002
FAX: (916) 900-5333

REDDING DISTRICT

VIC: Charles Palmer, DVM, MPVM
2135 Civic Center Drive, Room 8
Redding, CA 96001-2794
Telephone: (530) 225-2140
FAX: (530) 225-2240

MODESTO DISTRICT

VIC: Randy Anderson, DVM, MPVM
Stanislaus County Agricultural Center
Tuolumne Building
3800 Cornucopia Way, Suite F
Modesto, CA 95358
Telephone: (209) 491-9350
FAX: (209) 491-9353

TULARE DISTRICT

VIC: Gregory Ledbetter, DVM, MPVM
18830 Road 112
Tulare CA 93274
Telephone: (559) 685-3500
FAX: (559) 685-3503

ONTARIO DISTRICT

VIC: Predrag Pecic, DVM
1910 S. Archibald Avenue, Suite Y
Ontario, CA 91761
Telephone: (909) 947-4462
FAX: (909) 923-5128
<http://www.cdfa.ca.gov>



CENTRAL DAVIS LABORATORY

Director: Richard Breitmeyer, DVM, MPVM
University of California
P. O. Box 1770
Davis, CA 95617-1770
Telephone: (530) 752-8700
FAX: (530) 752-5680

TURLOCK LABORATORY

Chief: Gabriel Senies-Cue, DVM, EPAA, MS
1550 North Soderquist Road
Turlock, CA 95381
Telephone: (209) 634-5837
FAX: (209) 667-4261

TULARE LABORATORY

Chief: John Adaska, MPVM, PhD
VMTRC - CAHFS
18830 Road 112
Tulare, CA 93274
Telephone: (559) 688-7543
FAX: (559) 686-4231

SAN BERNARDINO LABORATORY

Chief: Robert Moeller, DVM
105 West Central Avenue
San Bernardino, CA 92408
Telephone: (909) 383-4287
FAX: (909) 884-5980

<http://cahfs.ucdavis.edu>



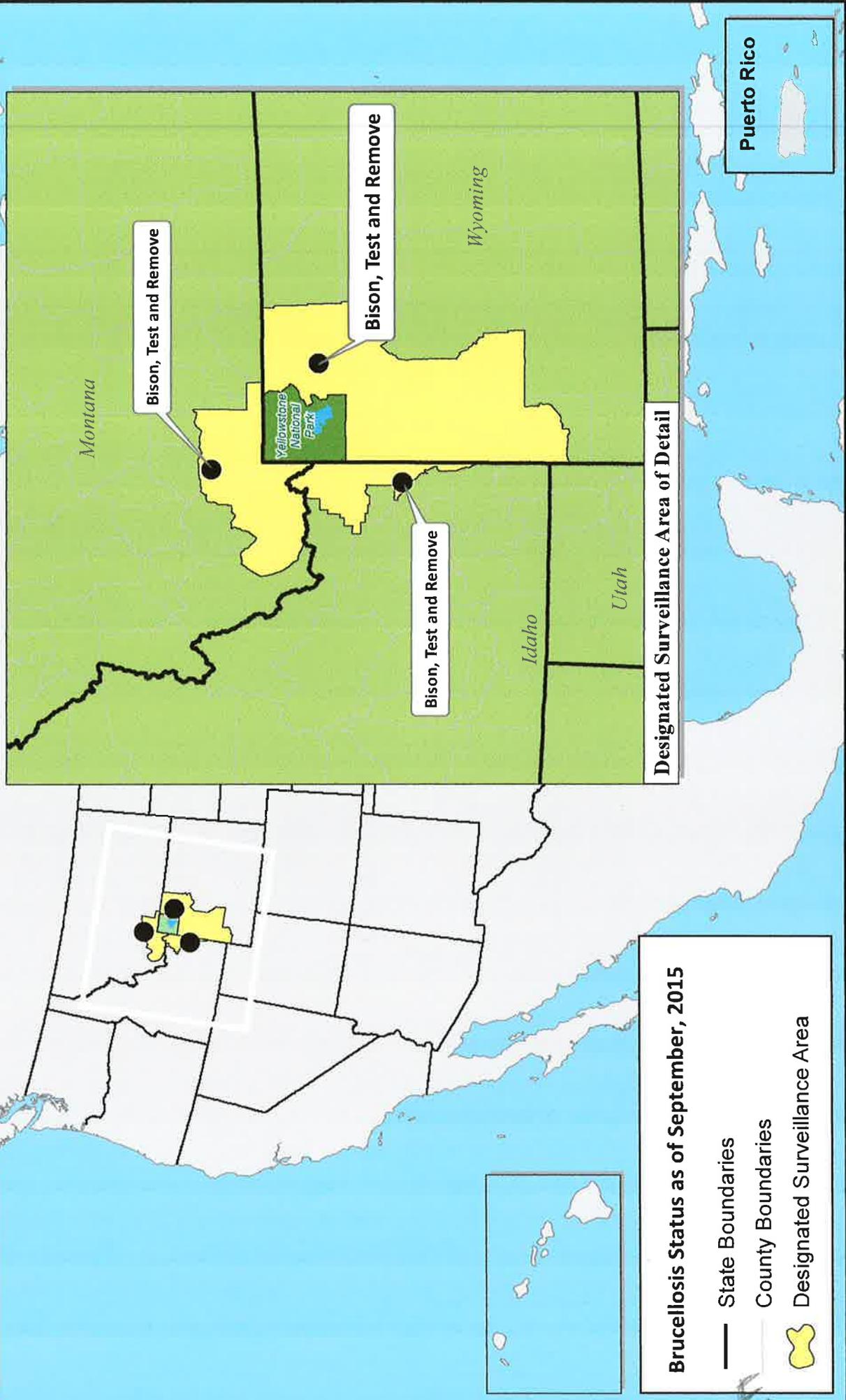
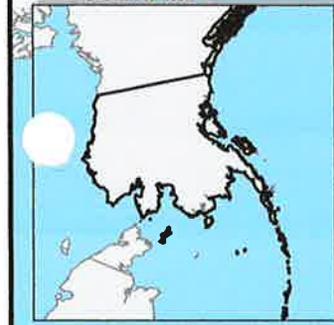
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United States Bovine Brucellosis Affected Herd Investigations and Designated Surveillance Areas



Cattle Health Advisory Task Force Meeting Minutes
California Department of Food and Agriculture, Conference Room 101
2800 Gateway Oaks Drive, Sacramento, CA 95833

Wednesday, April 22, 2015

A meeting of the Cattle Health Advisory Task Force was called to order by Chairman Justin Oldfield at **10:05 AM**.

Members Present*

Dr. Richard Breitmeyer
Dr. Gene Harlan
Dr. Normal LaFaunce
Dr. Terry Lehenbauer
Melissa Lema
Forrest Mangan
Justin Oldfield
James Oltjen
Dr. Aubrey Sloan
Dr. Charlie Tobias
Dr. John Zimmerman

Members Not Present

Kevin Abernathy
Dr. Ashley Cockrell
Larry Massa

*Quorum reached

Others in Attendance

Jake Bettencourt
Cris Carlson
Ria de Grassi
Dr. Anita Edmondson
Dr. Scott Essex
Dave Fischer
Dr. Kent Fowler
Beth Francia
Dr. Michael Greenlee
Dr. Ann Ikelman
Dr. Annette Jones
Rachelle Kennedy
Dr. Greg Ledbetter

Dr. Alyssa Louie
Duane Martin
Duane Martin Jr.
Dr. Beatriz Martinez-Lopez
Dr. Bret McNabb
Dr. Charles Palmer
Brad Peek
Dr. Michael Poulos
Dr. Annette Rink
John Suther
Gin Townley
Victor Velez

Dr. Kent Fowler introduced new Animal Health Branch staff, Dr. Ann Ikelman and Dr. Alyssa Louie, followed by self-introductions of all present.

Minutes from the previous meeting on October 29, 2014 were reviewed by members. **Dr. Gene Harlan moved to approve the minutes, Dr. Charlie Tobias seconded the motion. Motion carried.**

The Action Items from the previous meeting were tabled for later discussion.

F

AGENCY UPDATES

CDFA/Animal Health and Food Safety Services

Dr. Annette Jones:

- High-path avian influenza (HPAI) significantly affecting the Midwest; California not in the news as much following our quick and quiet response to HPAI.
- Strain of HPAI fairly robust in wild birds, transmission path into high biosecurity commercial flocks undetermined – studies in the Midwest working to identify the root cause and have many cases to work with.
- Animal Health Branch (AHB) reviewing resources to avoid HPAI draining the other programs (e.g. cattle health). Dr. Fowler working to fill positions in AHB to help gear up and prepare for upcoming fall weather and potential increase in HPAI incidents.
- Budget – pushing to have minimum base infrastructure for lab and AHB staff; funding within Governor's budget should help ensure the lab system continues its capability for the best diagnostics, and to help open the Tulare lab facility.

Dr. Kent Fowler:

- Appreciates AHB staff response to AI outbreaks - for stepping up and getting things done in a timely manner.

USDA – No representatives present at this meeting.

Dr. Richard Breitmeyer, CAHFS Lab Director:

- The large scale of AI affected premises and depopulation occurring elsewhere in US could still occur in CA; our fast detection and response was because of our lab system. Lab diagnosis moved quickly, demonstrating how the system should work, and the importance of maintaining infrastructure and funding.
- South Valley – Tulare lab having a celebration for crew, and should be online early 2016 with a move-in shortly after (48 million dollar lab and about 20 years of time put into getting here).
- North Valley – moving forward with finding a site for Turlock's new lab, Stanislaus County receptive.
- Many other recent changes, as experienced faculty are retiring; putting effort into recruiting new multispecies pathologists and microbiologists, but overall not talking about shutting labs down but building new ones.

John Suther, Branch Chief for Livestock Identification:

- Working to hire more brand inspectors to cover key areas.
- Will work with AHB to enforce the new Trich regulations.

Dr. Michael Greenlee, State Veterinarian, Nevada Dept. of Ag:

- It was noted that Trich is alive and well in NV, tends to be in clusters and cycling around Paradise Valley; however, producers are paying attention and testing more as requested, finding bulls and removing them.
- They just received ADT cooperative agreement funds from USDA to support digitalized brand inspections - using funds to get tablets into the field so access to inspection data is immediate.

Dr. Annette Rink, Supervisor, Animal Disease Laboratory, Nevada Dept. of Ag:

- Commented on the success of offering/asking producers to re-test “Trich suspect” bulls; they are getting a good response and 50% of re-tests come up Trich positive.

Forrest Mangan, LMA:

- Animal handling – hired a 3rd party company to do animal handling audits/assessments at livestock markets.
- CA Livestock Markets new president is Brad Peek.

Ria de Grassi, CA Farm Bureau:

- Lot of antibiotic resistance issues.
- Attended a public evening screening and question-and-answer session (with filmmaker Michael Graziano) of the film Resistance <http://www.resistancethefilm.com/> on the U.C. Davis campus (April 9).
- U.C. Davis evolutionary biologist professor Jonathan Eisen arranged the free showing and also is interviewed in the film along with Congresswoman Louise Slaughter (author of PAMTA, the Preservation of Antibiotics for Medical Treatment Act) and former USDA Secretary Dan Glickman.
- The film discusses the human uses of antibiotics, is critical of the use of antibiotics in animal agriculture, and explores the relationship of those to the development of antibiotic resistance.
- The film is promoted as a documentary and has been shown across the U.S. during the past year. It can be viewed on iTunes and Netflix.
- The Davis screening did not appear to include representation from the School of Veterinary Medicine in the audience.
- U.C. Berkeley hosted an antibiotics resistance panel on April 21 that was streamed live on the internet; that panel featured journalists Michael Pollan and Maryn McKenna and largely blamed livestock use of antibiotics for human resistance. <http://alumni.berkeley.edu/california-magazine/just-in/2015-04-22/antibiotic-overload-experts-blame-livestock-use-human> ”

Justin Oldfield, Vice President, Government Affairs, CCA:

- An agreement was recently finalized with SuKarne Produccion, Mexicali, Baja California, Mexico to slaughter cattle export from the Imperial Valley, US.
 - After National Beef closed last year, cattle from Imperial Valley went to other plants, notably JBS in Arizona.
 - “One World Beef” (Brandt’s Beef) purchased the Brawley facility and plan to open fall 2015.
- Foothill Abortion: vaccine trial going well; 25,000 doses available; ranchers to sign up for trial; pricing and start date to be determined.
- Antibiotics legislation: In 2014, SB 835 from Senator Hill (San Mateo) was supported by CCA - worked together to make amendments for phasing out antibiotic use and feed additives.
- Governor vetoed bill in late 2014 for being “weak” and directed CDFA to work with legislature on new rules. A new proposed bill covers 3 broad areas:
 - Rule out OTC as we know it today (e.g. penicillin, tetracycline, injectable)
 - Stewardship program to be adopted
 - Statewide tracking program for treated animals (e.g. dose, animal, reason)
- CDC, CDFA, USDA, CCA rallying efforts to work on agreements.
- The main concern of producers and vets is access to antibiotics.
- Natural Resources Defense Council (NRDC) wants the bill to be more stringent.

Dr. Annette Jones commented on CVMA's Ag Committee being engaged in the antibiotics issue.

- They have a key position between organizations like HSUS, NRDC and animal agriculture.
- CVMA and small animal practitioners can bring credibility and weight to the antibiotic discussion.
- Dr. Terry Lehenbauer participated in the working group
 - Potential nominee for a position on the (U.S.) Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria."

Dr. Scott Essex, Oregon Dept. of Ag.:

- 5 positive Trich herds in Oregon and 6 positive in P-P herds.
- Suspect bulls required to re-test for verification. There is 100% cooperation in following up a suspect bull, and the majority turn up positive.
- Trich rule changes:
 - Will accept imported virgin bulls up to 18 months (increased from 12 months) without a trich test.
 - Sexual rest prior to Trich test increasing from 10 to 14 days.

Melissa Lema, Western United Dairyman:

- Following the antibiotics issue, especially at federal level after the bulk tank sampling study was released (conditions/risk not as bad as they thought).
- Dealing with big dip in prices for dairyman and milk marketing.
- Information sessions for producers coming up first week in May in Chico, Fresno, Los Angeles.

TRICHOMONOSIS

Dr. Anita Edmondson gave a presentation on California Trich Program, introduced the Trich CONSULT www.trichconsult.org, and reviewed the proposed changes to the regulations. This was followed by discussion on the proposed regulation changes and enforcement concerns. The proposed regulations that stimulated discussion are as follows:

- Exemptions to test for bulls entering or sold in CA if for exhibition, going directly to slaughter, moving to feedlot and subsequent slaughter within 3 days
 - Discussion about follow-up, enforcement, wording of regulation.
- DNA detection/amplification test required for Trich testing bulls to harmonize with national standards
 - Concerns discussed about taking accredited, certified vets, doing culture tests, out of the diagnosis; private vets often get confirmation on samples that are only suspect on PCR.
 - Focus should be on culture technique and getting good samples. Submission of PCR samples not always convenient for weekends, etc.
 - Concerns discussed about false negatives from culture, as well as challenges in shipping logistics and sample contamination.
 - More comments about the potential for false negatives from culture, and that not all veterinarians are making producers aware of the sensitivity of culture or the risk of not doing 3 full negative tests.
 - Statement that the request from industry was to strengthen the Trich program, and PCR would almost certainly do that (find more infected bulls).
 - All recognize there are many practitioners competent in Trich testing and culture, but some who do not do a lot of testing.

***Action Item:** Go through changes for CA Trich Program and support as a committee, or support with amendments.

Justin Oldfield presented a resolution to support the changes to CA Trich Program as presented. **Dr. Bud Sloan moved to support the resolution. Dr. Charlie Tobias seconded the motion.**

Discussion:

1. Is additional language needed on the "Feedlot" option for slaughter bulls?
 - It was suggested that a signed acknowledgment, similar to the slaughter channel agreement, could be used for "Feedlots".
 - Some had concerns that people may use the "Feedlot" option to get around the Trich test if there was no follow-up or other controls; people could just say they are going to a feedlot and then resell/use for breeding.
 - Others commented that the regulation language for the "Feedlot" option was clear, and an additional signature would be unnecessary.
 - **Dr. Bud Sloan moved to amend the regulation section on the Feedlot.**
 - i. **No second. Motion fails.**
2. Should culture be an official test for sale bulls?
 - Discussion started with the importance of harmonizing tests between Western states - PCR being required for interstate movement - but that we should recognize the value of the training and use of private practitioners and labs.
 - Clarification made that the culture test is still an official test *in herd surveillance*, but not for interstate movement, sale bulls, or pasture to pasture herds.
 - Comments made that any difference in the requirements for in-state sale vs. interstate sale may be a problem.
 - Discussion that if there was a positive culture found during herd surveillance, PCR would still need to be done.
 - There were concerns about calling a test official (culture) if it would not be official for certain things, like moving interstate.
 - **Dr. Gene Harlan moved to amend the regulation on the culture test.**
 - i. **No second. Motion fails.**

Justin Oldfield called for a vote on the original resolution to support the proposed Trich regulation changes as presented by CDFA. A vote in favor was unanimous. Motion passes.

Working Lunch: Dr. Bret McNabb presented new Trich training video, which can be edited and changed as regulations shift.

Dr. Kent Fowler presented a Trich update provided by Dr. Kris Clothier, "T. foetus Testing Update"

- Number of culture tests had decreased by around 1,000 over prior years.
- PCR has not increased by a similar amount over the past couple years.
- T. foetus prevalence generally decreasing over several years.
- Pooling would miss a lot of infected bulls; most agree pooling might be utilized for low-risk, herd screening or surveillance, but not for high-risk or movement.

Dr. Rink commented on the pooling and use of Biomed tubes: any changes to the test can potentially weaken the value of the test.

LIVESTOCK TRACEABILITY/MOVEMENT ISSUES

Victor Velez gave a presentation on proposed changes to ADT regulations, implementation and enforcement.

This was followed by discussion and concerns about the proposed regulations. The following issues were discussed:

1. Official ID before leave premise of origin/birth
 - There were concerns about the time and money associated with enforcing this regulation at the saleyard.
 - Discussion about outreach/education focused on the producers and workers - to get a tag in every calf before leaving birth premises – then re-evaluate down the line; may use violations.
 - Holstein steers need to be wearing the ID but that ID doesn't need to be recorded on the CVI or by the saleyards.
 - CDFA/USDA will be enforcing the ID requirements, not the saleyards.
 - Saleyards can tag the cattle that arrive without tags if they are an approved tagging site.
 - If cattle come without meeting the ID requirements for sale, they are slaughter only (ADT states they cannot accept).
 - Farm of Origin concerns expressed.
 - Opposition to the 4 month together requirement. How would saleyard know? Discuss enforcement by USDA/CDFA, not by saleyard.
2. ADT regulations, streamlining process, data use and Brucellosis mature vaccination program.
 - Comments made that electronic Brand Inspection data will provide a lot of information on the movement of cattle, providing better traceability than CVI information. Why aren't CVIs electronic?
 - Comments made about making sure ADT fundamentals are working before tackling new ADT requirements.
 - Concerns expressed about CA's lack of a mature Brucellosis vaccination program.
3. Non-Brucellosis vaccinated heifers to be spayed on arrival.
 - Questions and concerns about the ID requirement on heifers entering California to be spayed several month later.
 - Concerns about the lack of outreach to other states about the need for ID.
 - Statement that, for now, ID when spayed; but goal is for ID before they enter California.

***Action Item:** Justin Oldfield tabled these discussions and suggested developing a **Brucellosis working group**, as many of the ID issues are driven by the Brucellosis vaccination requirements. The names of those to be involved in the work group are: Dr. Bud Sloan, Dr. Gene Harlan, Justin Oldfield, Brad Peek, Duane Martin Jr., additional producers and CDFA as advisors.

Several in attendance noted that, when the possibility of removing the Brucellosis vaccination program has been presented to the cattle industry, including Farm Bureau, CCA and dairy groups, there was always a strong response to keep the vaccination mandate (as cheap insurance). The cattle industry is the driving force behind the state brucellosis requirements.

No cattle industry groups have requested the AHB develop a mature brucellosis vaccination program; this committee has previously voted against developing a mature vaccination program because of the risks,

the liability and the questionable efficacy of the vaccine in low doses, in favor of handling non-vaccinated cattle on a case-by-case basis.

BOVINE TB PROGRAM

Dr. Anita Edmondson gave a presentation on CA Bovine TB Update.

- Current statistics in U.S. and CA
- Plant granuloma submission rates across U.S. and over time (seeing drops in rates)
- USDA/APHIS slaughter surveillance cash award program back up and running

CYSTICERCOSIS PROJECT

Dr. Beatriz Martinez-Lopez gave a presentation on Spatial epidemiology, risk factors and economic impact associated with bovine cysticercosis (and other diagnoses) found at processing plants in California.

- Collaborative work and study to try and understand whether cysticercosis cases are emerging/increasing, their risk factors (e.g. water contamination, feed/fecal contamination, environment vs. anthropogenic management factors, biosecurity), spatial and temporal trends, and their economic impacts using slaughter surveillance data.
- Human to cattle spread may be similar to spread of bovine TB from people to cattle.

No additional comments for matters not on the Agenda.

Review of four Action Items from October 29, 2014 meeting:

1. Committee to form a FMD focus group
2. Committee to form a TB focus group
3. AHB to prepare a draft of "Bull Slaughter Agreement"
4. AHB to prepare draft regulations for updating the Trichomonosis program

Items 3 and 4 have been completed. Items 1 and 2 are still *items of interest*, but can be removed from active action items.

Announcements:

- Oaths need to be returned to AHB
- Next meeting scheduled 6 months from now. Requested it be after the CCA meeting

Dr. Gene Harlan moved to adjourn the meeting. Motion was seconded by Dr. Terry Lehenbauer. Meeting adjourned at 2:45 PM.

Action Items from April 22, 2015 CHATF meeting:

1. Form Brucellosis working group.
2. Future discussion and amendments for Trich regulations (support for the current proposed changes passed by unanimous vote today).

Propose December 9, 2015 for next meeting.

CALIFORNIA CATTLEMEN'S ASSOCIATION

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PHONE: (916) 444-0845
FAX: (916) 444-2194
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December 16, 2013

The Honorable Karen Ross
Secretary of Food and Agriculture
Department of Food and Agriculture
1220 N Street
Sacramento, CA 95814

Dear Secretary Ross,

The California Cattlemen's Association (CCA) would respectfully request the Department of Food and Agriculture (CDFA) initiate a proposed rulemaking process to **delete** Section §820.4, Article 12, Division 2 of Title 3 (Food and Agriculture) of the California Code of Regulations. This section currently requires all bovine bulls over 18 months of age sold at public livestock markets to be sold for slaughter only unless accompanied by a negative test result for trichomonosis taken within the last 60 days.

At the most recent CCA Annual Convention, CCA members voted unanimously to petition CDFA to remove this regulation which our members agree has served its purpose in reducing the presence of trichomonosis in our state's breeding herd but is no longer necessary. All sectors of the beef cattle industry will remain vigilant to ensure any bulls found to be positive with trichomonosis be sold immediately for slaughter. CCA believes this objective can continue to be accomplished without Section §820.4 in law.

Section §820.4 is limited in scope and only applies to the sale of bulls sold at public livestock markets but does not govern the sale of bulls sold private treaty. In addition, no data exists demonstrating that this regulation will serve to further decrease the risk of introducing cases of trichomonosis to the state's breeding herd from bulls sold at public livestock auctions. Under today's situation of limited budgets and staff resources, this regulation has also been a challenge to fully administer and enforce by CDFA staff.

Even without Section §820.4 in law, California's public livestock markets will continue to work to protect the health and integrity of their buyers' breeding cattle. In practice, most culled bulls will continue to be sold directly for slaughter. However, the regulation will no longer impede a buyer wishing to purchase and slaughter a bull for their own use from doing so without a registered slaughter channel agreement. As such, CCA believes the status quo will not change in the absence of Section §820.4 in most circumstances and the threat or risk of introducing trichomonosis by bulls sold at public livestock markets will remain extremely low.

The elimination of Section §820.4 will also not change the existing requirement that bulls entering California be accompanied by a current negative trichomonosis test. In addition, if a breeding herd is found to be infected, CDFA will retain the authority to quarantine the infected

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FEEDER COUNCIL VICECHAIR
EL CENTRO

GA

herd and any surrounding herds to ensure that any animal found to be positive with trichomonosis is sent directly to slaughter.

CCA appreciates your consideration of our request and we look forward to working with you and your staff to realize this objective. Do not hesitate to contact me directly if you have any questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Justin Oldfield".

Justin Oldfield
Vice President, Government Relations

CC: Dr. Annette Jones, California State Veterinarian
Dr. Kent Fowler, Animal Health Branch Chief, CDFA
Forrest Mangan, California Livestock Auction Markets Association

the religious and spiritual welfare of all interested inmates. The CDCR regulations for diet accommodations, including kosher diets, are accordingly designed to be fully inclusive subject to legitimate administrative and budgetary concerns. Under Title 15 section 3054(d), CDCR allows three religious diet options including a vegetarian diet, a Jewish kosher diet, and a religious meat alternate.

Section 3054.2(a), the regulation that petitioner challenges, provides in full that "Jewish kosher meals shall be available at designated institutions. Jewish inmates may participate in the program, as determined by a Jewish Chaplain." This regulation is tailored to accommodate inmates who are recognized to have a need of a kosher diet. Based on the self-described beliefs of the petitioner, there is no requirement for CDCR to provide the petitioner with a kosher diet accommodation. This assessment does not preclude the petitioner from seeking the vegetarian diet or the religious meat alternate diet if necessary.

**DEPARTMENT OF FOOD
AND AGRICULTURE**

**NOTICE OF DECISION ON PETITION FOR
RULEMAKING
(Government Code Section 11340.7)**

By letter dated December 16, 2013, Justin Oldfield, Vice President, Government Relations, California Cattlemen's Association, (Petitioner) petitioned the Department of Food and Agriculture (Department) of the State of California in accordance with Government Code section 11340.6. The petitioner requested the Department to repeal section 820.4 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations. Regulation section 820.4 pertains to the sale of bulls within California. It requires that all bulls over 18 months of age sold at public livestock markets to be sold for slaughter unless the bulls are accompanied by a negative test result for trichomonosis taken within the last 60 days prior to sale.

**PROVISIONS OF THE CODE OF REGULATIONS
REQUESTED TO BE AFFECTED**

Article 12 (Bovine Trichomonosis Control Program), of Chapter 2 (Livestock Disease Control [Animal Quarantine]), Division 2 (Animal Industry), Title 3, California Code of Regulations.

AUTHORITY AND REFERENCE

Authority: Sections 407 and 10610, Food and Agricultural Code.

Reference: Sections 9166, 9167, 9562 and 10610, Food and Agricultural Code.

CONTACT PERSON

Any interested person may obtain a copy of the petition by contacting the following person:

Nancy Grillo
Regulation Coordinator
Department of Food and Agriculture
Animal Health and Food Safety Services
1220 N Street
Sacramento, CA 95814
(916) 900-5033
E-mail: nancy.grillo@cdfa.ca.gov

DEPARTMENT DECISION

On January 13, 2014, the Department responded to the Petitioner accepting the petition in full, for the reasons set forth below.

**REASONS SUPPORTING THE
DEPARTMENT'S DETERMINATION**

The Department consulted with the Cattle Health Advisory Task Force [pursuant to section 10610 of the Food and Agricultural Code] and in accordance with Government Code section 11340.7, the request to repeal regulation section 820.4 was evaluated based on the following information:

- 1) Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations, specifies the requirements for the control of trichomonosis in California. It specifies the requirements for bulls entering the state, vaccination, testing, and permit requirements, reporting of infected herds, and contains quarantine provisions for trichomonosis-infected cattle in the state. Section 820.4 of Article 12 pertains to the sale of bulls within California. It requires all bulls over 18 months of age sold at public livestock markets to be sold for slaughter unless the bulls are accompanied by a negative test result for trichomonosis taken within the last 60 days prior to sale.

- 2) Trichomonosis is a venereal disease of cattle that causes infertility and occasional abortions in cows and heifers. It is caused by *Trichomonas fetus*, a small motile protozoan found only in the reproductive tract of the bull and cow. The most effective way to control trichomonosis is to prevent the introduction of the organism into a herd. This is primarily accomplished through testing all new bulls prior to entry into the herd and preventing unwanted bulls from entering through damaged fence lines. A vaccine for trichomonosis is available and labeled for use in controlling the disease in cows. Currently, the vaccine is not labeled for use in bulls. Producers are encouraged to work with their veterinarian to develop appropriate protocols for controlling trichomonosis and other reproductive diseases in their herds.
- 3) The Department believes that there are existing provisions in place under Title 3 of the California Code of Regulations to prevent and control animal diseases, including trichomonosis. The Department also has in place animal quarantine provisions [sections 9501–9702, Food and Agricultural Code] to ensure that any animal found to be positive with trichomonosis is sent directly to slaughter.

The Department also agreed with the reasons provided in the petition to repeal section 820.4 from Title 3 of the California Code of Regulations, which were stated in the Department’s final decision to the Petitioner, which reads as follows:

January 13, 2014

Justin Oldfield
Vice President, Government Relations
California Cattlemen’s Association
1221 H Street
Sacramento, CA 95814–1910

Dear Mr. Oldfield,

The California Department of Food and Agriculture (CDFA) has received your petition requesting that it repeal section 820.4 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations. (Petition from the California Cattlemen’s Association, dated December 16, 2013.) Upon consultation with the Cattle Health Advisory Task Force and in accordance with the

requirements of Government Code section 11340.7, CDFA has granted the petition.

The CDFA bases its decision upon the fact that it agrees with the arguments in favor of the repeal set forth in the petition:

- o The regulation is limited in scope and only applies to the sale of bulls sold at public livestock markets but does not govern the sale of bulls sold by private treaty.
- o No data exists demonstrating that this regulation will serve to further decrease the risk of introducing cases of trichomonosis to the state’s breeding herd from bulls sold at public livestock auctions.
- o California’s public livestock markets will continue to work to protect the health and integrity of their buyers’ breeding cattle. In practice, most culled bulls will continue to be sold directly for slaughter; however, the regulation will no longer impede a buyer wishing to purchase and slaughter a bull for their own use from doing so without a registered slaughter channel agreement.
- o There are adequate regulations in place to prevent and control trichomonosis in California. Existing regulations require bulls entering California be accompanied with a current negative trichomonosis test. In addition, if a breeding herd is found to be infected, CDFA has the existing regulatory authority to quarantine the infected herd and any surrounding herds to ensure that any animal found to be positive with trichomonosis is sent directly to slaughter.

Accordingly, CDFA shall proceed with the repeal of section 820.4 from Title 3 of the California Code of Regulations by submitting a draft proposal to the Cattle Health Advisory Task Force in April 2014. After considering the recommendations of the Task Force, CDFA will promptly submit a rulemaking action to the Office of Administrative Law for the repeal in accordance with the requirements of the Administrative Procedure Act.

Sincerely,

Annette Jones, D.V.M.
State Veterinarian and Director

cc: Karen Ross, Secretary, CDFA
Dr. Kent Fowler, Chief, Animal Health Branch,
CDFA
Cattle Health Advisory Task Force Members

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January 16, 2015

The Honorable Karen Ross
Secretary of Food & Agriculture
California Department of Food & Agriculture
1220 N Street
Sacramento, CA 95814

Dear Secretary Ross,

The California Cattlemen's Association (CCA) respectfully requests the California Department of Food and Agriculture (CDFA) withdraw a petition submitted by CCA on December 16, 2013 requesting CDFA eliminate Section §820.4, Article 12, Division 2 of Title 3 (Food and Agriculture) of the California Code of Regulations.

Following comprehensive discussions with other impacted stakeholders, CCA members approved a new policy resolution at the most recent Annual Convention held in Sparks, Nevada on November 22, 2014 advocating that the aforementioned regulations pertaining to the sale of bulls over 18-months of age sold at public livestock auction markets remain intact.

In turn, CCA requests the following amendments be made to Section §820.4 regarding the intrastate sale of bulls at public livestock auction markets and Section §820.55 regarding Trichomonosis tests:

1. CDFA initiate a mandatory color coded identification program for all bulls that undergo a Trichomonosis test, ear tag colors correspond to the year the test was completed and the ear tag colors mimic the colors prescribed by the Oregon Department of Agriculture and Nevada Department of Agriculture.
2. CDFA require that any bull older than 18-months of age sold for breeding undergo a Trichomonosis test within 60 days preceding any change of ownership, irrespective if the animal is sold at a public livestock auction market or private treaty.
3. CDFA exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age used solely for artificial insemination using semen extension and preservation protocols that meet Certified Semen Services standards so long as the bull is confined and never exposed to sexually intact female cattle.
4. CDFA exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age used solely for exhibition purposes as defined so long as the animal remains under confinement and at no time is allowed to access or comingle with sexually intact female cattle.

BILLY FLOURNOY
PRESIDENT
LIKELY

ROB VON DER LIETH
TREASURER
COPPEROPOLIS

BILLY GATLIN
EXECUTIVE VICE PRESIDENT
HERALD

RICH ROSS
SECOND VICE PRESIDENT
LINCOLN

MARK LACEY
SECOND VICE PRESIDENT
INDEPENDENCE

DAVE DALEY
FIRST VICE PRESIDENT
CHICO

BILL BRANDENBERG
FEEDER COUNCIL CHAIR
EL CENTRO

JACK LAVERS
SECOND VICE PRESIDENT
GLENNVILLE

MIKE SMITH
FEEDER COUNCIL VICECHAIR
SELMA

H

5. CDFA exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age sold solely for slaughter to a recognized buyer with a signed bull slaughter channel agreement provided by CDFA or to a feedlot where cattle are fed solely for slaughter so long as the animal is confined and never exposed to sexually intact female cattle.

These amendments will enhance the effectiveness of the current Trichomonosis control program while rectifying deficiencies that discriminate against the sale of bulls at public livestock auction markets. CCA respectfully requests appropriate amendments be offered by CDFA to the California Code of Regulations at your earliest possible convenience.

Sincerely,

A handwritten signature in black ink, appearing to read "Justin Oldfield". The signature is written in a cursive, flowing style with a large initial "J".

Justin Oldfield
Vice President, Government Relations

TSDs describe non-cancer risk assessment (derivation of acute, 8-hour and chronic Reference Exposure Levels), derivation of cancer potency factors, and exposure assessment methodology including stochastic risk assessment. These TSDs underwent public and peer review, were approved by the State's Scientific Review Panel on Toxic Air Contaminants, and adopted by OEHHA for use in the Air Toxics Hot Spots program. The final Guidance Manual combines the critical information from the three TSDs into a guidance manual for the preparation of health risk assessments.

The document will be available on the OEHHA Home Page at <http://www.oehha.ca.gov> on **March 6, 2015**.

<p>RULEMAKING PETITION DECISION</p>
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**DEPARTMENT OF FOOD AND
AGRICULTURE**

(Government Code Section 11340.7)

By letter dated December 16, 2013, Justin Oldfield, Vice President, Government Relations, California Cattlemen's Association, (Petitioner) petitioned the Department of Food and Agriculture (Department) of the State of California in accordance with Government Code section 11340.6. The Petitioner requested the Department to repeal section 820.4 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations. Regulation section 820.4 pertains to the sale of bulls within California. It requires that all bulls over 18 months of age sold at public livestock markets to be sold for slaughter unless the bulls are accompanied by a negative test result for Trichomonosis taken within the last 60 days prior to sale.

By letter dated January 16, 2015, Justin Oldfield, Vice President, Government Relations, California Cattlemen's Association, (Petitioner) petitioned the Department to withdraw the original petition dated December 16, 2013 requesting the repeal of regulation section 820.4 and instead requested the Department to amend the regulation. Therefore, in accordance with Government Code section 11340.6, the Petitioner requested the amendment of regulation section 820.4 which pertains to the sale of bulls within California. It requires that all bulls over 18 months of age sold at public livestock markets to be sold for slaughter unless the

bulls are accompanied by a negative test result for Trichomonosis taken within the last 60 days prior to sale.

**PROVISIONS OF THE CODE OF REGULATIONS
REQUESTED TO BE AFFECTED**

Article 12 (Bovine Trichomonosis Control Program), of Chapter 2 (Livestock Disease Control [Animal Quarantine]), Division 2 (Animal Industry), Title 3, California Code of Regulations.

AUTHORITY AND REFERENCE

Authority: Sections 407 and 10610, Food and Agricultural Code.

Reference: Sections 9166, 9167, 9562 and 10610, Food and Agricultural Code.

CONTACT PERSON

Any interested person may obtain a copy of the petition by contacting the following person:

Nancy Grillo, Regulation Coordinator
Department of Food and Agriculture
Animal Health and Food Safety Services
1220 N Street,
Sacramento, CA 95814
Phone: (916) 900-5033
E-mail: nancy.grillo@cdfa.ca.gov

DEPARTMENT DECISION

On January 13, 2014, the Department responded to the original petition and accepted it in full and provided the reasons for the decision. The Department's decision was published in the California Regulatory Notice Register, Register 2014, No. 5-Z, January 31, 2014 [Notice File Number Z-2014-0115-01].

On February 6, 2015, the Department accepted the new petition in full for the reasons set forth below.

**REASONS SUPPORTING THE
DEPARTMENT'S DETERMINATION**

The Department consulted with the Cattle Health Advisory Task Force [pursuant to section 10610 of the Food and Agricultural Code] and in accordance with Government Code section 11340.7, the request to amend regulation section 820.4 was evaluated based on the following information:

- 1) Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations, specifies the requirements for the control of Trichomonosis in California. It specifies the requirements for bulls entering the state, vaccination, testing, and permit requirements, reporting of infected herds, and contains quarantine provisions for Trichomonosis infected cattle in the state. Section 820.4 of Article 12 pertains to the sale of bulls within California. It requires all bulls over 18 months of age sold at public livestock markets to be sold for slaughter unless the bulls are accompanied by a negative test result for Trichomonosis taken within the last 60 days prior to sale.
- 2) Trichomonosis is a venereal disease of cattle that causes infertility and occasional abortions in cows and heifers. It is caused by *Trichomonas fetus*, a small motile protozoan found only in the reproductive tract of the bull and cow. The most effective way to control Trichomonosis is to prevent the introduction of the organism into a herd. This is primarily accomplished through testing all new bulls prior to entry into the herd and preventing unwanted bulls from entering through damaged fence lines. A vaccine for Trichomonosis is available and labeled for use in controlling the disease in cows. Currently, the vaccine is not labeled for use in bulls. Producers are encouraged to work with their veterinarian to develop appropriate protocols for controlling Trichomonosis and other reproductive diseases in their herds.
- 3) The Department believes the amendments suggested by the Petitioner will enhance the effectiveness of the current Trichomonosis control program while rectifying deficiencies that might discriminate against the sale of bulls at public livestock auction markets.

The Department also agreed with the reasons provided in the petition to amend section 820.4 of Title 3 of the California Code of Regulations, which were stated in the Department's final decision to the Petitioner, which reads as follows:

February 6, 2015

Justin Oldfield
 Vice President, Government Relations
 California Cattlemen's Association
 1221 H Street
 Sacramento, CA 95814-1910

Dear Mr. Oldfield,

The California Department of Food and Agriculture (CDFA) received your letter to withdraw the petition dated December 16, 2013 to repeal section 820.4 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations and instead amend regulation section 820.4 (petition from the California Cattlemen's Association (CCA), dated January 16, 2015). Upon consultation with the Cattle Health Advisory Task Force and in accordance with the requirements of Government Code section 11340.7, CDFA has granted the petition. CDFA bases its decision upon the fact that it agrees with the arguments in favor of the amendments.

The original petition requested the repeal of the Trichomonosis testing requirements because some salesyards believed the regulation was unfair, as it only applied to bulls sold in the sale and salesyards could not sell the bull without a test (except to slaughter). This resulted in some bulls sold privately, not through the salesyard. Subsequently, the cattle industry and CDFA believed that bulls sold privately, not through the salesyards, could not effectively be tracked in cases of a Trichomonosis outbreak. CDFA agrees with the compromise as stated by CCA in its petition to amend regulation section 820.4 instead of repealing it. It would require the testing of all bulls changing ownership, and allow specific exemptions to match those for existing interstate movement.

CDFA agrees with CCA to amend regulation section 820.4, as follows:

- Initiate a mandatory color coded identification program for all bulls that undergo a Trichomonosis test;
- Require that any bull older than 18-months of age sold for breeding undergo a Trichomonosis test within 60 days preceding any change of ownership, irrespective if the animal is sold at a public livestock auction market or private treaty;
- Exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age used solely for artificial insemination using semen extension and preservation protocols that meet Certified Semen Services standards so long as the bull is confined and never exposed to sexually intact female cattle;
- Exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age used solely for exhibition purposes as defined so long as the animal remains under confinement and at no time is allowed

access or comingle with sexually intact female cattle; and,

- Exempt the requirement of a mandatory Trichomonosis test for a bull older than 18-months of age sold solely for slaughter to a recognized buyer with a signed bull slaughter channel agreement provided by the Department or to a feedlot where cattle are fed solely for slaughter so long as the animal is confined and never exposed to sexually intact female cattle.

CDFA believes that the amendments proposed by CCA will harmonize an effective Trichomonosis program because the proposal would require all bulls 18-months of age and over sold in California to be tested for Trichomonosis; current regulations only require this test for bulls sold through public sales. The proposal would exempt specific classes of sale bulls from the test requirement; current regulations allows these test-exemptions for bulls entering California from other states but fail to exempt California bulls from the test.

Accordingly, CDFA shall proceed with amending section 820.4 of Title 3 of the California Code of Regulations. The Department will promptly submit a rule-making action to the Office of Administrative Law for the amendment in accordance with the requirements of the Administrative Procedure Act.

Sincerely,

Annette Jones, D.V.M.
State Veterinarian and Director

cc:
Karen Ross, Secretary, CDFA
Dr. Kent Fowler, Chief, Animal Health Branch, CDFA
Cattle Health Advisory Task Force Members

SUMMARY OF REGULATORY ACTIONS

REGULATIONS FILED WITH SECRETARY OF STATE

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA 95814, (916) 653-7715. Please have the agency name and the date filed (see below) when making a request.

File# 2015-0218-01
BOARD OF GOVERNORS, CALIFORNIA COMMUNITY COLLEGES
Financial Assistance Awards

The Board of Governors of the California Community Colleges submitted to OAL this action dealing with financial assistance awards as a print only file. Pursuant to Education Code section 70901.5, this action was filed with the Secretary of State by the Board on February 18, 2015, is exempt from the Administrative Procedure Act and OAL review, and was submitted to OAL only for the purpose of publishing the regulation in the California Code of Regulations.

Title 5
California Code of Regulations
ADOPT: 58621 AMEND: 58601, 58612, 58620
Filed 02/18/2015
Effective 03/20/2015
Agency Contact: Julia Blair (916) 445-6272

File# 2015-0203-04
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
Conflict-of-Interest Code

This is an adoption to a Conflict-of-Interest Code that has been approved by the Fair Political Practices Commission and is being submitted for filing with the Secretary of State and printing in the California Code of Regulations only.

Title 2
California Code of Regulations
ADOPT: 59760
Filed 02/23/2015
Effective 03/25/2015
Agency Contact: Leslie Lopez (916) 653-3358

File# 2015-0209-03
CALIFORNIA HEALTH BENEFIT EXCHANGE
2016 Standard Benefit Design

This action adopts the 2016 Standard Benefit Plan Designs, which standardize the way health insurance issuers design their health plans.

Title 10
California Code of Regulations
ADOPT: 6432
Filed 02/19/2015
Effective 02/19/2015
Agency Contact: Andrea Rosen (916) 228-8343

File# 2015-0206-01
DEPARTMENT OF FOOD AND AGRICULTURE
Conflict-of-Interest Code

This Conflict-of-Interest Code filing by the Department of Food and Agriculture (DFA) was approved by



WA Dept of Agriculture – Order Form

Premises#: 00FTMZY

Shipping Options:

Standard

Other _____

Account: 31972

Contact: David Hamman

Phone#: (360) _____

Date: 7/16/14

Ship to Address:

WSDA Animal Disease Traceability
1111 Washington St SE
Olympia WA 98504-2560

NUES TAGS (Green)

\$0.25 each for quantities of 3000 or more (freight prepaid)
\$0.27 each for quantities of 2999 or less (plus freight charges)

State code/State Abbreviation: WA

Three digit Letter code: WA DAG

(If series goes over 9999 on the bottom, the next alpha sequence is used. Example: ABA, ABB)



Four Digit Numbers

SKU: NUES-CP74M/CP74F-G

QTY: 10,000

Beginning: 0001

Ending: 0000 = 10,000 tags

TRICH Tags

Trich Tag Color: Yellow

\$0.74 each for quantities of 3000 or more (freight prepaid)
\$0.76 each for quantities of 2999 or less (plus freight charges)

State code/State Abbreviation: WA



SKU: TRIWSAS-GTLF1/GESM-BY

QTY: 3,000

(The B at the end of SKU will change each year to equal the TRICH year color)

Five Digit Numbers

Beginning: 00001 Ending 03000

WA Brucellosis RFID AIN Tags

\$1.85 per tag packaged 20 tags per bag
(5 tags per tray)



SKU: WA-USDA840HDX-BO/GESM1-O

QTY: _____



SKU: USDA840HDX/GESM-W

QTY: _____

APPLICATORS



Universal Total Tagger
Product Code: APP-UTT
Price: \$17.33

QTY: _____ Tagger(s)



Universal Total Tagger + (with flip-pin feature)
Code: APP-UTT-PLUS
Price: \$38.45

QTY: _____ Tagger(s)



Global Retract-O-Matic
Product Code: APP-RET-GLOBAL
Price: \$43.45

QTY: _____ Tagger(s)

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Washington's Requirement

Washington has mandatory Trichomoniasis requirements for all imported bulls. Bulls meeting Washington's import requirements will be identified with official identification or an official trichomoniasis bangle tag. Washington also has in-state trichomoniasis requirements for any sexually intact bovine that is found test-positive for trichomoniasis or any herd in which one or more bulls or cows are found test-positive for trichomoniasis. Bulls in slaughter pen at livestock markets must have a negative Trichomoniasis (qPCR) test before departing for any destination other than to remain in slaughter channels.

Bovine can be identified with the Washington State official Trichomoniasis ear tag or any other official identification approved by the state.

Washington's Trichomoniasis Tag

Washington has a trichomoniasis ear tag that meets in-state and for Washington bulls leaving the state to meet destination testing requirements. The visual tag is tamperproof, 3" wide x 2 1/4" tall with a self piercing male button (back) printed with WA and the current Trich year. The female portion of the tag (front) has WA TRICH printed above a 5 digit number.

State Trich certified accredited veterinarians can order tags from WSDA. Trich tags are packaged 25/bag.

Trichomoniasis Year

The Trichomoniasis year is defined as September 1 - August 31, so application of the appropriate tag color will change each year on September 1. Previous year Trichomoniasis tags will be removed and replaced with the tag consistent with the current year's test. Year-to-year continuity of bovine Trich identification should be maintained either using other individual animal identification such as a ranch tag, tattoo, brucellosis's alphanumeric ID tag or RFID tag. Trichomoniasis bangle tag colors repeat every 5 years.

Trich Year	Test Period	Tag Color
2012	Sep 1, 2011 – Aug 31, 2012	White
2013	Sep 1, 2012 – Aug 31, 2013	Orange
2014	Sep 1, 2013 – Aug 31, 2014	Blue
2015	Sep 1, 2014 – Aug 31, 2015	Yellow
2016	Sep 1, 2015 – Aug 31, 2016	Green
2017	Sep 1, 2016 – Aug 31, 2017	White

Washington Administrative Code (WAC) relating to Bovine Trichomoniasis requirements

WAC 16-86-115 Trichomoniasis in Washington cattle.

WAC 16-54-086 (Import) Bovine Trichomoniasis requirements.

WAC 16-86-005 Definitions (contains herd plan and virgin bulls definition).

WAC 16-86-116 Duties of Certified, Accredited Veterinarians – Training requirement for veterinarians performing trichomoniasis testing in cattle.

For more information on Washington Administrative Code (WAC) relating to Bovine Trichomoniasis requirements visit: <http://apps.leg.wa.gov/wac/>

Washington State Department of Agriculture

Animal Services Division
Animal Health Program
1111 Washington Street SE
PO Box 42577
Olympia, WA 98504

Phone (360) 902-1878
Fax (360) 902-2087
E-mail ahhealth@agr.wa.gov

<http://agr.wa.gov/FoodAnimal/AnimalHealth/>

Special thanks to California Department of Food and Agriculture for shared use of this content



R - 6/2011

Bovine Trichomoniasis In Washington State



Overview for Cattle Producers

Washington State
Department of Agriculture
Animal Services

Bovine Trichomoniasis

Trichomoniasis is a venereal disease among cattle that can cause abortions, low pregnancy rates and delayed or prolonged calving seasons. The disease is present in the U.S., and can have severe economic costs for Washington's beef producers. Tight economic conditions may allow the disease to spread undetected (e.g. less pregnancy checking, longer breeding seasons, purchase of bargain cows), but trichomoniasis can be prevented and controlled through management.

Cause

Trichomoniasis is caused by a sexually transmitted parasite (*Tritrichomonas foetus*). The protozoa can survive and grow in the folds of the penis. Bulls over three years of age rarely clear the parasite once they become infected, and serve as long-term carriers.

The parasite may also live in the reproductive tract of infected cows, though they often clear the infection within three months. Immunity to trichomoniasis lasts less than a year, so cows may be re-infected. Some infected cows may carry the infection into the next breeding season.

Spread

Trichomoniasis is spread by breeding activity. Infected bulls continue to breed normally and spread the infection to cows, which pass it to uninfected bulls when they rebreed. Bull-to-bull is rare; cow-to-cow transmission does not occur.

Trichomoniasis is more common in breeding pastures where multiple herds are mixed (e.g. community pastures), or in herds that purchase open cows or mature, untested breeding bulls. The parasite is sensitive to freezing, drying, and sunlight, and cannot survive outside the animal.

Symptoms

Infected bulls show no symptoms. Infected cows usually abort early in the first trimester resulting in repeat breeding, irregular heat cycles, longer calving intervals, and reduced pregnancy rates. The uterus may become infected in some cases.

In uninfected herds, the majority of cows should be pregnant and calve in the first 45 days of the calving period, given proper management

(good body condition score, short breeding season) and no other reproductive problems.

Trichomoniasis abortions peak at 50 to 70 days of gestation. So in trichomoniasis infected herds with a short breeding season, many cows may be open in fall. In infected herds with a long breeding season, many cows calve in the second half of the calving season.

Testing

For best results, tested animals should have a minimum of 4-days without sexual activity before they are sampled.

Several different methods are used in the U.S. to collect and test for trichomoniasis. Washington uses the InPouch TF to collect smegma samples for transport to a certified lab. The lab conducts a Polymerase Chain Reaction test and returns the result to the veterinarian and the state veterinarian's office.

Treatment and Vaccination

Antibiotics and vaccination are not generally economical or effective because the protozoa do not live within the bloodstream. This makes it difficult for antibiotics and vaccines to reach the parasite. The preventative value of vaccination is relatively short-lived, but may help in some cases.

Control and Prevention

Appropriate management of the breeding herd helps to prevent the introduction of the disease to uninfected herds, and in eliminating the parasite from infected herds.

Control of trichomoniasis in infected herds:

- Test all non-virgin bulls.
- Cull infected bulls, and replace with virgin bulls. Virgin bulls have not been exposed to infected cows, and have not been shown to harbor the infection.
- Pregnancy check and cull open and late-calving females.
- Send culled animals to slaughter to avoid infecting other herds.

- Use home-raised replacements, or purchase pregnant replacements from reputable sources.
- Separate replacements from mature animals.

Minimizing the risk of trichomoniasis infections in uninfected (clean) herds:

- Purchase only virgin or tested bulls.
- Do not borrow, rent, lease or buy untested bulls that have been used for breeding.
- Cull open and late-calving cows.
- Winter cows and bulls separately to minimize infection of bulls by late calving or late cycling cows.
- Do not purchase open cows.
- Use home-raised replacements, or purchase pregnant replacement females from reputable sources.
- Separate replacements from mature animals.
- Avoid commingling of breeding herds, if possible.
- Check fences regularly to keep other animals out.

Community pastures

- Producers using community pasture need to establish, implement and police biosecurity policies that help avoid trichomoniasis, such as:
- Test and cull infected herd and patron bulls.
 - Consider wintering bulls used on community pastures away from cows to avoid re-infecting cows.
 - Accept only virgin heifers and cows with a calf at side.
 - If facilities, fencing and labor are adequate, community pastures may set aside "clean" pastures for cows from uninfected herds with calves at side, and "infected" pastures for infected herds, or herds with open cows.

Danger to humans

Bovine trichomoniasis is not believed to be a risk to humans. Human trichomoniasis is caused by a different organism (*Trichomonas vaginalis*). Trichomoniasis is not a food safety risk, and is not the same as trichinosis. Trichinosis is a parasite found in animals that eat meat.

Other considerations

Reproductive failure can also result from a variety of other nutritional, injury or infectious causes. A sound herd health program, developed in collaboration with your veterinarian, will help to minimize these risks.

**California Animal Health and Food Safety
Laboratory System**

<http://cahfs.ucdavis.edu>



**Trichomonas Submission Form:
DVM must also submit CDFA
Trichomonosis Test Report form to
complete official testing**

CAHFS Accn. # _____
 Rec'd by _____
 Case Coordinator _____
 Accn Type _____
 # of Samples _____
 Date Rec'd _____
 Section _____
 Bill To: Vet Clinic Owner Other
 Carrier _____

To be completed by Clinic / Veterinarian: (Check box next to requested test)

Veterinarian's Name _____	Owner's Name _____
Clinic Name _____	Ranch _____
Address _____	Address _____
City _____ State _____ Zip _____	City _____ State _____ Zip _____
Phone _____ Fax _____	Phone _____
Email _____	Email _____

CHECK INDIVIDUAL BOX FOR REQUESTED TESTING

InPouch-TF - Standard Culture <input type="checkbox"/>	10131	10130	LRS or Saline - Standard Culture <input type="checkbox"/>
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Ship Ambient. Must receive InPouches within 48 hrs of collection	Date _____	Time _____
	Samples Collected _____	
	# of Samples Submitted _____	

InPouch-TF 24hr Incubation & qPCR <input type="checkbox"/>	10571	Date _____	Time _____
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Ship Ambient. Must receive InPouches within 48 hrs of collection	Samples Collected _____	
	# of InPouches Submitted _____	
	PCR done only on InPouch samples	

Frozen InPouch-TF for qPCR <input type="checkbox"/>	10572	Date _____	Time _____
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Freeze InPouch. Ship overnight. Pack on ice or frozen gel packs	Samples Collected _____	
	# of InPouches Submitted _____	
	Total Incubation Time by DVM at 37°C (hrs): _____	

POSITIVE InPouch-TF Confirm by qPCR <input type="checkbox"/>	0153	Date _____	Time _____
--	------	------------	------------

Freeze InPouch. Ship overnight. Pack on ice or frozen gel packs	Samples Collected _____	
	When were organisms seen: Date _____ Day of incubation _____	

For Laboratory Use Only:	Temperature at lab receipt: _____ °F	Tech: _____
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I understand that specimens submitted are the property of CAHFS. Client information provided to CAHFS, and the test results from samples submitted to CAHFS, will be treated as confidential information consistent with applicable legal standards, including, but not limited to, California Business and Professions Code section 4857 and Evidence Code 1040. Such confidential information will not be divulged to third parties without written consent of the client, except when required by law, which includes requirements that test results be provided to regulatory agencies. University, its officers, employees, and agents shall not be accountable for any loss, expense (including attorneys' fees), damage, or liability of any kind resulting from or arising out of services provided hereunder unless caused by negligent or willful acts or omissions by University, its officers, employees, or agents.

Signature of Submitter: _____ **Date:** _____

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CAHFS Trichomonas/Tritrichomonas foetus testing
CAHFS offers different testing methods based on the needs of the herd

**All submissions must be accompanied by a completed CDFA Bovine Trichomonas Test Report Form
Do not remove any pages from the form before testing is complete; or use electronic link below and
submit original form. All results will be reported to CDFA**

Link to CDFA form: [http://www.cdfa.ca.gov/ahfss/Animal Health/pdfs/AHB 76-199 TrichReporting ELECTRONIC.pdf](http://www.cdfa.ca.gov/ahfss/Animal%20Health/pdfs/AHB%2076-199%20TrichReporting%20ELECTRONIC.pdf)

Tritrichomonas foetus real-time PCR (qPCR) testing options

- Testing is performed on BioMed Diagnostics InPouch-TF (IP) samples only (not tubes or washes)
- Samples submitted to Turlock, San Bernardino, or Tulare branches will be sent to Davis for testing
- Two options for PCR testing are available
 - 1. InPouch-TF 24-hr Incubations at Lab and qPCR**
 - Inoculated IP must be received **within 48 hours of collection** and maintained at **65°F - 95°F**
 - Samples can't be received on weekends so must arrive at the lab Monday-Friday
 - Samples arriving outside of temperature guidelines can be tested "for unofficial purposes" only
 - Results are "Positive", "Negative", or "Inconclusive" (which means bulls are below the Positive range but may have low numbers of *T. foetus* and should be re-tested)
 - 2. Frozen InPouch-TF for qPCR (Vet Incubation)**
 - i. IP that can't be delivered to the lab in specified time frame can be incubated by DVM for 24 hr then frozen; samples must be shipped to **arrive frozen (≤ 40°F)** and received Monday-Friday
 - ii. Samples arriving outside of temperature guidelines can be tested "for unofficial purposes" only
- Results are "Positive", "Negative", or "Inconclusive" (which means bulls are below the Positive range but may have low numbers of *T. foetus* and should be re-tested)

Trichomonas culture testing options

- Trichomonas culture can be performed on
 - 1. Inoculated InPouch-TF**
 - 2. Sterile saline/LRS tubes (1.5ml) can be submitted for culture; saline/LRS samples are inoculated into laboratory culture media upon arrival**
- Samples must be received **within 48 hours of collection** and maintained at **65°F - 95°F**
- Samples arriving outside of temperature guidelines can be tested "for unofficial purposes" only
- Samples will be examined for 6 days for the presence of motile trichomonads
- If trichomonads are detected, sample will be tested for *T. foetus* by PCR at no additional charge
- CDFA-approved veterinarians can do routine cultures in their laboratories; if suspect Trichomonads are seen, freeze the entire pouch and ship to arrive frozen (≤ 40°F) Monday-Friday for confirmatory PCR (at no cost to the submitter)

Additional information

- **InPouch-TF** that are contaminated with bacteria (distended with gas, discolored) **can't** be tested by culture or PCR; new samples will need to be submitted to complete testing
- **Expired InPouch-TF samples** can be tested "for unofficial purposes" only
- Results of testing on pooled samples is not accepted by CDFA and can't be performed at CAHFS
- Samples in BioMed Transport Tubes are not accepted by CDFA and can't be tested at CAHFS
- Please notify the lab if you plan to submit **more than 30 samples** so we can have sufficient media
- Samples are tested on a "first-come, first-serve" basis; please plan your testing accordingly

Contact information:

Dr. Kris Clothier
CAHFS, UC Davis
Bacteriology Discipline Head
(530) 752-8700



USDA Process Verified Program

1 Purpose

The Agricultural Marketing Service (AMS), Livestock, Poultry, and Seed (LPS) Program, Quality Assessment Division (QAD) Audit Services Branch (ASB), offers the USDA Process Verified Program as a means to facilitate the marketing of agricultural products and to follow this procedure to objectively evaluate USDA Process Verified Programs applicants. The USDA Process Verified Program allows applicants (1) to identify their process points for verification and (2) the opportunity to assure customers of their ability to provide consistent quality products or services. This procedure provides applicants the requirements for developing and maintaining a USDA Process Verified Program.

2 Scope

The USDA Process Verified Program verifies that an applicant's business process or portion of their business process, including process verified points, are supported by a documented quality management system. The applicant's quality management system describes how they adhere to various defined requirements, and the scope of their program, which may include all phases of production and marketing, from genetic development through retail distribution.

Where any requirements cannot be applied due to the nature of an applicant's company and its product or service, these requirements may be considered for exclusion. Exclusions are limited to requirements within *Clause 4 Product Realization* and must not affect the applicant's ability to provide a conforming product or service. Additionally, exclusions do not alleviate the applicant's responsibility to provide a conforming product.

Products or services produced under a USDA Quality System Assessment (QSA) Program may be incorporated into a USDA Process Verified Program provided that (1) the products or services meet process verified points of the program and (2) additional requirements are met that are listed in this procedure.

3 Methodology

The ASB uses the International Organization for Standardization's (ISO) 9000 series standards for documented quality management systems as a format for evaluating USDA Process Verified Program documentation to ensure consistent auditing practices and promote international recognition of audit results.

4 References

QAD 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
QAD 1115 Procedure, Program Review Committee Procedures

5 Responsibilities

The ASB and applicants must meet all applicable requirements outlined in this Procedure and *QAD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.





Any suggested changes to this Procedure should be submitted to the ASB via email to QAD.AuditService@ams.usda.gov. Please include the procedure name i.e. "QAD 1001 Suggested Changes" in the subject line of the message.

6 Process Verified Points

6.1 Process verified points must be verifiable, repeatable, auditable, feasible, and factual.

6.2 Process verified points must not be requirements of 1) regulations or 2) quality management system criteria listed within this procedure.

6.3 Allowable process verified points may include:

- a) Adherence to a recognized standard, documentation, monitoring, or auditing that is not otherwise required by the quality management system or regulation
- b) A production and/or handling practice that provides specific information to consumers to enable them to make informed decisions on the products that they buy
- c) A service with a characteristic for that type of operation
- d) A quantifiable characteristic such as size, weight, or age
- e) A characteristic, practice, or requirement that is specifically requested by a customer or consumer

6.4 A Program Review Committee conducts reviews of all new process verified points to ensure that the above requirements are met.

7 Audit Frequency

7.1 After new programs receive a satisfactory desk audit, the applicant receives an onsite audit (the initial audit). The initial audit is followed by a surveillance audit within 6 months to ensure the program is being maintained. An annual renewal audit is conducted within 12 months from the initial onsite audit with subsequent audits conducted annually thereafter.

7.2 Approved programs are audited annually.

7.3 More frequent audits may be conducted at the applicant's expense when (1) numerous minor non-conformances or a major non-conformance are identified during the audit; (2) for cause; or (3) directed by the QAD Director.

7.4 Sites where key management system and process point activities occur such as an applicant office, a feed mill, processing facility, feedlot, etc.

8 Program Review Committee

8.1 The Program Review Committee makes decisions on program inquiries (including process points), new applications, approvals, denials, significant changes, reinstatements, withdrawals, and suspensions. The Program Review Committee may also be used to address Complaints.

8.2 The Program Review Committee reviews new program applications and extension of scope requests. For new applications, the applicant's process verified points are reviewed by a Program Review Committee prior to the initial desk audit. The purpose of the review is to determine if the



ASB has the capability to conduct the audit. This, in part, is determined by evaluating the ASB's policies to ensure the work falls within the scope of the program and doesn't conflict with any other established policies, determining if subject matter experts and auditors with the competence necessary to perform the audit are available, and determining if the workload will allow the audit to be performed in a timely manner.

- 8.3 The Program Review Committee reviews process points submitted through inquiries, new applications, and requests to extend the scope of approved programs. The purpose of the review is to determine if the process verified points included within the applicant's program are verifiable, repeatable, feasible, auditable, and factual.
- 8.4 The Program Review Committee reviews the results of initial audits, annual surveillance audits, and extension of scope requests, as applicable when making decisions. Decisions regarding suspension and withdrawal are limited to those based on the findings of the audit.
- 8.5 The Program Review Committee makes the final decision regarding program status, except for decisions regarding reduction of scope; they may be made by the Program Manager.
- 8.6 Appeals to the Program Review Committee decisions are reviewed by the ASB Chief.
- 8.7 The review is conducted and recorded in accordance to the *QAD 1115 Procedure*.

9 Listing of Approved Programs

Approved programs are listed on the USDA Process Verified Program website at <http://processverified.usda.gov/>. The listing includes the following information about the approved program:

- a) Applicant name
- b) Applicant contact information
- c) Process Verified Points
- d) Reference to basis for process verified points; definition or standard
- e) Report reference number (approval number)
- f) Renewal date

10 Certificate of Conformance

The Program Manager issues a *Certificate of Conformance* to all applicants with approved programs. The *Certificate of Conformance* identifies the program, location, scope, certificate number, issue date, and renewal date.

11 Program Requirements (Clauses 1 to 6)

Applicants must submit a documented program that addresses the program requirements as outlined in the following clauses (Clauses 1 to 6).



1 Quality Management System

1.1 General Requirements

1.1.1 The applicant must establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Program.

1.1.2 The applicant must:

- a) Determine the processes needed for the quality management system and their application throughout the organization
- b) Determine the sequence and interaction of these processes
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- e) Monitor, measure, where applicable, and analyze these processes
- f) Implement actions necessary to achieve planned results and continual improvement of these processes

1.1.3 These processes must be managed by the applicant in accordance with the requirements of this Program.

1.1.4 Where an applicant chooses to outsource any process that affects product conformity to requirements, the applicant must ensure control over such processes. The type and extent of control to be applied to these outsourced processes must be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization, measurement, analysis, and improvement.

NOTE 2: An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility to conform to customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- a) *The potential impact of the outsourced process on the organization's capability to provide product that conforms to the requirements*
- b) *The degree to which the control for the process is shared*
- c) *The capability of achieving the necessary control through the application of Clause 4.5*



1.2 Documentation Requirements

1.2.1 General

1.2.1.1 The applicant's quality management system documentation must include;

- a) A quality manual
- b) Documented and defined process verified points
- c) Documented statements of a quality policy and quality objectives
- d) Documented procedures and records required by this Program
- e) Documents, including records, determined by the applicant to be necessary to ensure the effective planning, operation, and control of its process.

NOTE 1: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the quality management system documentation can differ from one applicant to another due to a) the size of organization and type of activities; b) the complexity of processes and their interactions; and c) the competence of personnel.

NOTE 3: The documentation can be in any form or type of medium.

1.2.2 Quality Manual

1.2.2.1 The applicant must establish and maintain a quality manual that meets the requirements of this Program and includes:

- a) The scope of the quality management system, including details of and justification for any exclusions
- b) The process verified points
- c) The documented procedures established for the quality management system, or reference to them; including records maintained for the quality management system
- d) A description of the interaction between the processes of the quality management system
- e) Other documents as required by the quality management system

1.2.3 Control of Documents

1.2.3.1 Documents required by the quality management system must be controlled. Records are a special type of document and must be controlled according to the requirements given in Clause 1.2.4.

1.2.3.2 A master document list must be established that shows the most current issue of the quality management system procedures, work instructions, forms, tags, and labels used to track or demonstrate conformance.



1.2.3.3 A documented procedure must be established to define the controls needed to:

- a) Approve documents for adequacy prior to issue
- b) Review and update as necessary and re-approve documents
- c) Ensure that changes and the current revision status of documents are identified on all pages
- d) Ensure that relevant versions of applicable documents are available at points of use
- e) Ensure that documents remain legible and readily identifiable
- f) Ensure that documents of external origin determined by the applicant to be necessary for the planning and operation of the quality management system are identified and their distribution controlled;
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
- h) Retain all documents for the timeframe necessary to provide evidence of conformance

1.2.3.4 Changes significantly affecting the approved program, such as intended modification to the program, manufacturing process, or if relevant, its quality management system, which affects the conformity of the program including product produced under the program, must be submitted to the AMS Branch for approval prior to implementation.

1.2.4 Control of Records

1.2.4.1 Records must be established to provide evidence of conformity to requirements, including the process verified points, and of the effective operation of the quality management system must be controlled. Records must remain legible, readily identifiable, and retrievable.

1.2.4.2 A documented procedure must be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

1.2.4.3 Records must be retained for the timeframe necessary to provide evidence of conformance.

2 Management Responsibility

2.1 Management Commitment

2.1.1 Top management must provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customers as well as statutory and regulatory requirements
- b) Establishing the quality policy
- c) Ensuring that quality objectives are established
- d) Conducting management reviews
- e) Ensuring the availability of resources

2.2 Customer Focus

2.2.1 Top management must ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see Clauses 4.2.1 and 5.2.1).



2.3 Quality Policy

2.3.1 Top management must ensure that the quality policy:

- a) Is appropriate to the purpose of the organization in relation to its USDA Process Verified Program
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
- c) Provides a framework for establishing and reviewing quality objectives
- d) Is communicated and understood within the organization
- e) Is reviewed for continuing suitability

2.4 Planning

2.4.1 Quality Objective

2.4.1.1 Top management must ensure that quality objectives, including those needed to meet requirements for product (see Clause 4.1a), are established at relevant functions and levels within the organization. The quality objectives must be measurable and consistent with the quality policy.

2.4.2 Quality Management System Planning

2.4.2.1 Top management must ensure that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in Clause 4.1, as well as the quality objectives
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

2.4.3 Process Verified Points

2.4.3.1 Top management must ensure that the process verified points are:

- a) Established and stated in the quality manual;
- b) Included as part of the overall quality management system; and
- c) Verifiable, repeatable, auditable, feasible, and factual.

2.5 Responsibility, Authority, and Communication

2.5.1 Responsibility and Authority

2.5.1.1 Top management must ensure that responsibilities and authorities are defined and communicated within the organization.

2.5.1.2 An organization chart or similar document listing all personnel, their responsibilities, and authorities assigned to managerial positions within the program must be included in the quality manual.

2.5.2 Management Representative

2.5.2.1 Top management must appoint a member of the applicant's management who, irrespective of other responsibilities, must have responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented, and maintained



- b) Reporting to top management on the performance of the quality management system and any need for improvement
- c) Ensuring the promotion of awareness of customer requirements throughout the organization

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

2.5.3 Internal Communication

2.5.3.1 Top management must ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

2.6 Management Review

2.6.1 General

2.6.1.1 Top management must review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review must include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy, quality objectives, and process verified points.

2.6.1.2 Records from management reviews must be maintained.

2.6.2 Review Input

2.6.2.1 The input to management review must include information on:

- a) Results of audits
- b) Customer feedback
- c) Process performance and product conformity
- d) Status of preventive and corrective actions
- e) Follow-up actions from previous management reviews
- f) Changes that could affect the quality management system
- g) Recommendations for improvement

2.6.3 Review Output

2.6.3.1 The output from the management review must include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes
- b) Improvement of product related to customer requirements
- c) Resource needs



3 Resource Management

3.1 Provision of Resources

3.1.1 The applicant must determine and provide the resources needed:

- a) To implement and maintain the quality management system and continually improve its effectiveness
- b) To enhance customer satisfaction by meeting customer requirements

3.2 Human Resources

3.2.1 General

3.2.1.1 Personnel performing work affecting conformity to product requirements must be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

3.2.2 Competence, Awareness, and Training

3.2.2.1 The applicant must determine the necessary competence for personnel performing work affecting conformity to product requirements.

3.2.2.2 The applicant must determine the criteria for training and must provide training to achieve the necessary competence for personnel performing work affecting conformity to product requirements.

3.2.2.3 The applicant must have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the quality management system.

3.2.2.4 The documented procedure must include:

- a) Providing training or take other actions to satisfy these needs
- b) Evaluating the effectiveness of the actions taken
- c) Ensuring that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives

3.2.2.5 The applicant must maintain appropriate records of education, training, skills, and experience. Training records must include the scope of the training received.

3.3 Infrastructure

3.3.1 The applicant must determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workspace, and associated utilities
- b) Processing equipment (both hardware and software)
- c) Supporting services (such as transport, communication, or information systems)



3.4 Work Environment

3.5 The applicant must determine and manage the work environment needed to achieve conformity to product requirements.

NOTE: The term “work environment” relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).

4 Product Realization

4.1 Planning of Product Realization

4.1.1 The applicant must plan and develop the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the quality management system (see Clause 1.1).

4.1.2 In planning product realization, the applicant must determine the following, as appropriate:

- a) Quality objectives and requirements for the product
- b) The need to establish processes, documents, and provide resources specific to the product
- c) Required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements

4.1.3 The output of this planning must be in a form suitable for the applicant’s methods of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project, or contract, can be referred to as a quality plan.

NOTE 2: The applicant may also apply the requirements given in 10.4 to the development of product realization processes.

4.2 Customer-related Processes

4.2.1 Determination of Requirements Related to the Product

4.2.1.1 The applicant must determine:

- a) The process verified points
- b) Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- c) Requirements not stated by the customer but necessary for specified or intended uses, where known
- d) Statutory and regulatory requirements applicable to the product
- e) Any additional requirements considered necessary by the applicant



NOTE: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance and supplementary services, such as recycling or final disposal.

4.2.2 Review of Requirements Related to the Product

4.2.2.1 The applicant must review the requirements related to the product. This review must be conducted prior to the applicant's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and must ensure that:

- a) Product requirements are defined
- b) Contract or order requirements differing from those previously expressed are resolved
- c) The applicant has the ability to meet the defined requirements

4.2.2.2 Records of the results of the review and actions arising from the review must be maintained.

4.2.2.3 Where the customer provides no documented statement of requirement, the customer requirements must be confirmed by the applicant before acceptance.

4.2.2.4 Where product requirements are changed, the applicant must ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

4.3 Customer Communication

4.3.1 The applicant must determine and implement effective arrangements for communicating with customers in relation to:

- a) Product information
- b) Enquiries, contracts or order handling, including amendments
- c) Customer feedback, including customer complaints

4.4 Design and Development

4.4.1 Design and Development Planning

4.4.1.1 The applicant must plan and control the design and development of product.

4.4.1.2 During the design and development planning, the applicant must determine:

- a) The design and development stages
- b) The review, verification, and validation that are appropriate to each design and development stage
- c) The responsibilities and authorities for design and development



4.4.1.3 The applicant must manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

4.4.1.4 Planning output must be updated, as appropriate, as the design and development progresses.

NOTE: Design and development review, verification, and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the applicant.

4.4.2 Design and Development Inputs

4.4.2.1 Inputs relating to product requirements must be determined and records maintained. These inputs must include:

- a) Functional and performance requirements
- b) Applicable statutory and regulatory requirements
- c) Where applicable, information derived from previous similar designs
- d) Other requirements essential for design and development

4.4.2.2 These inputs must be reviewed for adequacy. Requirements must be complete, unambiguous, and not in conflict with each other.

4.4.3 Design and Development Outputs

4.4.3.1 The outputs of design and development must be in the form suitable for verification against the design and development input and must be approved prior to release.

4.4.3.2 Design and development outputs must:

- a) Meet the input requirements for design and development
- b) Provide appropriate information for purchasing, production, and service provision
- c) Contain or reference product acceptance criteria
- d) Specify the characteristics of the product that are essential for its safe and proper use

NOTE: Information for production and service provision can include details for the preservation of product.

4.4.4 Design and Development Review

4.4.4.1 At suitable stages, systematic reviews of design and development must be performed in accordance with planned arrangements (see Clause 4.4.1)

- a) To evaluate the ability of the results of design and development to meet requirements
- b) To identify any problems and propose necessary actions

4.4.4.2 Participants in such reviews must include representatives of functions concerned with the design and development stage(s) being reviewed.

4.4.4.3 Records of the results of the reviews and any necessary actions must be maintained.



4.4.5 Design and Development Verification

4.4.5.1 Verification must be performed in accordance with planned arrangements (see Clause 4.4.1) to ensure that the design and development outputs have met the design and development input requirements.

4.4.5.2 Records of the results of the verification and any necessary actions must be maintained.

4.4.6 Design and Development Validation

4.4.6.1 Design and development validation must be performed in accordance with planned arrangements (see Clause 4.4.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation must be completed prior to the delivery or implementation of the product.

4.4.6.2 Records of the results of validation and any necessary actions must be maintained.

4.4.7 Control of Design and Development Changes

4.4.7.1 Design and development changes must be identified and records maintained. The changes must be reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design and development changes must include evaluation of the effect of the changes on constituent parts and product already delivered.

4.4.7.2 Records of the results of the review of changes and any necessary actions must be maintained.

4.5 Purchasing

4.5.1 Purchasing Process

4.5.1.1 The applicant must ensure that product purchased and/or received from outside establishments and used in the program conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased and/or received product must be dependent upon the effect of the purchased and/or received product on subsequent product realization or the final product.

4.5.1.2 The applicant must evaluate and select suppliers based on their ability to supply product in accordance with the applicant's requirements. Criteria for selection, evaluation, and re-evaluation must be established and documented.

4.5.1.3 Records of the results of evaluations and any necessary actions arising from the evaluation must be maintained.

4.5.2 Purchasing Information

4.5.2.1 Documented purchasing information must describe the product to be purchased and/or received, including where appropriate:

- a) Requirements for approval of product, procedures, processes, and equipment
- b) Requirements for qualification of personnel
- c) Quality management system requirements



4.5.2.2 The applicant must ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

4.5.3 Verification of Purchased Product

4.5.3.1 The applicant must establish, document, and implement the inspection of other activities necessary for ensuring that purchased and/or received product meets specified purchase requirements.

4.5.3.2 Where the applicant or its customer intends to perform verification at the supplier's premises, the applicant must state the intended verification arrangements and method of product release in the purchasing information.

4.5.3.3 The applicant must maintain records to provide evidence of conformity to the purchasing process and of the effective operation of the purchasing process.

4.6 Production and Service Provision

4.6.1 Control of Production and Service Provision

4.6.1.1 The applicant must plan and carry out production and service provision under controlled conditions.

4.6.1.2 Controlled conditions must include, as applicable:

- a) The availability of information that describes the characteristics of the product
- b) The availability of work instructions, as necessary
- c) The use of suitable equipment
- d) The availability and use of monitoring and measuring equipment
- e) The implementation of monitoring and measurement
- f) The implementation of product release, delivery, and post-delivery activities

4.6.2 Validation of Processes for Production and Service Provision

4.6.2.1 The applicant must validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

4.6.2.2 Validation must demonstrate the ability of these processes to achieve planned results.

4.6.2.3 The applicant must establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes
- b) Approval of equipment and qualification of the personnel
- c) Use of specific methods and procedures
- d) Requirements for records
- e) Re-validation



4.6.3 Identification and Traceability

4.6.3.1 The applicant must have a documented procedure to identify the product (raw materials and finished product) by suitable means throughout product realization, where appropriate.

4.6.3.2 The documented procedure must describe the method for:

- a) Identifying product by suitable means throughout product realization, where appropriate
- b) Identifying the product status with respect to monitoring and measurement requirements throughout product realization
- c) Controlling and recording the unique identification of the product, when traceability is a requirement
- d) Controlling and recording the use of the "USDA Process Verified" shield or the term "USDA Process Verified", if applicable

4.6.3.3 The unique identification of the product must be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.

4.6.3.4 The applicant must maintain records of all products as identified and records of all changes of identities.

4.6.4 Customer Property

4.6.4.1 The applicant must exercise care with customer property while it is under the applicant's control or being used by the applicant. The applicant must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, the applicant must report this to the customer and maintain records.

NOTE: Customer property can include intellectual property and personal data.

4.6.5 Preservation of Product

4.6.5.1 The applicant must preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation must include identification, handling, packaging, storage, and protection. Preservation must also apply to the constituent parts of a product.

4.7 Control of Monitoring and Measuring Equipment

4.7.1 The applicant must determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements (see Clause 2.4.3).

4.7.2 The applicant must establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

4.7.3 Where necessary to ensure valid results, measuring equipment must:



- a) Be calibrated and/or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification must be recorded
- b) Be adjusted or re-adjusted as necessary
- c) Have identification in order to determine its calibration status
- d) Be safeguarded from adjustments that would invalidate the measurement result
- e) Be protected from damage and deterioration during handling, maintenance, and storage

4.7.4 In addition, the applicant must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The applicant must take appropriate action on the equipment and any product affected.

4.7.5 Records of the results of calibration and verification must be maintained.

4.7.6 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application must be confirmed. This must be undertaken prior to initial use and reconfirmed as necessary.

NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

5 Measurement, Analysis, and Improvement

5.1 General

5.1.1 The applicant must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformance to product requirements
- b) To ensure conformity of the quality management system
- c) To continually improve the effectiveness of the quality management

5.1.2 This must include determination of applicable methods, including statistical techniques, and the extent of their use.

5.2 Monitoring and Measurement

5.2.1 Customer Perception

5.2.1.1 As one of the measurements of the performance of the quality management system, the applicant must monitor information relating to customer perception as to whether the applicant has met customer requirements. The methods for obtaining and using this information must be determined.

5.2.1.2 The applicant must maintain records relating to customer perception relating to conformance of the program or products produced under the program.



5.2.1.3 The applicant must take appropriate action addressing customer complaints and any deficiencies found in the program, or product, if applicable, that affect conformance. The applicant must maintain records of such actions taken.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.

5.2.2 Internal Audit

5.2.2.1 The applicant must conduct internal audits at planned intervals to determine whether the quality management system:

- a) Conforms to the planned arrangements (see Clause 4.1), to the requirements of this document and to the quality management system requirements established by the applicant
- b) Is effectively implemented and maintained

5.2.2.2 An audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods must be defined. The selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Auditors must not audit their own work.

5.2.2.3 The responsibilities and requirements for planning and conducting audits, selecting auditors, reporting results, conducting follow-up activities, and maintaining records must be defined in a documented procedure.

5.2.2.4 Records of the audits and their results must be maintained.

5.2.2.5 The management responsible for the area being audited must ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities must include the verification of the actions taken and the reporting of verification results (see Clause 5.5.2).

NOTE 1: See ISO 19011 for guidance.

NOTE 2: Prior to initial approval of a program, the applicant must conduct an internal audit and submit those results to the AMS Branch as part of the application for service.

5.2.3 Monitoring and Measurement of Processes

5.2.3.1 The applicant must apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the applicant consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to



their impact on the conformity to product requirements and on the effectiveness of the quality management system.

5.2.4 Monitoring and Measurement of Product

5.2.4.1 The applicant must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see Clause 4.1).

5.2.4.2 Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of product for delivery to the customer.

5.2.4.3 The release of product and delivery of service to the customer must not proceed until the planned arrangements (see Clause 4.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

5.3 Control of Non-conforming Product

5.3.1 The applicant must ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

5.3.2 A documented procedure must be established to define the identification of non-conforming product; the controls used to prevent the unintended use or delivery of non-conforming product; and the related responsibilities and authorities for dealing with non-conforming product.

5.3.3 The applicant must deal with non-conforming product by one or more of the following ways:

- a) By taking action to eliminate the detected non-conformity
- b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer
- c) By taking action to preclude its original intended use or application

5.3.4 Records of the nature of non-conformances and any subsequent actions taken, including concessions obtained, must be maintained.

5.3.5 When non-conforming product is corrected, it must be subject to re-verification to demonstrate conformance to the requirements.

5.3.6 When non-conforming product is detected after delivery or use has started, the applicant must take action appropriate to the effects, or potential effects, of the non-conformance.

5.4 Analysis of Data

5.4.1 The applicant must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This must include data generated as a result of monitoring and measurement and from other relevant sources.



5.4.2 The analysis of data must provide information relating to:

- a) Customer satisfaction (see Clause 5.2.1)
- b) Conformity to product requirements (see Clause 5.2.4)
- c) Characteristics and trends of processes and products including opportunities for preventive action (see Clauses 5.2.3 and 5.2.4)
- d) Suppliers (see Clause 4.5)

5.5 Improvement

5.5.1 Continual Improvement

5.5.1.1 The applicant must continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

5.5.2 Corrective Action

5.5.2.1 The applicant must take action to eliminate the cause(s) of non-conformances in order to prevent recurrence. Corrective actions must be appropriate to the effects of the non-conformances encountered.

5.5.2.2 A documented procedure must be established to define requirements for:

- a) Reviewing non-conformances (including customer complaints)
- b) Determining the causes of non-conformances
- c) Evaluating the need for action to ensure that non-conformances do not recur
- d) Determining and implementing action needed
- e) Records of the results of action taken
- f) Reviewing the effectiveness of corrective action taken

5.5.3 Preventive Action

5.5.3.1 The applicant must determine action to eliminate the causes of potential non-conformances in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

5.5.3.2 A documented procedure must be established to define requirements for:

- a) Determining potential non-conformances and their causes
- b) Evaluating the need for action to prevent occurrence of non-conformances
- c) Determining and implementing action needed
- d) Records of results of action taken
- e) Reviewing the effectiveness of preventive action taken

6. Use of the USDA Process Verified Shield and Statement (Promotional Materials)

6.1 Information about the use of the USDA Process Verified Program shield and/or statement is available at <http://www.ams.usda.gov/services/auditing/pvp-shield>.



6.2 The applicant must have a defined process to ensure the USDA Process Verified Program shield and/or the statement is used appropriately in accordance with this procedure.

6.3 Applicants that use the USDA Process Verified Program shield and/or the statement in promotional material must ensure that the shield and/or the statement are used in direct association with a clear description of the process verified point(s). Applicants must also ensure that the USDA Process Verified Program shield and/or the term are not misrepresented and are not used in association with any other applicant claims.

6.4 Applicants that include a company designed logo which displays the term "USDA Process Verified" statement on labels or promotional materials must also include the USDA Process Verified Program shield and the web address "<http://processverified.usda.gov/>" on the label and in the promotional materials.

6.5 Applicants may not make statements in reference to or in conjunction with the applicants approved Process Verified Program, process verified points, or in association with the USDA Process Verified Program shield and/or the statement that are disparaging toward other agricultural products and/or other sections of the agricultural industry.

6.6 The use of the USDA Process Verified Program shield and/or statement on a label must meet one of the following conditions:

- a) The process verified points are printed immediately adjacent to the USDA Process Verified Program shield and/or statement.
- b) An asterisk referring the consumer to the information panel for further information about the process verified points is printed with the USDA Process Verified Program shield and/or the statement.
- c) An asterisk referring the consumer to point of sale information is printed with the USDA Process Verified Program shield and/or the statement. In this situation, the applicant must ensure that the point of sale information is readily available and within close proximity of the display counter containing the product.

6.7 The client may create their own logo and use the term "USDA Process Verified" as long as it meets the following design requirements:

- a) All logos must include the words "USDA," "Process," and "Verified" in their logo.
- b) No emphasis is placed on any individual word or letter, except for the word "USDA."
- c) The font size must be approximately the same for all three words: "USDA," "Process," and "Verified." However, the word "USDA" may be a larger font size than the words "Process" and "Verified."



- d) The words "USDA," "Process," and "Verified" must be presented in order as "USDA Process Verified," when written horizontally, and that the end user understands the wording to effectively represent the USDA Process Verified Program.
- e) Any words, graphics, marketing terms, and/or label claims directly associated with the term must be part of the approved USDA Process Verified Program.
- f) The approved design must be used in conjunction with the USDA Process Verified shield.
- g) The approved design must be submitted electronically to the ASB to be posted on the *Official Listing*.

6.8 Promotional materials must include the USDA Process Verified Program web address (<http://processverified.usda.gov/>) in close proximity to either the USDA Process Verified shield or process verified points.

6.8 All promotional materials, including labels, packaging, and other marketing materials, must be submitted to the ASB for review and approval to ensure the USDA Process Verified Program shield and/or the statement and the associated process points are accurately represented.

6.9 The USDA Process Verified Program does not relieve applicants from meeting regulatory requirements.



Appendix A - Definitions

1. **Conforming Product** – product within the QMS that meets, and can be verified as meeting, the product requirements. Such product may be identified and/or labeled as meeting the requirements of the USDA Process Verified Program.
2. **Corrective Action** – action to eliminate the cause of a detected non-conformance.
3. **Correction:** Action taken to eliminate a detected non-conformity. (rework, bringing product into conformance, diverting product, not using product, scrapping product, etc.)
4. **Customer Satisfaction** – customer’s perception of the degree to which the customer’s requirements have been fulfilled.
5. **Measurement** – the actual determination of a value. Requires the use of a device to determine the numerical value of a product characteristic or process parameter at a given time.
6. **Monitoring** – a general term implying oversight over time. (Examples: normal process observation by employees, daily supervision by managers, automated alarms, etc.)
7. **Non-conforming Product** – product within the QMS that does not meet, or cannot be verified as meeting, the product requirements. This includes raw materials and finished products. Non-conforming raw materials must be excluded from use within the program; and non-conforming finished products must be excluded from delivery. Additionally, the company must take appropriate actions when non-conforming product is detected after delivery or use has started.
8. **Objective Evidence** – data supporting the existence or verity of something.
9. **Planned Arrangements** – arrangements that have been pre-determined.
10. **Planned Results** - includes, but is not limited to, the requirements of this document, the requirements outlined in the client's quality management system, and the specified process verified points.
11. **Preventative Action** – action to eliminate the cause of a potential non-conformance.
12. **Procedure** – a specified way to carry out an activity or a process. Procedures can be documented or not. The Process Verified Program requires 10 documented procedures.
13. **Process Verified Points** – the specified requirements of the product which are achieved through the implementation of a quality management system.
14. **Process** – a set of interrelated or interacting activities which transforms inputs into outputs.



Appendix A – Definitions (continued)

- 15. Product** - the result of a process. There are 4 product categories: (a) processed materials (e.g. a raw material or finished good); (b) services (e.g. transport); (c) software (e.g. computer programs); and (d) hardware (e.g. equipment).
- a) A product which is a processed material may change from within a quality management system depending upon where it is within the product realization process.
 - b) A service is the result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible.
 - c) Software consists of information and is generally intangible and can be in the form of approaches, transactions, or procedures.
 - d) Hardware is generally tangible and its amount is a countable characteristic.
- 16. Product Realization** – the process of developing a product from initial acceptance of the raw materials into the program through production to delivery to the customer.
- 17. Product Requirements** – includes, but is not limited to, the requirements of this Procedure, the requirements outlined in the QMS, the customer requirements, and the specified process verification points.
- 18. Quality Policy** – the overall intentions and direction of a company related to quality and formally expressed by top management.
- 19. Quality Objective** – something sought, or aimed for, related to quality. These are generally based on the quality policy and specified for relevant functions and levels in the company.
- 20. Record** – a document that states results achieved or provides evidence of activities performed. The Process Verified Program requires 20 records.
- 21. Top Management** – a person or group of people who direct and control the company at the highest level.
- 22. Validation** – confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
- 23. Verification** – confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.



USDA Quality System Assessment (QSA) Program

1 Purpose

This Procedure provides the requirements of a USDA Quality System Assessment (QSA) Program. It also provides the criteria used in the objective evaluation of USDA QSA Programs that are submitted for approval. Evaluations are conducted by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Grading and Verification Division (GVD).

2 Scope

This Procedure applies to marketing programs for agricultural products, including services, that are submitted to the GVD for verification and monitoring. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing from genetic development through retail distribution, or any portion as described in the scope of the submitted program.

If any program requirements can not be applied due to the nature of a company and its product, then these requirements may be considered for exclusion. Exclusions are limited to program requirements within *Clause 4 Product Realization* and must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

3 References

GVD 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
Applicable GVD Program Procedure

4 Responsibilities

Companies must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *GVD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

The GVD must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *GVD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

5 Audit Frequency

All approved programs will be audited at least twice per fiscal year (October 1 to September 30). However, more frequent audits may be conducted (1) if either numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners or other financial interested parties; or (4) as directed by the GVD Deputy Director.

"The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of color, race, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer."





6 Listing of Approved Programs

Approved programs will be listed on the applicable Program website or on the USDA QSA Program website at <http://www.ams.usda.gov/lsg/arc/qsap.htm>. Information about the approved program will be in accordance with the applicable Program Procedure. The approved program listing on the USDA QSA Program website will include the following information:

- a) Company name;
- b) Company contact information;
- c) Program requirements;
- d) Report reference number (approval number); and
- e) Renewal date.

7 Program Requirements (Clauses 1 to 5)

Companies must submit a documented program that addresses the program requirements as outlined in the following clauses (Clauses 1 to 5).

1 Quality Management System

1.1 General Requirements

A quality management system (QMS) must be established, documented, implemented, and maintained which ensures that products conform to the requirements of this Procedure, the applicable Program Procedure, and to specified product requirements.

1.2 Documentation Requirements

1.2.1 General

The company must prepare and maintain a QMS that includes:

- a) Documented specified product requirements;
- b) A quality manual;
- c) Documented procedures required by this Procedure;
- d) Documents necessary to ensure the effective operation and control of its processes; and
- e) Records required by this Procedure.

1.2.2 Quality Manual

The company must establish and maintain a quality manual that includes at a minimum:

- a) An organizational chart or similar document listing all personnel assigned to managerial positions within the program;
- b) A description of the scope of the QMS, including details of and justification for exclusions;
- c) The specified product requirements;
- d) Documented procedures established for the QMS;
- e) A master document list that shows the most current issue of all QMS procedures, forms, tags, and labels used to track or demonstrate conformance; and
- f) All other documentation as required by this Procedure.

The quality manual must be controlled and available for review at all associated sites where activities are conducted.



1.2.3 Control of Documents

The company must control all documents required by this Procedure.

Control of documents includes at a minimum:

- a) All documents must contain the current revision status of the document.
- b) The company must ensure that relevant versions of applicable documents are available at all associated sites where activities are conducted.
- c) The company must prevent the use of obsolete or unapproved documents.
- d) All documents must be retained for a minimum of 1 year.

Substantive changes to QMS documentation must be submitted to the GVD for approval prior to implementation.

1.2.4 Control of Records

The company must establish and maintain records to provide evidence of conformity to program requirements, to specified product requirements, and of the effective operation of the QMS.

Control of records includes at a minimum:

- a) The company must control all records required by this Procedure.
- b) Records must be stored in a manner so as to prevent loss, damage, or alteration.
- c) Records must be legible, easily accessible, and readily available.
- d) All records must be retained for a minimum of 1 year.

2 Management Responsibility

Management must ensure that specified product requirements are established at relevant functions and levels within the company.

Management must ensure that QMS responsibilities and authorities are defined and communicated within the company.

The company must have an organizational chart or similar document listing all personnel assigned to managerial positions within the program.

All personnel listed must have their responsibilities and authorities outlined in an auditable method.

A management representative, who has the authority to act on behalf of the company at all locations where program activities are conducted, must be designated.

The management representative must have the responsibility and authority for ensuring that processes needed for the QMS are established, implemented, and maintained.



3 Human Resources - Competence, Awareness, and Training

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.

The company must provide training to all personnel with QMS responsibilities.

The company must have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the QMS.

The documented procedure must define the methods for:

- a) Determining the necessary competence for personnel performing work affecting product quality;
- b) Determining the criteria for training;
- c) Evaluating the effectiveness of the training; and
- d) Ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The company must maintain appropriate records of education, training, skills, and experience, as applicable. These records must include the scope of the training received.

4 Product Realization

4.1 General

Where any program requirements within *Clause 4 Product Realization* can not be applied due to the nature of a company and its product, these requirements may be considered for exclusion. Exclusions must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

4.2 Receiving Process

The company must ensure that product purchased or received from outside establishments and used in the program conform to specified receiving requirements.

The company must ensure the adequacy of specified receiving requirements prior to their communication to the supplier.

The company must evaluate and select suppliers based on their ability to supply product that conforms to the specified receiving requirements.

The company must establish and implement the inspection or other activities necessary for ensuring that product purchased or received from outside establishments and used in the program conform to specific receiving requirements.

The company must have a documented procedure addressing products purchased or received from outside establishments.



The documented procedure must describe:

- a) All product purchased and/or received from outside establishments regardless of its use within the program;
- b) The specified receiving requirements for acceptance of products to be used in the program;
- c) The criteria and process for supplier selection, evaluation, and re-evaluation; and
- d) The process used to ensure that purchased product and/or product received from outside establishments and used in the program conform to specific receiving requirements.

The company must maintain records of the results of supplier evaluations and any necessary actions arising from the evaluation.

The company must maintain records to provide evidence of conformity to the receiving process and of the effective operation of the receiving process.

4.3 Identification and Traceability

The company must have a documented procedure to identify product (raw materials and/or finished product) by suitable means throughout product realization, where appropriate.

The documented procedure must describe the method for:

- a) Identifying the product throughout product realization;
- b) Controlling and recording the unique identification of the product; and
- c) Identifying the product status with respect to monitoring and measurement requirements.

The method for identifying the product must:

- a) Be unique to the program. When applicable, animals must be identified with ear tags or other permanent identification; and
- b) Be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.

The company must maintain records of all products as identified and records of all changes of identities.

4.4 Preservation of Product

The company must preserve the conformity of product during internal processing and delivery to the intended destination.

The preservation must include identification, handling, packaging, storage, and protection. It must also apply to the constituent parts of a product.

4.5 Control of Monitoring and Measuring Devices

The company must determine the monitoring and measurement to be undertaken to provide evidence of conformity to specified product requirements.

The company must determine the monitoring and measurement devices needed to provide evidence of conformity to specified product requirements.



The company must establish processes to ensure that monitoring and measurement can be conducted and are conducted in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment must:

- a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification must be recorded;
- b) Be adjusted or re-adjusted as necessary;
- c) Be identified to enable the calibration status to be determined;
- d) Be safeguarded from adjustment that would invalidate the measurement result; and
- e) Be protected from damage and deterioration during handling, maintenance, and storage.

The company must assess and record the validity of the previous measuring results when the equipment is found not to conform to the requirements. The company must take appropriate action on the equipment and any product affected.

The company must confirm the ability of computer software to satisfy the intended application when used in the monitoring and measurement of specified requirements. This must be performed prior to initial use and reconfirmed as necessary.

The company must maintain records of the results of calibration and verification.

5 Measurement, Analysis, and Improvement

5.1 General

The company must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformity of the product;
- b) To ensure conformity of the QMS; and
- c) To continually improve the effectiveness of the QMS.

The plan must include a determination of application methods, including statistical techniques, and the extent of their use.

When statistical methods are used to control product quality or integrity, the basis for those procedures must be clearly defined.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

The company must monitor information relating to customer perception as to whether the company has met customer requirements. This information must be reviewed as a performance measurement of the QMS.

The company must determine the methods for obtaining and using this information.

The company must maintain records relating to customer perception.



5.2.3 Monitoring and Measurement of Processes

The company must apply suitable methods for monitoring and, where applicable, measurement of the QMS processes.

These methods must demonstrate the ability of the processes to meet product requirements.

When product requirements are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product.

5.2.4 Monitoring and Measurement of Product

The company must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be conducted at appropriate stages of the product realization process.

The company must ensure that product requirements have been met prior to product release and service delivery, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The company must maintain records to verify evidence of conformity to product requirements. Records must indicate the person(s) authorizing release of product.

5.3 Control of Non-conforming Product within the QMS

The company must ensure that non-conforming product (raw material and/or finished product) is identified and controlled to prevent its unintended use or delivery.

The company must have a documented procedure that defines:

- a) The identification of non-conforming product;
- b) The controls used to ensure the segregation of non-conforming product; and
- c) The related responsibilities and authorities for ensuring the segregation and disposition of non-conforming product.

The company must handle non-conforming product by one or more of the following methods:

- a) By taking action to eliminate the detected non-conformity;
- b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; or
- c) By taking action to preclude its original intended use or application.

When non-conforming product is corrected, it must be subject to re-verification to demonstrate conformity to the product requirements.

The company must take appropriate actions when non-conforming product is detected after delivery or use has started.

The company must maintain records of all non-conforming product and any subsequent actions taken, including concessions obtained.



5.4 Improvement

5.4.1 Continual Improvement

The company must continually improve the effectiveness of the QMS through the use of the quality objectives, customer feedback, audit results, and corrective and preventative actions.

The company must ensure that the integrity of the QMS is maintained when changes to it are planned and implemented.

5.4.2 Corrective Action

The company must take action to eliminate the cause of non-conformance in order to prevent recurrence.

Corrective actions must be appropriate to the effects of the non-conformances encountered.

The company must maintain records of the results of any actions taken.

5.4.3 Preventative Action

The company must determine and implement action to eliminate the causes of potential non-conformances in order to prevent their occurrence.

Preventative actions must be appropriate to the effects of the potential problems.

The company must maintain records of the results of any actions taken.



Appendix A - Definitions

Conforming Product – product within the QMS that meets, and can be verified as meeting, the specified product requirements. Such product must be identified as meeting the specified product requirements in accordance with the QMS and the applicable Program Procedure.

Corrective Action – action to eliminate the cause of a detected non-conformance.

Correction – action to eliminate a detected non-conformance.

Customer Satisfaction – customer's perception of the degree to which the customer's requirements have been fulfilled.

Non-conforming Product – product within the QMS that does not meet, or can not be verified as meeting, the specified product requirements. This includes raw materials and finished products. Non-conforming raw materials must be excluded from use within the program; and non-conforming finished products must be excluded from delivery.

Preventative Action – action to eliminate the cause of a potential non-conformance.

Process – a set of interrelated or interacting activities which transforms inputs into outputs.

Product – a raw material or a finished good. The type of product depends upon where it is within product realization.

Product Realization – the process of developing a product from initial acceptance of the raw materials through production to delivery.

Product Requirements – includes, but is not limited to, the requirements of this Procedure, the requirements outlined in the QMS, the customer requirements, and the specified product requirements.

Specified Product Requirements – the requirements listed within the applicable Program Procedure or as stated by the company.



Appendix B – Documentation Requirements

1. Clause 1.2.2 - Quality Manual
2. Documented Procedures:
 - 1) Clause 3 – training of personnel
 - 2) Clause 4.2 – receiving of product from outside sources
 - 3) Clause 4.3 – identification and traceability
 - 4) Clause 5.3 – control of non-conforming product
3. Records:
 - 1) Clause 3 – training, education, skills and/or experience
 - 2) Clause 4.2 – results of supplier evaluations and any necessary actions
 - 3) Clause 4.2 – evidence of conformity to the receiving process and it's effective operation
 - 4) Clause 4.3 – product identification and changes of identities
 - 5) Clause 4.5 – results of calibration and verification
 - 6) Clause 5.2.1 – customer perception
 - 7) Clause 5.2.4 – evidence of conformity to specified product requirements
 - 8) Clause 5.3 – non-conforming product and subsequent actions taken
 - 9) Clause 5.4.2 – corrective actions
 - 10) Clause 5.4.3 – preventative actions
4. Any other documents necessary to ensure the effective operation and control of the QMS.

Animal Disease Traceability

General Standards

January 2, 2015 Version 2.4

UNITED STATES DEPARTMENT OF
AGRICULTURE

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Animal Disease Traceability

General Standards

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Preface

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has established traceability regulations for livestock moving interstate. The purpose of the regulations is to improve the ability of APHIS to trace livestock when disease is found.

The final rule, "Traceability for Livestock Moving Interstate," references this Animal Disease Traceability General Standards document. This general standards document provides details on numbering systems and official identification devices that are authorized under the final rule. Additional information, including listing of official identification devices, is provided at <http://www.aphis.usda.gov/traceability/>.

Section A: Data Standards

Official Identification Numbers - Animals

Official identification numbering systems are fundamental to animal disease programs. Numbers for both individual animals and groups of animals are defined to support methods of official identification for the various species and for meeting production management practices. Official animal identification devices, such as eartags, have an official identification number imprinted on them. Group/lot numbers are associated to the animals through records maintained by individuals responsible for the group throughout the production chain.

Official identification numbers are nationally unique numbers permanently associated with individual animals or groups of animals. Official identification numbers are associated with individual animals or groups of animals through official identification devices or methods. Official identification numbers adhere to one of the following numbering systems:

- National Uniform Eartagging System (NUES)
- Animal identification number (AIN)
- Location-based number system
- Flock-based number system
- Any other numbering system approved by the APHIS Administrator for the official identification of animals

Individual Animal Numbers

Official animal numbering systems provide a way to uniquely identify individual animals. Official identification for certain species is based on identification devices (e.g., official eartags) that have an official animal number imprinted on them. Official identification devices that adhere to these numbering standards are listed in Section B of this report. The following table specifies the format for each official numbering system used for individual animals.

Table 1. Official Identification Numbers				
Data Element	Length	Format	Example	Comments
National Uniform Eartagging System (NUES)	9 or 8	Alphanumeric	23 ELV 4574 PA ELV 4574 23 DX 1234 PA DX 1234	
	[2]		23 PA	Default is State or Tribe numeric code. State postal abbreviation is optional.
	[3] or [2]		ELV AB	Use of the 2 alpha postal abbreviation is reserved for scrapie program tags
	[4]		4574	4 digits in a chronological numerical sequence.
Animal Identification Number (AIN)¹	15	Numeric	840003456789012	
	[3]		840	The first 3 digits are the country code (840 = USA). (See note below regarding USA and manufacturer codes.)
	[12]		003456789012	The last 12 digits are the animal number. Start number > 3,000,000,000.
Flock-based number with a herd management number	15 Max.	Alphanumeric	MN0456 4275	
	[9] Max.		MN0456	See flock standard below.
	[6] Max.		4275	Unique herd management number.
Location-based number with a herd management number	14 Max.	Alphanumeric	IA123456 123456	
	[8] Max.		IA123456	See LID and PIN standard below.
	[6] Max.		123456	Unique herd management number.
<p>¹The alpha characters USA or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording may be used as an alternative to the 840 or other prefix representing a U.S. territory; however, only the AIN beginning with the 840 or other prefix representing a U.S. territory will be recognized as official for use on AIN tags applied to animals on or after March 11, 2015.</p> <p>Note: AINs beginning with the 840 prefix may not be applied to animals known to have been born outside the United States.</p>				

Animal Group Identification Numbers

Group/Lot Identification Numbers (GINs)

The use of GINs provides a way to uniquely identify a unit of animals of the same species that is managed as one group throughout the preharvest production chain. The GIN consists of the following:

- One of the location identifiers (premises identification number (PIN) or location identification number (LID)) defined in the following pages
- A six-digit representation of the date on which the group or lot of animals was assembled or date the group was initiated if more than one day (MM/DD/YY)
- Two additional digits, ranging from 01 to 99, for the numbering of different groups or lots of animals assembled on the same premises on the same day. When more than one group of animals is assembled, the groups would be designated consecutively as 01, 02, 03, etc.

Flock Identification Numbers

The National Scrapie Eradication Program furnishes ear tags to sheep and goat producers. The numbering system for these tags combines a nationally unique flock identification number (FIN) with the producer's unique livestock production numbering system. This flock-based numbering system represents an animal group that is associated with one or more locations. The system serves the sheep and goat industries well in their disease control and eradication efforts.

A State or Federal animal health authority assigns the FIN to a group of animals managed as a unit on one or more premises under the same ownership.

The following table specifies the official GINs.

Table 2. Animal Group Identification Numbers				
Data Element	Length	Format	Example	Comments
Group/Lot ID Number (GIN) - Using a PIN	15	Alphanumeric	004T56711221105	
	[7]		004T567	The first 7 characters are the PIN.
	[6]		112211	The next 6 characters are the date the lot was established: MMDDYY.
	[2]		05	The last 2 characters are the number (count 01-99) of the group assembled at a premises on the same day. (01 is the default when one group is assembled.)
Group/Lot ID Number (GIN)¹ - Using a LID	14 or 16	Alphanumeric	WA123411221105 MN12347811221105	
	[6] or [8]		WA1234 MN123478	The first 6 or 8 characters are the location ID number.
	[6]		112211	The next 6 characters are the date the lot was established: MMDDYY.
	[2]		05	The last 2 characters are the number (count 01-99) of the group assembled at a premises on the same day. (01 is the default when one group is assembled.)
Flock Identification Number (FIN)	9 Max	Alphanumeric		
	[2]		PA	State postal abbreviation required as the first two characters.
	Max of [7]		723456A	FINs exclude the letters I, O, or Q from the characters following the State abbreviation.

¹ LIDs may also use the 7-character format. The check digit must be used as prescribed for PINs.

Location Numbering Systems

States and Tribes may elect to use location identifiers to support their animal disease traceability plan. Two processes, explained below, support the administration of location identifiers that adhere to the standards defined in Table 3. PINs are available through the PIN allocator, a software application tool that APHIS provides access to for States and Tribes electing to use it. States may also use their own process for administering unique State-issued location identifiers. In these situations the State or Tribe has their own local system and process for issuing location numbers to locations. To avoid confusion in presenting these options in this document, State-

issued location identifiers are referred to as LIDs, and the location numbers States and Tribes obtain through the allocator are referred to as PINs (or standardized PINs). States and Tribes may choose to use other terms in their materials.

States and Tribes are not required to provide PINs or LIDs for the administration of their traceability plans. However, if they choose to use location identifiers to administer their traceability activities, following the standards below will ensure that their information systems are compatible with other traceability and animal health databases.

Location Identification Numbers

LIDs are administered through a State’s or Tribe’s internal system. All LIDs start with the State or Tribe code which makes the LIDs nationally unique. They consist of six or eight alphanumeric characters. Additionally, seven alphanumeric characters may be used only when the last character is a check digit based on ISO 7064:1983, a standard published by the International Organization for Standardization (ISO). Using the State postal abbreviation as the first two characters ensures.

Premises Identification Numbers

States and Tribes may elect to use the PIN in their traceability system. The standardized PIN, obtained through the APHIS PIN allocator, consists of seven alphanumeric characters. The last character is a check digit based on ISO 7064:1983. States may use the State’s postal abbreviation as the first two of the seven characters (for example, OH341T4) unless the State is using a seven-character LID. Tribes may also have codes reserved for use with PINs they administer. The codes for Tribes will be assigned upon request. States and Tribes obtaining PINs from the PIN allocator may use either the Standardized Premises Identification System or a Compliant Premises Identification System. The standardized and compliant systems are defined in the Animal Disease Traceability Information Technology technical document.

The LID and PIN data standards are defined in the following table.

Data Element	Length	Format	Example	Comments
LID ¹	6	Alphanumeric	MN4321	First 2 characters are the State postal abbreviation.
	8	Alphanumeric	CA654321	First 2 characters are the State postal abbreviation.
PIN	7	Alphanumeric	A123R69	Last character is a check digit. ²

¹ States and Tribes may issue LIDs in the 7-character format only when the ISO 7064:1983 check digit is used as the last character.
² The check digit calculation algorithm is based on ISO 7064:1983, “Data Processing – Check Character Systems.” (See Animal Disease Traceability Technical Standards document.)

Note: To avoid confusion with the numbers 0 and 1, the LID and PIN will not contain the letters O or I except when the letters are contained in the State or Tribal code.

State and Tribal Codes

State and Tribal codes used with NUES tags and location identifiers are listed below. Additional codes for Tribes will be established upon request to APHIS.

Table 4. State, Tribe, and Territory Codes					
Sort by Name			Sort by Numeric Code		
Alabama	AL	64	Maine	ME	11
Alaska	AK	96	New Hampshire	NH	12
American Samoa	AS	99	Vermont	VT	13
Arizona	AZ	86	Massachusetts	MA	14
Arkansas	AR	71	Rhode Island	RI	15
California	CA	93	Connecticut	CT	16
Cherokee Nation	CN	79	New York	NY	21
Colorado	CO	84	New Jersey	NJ	22
Commonwealth of the N. Marianas	MP	98	Pennsylvania	PA	23
Connecticut	CT	16	Ohio	OH	31
Delaware	DE	50	Indiana	IN	32
Florida	FL	58	Illinois	IL	33
Georgia	GA	57	Michigan	MI	34
Guam	GU	97	Wisconsin	WI	35
Hawaii	HI	95	Minnesota	MN	41
Hualapai Tribe	HT	78	Iowa	IA	42
Idaho	ID	82	Missouri	MO	43
Illinois	IL	33	North Dakota	ND	45
Indiana	IN	32	South Dakota	SD	46
Iowa	IA	42	Nebraska	NE	47
Kansas	KS	48	Kansas	KS	48
Kentucky	KY	61	Delaware	DE	50
Louisiana	LA	72	Maryland	MD	51
Maine	ME	11	Virginia	VA	52
Maryland	MD	51	West Virginia	WV	54
Massachusetts	MA	14	North Carolina	NC	55
Michigan	MI	34	South Carolina	SC	56
Minnesota	MN	41	Georgia	GA	57
Mississippi	MS	65	Florida	FL	58
Missouri	MO	43	Virgin Islands (U.S.)	VI	59
Montana	MT	81	Kentucky	KY	61
Navajo Nation	NN	77	Tennessee	TN	63
Nebraska	NE	47	Alabama	AL	64
Nevada	NV	88	Mississippi	MS	65
New Hampshire	NH	12	Arkansas	AR	71
New Jersey	NJ	22	Louisiana	LA	72
New Mexico	NM	85	Oklahoma	OK	73
New York	NY	21	Texas	TX	74
North Carolina	NC	55	Navajo Nation	NN	77
North Dakota	ND	45	Hualapai Tribe	HT	78
Ohio	OH	31	Montana	MT	81
Oklahoma	OK	73	Idaho	ID	82
Oregon	OR	92	Colorado	CO	84
Pennsylvania	PA	23	New Mexico	NM	85
Puerto Rico	PR	94	Arizona	AZ	86
Rhode Island	RI	15	Utah	UT	87

Sort by Name			Sort by Numeric Code		
South Carolina	SC	56	Nevada	NV	88
South Dakota	SD	46	Washington	WA	91
Tennessee	TN	63	Oregon	OR	92
Texas	TX	74	California	CA	93
Utah	UT	87	Puerto Rico	PR	94
Vermont	VT	13	Hawaii	HI	95
Virgin Islands (U.S.)	VI	59	Alaska	AK	96
Virginia	VA	52	Guam	GU	97
Washington	WA	91	Commonwealth of the N. Marianas	MP	98
West Virginia	WV	54	American Samoa	AS	99
Wisconsin	WI	35	Maine	ME	11
Wyoming	WY	83	New Hampshire	NH	12

In addition to the codes listed above, the two letters “US” may be used as the first two characters on NUES tags.

Country Codes for U.S. Territories

ISO 3166 establishes country codes. The country code for the United States is 840. U.S. Territories may use their ISO country code as the first three characters of the AIN. The following table lists the ISO country codes for the U.S. Territories.

Territory	Code	Territory	Code
American Samoa	016	Northern Mariana Islands	580
Guam	316	Palau	585
Marshall Islands	584	Puerto Rico	630
Micronesia, Federated States of	583	Virgin Islands	850

Section B: Administration of Official Animal Identification Methods and Devices

Official identification methods and devices officially identify an animal or group of animals by applying an official identification number to an animal or associating an official identification number with an animal or group of animals. Tables 1 and 2 in Section A of this report list official animal numbering systems for livestock.

Official identification devices and methods are listed in the title 9 of the *Code of Federal Regulations* (9 CFR), part 86, by species.

Official Eartags

Official eartags, approved for certain species, are tags approved by APHIS that provide official identification numbers for individual animals. Before a manufacturer can produce and sell eartags bearing the official eartag shield, the tag must be approved by APHIS.

A description of the types of official eartags with the specifications and options as well as lists of official eartags that are currently approved are provided on the ADT Website at: <http://www.aphis.usda.gov/traceability/materials.shtml>.

The primary criteria for official eartags include the following:

- Imprinted with an official identification number (see Table 1)
- Official eartag shield The logo is a shield-shaped emblem with the letters "US" inside, representing the official eartag shield.
- Tamper evident, high retention
- Other characteristics defined through tag specification (defined on tag approval applications)

States obtaining official eartags direct from manufacturers may imprint their State's postal abbreviation inside the official eartag shield in lieu of the letters "US". Likewise, Tribes may imprint their alpha code (see Table 4).

Distribution of Official Identification Devices

Proper administration of official identification devices is critical to support animal disease traceability. APHIS provides certain official identification devices to producers to apply to their animals and to accredited veterinarians to apply to animals. Distribution records and records of tags applied by accredited veterinarians of these devices are to be administered as explained below.

National Uniform Eartagging System

NUES tags have historically been used by animal health officials in animal disease programs. The animal disease traceability framework allows producers to use NUES tags, commonly referred to as "brite" tags, when authorized by the State or Tribal animal health official. The

following provides a basic overview of the key points regarding the distribution of NUES tags to producers:

State, Tribal, and Territory animal health officials and accredited veterinarians¹ may provide NUES identification eartags to producers who wish to use them for official identification and other purposes without administering the eartags through a specific disease control program. Accredited veterinarians and others may also apply official eartags to animals for purposes other than official disease control purposes. For instance, accredited veterinarians may apply official eartags as part of the certification process for interstate movement, and operators of approved tagging sites² may apply eartags on behalf of producers. This does not apply to eartags that are specific to a disease program, such as brucellosis calfhooed vaccination eartags. This enables producers to use the eartags as a tool to qualify their animals for interstate movement. In such cases, the State, Tribe, or Territory animal health officials will maintain complete oversight for the integrity of the information.

One of the duties of State, Tribal, and Territorial animal health officials providing NUES tags is ensuring sufficient contact information is collected about where NUES eartags are distributed to meet the traceability needs of the State, Tribe, or Territory. At a minimum, the distribution records need to be maintained for 5 years and must include:

- The name of the person the tags are issued to or the owner or person responsible for the animals being tagged by accredited veterinarians or tagging site operators.
- The street address, city, State, and ZIP code where the tags are distributed or the premises where the animals that are being tagged reside.
- The identification numbers issued.
- The date the tags were issued.
- The name and contact information of the person issuing the tags.

States and Tribes may use the Animal Identification Management System (AIMS) to maintain NUES tag distribution records.

The use of the AIMS requires the use of either a LID or PIN for each distribution record entered into AIMS. APHIS will, upon request, provide an alternative database that would support the recording of distribution records with the above information only.

More specific details on the administration of NUES eartags is available in VS Memorandum 578.12: Distribution and Use of Official Identification Eartags with Numbers Conforming to the National Uniform Eartagging System (3/15/2011)

Producers considering the use of and availability of NUES tags should contact their State or Tribal animal health official.

¹ Producers may be able to obtain NUES eartags directly from State or Tribal animal health officials depending on the policies established at the State or Tribal level.

² See "Approved Tagging Site" description on p. 14

Animal Identification Number Devices

AIN device managers and resellers distribute AIN devices with the 840 prefix to producers. APHIS, through an application and approval process, approves AIN devices that meet established standards. Approved AIN manufacturers are allocated the 840 numbers and are authorized to imprint or encode the AIN only on their approved devices.

AIN device manufacturers distribute AIN devices through AIN device managers, or may act as an AIN manager themselves. All distribution records of 840 AIN tags administered by AIN managers and State and Federal animal health officials must be reported to the AIMS by the person who has possession of the device when distributing the device to the next individual, whether it is a producer or another reseller. All recipients of AIN devices must first have a LID or PIN as defined in Section A and provide that number to the person that they are obtaining the devices from. The person responsible for the distribution of the AIN devices is responsible for the entry of the distribution record into AIMS. The record includes the AINs, date of distribution, and LID or PIN/NPN where the devices were distributed. Details of the processes available for completing these distribution records are provided in the AIMS user manual.

Producers electing to use AIN devices may contact the supplier of the tags in their area. The complete listing of AIN devices and the AIN tag manufacturer's information is at http://www.aphis.usda.gov/traceability/downloads/AIN_device_list.pdf.

When accredited veterinarians obtain 840 AIN tags direct from an AIN device manufacturer for distribution or for use where they apply the tags, they are responsible for reporting the tag distribution or tag applied records to AIMS. In this case, they are acting as an AIN tag manager and must establish a marketing arrangement with the tag manufacturer.

When accredited veterinarians obtain AIN 840 tags from a State or Federal Animal Health Official the records of tags applied or distributed are to be reported as directed by the State or Federal Animal Health Official that provided the tags.

State and Federal animal health officials may also use AIN devices when they administer animal disease programs and are not required to be an AIN device manager. However, State Animal Health official that utilize AIN 840 tags as part of their ADT activities must maintain a complete record of the tag distribution records on an information system. The States may utilize AIMS as the information system to meet this requirement or their internal animal health information system that has tag distribution recording capability.

Sheep and Goat Tags

Administration of official identification requirements for scrapie program tags is explained in the Scrapie Eradication Uniform Methods and Rules document at http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/umr_scrapie.pdf.

Premises Identification Number Tags for Slaughter Swine

PIN tags for slaughter swine provide an option to officially identify sows and boars to the premises where they were kept immediately before entering harvest channels. PIN tags for

slaughter swine may be obtained from authorized manufacturers. As with the USDA backtag applied at markets, the PIN tag will be collected as an official form of identification to be associated with any blood or tissue samples collected for disease surveillance. If a PIN tag includes a manufacturer printed number that is unique within a herd, the tag would also qualify as an official eartag for interstate movement of individual animals.

Replacement of Official Identification Eartags

Replacement eartags for retagging animals that lose their official eartag are defined in 9 CFR 86.4 (d) removal or loss of official identification devices.

Issuance of Duplicate Official Identification Eartags

Duplicate official identification eartags may be obtained from approved eartag manufacturers when an official eartag was lost and the owner or person responsible for the animal needs to retag the animal with the official identification number of the lost eartag. This may be a standard practice for some breed registries or other genetic companies that use official eartags in their programs. For AIN eartags, the manufacturer will submit a record to AIMS with the information on the reissuance and distribution of the duplicate eartag. Additionally, the eartag manufacturer will imprint the designated symbol on the eartag to reflect that the tag is a duplicate of a previously issued tag. When the duplicate eartag contains radio frequency identification technology, the manufacturer will encode the number in accordance with ISO 11784 for administering transponders.

Approved Tagging Sites

Approved tagging sites are locations 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 tagging site. In these cases, livestock required to be officially identified may be moved interstate and officially identified at the approved tagging site.

The animals must be officially identified at the tagging site before they are commingled with animals from other premises or identified by other practices that will ensure the identity of the animal is accurately maintained until tagging. This will ensure the official identification numbers of the eartags are correlated to the owner of the animals (or person responsible) when shipped to the tagging site. For example, a livestock market, acting as an approved tagging site, may use backtags to temporarily identify the animal upon unloading. The approved tagging site, at a minimum, must:

- Obtain official identification eartags only as directed by APHIS, State, or Tribal animal health officials.
- Unload animals requiring official identification only when the owner or the person in possession, care, or control of the animals when they are brought to the tagging site agrees to have the animals officially identified in accordance with approved tagging site protocols.
- Maintain tagging records using forms or electronic systems as directed by APHIS, State, or Tribal animal health officials to include, at a minimum:
 - The name of the owner or person responsible for the animals tagged and their street address, city, State, and ZIP code

- The official identification numbers of the tags applied associated with the owner or person responsible for the animals.
- The date the official identification eartags were applied.
- Submit the records of tags applied to the designated animal health official as directed by APHIS, State, or Tribal animal health officials.
- Ensure the security of official eartags and distribution records by:
 - Maintaining a record of all official identification eartags received, distributed, and applied at the tagging site.
 - Keeping the inventory of tags and records in a secure place accessible only to tagging site personnel.
 - Reporting any tags lost or stolen immediately to the appropriate State or Federal animal health official.
- Tag all animals in accordance with 9CFR 86.
 - Tag all animals that are required to be identified.
 - Only tag animals that are not already officially identified. Do not apply additional official eartags except as provided in 9CFR 86.4(c)
 - Removal and/or replacement of official identification devices must be in accordance with 9CFR 86.4(d) and (e)

When animals are moved to an approved tagging site to fulfill the official identification requirements, the interstate certificate of veterinary inspection or other movement document must contain a statement verifying that the official eartags are to be applied at an approved tagging site along with the name and complete address of the tagging site. States will provide public listing of tagging sites.

Entities interested in becoming an approved tagging site should contact their APHIS, State, or Tribal animal health official.

Appendix 1: Draft Agreement for Approved Livestock Marketing Facilities

On January 2, 2015 USDA published a proposed rule on approved Livestock Marketing Facilities. In the proposed rule USDA acknowledged that the Approved Livestock Marketing Facility Agreement would be removed from the regulatory text and fully contained in the ADT General Standards document. The following pages provide the draft agreement for public review. The rule defines the agreement as one reached between a livestock marketing facility and APHIS and executed in accordance with 9 CFR 71.20, in which the facility agrees to adhere to the structural and procedural standards specified within the agreement. The modified agreement contains several changes from the previous version which are further outlined in the proposed rule. This agreement will be finalized when APHIS publishes the final rule on approved Livestock Marketing Facilities.

United States Department of Agriculture (USDA) Animal Plant Health Inspection Services (APHIS)

DRAFT - Approved Livestock Marketing Facility Agreement

This agreement is between the Animal and Plant Health Inspection Service, Veterinary Services, United States Department of Agriculture (USDA), hereinafter referred to as “APHIS,” and the business or person legally responsible for the facility listed in Part II. States agencies responsible for the administration of animal health programs may participate in the agreement, and are hereinafter referred to as the “State”.

I. PURPOSE

This agreement establishes collaboration among APHIS, the States, and Approved Livestock Marketing Facilities for the handling of livestock that have moved or will move interstate, including interstate commerce, pursuant to Title 9 of the *Code of Federal Regulations* (9 CFR).

II. FACILITY INFORMATION

Name of Facility:				
Address (Physical Location):				
Address (Mailing address if different):				
City:			State:	ZIP Code:
Office Phone:		Cell Phone:		
Fax:		Email Address:		
Responsible Person ³	Last Name:		First Name:	
Type of Facility	<input type="checkbox"/> Market - Auction Barn /Stockyard	<input type="checkbox"/> Buying Station	<input type="checkbox"/> Dealer Facility	<input type="checkbox"/> Other _____
Regular Scheduled Sales :				
Premises ID or Location Identification Number		I do not have a location identification number. Please issue my location a number. (Check adjacent box)		<input type="checkbox"/>
Additional Comments:				

³ Person legally responsible for the management and day-to-day operation of the livestock facility.

III. AGREEMENT PROVISIONS

A. Cooperation

1. The State and APHIS will receive a schedule of the facility's sale days, which will indicate the types of animals to be handled at the facility on each sale day. The State and APHIS will be notified of any changes to the schedule before they are made.
2. State and APHIS representatives shall be granted access to the facility during normal business hours to evaluate whether the facility and its operations are in compliance with the applicable provisions of this agreement and 9 CFR, subchapter C.
3. When requested the facility will allow a State or APHIS representative to perform duties at the facility in accordance with State or Federal regulations and will support the representative's work, including the collection of samples for diagnostic testing.
4. A State or APHIS representative or accredited veterinarian is to be immediately notified of the presence at the facility of any livestock known to be infected, exposed, high-risk, or suspect animals, or known to have tested positive for, or that show signs of possibly being infected with, any infectious, contagious, or communicable disease.
5. Any reactor, suspect, exposed, high-risk, or scrapie-positive livestock shall be held in quarantined pens apart from all other livestock at the facility. This requirement shall not apply to scrapie-exposed sheep that are not also designated high-risk animals or to sheep or goats designated under 9 CFR part 79 as scrapie-exposed or high-risk animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or a certificate issued by an accredited veterinarian stating the animals are open; or that the animals are under 12 months of age and are not visibly pregnant and are maintained in the same pen only with other animals that will be moved directly to slaughter or to a terminal feedlot in accordance with 9 CFR parts 71 and 79.
6. No reactor, suspect, exposed, high-risk, or scrapie-positive livestock, nor any livestock that show signs of being infected with or that have tested positive for any infectious, contagious, or communicable disease, may be sold at or moved from the facility, except in accordance with 9 CFR parts 71, 75, 77, 78, 79, 80, 81, 85, and 86.
7. Availability and Services of Accredited Veterinarians
 - a. APHIS strongly encourages having an accredited veterinarian available to inspect livestock for clinical evidence of contagious, infectious, communicable, or parasitic diseases.
 - b. An accredited veterinarian must be available to provide services, including:
 - i. Inspection of all livestock that require issuance of an Interstate Certificate of Veterinary Inspection (ICVI) by Federal regulation before leaving the facility, unless otherwise exempt.
 - ii. Inspection of all livestock exempted from an ICVI, based on facility approval, before they leave the facility. For example, 9 CFR 86.4 provides an ICVI exemption for cattle moving interstate to an approved livestock facility when accompanied by an owner-shipper statement. These cattle must be inspected at the facility by an accredited veterinarian unless the inspection is waived by the animal health official of the State where the facility is located.
 - c. The Facility:
 - i. Shall arrange for an accredited veterinarian to be available when needed at the facility to carry out State and Federal regulations, including but not limited to the issuance of ICVIs.
 - ii. May not sell livestock to out-of-State buyers or allow the animals to move to interstate destinations requiring ICVIs under 9 CFR part 86 or State of destination import requirements unless the facility operator makes available an accredited veterinarian to complete the certificates.
 - iii. Shall see that buyers and consignors are aware of ICVI requirements.

- iv. Shall see that the accredited veterinarian is advised of livestock being moved interstate or that need an ICVI.
- v. Shall indicate the management's plan for having an accredited veterinarian available to meet the requirements of 9 CFR by selecting the most appropriate response below:

- An accredited veterinarian will be onsite to inspect the health of the livestock that enter the facility, issue ICVIs, and provide other services necessary to meet all State and Federal regulations.
- An accredited veterinarian will not be onsite during sales days, but will be available (on call) to provide accredited veterinarian services necessary to meet all State and Federal regulations.

Name of accredited veterinarians or clinics providing services at the facility:

1.

2.

3.

4.

- d. The facility will advise the State and federal animal health officials of any change regarding the availability of accredited veterinarians.
- e. APHIS has permission to use the information provided by the facility to indicate the availability of accredited veterinarians in its listing of Approved Livestock Marketing Facilities.
- f. APHIS or the State, at a minimum, will complete an inspection of each approved marketing facility twice a year.

8. Availability of USDA-Approved Backtags

- a. APHIS will provide USDA-approved backtags and backtag glue to Approved Livestock Marketing Facilities at no charge.
- b. The person responsible for the facility shall see that backtags are properly applied to the animals.
- c. The person responsible for the facility shall maintain a record of applied backtags in accordance with APHIS policies.

B. Records

- 1. Documents such as weight tickets, sales slips, and records of origin, identification, and destination that relate to livestock that are in, or that have been in, the facility shall be maintained by the facility for 5 years in the case of cattle, horses, and sheep or goats; and 2 years for swine and poultry.
- 2. APHIS and State representatives shall be permitted to review and copy those documents during normal business hours.

C. Identification

- 1. All livestock must be officially identified in accordance with the applicable regulations in 9 CFR, including but not limited to parts 71, 75, 77, 78, 79, 80, 81, 85 and 86 at the time of, or before, entry into the facility.
- 2. USDA-approved backtags will be used, and records of use kept, as provided in the Animal Disease Traceability General Standards document.

D. Cleaning and Disinfection

1. The facility, including all yards, docks, pens, alleys, sale rings, chutes, scales, means of conveyance, and their associated equipment, shall be maintained in a clean and sanitary condition. The facility shall be responsible for the cleaning and disinfection of the facility in accordance with 9 CFR part 71 and for maintaining an adequate supply of disinfectant and serviceable equipment for cleaning and disinfection.

E. General Facilities and Equipment Standards

1. All facilities and equipment shall be maintained in a state of good repair. The facility shall contain well-constructed and well-lighted livestock handling chutes, pens, alleys, and sales rings for the inspection, examination, identification, vaccination, testing, and branding of livestock.
2. Isolation or quarantine pens shall be designated. Isolation or quarantine pens shall be clearly labeled with paint or placarded with the word "Isolation" or "Quarantine," or the name of the disease of concern, when in use and shall be cleaned and disinfected between uses.
3. Isolation or quarantine pens shall be constructed in a manner that prevents direct contact of livestock of concern with other livestock in alleyways, adjoining pens, or other areas of the facility.
4. Isolation or quarantine pens shall have adequate drainage, and the floors and those parts of the sides of the isolation or quarantine pens with which clinically ill, reactor, suspect, exposed, high-risk, or scrapie-positive livestock; their excrement; or their discharges may have contact shall be constructed of materials that are substantially impervious to moisture and able to withstand continual cleaning and disinfection.
5. Electrical outlets shall be provided as necessary.
6. Space shall be furnished when necessary for conducting diagnostic tests. All test reagents, testing equipment, and documents relating to the State-Federal cooperative eradication programs on the facility's premises shall be secured to prevent misuse and theft. Adequate heat, cooling, electricity, water piped to a properly drained sink, and sanitation shall be provided for properly conducting diagnostic tests.
7. Vector Control Program: If present, biting insects should be controlled so as to reduce or eliminate the transmission of blood borne infectious diseases. The method or combination of methods should be effective for the purpose and may include, but are not limited to: manure management, shelter and screening, establishing and maintaining proper drainage and elimination of standing water or wet areas, fans or "air curtains", pesticide application, baits, fly strips, or other effective means.

F. Standards for Handling Different Classes of Livestock

Check only those that apply at this facility

1. Cattle and bison:
 - a. This facility will handle:
 - i. Cattle:
 - ii. Bison:
 - iii. Cattle and/or bison known to be brucellosis reactors, suspects, or exposed. Such cattle and bison will handled as described below: ...
 - b. Cattle and bison entering the facility shall be received, handled, and released by the facility only in accordance with 9 CFR including, but not limited to parts 71, 78, and 86.
 - c. If the facility handles cattle and bison known to be brucellosis reactors, suspects, or exposed, such cattle and bison will handled in accordance with the following:
 - i. All brucellosis reactor, brucellosis suspect, and brucellosis exposed cattle or bison arriving at the facility shall be placed in quarantined pens

- and consigned from the facility only in accordance with 9 CFR part 78.
- ii. Any cattle or bison classified as brucellosis reactors at the facility shall be identified in accordance with 9 CFR part 78, placed in quarantined pens, and consigned from the facility only to a recognized slaughtering establishment or an approved intermediate handling facility in accordance with 9 CFR part 78.
- iii. Any cattle or bison classified as brucellosis exposed at the facility shall be identified in accordance with 9 CFR part 78, placed in quarantined pens, and consigned from the facility only to a recognized slaughtering establishment, approved intermediate handling facility, quarantined feedlot, or farm of origin in accordance with 9 CFR part 78.
- iv. The identity of cattle from quarantined areas shall be maintained, and test-eligible cattle from quarantined areas shall not be placed in pens with cattle from any other area until they have fulfilled the requirements of 9 CFR part 78 and State regulations for release from the facility.

2. Horses:

- a. This facility will handle:
 - i. Horses:
 - ii. Horses that are known equine infectious anemia (EIA) reactors:
- b. Horses that enter the facility shall be received, handled, and released by the livestock facility only in accordance with 9 CFR parts 71 and 75.
- c. If this facility handles horses that are known equine infectious anemia (EIA) reactors, it must do so in accordance with the following:
 - i. Any horses classified as EIA reactors and accepted by the facility for sale shall be placed in quarantined pens at least 200 yards from all non-EIA-reactor horses and follow vector control protocols listed in III.E.7 of this agreement.
 - ii. Any horses classified as EIA reactors and accepted by the facility for sale shall be consigned from the facility only to a slaughtering establishment or to the home farm of the reactor in accordance with 9 CFR part 75.

3. Sheep and Goats

- a. This facility will handle:
 -
 - i. Breeding sheep or goats:
 -
 - ii. Slaughter sheep or goats over 18 months of age:
 - iii. Slaughter sheep or goats under 18 months of age:
 - iv. Sheep or goats for feeding for slaughter under 18 months of age:
 - v. Scrapie-exposed goats or high-risk sheep or goats:
- b. All sheep and goats that enter the facility must be received, handled, and released by the facility only in accordance with 9 CFR parts 71 and 79.
- c. All sheep and goats at the facility must be officially identified and relevant records related to those identified animals must be maintained by the facility operator, as required under 9 CFR part 79.
- d. The identity of sheep and goats from consistent States and inconsistent States must be maintained by the facility operator.
- e. Sexually intact animals that do not meet the requirements of part 79 to be sold as breeding animals must be maintained in separated enclosures at all times

from animals that may be offered for sale as breeding animals unless all animals maintained in an enclosure arrived at the facility as part of the same consignment and are separated before sale.

- f. Any sheep or goats that are designated, with regard to scrapie, as high-risk, suspect, or scrapie-positive animals, and goats designated with regard to scrapie as exposed animals, excluding slaughter sheep or goats that are designated as exposed or high-risk animals and are not pregnant, must be held in quarantined pens while at the facility.
- g. The facility operator must ensure that buyers are notified when sheep or goats that may move only for slaughter or feeding for slaughter are being sold and the bill of sale must clearly indicate that the animals were sold for slaughter only.

4. Swine

a. This facility will handle:

- i. Breeding swine:
- ii. Slaughter swine:
- iii. Feeder swine:
- iv. Pseudorabies reactor, suspect, or exposed swine:

- b. Swine that enter the facility shall be received, handled, and released by the livestock facility only in accordance with 9 CFR parts 71, 78, and 85.
- c. Pens, alleys, and sales rings for holding, inspecting, and otherwise handling swine shall be imperviously surfaced.
- d. Slaughter swine may be handled only on days when no feeder swine or breeder swine are present at the facility, unless the facility has provisions to keep slaughter swine physically separated from feeder swine and breeder swine or unless those areas of the facility used by slaughter swine have been cleaned and disinfected before being used by feeder swine or breeder swine.
- e. No feeder swine or breeder swine may remain in the livestock facility for more than 72 hours, and no slaughter swine may remain in the livestock market for more than 120 hours.
- f. Feeder swine shall be kept apart from other swine while in the livestock facility.
- g. No release shall be issued for the removal of slaughter swine from the livestock facility unless the slaughter swine are consigned for immediate slaughter or to another slaughter market and the consignee is identified on the release document.

8. Other species

a. List other species that are handled at this facility: _____

IV. OFFICIAL IDENTIFICATION TAGGING SERVICES

1. Approved Tagging Site

- a. The individual responsible for this facility asks for the facility to be an approved tagging site as defined in 9 CFR part 86. This allows a tagging site to receive cattle and bison that moved interstate without official identification with the official eartags applied after their arrival. Yes No
- b. If the responsible individual answers “yes” to the previous question, he or she has reviewed and agrees to the terms and conditions of approved tagging sites

provided in the addendum to this agreement by State or Federal animal health officials. Yes No

- 2. Tagging services for sheep and goats
 - a. The individual responsible for the facility asks that the facility be authorized to provide tagging services for sheep and goats in accordance with 9 CFR part 79, "Scrapie in Sheep and Goats." Yes No

V. WITHDRAWAL OF APPROVAL

- 1. APHIS may withdraw the approval of a livestock marketing facility on determining that the livestock facility is not or has not been maintained and operated in accordance with this agreement or 9 CFR.
 - a. In the case of withdrawal, before such action is taken, the facility will be informed of the reasons for the proposed withdrawal. The facility may appeal the proposed withdrawal in writing to APHIS within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons on which the facility relies to show that the reasons for the proposed withdrawal are incorrect or do not support withdrawal of approval of the livestock facility. APHIS will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for the decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. APHIS will adopt rules of practice concerning the hearing. However, withdrawal shall become effective pending final determination in the proceeding when APHIS determines that such action is necessary to protect the public health, interest, or safety. Such withdrawal shall be effective on oral or written notification, whichever is earlier, to the person responsible for the facility. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. This withdrawal shall continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by APHIS.
 - b. Approval for a livestock marketing facility will be automatically withdrawn by APHIS when:
 - i. The facility notifies APHIS, in writing, that the facility will no longer handle livestock moved interstate under this agreement; or
 - ii. The person who signed the agreement is no longer responsible for the day-to-day operations of the facility.

VI. EFFECTIVE DATE, DURATION, AND RENEWAL/AMENDMENTS

This agreement is effective on the date of the APHIS signature and continues unless withdrawn by APHIS as defined in Article V of this agreement or a change is made to 9 CFR that necessitates a revision. The agreement may be renewed or amended at any time to update the information provided by the facility.

VII. SIGNATURE OF INDIVIDUAL RESPONSIBLE FOR FACILITY

I verify the above information to be accurate and hereby request approval for this facility to operate as an Approved Livestock Marketing Facility for the classes of livestock indicated in paragraphs II. F. of this agreement. I acknowledge that I have either received a copy of the applicable parts of 9 CFR or have internet access to the CFR. I further acknowledge that I have been informed and understand that failure to abide by the provisions of this agreement and all applicable provisions of Title 9, Chapter I, of the Code of Federal Regulations (9 CFR) constitutes a basis for the withdrawal of this approval.

Print Name:

Signature:

Date:

VIII. STATE OR FEDERAL REPRESENTATIVE VISITING FACILITY

Representative who discussed agreement with responsible individual at the facility

Agency:

Print Name:

Signature:

Date:

IX. APPROVALS AND SIGNATURES OF STATE AND APHIS REPRESENTATIVES

A. The facility is granted approval for:

Approved Livestock Marketing Facility: Yes No

Approved Tagging Site: Yes No

APHIS Representatives

Print Name:

Signature:

Date:

State Representative

Name of Agency/Department:

Print Name:

Signature:

Date:

(Approved by the Office of Management and Budget under control numbers 0579-0258 and 0579-0342)

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

July 2012



**Regulatory Impact Analysis &
Final Regulatory Flexibility Analysis**

**Final Rule
APHIS-2009-0091
RIN 0579-AD24**

Traceability for Livestock Moving Interstate

Policy & Program Development

Policy Analysis & Development

N

Summary

APHIS is establishing general traceability regulations for livestock moving interstate. The purpose is to improve APHIS' ability to trace livestock in the event disease is found. In this analysis, we examine expected benefits and costs of the rule in accordance with Executive Orders 12866 and 13563. Benefits are expected to exceed the costs overall. Possible impacts on small entities are considered in accordance with the Regulatory Flexibility Act.

While the rule applies to cattle and bison, horses and other equine species, poultry, sheep and goats, swine, and captive cervids, the focus of this analysis is on expected economic effects for the beef and dairy cattle industries. These enterprises are likely to be most affected operationally by the rule. For the other species, APHIS will largely maintain and build on the identification requirements of existing disease program regulations.

Costs for cattle producers are estimated in terms of activities that will need to be conducted for official animal identification and issuance of an interstate certificate of veterinary inspection (ICVI), or other movement documentation, for livestock moved interstate. Incremental costs incurred are expected to vary depending upon a number of factors, including whether an enterprise does or does not already use eartags to identify individual cattle. For many operators, costs of official animal identification and ICVIs will be similar, respectively, to costs associated with current animal identification practices and the inshipment documentation currently required by individual States. Existing expenditures for these activities represent cost baselines for the private sector. To the extent that official animal identification and ICVIs will simply replace current requirements, the incremental costs of the rule for private enterprises will be minimal.

There are two main cost components for the rule, using eartags to identify cattle and having certificates for cattle moved interstate. Approximately 20 percent of cattle are not currently eartagged as part of routine management practices, and an estimated 45 percent of cattle are identified for management purposes other than by using official identification. Annual incremental costs of official identification for cattle enterprises are estimated to total from \$12.5 million to \$30.5 million, assuming producers who are not already using official identification will tag their cattle as an activity separate from other routine management practices. More likely, some producers who are not already using official eartags can be expected to combine tagging with other routine activities such as vaccination or de-worming, thereby avoiding the costs associated with working cattle through a chute an additional time. Under this second scenario, the total incremental cost of official identification will range from \$8.9 million to \$19.7 million.

All States currently require a certificate of veterinary inspection, commonly referred to as a health certificate, for the inshipment from other States of breeder cattle and 48 States require a health certificate for feeder cattle. Annual incremental costs of the rule for ICVIs are estimated to range between \$2 million and \$3.8 million. If States currently requiring documentation other than ICVIs such as owner-shipper statements or brand certificates continue to accept these documents in lieu of an ICVI, as permitted by this rule, the ICVI requirement in this rule will not result in any additional costs.

The combined annual costs of the rule for cattle operations of official identification and movement documentation will range between \$14.5 million and \$34.3 million, assuming official identification will be undertaken separately from other routine management practices; or

between \$10.9 million and \$23.5 million, assuming that some producers will combine tagging with other routine management practices that require working cattle through a chute.

Currently, States and Tribes bear responsibilities for the collection, maintenance, and retrieval of data on interstate livestock movements. These responsibilities will be maintained under the rule, but the way they are administered will likely change. Based on availability, Federal funding will be allocated to assist States and Tribes as necessary in automating data collection, maintenance, and retrieval to advance animal disease traceability.

Direct benefits of improved traceability include the public and private cost savings expected to be gained under the rule. Case studies for bovine tuberculosis, bovine brucellosis, and bovine spongiform encephalopathy (BSE) illustrate the inefficiencies currently often faced in tracing disease occurrences due to inadequate animal identification and the potential gains in terms of cost savings that may derive from the rule.

Benefits of the traceability system are for the most part potential benefits that rest on largely unknown probabilities of disease occurrence and reactions by domestic and foreign markets. The primary benefit of the regulations will be the enhanced ability of the United States to regionalize and compartmentalize animal health issues more quickly, minimizing losses and enabling reestablishment of foreign and domestic market access with minimum delay in the wake of an animal disease event.

Having a traceability system in place will allow the United States to trace animal disease more quickly and efficiently, thereby minimizing not only the spread of disease but also the trade impacts an outbreak may have. The value of U.S. exports of live cattle in 2010 was \$131.8 million, and the value of U.S. beef exports totaled \$2.8 billion. The value of U.S. cattle and calf production in 2009 was \$31.8 billion. For tagging cattle, the estimated incremental costs of the

rule for cattle enterprises—between \$14.5 million and \$34.3 million, assuming official identification is a separately performed activity, and between \$10.9 million and \$23.5 million, assuming official identification is combined by some operations with other routine management practices that require working cattle through a chute—represent about one-tenth of one percent of the value of domestic cattle and calf production. If there were an animal disease outbreak in the United States that affected our domestic and international beef markets, preservation of a very small proportion of these markets would justify estimated private sector costs attributable to the animal disease traceability program.

Most cattle operations in the United States are small entities. USDA will ensure the rule's workability and cost effectiveness by collaborating in its implementation with representatives from States, Tribes, and affected industries.

In the table on the following page, we summarize expected benefits and costs of this rule.

Summary table of expected benefits and costs of the animal disease traceability rule with respect to the cattle industry -

Benefits			
<ul style="list-style-type: none"> • More effective tracing of animal disease discoveries, that is, traces successfully accomplished more quickly than at present, with fewer private entities needing to be included in the traces; public resource savings. • Reduced risk of disease spread following an animal disease discovery, including discoveries where the disease has a long latency period, due to timely location of all animals that may have been infected or exposed; prevention or mitigation of negative domestic and international market impacts of disease occurrence. 			
Annual Costs			
Private Sector	Official Identification	ICVI	Total
-----Million Dollars-----			
Scenario 1, official identification undertaken separately from other management practices by producers not already using official ID	12.5 to 30.5	2.0 to 3.8	14.5 to 34.3
Scenario 2, official identification combined with other management practices by some producers not already using official ID	8.9 to 19.7	2.0 to 3.8	10.9 to 23.5
States			
Automation of data systems to provide electronic retrieval of ICVI data; incremental cost dependent on status of States' existing animal disease traceability systems and availability of Federal funding. USDA expects that the States will match approximately 20 percent of Federal money provided to them, either through State funding or in-kind contributions.			
U.S. Government			
\$14.2 million in FY 2012, for IT assistance to States (\$1.9 million), field implementation (\$9.6 million), and program administration (\$2.7 million).			

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officially identified and accompanied by documentation recording, among other things, the animal's official identification number and the locations from and to which it is being moved. Such requirements, however, do not apply to all livestock or to all interstate movements. This rulemaking is intended to address animal disease traceability gaps in the regulations and enhance our ability to safeguard animal health.

We are particularly concerned with current inadequacies in disease tracing capabilities in the cattle industry. Previously, many cattle received official identification through USDA's vaccination program for brucellosis, which requires that certain young female cattle and bison (aged 4 to 12 months) moving into and out of States or areas designated as Class B or Class C for brucellosis be vaccinated for the disease. These vaccinated calves must be permanently identified by means of a tattoo and either an official vaccination eartag or other official eartag if one is already attached to the animal (9 CFR part 78). Our eradication efforts have been tremendously successful, and now all 50 States are brucellosis-free. While this is certainly a positive development, it has resulted in a steep decline in the number of officially identified cattle. In 1988, when there were only 27 Class Free States and many more calves were subject to those requirements, 10 million calves were officially identified, but by 2010 that number had fallen to 3.1 million.

As a result of decreasing levels of official identification in cattle, the time required to conduct disease investigations is increasing. For example, investigations for bovine tuberculosis frequently now exceed 150 days, as USDA and State teams spend substantially more time and money in conducting tracebacks. The decreased level of official identification has resulted in an expansion of the scope of investigations needed to identify suspect and exposed animals, requiring the testing of thousands of cattle that would otherwise not have needed to be tested.

While the rule will apply to cattle and bison, horses and other equine species, poultry, sheep and goats, swine, and captive cervids, the focus of this analysis is on expected economic effects for the beef and dairy cattle industries. These enterprises will be most affected operationally by the rule. For the other species, APHIS will largely maintain and build on the identification requirements of existing disease program regulations, as discussed in the Supplemental Information to the rule. Most poultry moved interstate is already officially identified in accordance with the National Poultry Improvement Plan regulations or as agreed to by State animal health officials and the rule will allow for a group/lot identification number to be used. Consequently, we do not expect that there will be large incremental costs associated with this provision for poultry farms already in compliance with NPIP. Poultry moved interstate to live bird markets will need to have an ICVI or other documentation as agreed to by the shipping and receiving States. For equines, this rule is consistent with current industry practices for identification related to testing for equine infectious anemia. Horses and other equine species moved interstate will be required to be accompanied by an ICVI or other interstate movement document, as agreed to by the States or Tribes involved in the movement. For swine, sheep and goats moved interstate, this rule will not change currently required official identification devices or methods or movement documentation.

The rule has been developed in consideration of existing disease-specific livestock movement regulations and of what was learned from the National Animal Identification System (NAIS). The latter was initiated in 2004, as a means by which livestock producers could participate in national animal health safeguarding efforts. A benefit-cost study was commissioned by USDA, to comprehensively and quantitatively examine the program's

expected economic worth (NAIS Benefit-Cost Research Team 2009).¹ Although the regulatory approach taken in this rule differs from prior implementation strategies, parts of the benefit-cost study remain relevant and help inform our understanding of the costs and benefits of animal disease traceability.

Broad participation at public meetings has underscored the need for USDA to continue to maintain close collaboration with States, Tribes, and producers in the development of this rule. Based on input from these entities, the animal disease traceability program will rely on widely used and cost-effective methods to identify livestock moved interstate. The rule represents a flexible yet coordinated approach to animal disease traceability that will be outcome-based, empowering States, Tribes, and producers to determine the means of traceability that work best for them.

Response to Comments

It was claimed by some commenters that the regulatory impact analysis published in conjunction with the August 2011 proposed rule (preliminary RIA) grossly underestimated the economic cost that would be borne by U.S. cattle producers. Some commenters expressed the view that we did not properly account for the cost of Phase 2. The final rule provisions related to cattle will apply only to cattle over 18 months of age. Provisions for cattle under 18 months of age that were part of the planned Phase 2 are not included in this final rule. If USDA determines that there is a need to include cattle under 18 months of age in the animal disease traceability program, action will be undertaken through a separate rulemaking.

¹ Hereafter referred to as “the benefit-cost study.”

In the preliminary RIA, we estimated the additional costs expected to be incurred due to the provisions of the proposed rule. We acknowledged that a significant portion of the cattle industry already uses some method of identification, as reported in the National Animal Health Monitoring System 2007 and 2008 surveys. We noted that two-thirds of the beef operations and 90 percent of dairy operations use some method of identification.

Additionally, for beef operations, over 60 percent of the calves had some form of individual identification. Consideration of these existing practices is important when estimating new costs that may be attributed to the traceability requirements, as we believe that official eartags, in many cases, will likely be applied at the same time at which cattle are already being tagged or worked through chutes for other management purposes. Additionally, with an array of official eartags, producers may choose a single eartag that meets both management and official identification needs.

We expect the additional cost of official eartags will be small. Likewise, we believe that producers will continue to develop tagging practices that minimize the cost of applying official eartags. Producers that are not able to tag their own cattle may find a tagging site to be the most practical option for meeting the official identification requirements. We believe that the preliminary RIA accurately identified tagging costs that may occur at tagging sites. We acknowledge that our estimates for the number of animals moved interstate that would require official identification is based on several assumptions and that the estimation of costs involves many variables.

Regarding ICVI costs, we noted that most States already require ICVIs for many interstate movements. Thus, we do not believe the overall volume of ICVIs issued will increase significantly as a result of this rule. In this final rule, the exemption that allowed other

documentation to be used in lieu of an ICVI, provided that the shipping and receiving States or Tribes agreed, for cattle and bison under 18 months of age moving interstate has been extended to cover all ages and classes of cattle and bison. This revision will likely make the potential increase in the volume of ICVIs issued less than originally anticipated. In the preliminary RIA, we did account for the costs associated with these documents that are currently not required in two States for feeder cattle. Overall, we believe that estimates used in the preliminary RIA are reasonably accurate in describing expected cost impacts for producers.

One commenter asserted that the likely cost of the proposed rule to producers would range from \$1.2 billion to \$1.9 billion. The commenter cited testimony before the U.S. International Trade Commission (ITC). We believe that the costs described in that testimony included activities not associated with the provisions of the proposed rule. The estimated costs per calf cited in the U.S. ITC testimony included \$5 for tags, data management, and verification; \$7 for working calves, tag placement, and documentation; and \$8 for feedlot and harvest data collection and chute fees. The U.S. ITC testimony cited estimated losses due to shrinkage as \$10 to \$20 in lost income potential per calf. The U.S. ITC testimony was also based on an electronic animal identification system involving data management and verification activities at the producer level.

We are not disputing the cost factors for the practices referenced in the U.S. ITC report. However, we do not believe they reflect management practices necessary for producers to comply with the identification requirements of the traceability rule and, therefore, do not believe those cost factors are applicable in our economic analysis.

One commenter estimated the number of cattle moving interstate to be much higher than the 30 million estimated in the preliminary RIA. Our estimate of 30 million cattle moving

interstate uses data published by the USDA National Agricultural Statistics Service (NASS) in “Meat Animals Production, Disposition, and Income Summary”.

Commenters stated that we ignored the cost to distribute official identification devices and collect and maintain data on people receiving them and animals moved with them. It was stated that we also ignored the costs of official tags bearing the required emblem, the costs of replacing existing tag systems with official tags, the costs of equipment to read the tags, the costs of configuring corrals and handling facilities to allow for collection of identification information, and the costs associated with technology problems when tags are not read.

We included information in the preliminary RIA about the cost of the tags, the cost of the labor to work the cattle in chutes and apply the tags, and the cost of the ICVI when the official identification information is recorded. Since the U.S. Shield has been imprinted on the NUES tags obtained by APHIS for disease-control programs for many years, we do not agree that the standardized use of the official eartag shield will increase the cost of official eartags. This rulemaking is designed to allow producers to use tags that do not require any electronic or special equipment to read the official eartags.

As described in the preliminary RIA, States and Tribes would bear responsibility for the collection, maintenance, and retrieval of data on interstate livestock movements. Federal funding, as available, would be allocated to assist States and Tribes in meeting program goals. Additionally, APHIS continues to provide information systems that States and Tribes may elect to use at no charge.

Some commenters stated that we underestimated the cost to producers of the rulemaking because we did not factor in the costs of buying chutes in calculating the costs of tagging.

As stated previously, in the preliminary RIA, we attempted to determine only the costs and benefits that were associated with the provisions of the proposed rule. While we included estimated costs for chute operations for tagging, we did not include the entire costs of buying or renting chutes because we were only trying to determine the costs associated with the rule. If an operation does not currently own equipment needed for tagging, such as chutes, we note that tagging may take place at an approved tagging site. We do realize that some operations may elect to purchase a chute that will allow them to tag their own animals. However, we do not believe the investment in the chute will be made solely for applying the official eartags to the operation's cattle. Rather, the chute is likely to be used for many other management practices. Therefore, we believe that analyzing the cost of tagging animals at tagging sites provides a more reliable basis for a reasonable estimate of producer costs for tagging animals than would including the entire costs of buying or renting chutes in such an estimate.

Commenters stated that we did not adequately account for the added costs to producers, sale barns, veterinarians, and veterinary clinics that would be associated with our proposed ICVI requirements.

As mentioned previously, many States already require ICVIs for interstate movements of livestock covered in the traceability rule. Therefore, we do not believe the volume of ICVIs issued is likely to change significantly. We did, however, attempt to account for an increase in these costs to producers, which were projected to range from \$2.0 million to \$3.8 million. In this final rule, as we have already noted, the exemption allowing the use of other documentation in lieu of ICVIs has been extended to all ages and classes of cattle and bison when agreed to by the receiving and shipping States and Tribes, thus limiting the increase in the number of ICVIs issued. If sale barns and veterinarians are providing services associated with the rulemaking, we

anticipate that they will charge an appropriate price for those services. Costs that could be incurred by producers as a result were estimated in the preliminary RIA.

One commenter stated that our preliminary RIA grossly underestimated the costs of ICVIs for horse owners. Another stated that the increased costs for the ICVI would place a greater burden on the horse industry than on the cattle industry because horses move more regularly.

The preliminary RIA included information about estimated costs for equines. We estimated the incremental cost of an ICVI for most horses moved interstate to range between \$4.00 and \$7.50, based on the cost of testing for EIA. We estimated that the total additional cost for the equine industry could range from \$8.8 million to \$16.5 million, given the current number of EIA tests per year.

Many commenters expressed concerns about the potential economic burdens on small producers and livestock markets, arguing that the rulemaking favored larger, vertically integrated entities.

While APHIS is sensitive to these concerns, many commenters did not provide specific information to support these claims or provide traceability solutions that would be more cost effective. While larger, vertically integrated entities may realize economic benefits due to the size of their operations, those benefits will result from market forces and are not due to specific provisions of this rulemaking. However, in this final rule, we did add exemptions in response to comments from small poultry producers for certain movements, so as not to put such producers at a disadvantage. In particular, we exempted from the official identification requirements chicks moving interstate from a hatchery to a poultry producer or redistributor.

It was stated that the rulemaking would disadvantage U.S. producers because they would be required to meet our traceability requirements when moving cattle across State lines, while we would place no such requirement on foreign producers.

The official identification and documentation requirements for imported livestock are well established through 9 CFR part 93 and are not affected by this rulemaking. The requirements in part 93 are at least equivalent to those specified in this rulemaking, so domestic producers will not be placed at a competitive disadvantage.

It was stated that the proposed rule was unfair in that it would only regulate interstate movement. As a result, producers may choose to take cattle to in-State markets that are farther away, thus incurring increased transportation costs, in order to avoid the cost and burden of the proposed requirements. Producers and markets located in the interiors of States may be given an unfair competitive advantage by not having to comply.

We realize there are many factors that producers will consider when marketing their animals. While the cost of officially identifying animals moved interstate to a market may be considered, there are many other economic factors associated with marketing decisions, including, but not limited to, transportation costs and the availability of local and out-of-State buyers.

Many commenters viewed the proposed traceability program as an unfunded mandate. For example, it was said that State agencies would have to build database storage, management, and retrieval systems, which could strain their budgets. It was suggested that we provide funds to help States modernize and upgrade their data systems and train people to use them.

The preliminary RIA discussed the estimated Federal funding available to support animal disease traceability. A significant portion of the budgeted funds are targeted to field

implementation. However, APHIS has taken the position that it will not fund the development of duplicative information systems, as such investments cannot be justified. Rather, APHIS will provide information systems that the States and Tribes may use at no charge. If a State or Tribe elects to develop its own system, however, it will have to cover the cost. Federal funds, however, may be used for the overall administration of the local traceability activities.

It was stated that our proposed traceability system would enhance the bargaining power of packers at the expense of producers. The commenters who expressed this view did not describe how the proposed rule would alter the relative bargaining power of packers at the expense of producers, and we are unable to determine how this point is applicable to the rulemaking.

Many commenters noted that our preliminary RIA did not include a cost analysis for poultry producers. The preliminary RIA noted that there would be no additional costs for poultry enterprises that participate in the National Poultry Improvement Plan (NPIP). Participation by commercial poultry producers in NPIP is very high. As noted earlier, a primary concern about the cost of identifying individual birds, in particular chicks shipped from hatcheries, has been accounted for in the exemption from the official identification requirements for such poultry shipments. Likewise, it has been clarified that interstate movements to a custom slaughter facility are exempt from these traceability regulations. Poultry moved interstate to live bird markets would need to have an ICVI or other documentation as agreed to by the States. States have the option of maintaining current requirements for movement documentation, in which case no additional costs will be incurred.

It was stated by some commenters that the preliminary RIA indicated that the primary benefits of this rulemaking would be to minimize losses and enable the reestablishment of

foreign and domestic markets. This rationale was questioned. A commenter requested more detailed information on tuberculosis traceouts in the last 5 years and how animal identification has contributed to successful or unsuccessful traceouts. The commenter also requested data on foreign market access lost due to tuberculosis and brucellosis. Some other commenters stated that the discussion of benefits focused too much on the benefits of exports. It was maintained that, while exporters would likely benefit from the proposed rule, the costs would mainly be borne by domestic producers and related businesses.

The ability of U.S. producers to export affects all producers, even those who do not directly sell to an international market. Trade restrictions lead to products intended for the export market being diverted to the domestic market. An increase in the supply of a product that otherwise may have been exported on the domestic market may lead to lower prices in the short run. In the event that exports cannot be re-established, the likely result is a smaller domestic herd.

A commenter stated that since the potential cost-benefit ratio of the rule could not be determined, the costs should be borne by the Federal Government. The preliminary RIA provided our estimate of who would bear the costs and the amount of those costs. In cases where we cannot quantify benefits or costs, we have described those benefits and costs qualitatively. The benefits of an efficient system for tracing animal disease occurrences, as set forth in the proposed rule and in this document, would accrue directly to the livestock and meat industries and indirectly to other sectors of the economy.

Alternatives to the Final Rule

The National Animal Identification System (NAIS) was one alternative to the rule considered by APHIS. Although more than 500,000 livestock producers took part in NAIS,

these producers represented only 36 percent of livestock enterprises. This limited participation in the identification of livestock operations, which did not include animal identification, would have many omissions of records necessary to achieve timely traceability for an effective program.

As USDA considered alternatives to NAIS, we collaborated with industry to obtain their input on what options for identification and traceability they felt would work the best. As a result, and in contrast to NAIS, the rule will require traceability only for livestock moving interstate. It will also encourage the use of low-cost technology, such as metal eartags, for identifying livestock. Moreover, while the rule lists methods and devices approved by APHIS for identifying species of livestock covered by the rule, it will allow alternative means of identification, such as branding, as agreed upon by animal health officials in the shipping and receiving States or Tribes involved in an interstate movement.

The rule also stands in contrast to NAIS in terms of providing an adaptable approach that embraces the strengths and expertise of States, Tribes, and producers, while being less federally dictated. States and Tribes will be able to establish systems for tracing the interstate movement of livestock that work best for them. APHIS intends through future rulemaking to establish performance standards for States and Tribes, but will not require a one-size-fits-all approach.

Within the animal disease traceability framework, APHIS also considered (i) fully implementing official identification for all cattle upon promulgation of the final rule, or (ii) phasing in official identification of cattle under 18 months of age only after certain traceability performance criteria for older cattle are first met. Both of these alternatives were rejected. Instead, the provisions of this final rule for cattle will only pertain to those cattle over 18 months

of age. If USDA determines that there is a need to include cattle under 18 months of age in the animal disease traceability program, action will be undertaken through a separate rulemaking.

U.S. Cattle Production

Cattle production is one of the most important industries in the United States, generating \$43.8 billion in cash receipts during 2009 (USDA NASS 2010a). The structure of the cattle industry continues to change, with a greater proportion of cattle being raised on fewer and larger farms. The total number of cattle operations in the United States in 2009 was 950,000, of which 753,000 were cow-calf operations. During the last 20 years, the number of all cattle operations in the United States has fallen 28 percent, while beef cow operations have declined by 21 percent. Over this period, the average number of cattle per operation has increased by 36 percent to nearly 100 head for all cattle operations. In 2009, operations with 500 or more head accounted for 47.7 percent of the total cattle inventory, compared to 38.0 percent in 1999.

Although the total cattle inventory fell by 15 percent between 1979 and 2009, commercial beef production grew by 22 percent. The decline in cattle inventory has been offset by a 23 percent increase in the average dressed weight of federally inspected cattle.

The dairy industry in the United States has also undergone significant structural change (USDA NASS 2010b). Total milk cow operations have declined significantly, while the number of large operations has increased. There were 65,000 milk cow operations in 2009, compared to 97,460 in 2001, a decline of 33 percent in 8 years. Despite the large decrease in milk cow operations during this time period, milk cow numbers rose 1 percent (to 9.2 million head in 2009) and milk production increased by 15 percent (to 189,320 million pounds in 2009).

Between 2001 and 2009, the number of dairy operations with 500 or more head increased by 20 percent, from 2,795 to 3,350 establishments. The number of enterprises with 2,000 or

more head showed the greatest percentage increase (128 percent), rising from 325 to 740 operations. While the number of larger operations has grown, smaller operations have declined in number. Operations with fewer than 500 head fell from 94,665 in 2001, to 61,650 in 2009, a decline of 35 percent. Production per cow for both larger and smaller operations continues to increase as lower-producing cows are culled from herds and less efficient operations exit the industry.

In sum, greater concentration and operational efficiencies characterize both the beef and dairy cattle industries. In this environment, operators rely increasingly on interstate movement of their livestock to achieve their marketing objectives. The traceability requirements will further assure market participants that disease outbreaks can be contained without undue delay, minimizing market disruptions domestically and internationally.

Expected Costs

We address expected costs of the rule for the primary private and public entities that will be affected: cattle enterprises, equine and poultry enterprises, States and Tribes, and the Federal government. With respect to cattle producers, we provide general estimates of the costs of principal activities that will be required. For many operators, costs of official animal identification and interstate movement documentation under the rule will be much the same, respectively, as the costs associated with current herd management practices involving ear-tagging and State-required in-shipment documentation. Incremental costs for most equine and poultry enterprises are expected to be minimal due to current identification requirements related to, respectively, testing for equine infectious anemia and National Poultry Improvement Plan movement documentation. The vast majority of the commercial poultry industry participates in NPIP. We address concerns raised by backyard poultry growers by exempting chicks that move

interstate from hatcheries, and clarify that all livestock moved to custom slaughter are exempt.

These adjustments ensure that the rule will result in minimal cost, if any, to the backyard poultry growers. Impacts of the rule for States and Tribes are considered in terms of the need to upgrade data maintenance and retrieval capabilities in order to carry out the activities needed to trace livestock. Lastly, preliminary projections are presented of Federal funding that will be needed to implement the rule.

Cattle Enterprises

Unless specifically exempted, livestock moved interstate will have to be officially identified and accompanied by an ICVI or other acceptable documentation. Types of official individual animal identification numbers and group/lot identification numbers (GIN) are specified in the Animal Disease Traceability General Standards document that accompanies this rule. Cattle and bison required to be officially identified for interstate movement will be identified with either an official eartag or a GIN when appropriate.

Animal identification and certification currently practiced

An indication of the prevalence of current animal identification practices for adult cattle is provided in APHIS surveillance data for 2009 and 2010. Of a total of 156,952 cattle included in the survey (45,489 beef and 111,463 dairy), 46 percent had some form of an official USDA identification eartag (35 percent of beef cattle and 50 percent of dairy cattle surveyed). In addition, the survey noted a number of other types of identification used, including owner eartags, back tags, slaughter tracking eartags, and FSIS condemnation eartags.

Recent surveys by APHIS Veterinary Services, National Animal Health Monitoring System (NAHMS) regarding herd management practices of beef and dairy cattle producers also provide information on operators' current animal health monitoring and recordkeeping. The

NAHMS cow-calf survey (USDA APHIS 2008) found that two-thirds of operations used some form of individual animal identification on at least some cows, and nearly 80 percent of cows had some form of individual identification. Plastic eartags were the most common single type of individual cow identification for operations and individual cows (50.4 and 57.5 percent, respectively). Electronic identification or microchips were used on 0.8 percent of operations and 1.2 percent of individual cows.

The proportion of cow-calf operations that used any form of individual animal identification ranged from 59.3 percent of operations with 1 to 49 cows, to 89.1 percent of operations with 200 cows or more. Plastic eartags were the most common type of individual animal identification across all herd sizes.

Nearly half of cow-calf operations (46.7 percent) used some form of individual animal identification on at least some calves, and 64.8 percent of calves had some form of individual identification. The most common type of individual calf identification was a plastic eartag for operations (37.7 percent) and individual calves (50.2 percent). Electronic identification or microchip responders were used for calves on 0.7 percent of operations and 2.9 percent of individual calves.

About 40 percent of cow-calf operations with 1 to 49 cows used individual animal identification on at least some calves, compared with about 60 to 70 percent of operations in the other herd-size categories. As with cows, a plastic eartag was the most common type of individual animal identification for calves across all herd sizes.

The NAHMS dairy survey (USDA APHIS 2007) found that over 90 percent of dairy operations used some form of individual animal identification, and almost all cows (97.4 percent) had some form of individual animal identification. Most operations (86.5 percent) used

eartags on cows as a form of individual identification, and most cows (94.0 percent) had individual eartags. Various methods of electronic identification were used on 4.1 percent of dairy operations, accounting for 9.0 percent of cows. On operations that used individual animal identification, evaluating milk production and genetic improvements were the two most common reasons given (38.1 and 30.4 percent of operations, respectively).

These statistics on current animal identification practices support the expectation that incremental costs of official animal identification will be minimal for the majority of cattle enterprises.

We are unable to determine the number of cattle for which official identification will be required. Relevant sources (Shields and Mathews 2003, USDA NASS 2010c) do not provide information on interstate livestock movements specific to the categories of cattle that will be directly affected by the rule. Livestock marketing information includes animals shipped to slaughter. While data on States' inshipments exclude animals brought into a State for immediate slaughter, they include feeder cattle, which will be exempted from the identification requirements. In 2009, inshipments totaled 19,790,000 head; the Nation's cattle and calf inventory totaled 93,701,200 head on January 1, 2010. We note that this estimate includes beef cattle younger than 18 months and excludes cattle moved interstate directly to slaughter.

Under current regulations, animals are usually required to be accompanied by a shipper statement or health certificate when moving interstate. An APHIS or State representative or accredited veterinarian responsible for issuing a certificate of veterinary inspection must forward a copy of the certificate to the State animal health official in either the State of origin or the State of destination. Many States also require entry permits, which can be oral or written.

An ICVI, like animal health certificates currently required in the CFR, is to have the following information: certificate number, species, number of animals, purpose of movement, address at which the animals were loaded for interstate movement, destination address, names of the consignor and the consignee and their addresses if different from above, and official identification number of each animal or group of animals moved that is required to be officially identified (or if the sending and receiving States/Tribes have agreed upon an alternative form of identification, a record of that identification). If animals moving under a GIN also have individual official identification, only the GIN will have to be listed on the ICVI.

All States already require a certificate of veterinary inspection for breeding cattle received from other States, with the information required including, as a minimum, the items described above for an ICVI. The ICVI requirements will simply replace existing interstate movement documentation requirements. Currently 48 States use ICVIs for feeder cattle.

Unit costs

The Federal government will supply metal eartags and eartag applicators to States or Tribes free-of-charge for distribution to cattle operations, if resources allow.² An eartag applicator can last for several years. Table 1 shows the incremental, or additional, costs of official animal identification for enterprises that either do or do not already identify animals using eartags as a part of their routine management practices. For producers currently using official identification, there will be no additional cost. Approximately 35 percent of beef cattle currently have official identification. These producers are referred to as Group 1 in Table 1.

² The FY 2012 President's Budget requests funding to pay for the eartags. The cost of an eartag is about 10 cents. An estimated 30 million cattle are shipped interstate per year, including 19.5 million that are shipped without official identification (see table 3). We therefore estimate the total cost of official eartags needed because of the rule to be \$3.0 million per year. This cost will be offset to some extent by reduced costs to animal disease programs that currently pay for tags for cattle. If in the future, federally appropriated funds were not available to purchase these additional eartags, those producers not currently using official identification will purchase eartags, which will increase total producer costs by about \$1.95 million.

An estimated 45 percent of beef cattle have some type of identification for management purposes other than official identification. These producers are referred to as Group 2 in Table 1. The only additional costs for producers who are already tagging their cattle, but not using official identification, will be the labor required to attach the official animal identification during the same tagging event. As shown in table 1, this incremental cost is estimated to be \$0.18 per head. Chute operation costs, as well as costs of shrinkage and possible human or animal injury, are costs that the producer will bear in any case. Management style, working weights, and other factors can contribute to variations in costs, including shrinkage costs, from operation to operation.

The age at which cattle are identified using eartags, for those operations that do so, varies from one enterprise to the next. For management purposes, some producers tag young calves or heifers just before they are bred, while other producers do not tag their cattle until they are nearly ready for sale. Operations that tag calves at birth will have considerably lower costs associated with shrinkage compared to operations that tag their cattle just before the time of sale. The rule does not specify at what age cattle will need to be officially identified, only that it be accomplished prior to interstate movement for those animals that will require official identification. Official identification could provide additional benefits to an operator, depending on the type of managerial information included on the eartag beyond the requirements set forth in the Animal Disease Traceability General Standards document.

For the remaining 20 percent of cattle that will not be eartagged if it were not required by the rule, the chute operation costs and the costs of shrinkage and possible injury (as well as the cost to attach the eartag) are fully attributable to the rule. These producers are referred to as Group 3 in Table 1. The cost per head of official animal identification is estimated to range

between \$1.68 and \$4.68. The cost of tagging may be somewhat underestimated, since some period of time (5 to 15 minutes set-up time) will be needed to prepare for tagging. These cost estimates represent the cost if tagging were carried out independent of other cattle management activities. In practice, producers could choose to combine tagging with routine activities such as vaccinating or de-worming cattle. By combining tagging with other activities, producers will incur costs similar to Group 2 producers, \$0.18 per head. We anticipate that a significant portion of Group 3 producers will choose to change their management activities in this manner.

Table 1. Estimated producer incremental cost of official animal identification for cattle

	Group 1: Incremental cost if official identification is currently used ¹	Group 2: Incremental cost when incorporated into routine management practices ²	Group 3: Incremental cost when not incorporated into routine management practices ³
	Per Head		
Metal eartag ⁴	Zero	Zero	Zero
Eartag applicator ⁵	Zero	Zero	Zero
Chute operation ⁶	Zero	Zero	\$1.00 to \$2.50
Labor to attach the eartag ⁷	Zero	\$0.18	\$0.18
Shrinkage and injury ⁸	Zero	Zero	\$0.50 - \$2.00
Total	Zero	\$0.18	\$1.68 to \$4.68

¹ Estimated to comprise 35 percent of beef cattle.

² Estimated to comprise 45 percent of beef cattle.

³ Estimated to comprise 20 percent of beef cattle.

⁴ Metal tags with numbers conforming to the National Uniform Eartagging System (NUES) will be provided at the direction of State and Tribal animal health officials.

⁵ Eartag applicators will also be provided to producers for NUES tags.

⁶ Based on data presented in the benefit-cost study. For establishments that do not routinely eartag livestock, tagging may take place at an approved tagging site.

⁷ Based on a median farm worker's hourly wage (farm and ranch animals) of \$10.42, and assuming 1 minute is required to tag 1 animal (U.S. Department of Labor, <http://www.bls.gov/oes/2009/may/oes452093.htm>).

⁸ Assumed upper-bound shrinkage cost is \$1.90, based on a weight loss of about 0.2 percent, or about 2.5 pounds for a cow weighing 1,270 pounds, and a price of \$950 (http://www.ams.usda.gov/mnreports/gl_ls132.txt). Potential injury costs comprise the balance of this cost category. A range of \$0.50 to \$2.00 is used, allowing for subsequent gain by livestock on feed. Shrinkage may be less of an issue for replacement breeding stock, but potential injury costs will be an issue in all instances.

The rule will establish the ICVI as the primary document for the interstate movement of livestock. Other documentation for interstate movement, as agreed upon by two or more States/Tribes, will be acceptable. The rule will also define the minimum information required to be on an ICVI, as described above.

An ICVI will be issued only by a State, Federal, or accredited veterinarian. A copy of the ICVI (or other interstate movement document used in lieu of an ICVI or permit) will be required to be forwarded by the veterinarian to the State animal health official of the State of origin within 5 working days. The State of origin, then, will be required to forward a copy of the ICVI to the State of destination within 5 working days.

Table 2 compares the incremental cost of acquiring an ICVI by enterprises that are already using certificates of veterinary inspection for moving cattle interstate other than for immediate slaughter and enterprises that are not doing so. For the former group, the incremental cost may be additional charges by the veterinarian who is issuing the ICVI, if more time is required than when currently certifying livestock for interstate movement to meet States' requirements. Currently all 50 States require a certificate of veterinary inspection for breeder cattle and 48 States require one for feeder cattle. We estimate the incremental cost per head to range between zero and \$1.00.

For operations that will not otherwise have cattle certified for interstate movement, there will be the chute operation costs and the costs of shrinkage and possible injury for animals that will need individual animal identification recorded on the ICVI, as well as the costs of an accredited veterinarian. We estimate the incremental cost per head to range between \$4.00 and \$7.50 for cattle that need individual official identification recorded and between \$1.00 and \$3.00 for animals not required to have their identification recorded.

Cattle and bison under 18 months of age (excluding sexually intact dairy cattle, cattle and bison used for rodeo, exhibition, or recreational purposes) will not need to be identified, but will still require an ICVI for interstate movement. The ICVI will state the number and type of

animals (e.g., 40 mixed steers and heifers) and include a statement such as, "No official identification required at this time."

Table 2. Estimated producer incremental cost of interstate certificate of veterinary inspection (ICVI) for cattle

	Incremental cost for enterprises already utilizing certificates of veterinary inspection for moving cattle interstate other than for immediate slaughter	Incremental cost for enterprises not already utilizing certificates of veterinary inspection for moving cattle interstate other than for immediate slaughter
	Per Head	
Issuance of ICVI, including recording of the animal's official identification number ¹	Zero to \$1.00	\$1.00 to \$3.00
Chute operation ²	Zero	\$1.00 to \$2.50
Shrinkage and injury ³	Zero	\$0.50 - \$2.00
Total	Zero to \$1.00	\$1.00 to \$7.50

¹ Issued by an APHIS representative, State or Tribal representative, or accredited veterinarian.

² Based on data presented in the benefit-cost study. This cost only applies to cattle that will need to have individual animal identification recorded on the ICVI.

³ Assumed upper-bound shrinkage cost is \$1.90, based on a weight loss of about 0.2 percent, or about 2.5 pounds for a cow weighing 1,270 pounds, and a price of \$950 (http://www.ams.usda.gov/mnreports/gl_ls132.txt). Potential injury costs comprise the balance of this cost category. This cost only applies to cattle that will need to have individual animal identification recorded on the ICVI. A range of \$0.50 to \$2.00 is used, allowing for subsequent gain by livestock on feed. Shrinkage may be less of an issue for replacement breeding stock, but potential injury costs will be an issue in all instances.

The unit costs shown in tables 1 and 2 are generalized but indicative of their likely magnitude. Importantly, there are economies of size for both animal identification and ICVI activities. Costs per head will decrease as the numbers of animals officially identified and for which ICVIs are issued increase. Cattle enterprises range widely in the equipment that they will have available for the animal restraint necessary for eartagging and recording animal

identification for the issuance of an ICVI. Larger operations that regularly tag cattle for management purposes are more likely to have permanent chutes, and smaller operations may make use of portable chutes or take their cattle to a tagging site when it is necessary to acquire a movement certificate. If States currently require documentation other than ICVIs such as ownership statements or brand certificates and continue to accept these documents in lieu of an ICVI, as permitted by this rule, the ICVI requirement in this rule will not result in any additional costs.

As mentioned, USDA will bear the cost of the eartags and the eartag applicators as resources allow. The 10-cent metal eartags reflect USDA's intent to rely on low-cost technology. Although the metal tags are inexpensive, they are more labor-intensive than electronic systems when reading and recording animal identification data. Depending on an operator's management objectives, a different type of eartag, including ones that support automated data capture, may be chosen.

Unit charges for the services of an accredited veterinarian for issuing an ICVI will vary, depending on the number of ICVIs issued at a particular location and the travel time required. The incremental cost ranges shown in table 2, up to \$1.00 for enterprises already using certificates of veterinary inspection for moving non-slaughter cattle interstate and from \$1.00 to \$3.00 for enterprises not already doing so, represent the additional inspection and ICVI recording costs that may be charged in most instances.

Costs of retagging of cattle moved interstate will be much the same as the tagging costs shown in table 1. A State or Tribal animal health official or an area veterinarian-in-charge can authorize the replacement of lost eartags or ones that have deteriorated or are otherwise not usable. To facilitate traceback, records will need to be kept when official identification devices

are replaced under such circumstances. We observe that since most beef cattle under 18 months will be exempt from the traceability regulations, the need to retag cattle received by backgrounding operations may be relatively infrequent.³

Producers with only several head of cattle have various options to align with the identification requirements and to minimize their costs. Some may elect to officially tag calves at a young age when tagging can be done before a chute and corrals are needed to work the animals. When calves are older, many producers will likely officially identify their calves when they work the animals for other routine management practices such as vaccinating or deworming. Producers that sell at markets within their State can determine if they want to assume the responsibility of having their cattle eligible for interstate movement. If so, producers unable to tag their own animals may have calves tagged at a market that provides tagging services. The tagging and related marketing arrangements provided by auctions and markets to consigners will likely vary among regions of the country.

Total costs

Enterprises having the estimated 35 percent of cattle currently official identified will not incur any additional costs of tagging. Operators having the estimated 45 percent of cattle currently identified with some type of tag other than official identification will incur an estimated cost of \$0.18 per head. The remaining 20 percent of operations that do not currently use eartags will incur an estimated cost of \$1.68 to \$4.68 per head. As an example, if an operator were to move 20 head interstate, there will be no additional identification cost if the cattle are already

³ Backgrounding refers to an intermediate stage of beef production that lasts for several months before the cattle are moved to a feedlot. During the backgrounding period—when the animals eat roughage and/or light energy rations or graze pasture (native grass or winter wheat)—producers decide when to place them in feedlots to fatten for slaughter, based on market conditions and forage availability.

officially identified. If they would normally be tagged but not officially identified, the total incremental cost is estimated to be \$3.60 for a herd of 20 head. If the operator would not otherwise tag the cattle as a routine management practice, then the total incremental cost of official identification is estimated to range from \$33.60 to \$93.60 for the 20-head herd. The latter group of operators could improve the health and value of their herds by conducting other management practices that require using a chute, such as vaccinating and de-worming, at the same time that the cattle are officially identified.

For the same example, if the 20 head of cattle were already being moved interstate with a certificate of veterinary inspection, then the total incremental ICVI cost is estimated to range from between zero and \$20. If the cattle will not need a certificate of veterinary inspection for interstate movement if it were not for the rule, the total incremental cost will range between an estimated \$20 and \$150. The high-cost estimate will be incurred only if animals need to be worked in a chute specifically for the purpose of issuing an ICVI. Clearly, expected impacts of the rule depend on current identification practices and movement documentation. These costs could be different for cattle moved from and to States or Tribes that accept documentation other than ICVIs.

About 74 million cattle and calves were sold in 2007. Approximately 20 million head move interstate as breeding animals and feeders. Only a portion of the 20 million head will be affected by this rule, because cattle under 18 months of age will not require official identification. Conservatively, however, we include the full 20 million head in our cost calculations, given the uncertainty surrounding these statistics. We do not have information on the number of cattle moved interstate directly to slaughter, but estimate it to be about 10 million head, based upon USDA NASS "Meat Animals Production, Disposition, and Income 2009

Summary” data. Thus, a total of 30 million head or about 40 percent of cattle and calves sold are assumed to move interstate. Based on this quantity, we estimate total costs of official identification.

Table 3 shows the estimated total costs if all producers were to continue current management practices. For the operations already using official identification, there will be no additional animal identification cost attributable to this rule. For the 45 percent of operations using some tagging method but not using official identification, we estimate the incremental cost of tagging to be \$2.4 million. For the 20 percent of operations that do not currently use any tags, we estimate the incremental cost of tagging will range from \$10.0 million to \$28.1 million if they were to conduct tagging as an activity separate from other routine management practices. Total annual costs of official identification for cattle are estimated to range between \$12.5 million and \$30.5 million.

Table 3. Estimated costs of official identification with current management practices

	Estimated Number of Cattle Moving Interstate	Incremental Cost, Low Estimate ¹	Incremental Cost, High Estimate
Using Official ID	10,500,000	\$0	\$0
Tagging but not using official ID	13,500,000	\$2,430,000	\$2,430,000
Not tagging	6,000,000	\$10,080,000	\$28,080,000
Total	30,000,000	\$12,510,000	\$30,510,000

¹ The incremental costs are those costs of official identification that are attributed to this rule.

Table 4 shows the estimated total cost of official identification with modified management practices. As discussed in the Unit Costs section, a significant portion of the

producers who are currently not tagging can reduce the cost of tagging by combining it with other routine cattle management activities. Under modified management practices, producers will choose to combine tagging with other routine activities such as vaccinating or de-worming cattle, thereby avoiding the costs associated with working cattle through a chute an additional time. After considering public comments, we have increased the estimated cost of this second scenario in this Final Regulatory Impact Analysis. We recognize that all producers may not combine tagging with other management activities and therefore some will continue to incur higher costs.

Table 4. Estimated costs of official identification with modified management practices

	Estimated Number of Cattle Moving Interstate	Incremental Cost, Low Estimate ¹	Incremental Cost, High Estimate
Using Official ID	10,500,000	\$0	
Tagging but not using official ID	13,500,000	\$2,430,000	
Not currently tagging			
Incorporate Tagging	2,400,000	\$432,000	\$432,000
Use tagging service	3,600,000	\$6,048,000	\$16,848,000
Total	30,000,000	\$8,910,000	\$19,710,000

¹ The incremental costs are those costs of official identification that are attributed to this rule.

The additional cost of ICVIs in a traceability system will be minimal because all 50 States currently require a certificate of veterinary inspection for breeder cattle and 48 States require a certificate of veterinary inspection for feeder cattle. The rule will impose no additional

costs for an ICVI for breeder animals, which make up about 56 percent of the national herd (2007 Census of Agriculture). For feeder cattle moving to any State other than California or Texas, there will be no additional cost for ICVIs. Approximately two million cattle are moved into California and Texas. If cattle shipped into these two States required an ICVI, the additional cost will range from an estimated \$2.0 million to \$3.8 million, if the individual animal identification number is recorded. We anticipate that States not currently requiring ICVIs may continue to accept other documentation such, as owner-shipper statements or brand certificates, as permitted by this rule, in which case there will be no additional costs for movement documentation. However, we include these possible additional costs of movement documentation in our private-sector total cost estimates.

As stated previously, cattle and bison under 18 months of age (excluding sexually intact dairy cattle, cattle and bison used for rodeo, exhibition, or recreational purposes) will not need to be identified, but will still require an ICVI for interstate movement. The ICVI will state the number and type of animals (e.g., 40 mixed steers and heifers) and include a statement such as, "No official identification required at this time."

The combined annual costs of the rule for cattle operations of official identification and movement documentation are estimated to range between \$14.5 million and \$34.3 million, assuming official identification will be undertaken separately from other routine management practices; or between \$10.9 million and \$23.5 million, assuming that some tagging will be combined with other routine management practices that require working cattle through a chute.

Interstate Movement of Horses and Poultry

There are approximately 4.3 million on-farm horses and other equines (2007 Census of Agriculture). USDA does not count horses and other equine species on nonfarm operations. The

American Horse Council Foundation published an estimate of the U.S. horse inventory for 2003 based on a survey conducted by Deloitte Consulting, LLC. The Deloitte estimate was a total of 9.2 million horses.⁴ Among livestock, horses are unique in that they live longer, are generally more valuable, and are transported interstate more often. Many horses are routinely identified for breed registries, horse identification services, or to ensure the integrity of the racing industry.

There are approximately 2.2 million tests conducted annually for equine infectious anemia (EIA). Testing for EIA is a State requirement for all interstate movement and in some States for intrastate movement as well. Horses must be identified on the requisite EIA test-related paperwork. When horses move interstate to attend shows or exhibitions, registration is required upon entry. Accordingly, event officials are able to track horses moving interstate to the farm of origin.

In this rule, horses and other equines moved interstate will be required to be accompanied by an ICVI or other interstate movement document, as agreed to by the States or Tribes involved in the movement. Because horses moving interstate must already be tested for EIA and be identified in the test-related paperwork, the change from current to the requirements will be relatively small. In some cases the additional cost may be zero. In other cases, the additional cost of the ICVI may range from an estimated \$4.00 to \$7.50. If 2.2 million additional ICVIs were issued in addition to the EIA paperwork, the total additional cost could range from \$8.8 million to \$16.5 million. The 2007 Census of Agriculture estimates the market value of horses and equines sold to total \$2 billion. This understates the total value of horses and other equine species since it only considers those animals sold.

⁴ The large difference between the USDA-NASS estimate and the Deloitte estimate derives from differing list-development procedures and adjustment procedures for missing data.

In 2009, total U.S. production of broiler meat was 35.5 billion pounds with a retail value of \$44 billion. Poultry moved interstate will be required to be accompanied by an ICVI unless they are from a flock participating in the National Poultry Improvement Plan (NPIP) and are accompanied by the documentation required under the NPIP regulations or they are moved directly to a recognized slaughtering establishment. An ICVI will not be needed if the poultry are moved from the farm of origin for veterinary medical examination, treatment, or diagnostic purposes and either returned to the farm of origin without change in ownership or euthanized and disposed of at the veterinary facility.

The documentation requirement will not result in any additional costs for poultry enterprises that participate in NPIP. Poultry moved interstate to live bird markets (LBM) will need to have an ICVI or other documentation as agreed to by the States. Live bird markets are concentrated in the Northeast, specifically in New York and New Jersey. There are about 109 LBM's in New York and New Jersey with 191 suppliers located in 12 different States. Both New York and New Jersey currently require movement documentation for poultry moving to live bird markets. Southern California has the second biggest concentration of LBM's. There are about 35 LBM in southern California and fewer than 50 in the entire State. It is estimated that there are 12 to 15 producers who supply poultry for LBM in southern California. Other areas of the country have few live bird markets.

The period of highest LBM demand is from November through February. In New York and New Jersey, approximately 700,000 birds circulate through the market during that time. By comparison, the southern California LBM handles about 30,000 birds in that same time. During non-peak months, the daily population of birds in Southern California LBM is approximately 8,300 live birds (Cardona et al. 2009).

APHIS does not have an estimate of the possible costs of the rule for enterprises that move poultry interstate to the live bird markets if ICVIs were to be required. If New York and New Jersey maintain current requirements for movement documentation, the rule will not result in additional costs.

States and Tribes

Expected costs of the rule for States and Tribes are related to changes in their animal disease traceability activities. States and Tribes bear responsibilities for the collection, maintenance, and retrieval of data on interstate livestock movements. While these responsibilities will be maintained under the rule, the way they are administered will likely change. Federal funding, as available, will be allocated to assist States and Tribes in making the necessary data collection, maintenance, and retrieval advancements.

Under the rule, after receiving a copy of an ICVI forwarded by the APHIS or State representative or accredited veterinarian who issued it, the State animal health official of the State of origin will be required to then forward a copy to the State animal health official of the State of destination within 5 working days. The 5-day limit for forwarding is intended to facilitate a traceback and/or trace forward investigation if an animal moved interstate in accordance with the regulations were found to be suspect or affected.

This rule will require that any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices maintain for a minimum of 5 years a record of the names and addresses of anyone to whom the devices were distributed. We will also require that approved livestock facilities keep for a minimum of 5 years any ICVIs or alternate documentation used in lieu of an ICVI, for covered livestock that enter the facilities. The 5-year requirement for maintaining records of official identification devices and ICVIs or other animal

movement documents is necessary because certain animal diseases, such as tuberculosis and bovine spongiform encephalopathy, have very long latency or incubation periods, which can make traceback efforts quite challenging. Such diseases may not manifest themselves until several years after it was officially identified and/or moved interstate. The recordkeeping requirements will enhance our ability to conduct traceback investigations of infected and exposed animals, even in cases where the disease that the animal has contracted or been exposed to has a very long latency period.

Current bovine tuberculosis regulations require dealers who purchase, deal in, or sell cattle or bison; or who act as a commission representative or broker; or who operate and conduct an auction in which cattle or bison are sold to maintain records for a period of 5 years.⁵ Because they have an existing recordkeeping system, we do not anticipate significant costs for maintaining a record of ICVIs or alternate documentation. We anticipate that accredited veterinarians will charge a price for their services that is adequate to cover the cost of any recordkeeping they do with respect to distribution of official identification devices. Federal funding (described below) will be available to States and Tribes to develop and implement an animal traceability approach. These funds may be used to enhance recordkeeping if needed.

Improvement by States and Tribes of their animal disease traceability capabilities, as envisioned, will require resources to increasingly automate their data systems to provide electronic retrieval of ICVI data, which will result in major advances in animal disease management. Data-entry costs will be incurred, but systems will be able to better facilitate the rapid retrieval of animal movement information, in contrast to the relatively inefficient, paper-based process that is now found in many States.

⁵ USDA APHIS 91-45-011 Bovine Tuberculosis Eradication Uniform Methods and Rules, Effective January 1, 2005, pg. 11-12.

Federal resources will be used to fund cooperative agreements with States and Tribes to implement the animal disease traceability plan. USDA expects that the States will match approximately 20 percent of the funds provided to them either through funds or in-kind contributions. For FY 2012, the projected appropriated Federal funding is \$14.2 million (table 5). Of this amount \$1.9 million is for information technology and \$9.6 million is for field implementation. A 20-percent share from the States will be about \$2.3 million. These funds will finance information technology improvements, field implementation, and program administration. With Federal assistance, gains from increased efficiencies of animal disease traceability by States and Tribes are expected to outweigh State- and Tribe-incurred costs.

In accordance with the Paperwork Reduction Act, the preamble to the rule describes the information collection or recordkeeping requirements contained in the rule. These requirements will be primarily borne by State, Tribal, and territorial animal health officials; accredited veterinarians; livestock market operators; and harvest facility employees. The Paperwork Reduction Act section estimates the time required to meet the requirements of the rule and asks for public comment.

Federal Funding

Table 5 shows the estimated Federal spending plan to develop and implement the animal disease traceability approach for fiscal year 2012, which includes carryover funding from previous years. These estimates are Federal costs only, and a significant portion of these funds will be provided to the States and Tribes. As mentioned, USDA expects that the States will match approximately 20 percent of the funds provided to them either through funds or in-kind contributions. This assumption is based on contributions of States toward current and past cooperative agreements in support of animal disease traceability.

Table 5. Projected Federal appropriated funding for supporting animal disease traceability activities, fiscal year 2012

	FY 2012
System funding (information technology)	\$1,900,000
Field implementation	\$9,611,600
Program administration	\$2,729,400
Total	\$14,241,000

Among implementation costs will be the recording of animal identification numbers retired at slaughter. In estimating this cost, we assume eartag numbers will be entered at a federally funded central tag processing center. APHIS estimates the cost of tag retirement and data entry will be about \$0.24 per tag. The aggregate cost is estimated to be \$1.7 million per year.⁶

Rule Elements that will lessen the Cost Burden for Producers

Enterprises that move their cattle interstate will bear certain costs when the rule becomes final, although, as noted, incremental costs for many operations may well be minimal. We identify here several elements of the rule that will further lessen the cost burden. A central tenet of the regulatory philosophy that underlies this rule—namely, allowing States, Tribes, and producers to find and use the approaches to traceability that work best for them—will enable entities to seek and employ low-cost means of achieving the rule’s objectives. For example, any two or more States or Tribes will be allowed to agree upon and use any form of animal identification for interstate movement of cattle under the regulations.

The collaborative manner in which the rule’s implementation is intended to advance will also help to minimize operational burdens. An advisory group that includes representation from

⁶ The cost of \$0.24 is for manual data entry with double entries to reduce errors. The estimated number of tags retired each year is 7 million, including slaughtered and rendered cattle.

APHIS, States, Tribes, and industry will offer recommendations on issues relating to traceability and provide feedback on the effectiveness of various elements of the traceability program.

In addition to individual identification of cattle and bison by means of official eartags, the rule will allow for the use of a group/lot identification number (GIN) when cattle or bison are eligible for interstate movement using group/lot identification. It will not be necessary to have the GIN attached to each animal, a provision in keeping with the rule's emphasis on allowing for maximum regulatory flexibility.

The cost burden will also be lessened by the phase-in of the rule's newly-defined identification numbers and systems and their similarity to existing numbers and systems. For example, the animal identification number (AIN) definition is similar to that in existing regulations. APHIS will phase-out existing AIN formats in order to achieve greater standardization of this numbering system, while providing producers with adequate notice of the change so they can work through existing inventories of eartags. This requirement will apply only to animals tagged one year or more after the effective date of the final rule. Producers will not have to retag animals that had been officially identified using the USA or manufacturer's code AIN prior to that date.

Existing regulations allow for the use of premises-based numbering systems on official eartags. Numbering systems using a premises identification number and a producer's production numbering system will continue to be allowed under the rule, but APHIS will expand the range of allowable location identifiers by defining a location-based numbering system.

There are two situations that are exempt from the traceability requirements: movement entirely within Tribal land that straddles a State line and the Tribe has a separate traceability system from the States in which its lands are located; and movement to a custom slaughter

facility in accordance with Federal and State regulations for preparation of meat for personal consumption.

There are also several instances in which cattle and bison could be moved interstate without an ICVI. These situations include:

- Movement as part of a commuter herd ⁷with 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, provided that the cattle and bison are officially identified there before they are commingled with cattle and bison from other premises.

Expected Benefits

The purpose of the rule is to improve livestock traceability in the event that disease is found. Benefits of improved tracing capabilities will extend to private producers in terms of the health of their own animals and the preservation of domestic and international markets. States, Tribes, and the Federal government will benefit from reduced animal disease management expenditures when there is a disease outbreak, as well as through general gains to the economy that derive from the establishment of improved animal health safeguards.

In the first section that follows, we examine the direct benefits of improved traceability by considering public and private cost savings expected under the rule. The tracing process is described. Given the variety of diseases traced, case studies are presented to illustrate the types

⁷ In this rule, a commuter herd is defined as a herd of cattle or bison moved interstate during the course of normal livestock management operations and without change of ownership directly between two premises, as provided in a commuter herd agreement. A commuter herd agreement is defined as a written agreement between the owner(s) of a herd of cattle or bison and the animal health officials for the States and/or Tribes of origin and destination specifying the conditions required for the interstate movement from one premises to another in the course of normal livestock management operations and specifying the time period, up to 1 year, that the agreement is effective. A commuter herd agreement will be subject to annual renewal. Meeting commuter-herd requirements in lieu of official identification requirements will still provide adequate traceability in our view.

of costs currently borne, their magnitudes, and potential savings. Due to the lack of specific information on economy-wide disease spread and impacts, the case studies illustrate the disease spread and economic impacts for selected instances where reliable information is available.

A second section highlights the market-related gains expected to be attributable to the rule. Improved animal disease traceability will help ensure that negative domestic and international market reactions to animal disease occurrences are minimized through efficient and quickly concluded epidemiological investigations.

Private and Public Sector Cost Savings

The time required to trace an animal's history of movement when there is disease discovery can largely determine the private and public costs that may be incurred. The traceability regulations will help to significantly reduce the amount of time needed to fully identify the number and location of animals that have been in contact with an infected animal. The longer it takes to complete the epidemiological investigation, the greater the number of entities and animals affected and the greater the geographical scope of an outbreak. It is critical that the tracing of animal movements be accomplished as quickly as possible.

Three cattle diseases are described and specific occurrences are used to demonstrate the benefits of traceability that will result from the rule. Specific disease occurrences are used to depict actual instances in which the tracing capability was hindered due to a lack of information required by epidemiologists when conducting disease investigations. This is not to suggest that all disease investigations are inefficient due to a lack of information, but to reflect how these investigations become more complicated and affect more producers when good information is not readily available. Most concerning are outcomes when an investigation cannot quantify or specifically account for all at-risk livestock.

The specific characteristics of diseases lead to differences among epidemiological investigations. Knowing the history of the animal is critical when dealing with a highly contagious disease, in particular its prior locations and contacts with other animals. The type of information and its completeness affect how the disease investigation is conducted. Complete information can help animal health officials to minimize the number of herds tested. When information is limited or vague, the testing of herds is expanded to ensure all possible herds are included. When the herd owner cannot provide information indicating the source herd of an animal of concern, the herds of all potential suppliers of the subject animal must be tested. Numbers of animals needing to be tested can rapidly multiply as all potential sources are considered. With official identification and good records, tracing can be restricted to a specific herd(s).

The trace process

In order to fully appreciate the costs and benefits of animal disease traceability, it is important to understand how a trace is conducted and the critical points that determine the length of time a trace will take. Time is the critical factor in a disease investigation. The more time it takes, the more herds and animals become infected or exposed, the more man-hours are needed to respond, and the more the industry suffers from the loss or delay of sales. Illustration 1 depicts a flow chart for a “typical” disease traceback of an infected animal from the point of slaughter. Keep in mind that there are myriad variables in tracing and every trace is unique. This illustration is intended to give the reader a basic understanding of the steps that are taken in a trace process that involves the cooperative efforts of State, Tribes, and Federal agencies.

The box at the top left represents an animal at an abattoir. At the plant, animal health officials spend a good deal of time collecting information and matching the information with

samples that were positive. Records of the animals that were killed are examined, including physical descriptions of the live animals, carcass weights, body scores, the order in which the animals were processed, and prices paid.

One of the key pieces of information is the approved USDA backtag. This is very important in tracing animals to the last herd of residence and allows the investigation to proceed towards the herd of origin. Most adult animals presented for slaughter within one week of tagging have official backtags at the time of slaughter. If the movement to slaughter takes more than a week, the majority of the backtags are lost. Yet, the value of backtags is apparent, as an estimated 90 percent of adult animals arrive at slaughter with USDA approved backtags. When an official USDA backtag is correlated with the animal of interest, the investigators can quickly identify the livestock market or dealer that supplied the animal to the abattoir.

If the backtag is not available, abattoir records are used to try to determine who supplied the animal. If the animal of interest was part of a group of animals from a single source that were penned together and slaughtered at the same time, the whole group can be traced back to the supplier. If the animal was commingled with animals from a variety of sources, the investigation must consider multiple potential suppliers.

At the livestock market or dealer, the time required to determine who the consignor of the animal was and where the animal resided prior to sale depends on the availability of appropriate records. If weight tickets, sales slips, and records of origin, identification, and destination are available, it can take one hour or less to complete the visit if a backtag is available, and a few hours if not. Currently, markets are required to maintain records of livestock transactions for 2 years. Some of our traces involve movements through markets that took place more than 2 years prior. If the market records are not available or incomplete, the investigator may need to

examine additional records and go to other sources of information including banks, post offices, county assessor offices, brand inspection offices, and law enforcement. In this case, the last herd of residence is found only after days, weeks, or not at all.

Another critical piece of information to aid in a disease investigation is the official eartag. If available, the eartag number can be traced to the herd in which the tag was applied and allow the investigation to proceed towards the animal's place of termination. The length of time required varies from minutes to days depending on how the records of official eartags are maintained. Regardless of how the records are kept, the information provides another means of locating additional herds that may be affected. When an animal has both an approved backtag and an official eartag, an investigation can proceed from two different directions simultaneously and reduce the total time required by half.

When animals are tested for official disease control program purposes, an official eartag is required and recorded on the test chart. Similarly, when adult animals are moved interstate, the official eartag is typically recorded on an ICVI. Examination of these types of records may identify additional herds in which the animal of interest resided.

Illustration 1. Cooperative Federal, State, Tribal tracing with official identification, backtag, and records

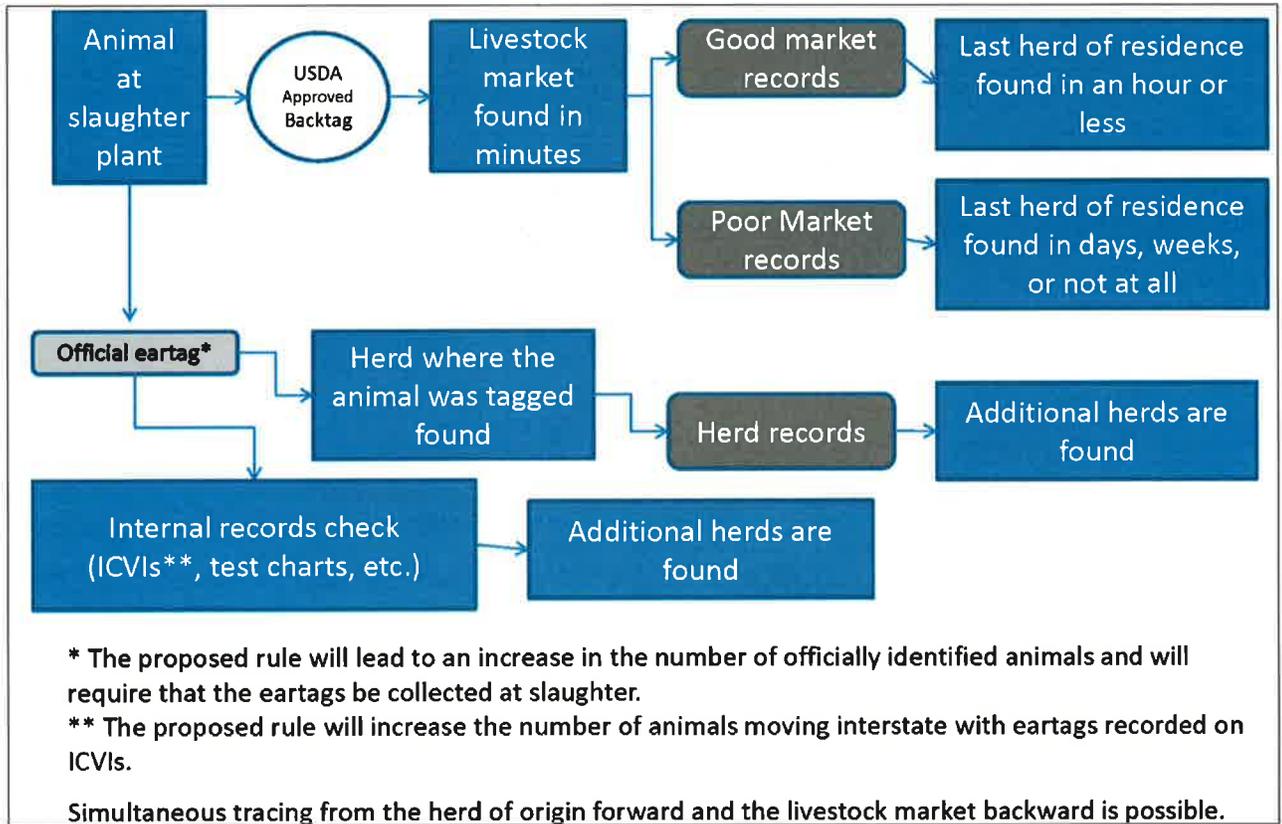
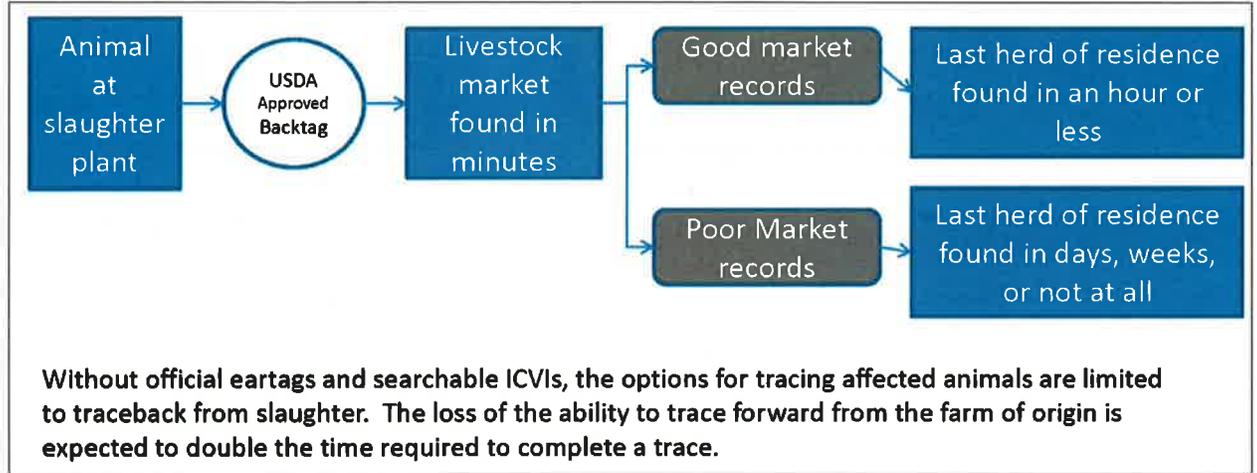


Illustration 2 shows that, without an official eartag, the only route for an investigation to take is through the livestock market. If records are not available, the source herd may never be found. Even if the herd is found, the time required to conduct the trace is expected to be at least twice what it would be if there were an official eartag because tracing forward from the source is not possible. It is clear that additional investigation routes through the use of eartag records and internal databases are essential.

Illustration 2. Cooperative Federal, State, Tribal tracing without official identification and records



To summarize, the critical points in the investigation include:

1. Is an official backtag available?
 - a. If “yes”
 - i. The time to trace to the market is minimal.
 - ii. An investigative route to the last herd of residence is possible
 - iii. The time at the market determining the last herd of residence is less than an hour.
 - b. If “no”
 - i. The time to trace to the market is longer.
 - ii. The time at the market is at least several hours.
2. Is an official eartag available?
 - a. If “yes”
 - i. An investigative route to the herd where the tag was applied is available

- ii. An investigative route to additional herds via internal database records is available.
 - b. If “no” these routes are not available and the time to conduct the trace could be doubled.
- 3. Are good market records available?
 - a. If “yes” the time at the market is less than an hour.
 - b. If “no” the time at the market is hours and other external sources of information may be required increasing the time to days or weeks.
- 4. Are records of official eartag distribution, official tests, and ICVIs easily searchable?
 - a. If “yes” the time to find additional herds may be minutes or hours.
 - b. If “no” the time to find additional herds may be hours, days, or weeks.

The rule will require all cattle over 18 months in interstate movement with some exceptions to be identified with official eartags. This will lead to an increase in the number of cattle with official identification at slaughter and provide animal disease investigators with the traceability route to additional herds. This addresses critical point #2.

One exception in the initial phase of implementing the rule is to allow USDA-approved backtags in lieu of official eartags for cattle moving directly to slaughter. This approach will help facilitate the use of backtags so cattle arriving at slaughter can be traced to the last herd of residence. This addresses critical point #1.

The rule has a recordkeeping requirement of 5 years for markets and slaughter establishments. The current requirement is 2 years. Cattle have a life span of several years. The new requirement will allow for more tracing information to be reported. This addresses critical point #3.

The rule includes the requirement for States and Tribes to maintain a record of official eartag distribution for at least 5 years. That will help our disease investigators quickly determine the herd in which an animal of interest was identified. Similarly, the rule will require States and Tribes to maintain a record of ICVIs issued for 5 years. These two requirements will address critical point #4.

Current animal diseases of concern in cattle Tuberculosis

Tuberculosis (TB) is a disease of concern today and provides a good reference to demonstrate the need for traceability. TB is a contagious disease of both animals and humans. Bovine TB can be transmitted from livestock to humans and other animals. No other TB organism has as great a host range as bovine TB, which can infect all warm-blooded vertebrates. Bovine TB has affected animal and human health since antiquity. Once the most prevalent infectious disease of cattle and swine in the United States, bovine TB caused more losses among U.S. farm animals in the early part of the 20th century than all other infectious diseases combined.

TB eradication efforts have been quite successful in the United States. Still, since 2002 the United States has spent over \$200 million on indemnities and control activities for diseased or suspect cattle and that amount is expected to rise as eradication efforts continue. In Michigan, the disease has seriously affected the State's livestock industry. The projected impact of the disease on Michigan's producers is estimated at \$121 million over 10 years.

In fiscal year (FY) 2010, 13 TB-affected cattle herds were confirmed in the United States. TB-affected herds were identified in Colorado (2), Kentucky (1), Michigan (5), Mississippi (1), Nebraska (1), Ohio (1), and South Dakota (2). The States of Kentucky, Mississippi, Ohio and South Dakota held accredited free status for TB for over 20 years. All affected herds identified

in FY 2010 were depopulated with Federal indemnity except for two beef herds in Michigan that are undergoing test-and-remove herd plans. The Ohio herd was detected during a dispersal sale and is no longer in existence.

From October 2010 through March 2011, six TB-affected cattle herds were confirmed in the United States. TB-affected herds were identified in Colorado (4), Indiana (1), and Michigan (1). All the affected herds in Colorado have been depopulated with Federal indemnity, and the disposition of the herds in Indiana and Michigan are pending.

The epidemiological investigation of animals found infected at slaughter is still the main method that is used to locate TB herds. Traceback investigations are conducted from the slaughter plant.

Brucellosis

Brucellosis is a contagious disease, caused by bacteria of the genus *Brucella* that affects both animals and humans. The disease mainly affects cattle, bison, and swine; however, goats, sheep, horses, and humans are susceptible as well. In its principal animal hosts, it causes loss of young through spontaneous abortion or birth of weak offspring, reduced milk production, and infertility. There is no economically feasible treatment for brucellosis in livestock. In humans, brucellosis initially causes flu-like symptoms, but the disease may develop into a variety of chronic conditions, including arthritis. Humans can be treated for brucellosis with antibiotics.

All 50 States have been officially classified Class Free for bovine brucellosis since July 2009, despite recent detections in a few States. During FY 2011, brucellosis was detected in four domestic cattle and bison herds in two States in the Greater Yellowstone Area (GYA)—two affected cattle herds and one affected privately owned bison herd in Wyoming, and one affected privately owned bison herd in Montana. All four herds are under quarantine with affected-herd plans, and intensive epidemiological investigations, including testing of area herds, are in

progress. No epidemiological links have been identified among these herds. Brucellosis-affected wild elk may be the most likely source of infection for these herds.

In late January 2011, Texas disclosed a brucellosis-affected cattle herd, the first detection of brucellosis in a cattle herd in Texas in over 5 years. This herd was depopulated, and a thorough epidemiological investigation is in progress. The GYA remains our primary focus for brucellosis in livestock because the disease is endemic in GYA wild elk and bison. There is no indication that brucellosis has spread outside the GYA.

Bovine Spongiform Encephalopathy

Bovine spongiform encephalopathy (BSE), widely referred to as "mad cow disease," is a chronic degenerative disease affecting the central nervous system of cattle. BSE is a progressive and fatal neurological disease of cattle caused by an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies.

The incubation period (the time from when an animal becomes infected until it first shows disease signs) averages 4 to 6 years, although the period can be longer or shorter. Following the onset of clinical signs, the animal's condition deteriorates until it either dies or is destroyed. The process of deterioration usually takes from 2 weeks to 6 months. Currently, there is no test to detect the disease in live cattle; veterinary pathologists confirm BSE by postmortem microscopic examination of brain tissue or by the detection of abnormal prions in brain tissue.

Four cases of BSE have been detected in the United States. The first case was in a cow in Washington State in 2003 that had been imported from Canada. BSE was subsequently detected in a 12-year-old beef cow in Texas in 2005, and in a 10-year-old beef cow in Alabama in 2006. Both of these indigenous cases were animals born before the feed ban implemented by the U.S. Food and Drug Administration in 1997. On April 24, 2012, USDA confirmed the nation's fourth

case of BSE in an animal that was sampled for the disease at a rendering facility in central California.

APHIS conducted BSE enhanced surveillance from 2004 to 2006. More than 830,000 samples were tested. This was a one-time effort to detect BSE at a very low-level and to provide information about prevalence. The results indicated that the prevalence of BSE in the United States was low—less than 1 infected animal per million based on a population of 42 million adult cattle.⁸

The ongoing BSE surveillance program was launched in 2006 and has continued. The goal of this program is not only to meet the World Organization for Animal Health (OIE) benchmark of detecting 1 case of BSE in 100,000 adult cattle with 95 percent confidence, but also to meet the higher U.S. standard of detecting 1 case of BSE in 1 million adult cattle with 95 percent confidence. Populations of cattle at higher risk for BSE have been targeted for surveillance, including but not limited to animals with central nervous system (CNS) signs and animals over 30 months of age condemned ante mortem at slaughter for CNS signs. More than 40,000 samples have been collected and tested in each year of the ongoing BSE surveillance program. This sampling strategy has far exceeded the level of testing required to meet OIE and U.S. internal surveillance goals.⁹

Animal disease traceback investigations

The following three tables summarize specific investigations for TB, brucellosis, and BSE occurrences.

⁸ http://www.aphis.usda.gov/publications/animal_health/content/printable_version/fs_BSE_ongoing_vs.pdf

⁹ http://www.aphis.usda.gov/newsroom/hot_issues/bse/surveillance/ongoing_surv_results.shtml

Table 5. Bovine tuberculosis

Date Investigation Opened: March 2010		Investigation Status: Ongoing
Incident	An adult cow (approximately 3.5 years) was slaughtered. The animal was part of a consignment from an auction market two days prior. On post mortem examination, the FSIS inspectors noticed lesions suggestive of a TB infection. The carcass was retained, tissues were collected, and tests were conducted. Four days later, National Veterinary Services Laboratories published a histopathology analysis with the diagnosis of <i>Mycobacteriosis</i> -compatible. The herd that marketed the animal before slaughter was found to be infected with TB.	
Method of Identification	The only identification available on the infected animal was a backtag collected at slaughter that had been applied at the auction market.	
Methods of Tracing	The auction market back tag was used to determine the consignor and in turn, the last farm location of the infected cow (or the index herd). Herd records of the index herd were examined for the two-year period prior to the detection of infection to determine what animals had left the farm. Three markets were the primary means for the owner to dispose of his cull animals. As a result, most of the adult animals that left this herd were identified by a backtag that had been applied at one of the three livestock markets. Herd records, while limited, were used to help determine movement of young animals sold from the herd.	
Investigative Summary	<p>The index herd consisted of approximately 900 animals. A caudal fold test was conducted on some of the animals: 48/168 (29 percent) heifers and 165/498 (33 percent) cows were positive. A gamma interferon test was conducted on 165 heifers, and 105 of them were positive. The herd was depopulated and samples were tested, confirming the previous tests.</p> <p>A thorough review of available herd records determined that a total of 1,627 adult animals left the index herd as culls being sold at one of the three auction markets during the previous two-year period. Using the backtags applied at the markets, 1,505 (92.5 percent) adult animals reported slaughtered out of State were verified. The other 122 (7.5 percent) adult animals were only reported as slaughtered, but could not be verified due to lack of permanent identification. Without verification, the possibility remains that some of the 122 adult animals may have been diverted from slaughter channels back to a farm.</p> <p>Epidemiological tracing was conducted using the animal identification information recorded on the herd test chart to determine where animals that entered the herd came from. Official eartags from 5 States were noted. Subsequent tracing through those States provided evidence of animals of interest having been in 5 additional States for a total of 10 States. Due to limited records, it was difficult to determine the locations of breeding and feeding animals from the index herd.</p> <p>The tracing of one- to five-day-old calves proved to be much different. Owner records indicated that 259 calves had been sold from the premises during the two previous years, and they all lacked any type of identification. The movements were documented on a brand inspection form completed by the owner and did not contain addresses, descriptions and in many cases, the total number of animals removed from the premises on a specific date. The brand authority intended for producers to utilize tracking methods on these animals and to record them; however, this was not the case.</p> <p>In total, 57 of the 259 calves (22 percent) were located at other farms. These calves were disposed of and tested for TB. Five of the 57 calves each located on a different farm were found to be positive for TB. This resulted in those five farms being declared infected premises and subsequently depopulated.</p>	

	<p>To date, the investigation has involved 426 locations in 12 States with 6 infected premises found.</p>
Cost	<p>The disease investigation resulted in the depopulation of 1,139 animals on 6 infected premises including the index premises. USDA has paid \$741,700 to producers for destroyed animals involved in this investigation. There were additional dollars paid for trucking and disposal that were not available. Estimated testing costs exceed \$2 million.</p> <p>It is estimated that this incident required an Animal Health Technician's time two days per week for the past year. This time could easily have been reduced by 50 percent with adequate identification and records.</p> <p>Testing costs in this case will exceed \$2 million. We believe improved traceability as a result of the rule will reduce costs by between \$600,000 and \$1 million.</p>
Impact	<p>As of March 2011, this incident was still ongoing. There were 426 different locations investigated with approximately 10 percent of the locations having herds that were tested for TB. In some cases, the tracing was stopped due to the lack of adequate identification and movement records. This is unfortunate because of the nature of this aggressive strain of TB, and the fact that infected herds were found.</p> <p>There are still 122 cull breeding animals that are unaccounted for. We do not know if they were slaughtered as expected or if they returned to a livestock operation. The uncertainty undermines the credibility of traceability efforts.</p> <p>Only 57 of the 259 calves (22 percent) were successfully traced, but they led to 5 infected premises. The inability to trace the remaining 198 calves causes serious concern and begs the questions: "What happened to the other 198 calves (88 percent), how many infected premises are left undetected, and how far has the infection spread?" While the cost of the investigation to date is significant, the inability to answer these questions quickly and accurately means sizable additional negative impacts as well as higher associated costs are likely to result from this case.</p>
Comparison with Rule on Traceability	<p>The rule will require the identification of all dairy cattle moving interstate, regardless of age. Adult dairy cattle will be required to have the official eartags recorded on an ICVI. Producer and livestock markets will be required to keep a copy of movement records for 5 years for all animals moving interstate. The amount of official identification and tracing information will increase significantly due to these activities.</p> <p>There has been an average of 31 positive cases for the past 5 years. On average, one million animals are tested annually for TB. If testing for TB could be better targeted to the herds that had actual contact with animals of interest provided by identification and records, the system will be more accurate and efficient. Only the known herds of interest will need to be tested. If the number of animals tested was reduced, we estimate the government and producer sectors' combined dollar savings associated with the testing alone will be between \$1.17 million (25% reduction in testing) and \$3.51 million (75% reduction in testing) annually. (State and Federal costs are shown below; producer costs are detailed in Table 8.)</p> <p>An animal disease traceability program allows for a more efficient use of resources as herds are tested based on clear documentation of their connection to the index animal. USDA or State employees perform most of the testing. As a result of fewer herds/animals tested, resource efficiencies are gained, and these employees will be available to fill mission critical activities in other areas. The potential values of these efficiencies are</p>

	summarized in the following table based at differing levels of projected reductions in the number of animals requiring testing for TB.	
	Costs to States and the Federal Government	
	Average number of TB trace tests per year ¹⁰	260,000
	Average cost per head to test (requires handling animals twice)	\$10.00 ¹¹
	Estimated cost of TB testing (State and Federal)	\$2,600,000
	Value associated with reduced number of animals requiring testing due to improved animal disease traceability	
	25% reduction	\$650,000
	50% reduction	\$1,300,000
	75% reduction	\$1,950,000

Table 6. Bovine brucellosis

Date Investigation Opened: January 2011		Investigation Status: Ongoing
Incident	Due to targeted animal disease surveillance, an adult bull at processing, moved interstate to an abattoir, was determined to be a reactor for bovine brucellosis. A disease investigation was initiated due to the classification of the official blood test.	
Method of Identification	The animal lacked an official animal identification number at the time of sampling. The bull was identified by carcass tag number on the slaughter plant kill sheet and associated with an owner.	
Methods of Tracing	Kill sheet information provided at the abattoir served as the sole basis for conducting the investigation. In this case, the animal's owner was also the feedlot owner where the animal was in residence prior to processing.	
Investigative Summary	<p>The investigation involved 155 bulls from two pens in one out-of-State feedlot that sourced animals from two different livestock markets in two additional States.</p> <p>As noted, the bulls had no official identification at processing and, correspondingly, the feedlot had no list of official animal identification for these animals. Brand inspection records retained by the feedlot accounted for 57 different brands for 149 of the bulls and 6 animals with no brands. Feedlot records indicated the 155 animals could have been sourced from 4 different livestock markets. As a result, the 4 involved livestock markets have identified 40 potential source locations in one State and another 17 potential source locations in yet another State. Because the five involved States (one State was mistakenly involved initially) are large beef-producing States, and with an assumption of 125 head herd size, the investigation will potentially involve testing at least 7,100 head of cattle for bovine brucellosis. The investigation remained open as of March 23, 2011.</p>	
Cost	Final costs have not been tabulated as the investigation is ongoing. With an estimated \$20 per head testing and personnel costs, this investigation will cost nearly \$150,000, assuming no additional positives are found. This estimate does not include producer costs. If the reactor animal had been officially identified and the number recorded at the time of processing, the investigation could have been more focused with a potential cost savings of \$120,000.	

¹⁰ USDA, APHIS, Veterinary Services data for 2010.

¹¹ Based on funds paid for fee-basis testing.

Impact	More herds than needed were tested and the cost of testing alone is significant. The added cost to producers may be even greater in terms of gathering the herd to be tested and restricted opportunities to conduct business as usual.
Comparison with Rule on Traceability	<p>The rule will require cattle 18 months-of-age and older to be officially identified and accompanied by an ICVI when moved interstate. This will provide the tools to accurately and efficiently investigate the incident and conclude it with minimal impact to producers and taxpayers.</p> <p>On average, 477 brucellosis reactor cattle have been identified annually for the past 5 years in the United States. Approximately 25 percent, or 120, of these cases require a similar degree of investigation to this case. Based upon BSE surveillance data referenced in table 9 of this document, approximately 60 percent of adult cattle lack official identification. It is estimated that 72 comparable brucellosis investigations are conducted annually without information readily available for effective and efficient official animal identification. This example shows an investigation that had potential costs savings of \$120,000. Conservatively assuming that 72 comparable investigations could save half that amount, the estimated savings would be \$4.32 million (72*\$60,000). Additional savings to the cattle industry as well as States and Tribes will also be realized, should official identification of adult cattle be routine. The benefit to bovine brucellosis disease investigations for the cattle industry, States and Tribes, and USDA could easily exceed \$5 million annually.</p>

Table 7. Bovine spongiform encephalopathy

Table 7. Bovine spongiform encephalopathy	
Date Investigation Opened: March 15, 2006	
Investigation Status: Closed May 1, 2006	
Incident	<p>A confirmed positive of a previously inconclusive bovine spongiform encephalopathy (BSE) sample from a 10-year-old cow in Alabama was made on March 15, 2006. The goal of the epidemiological investigation was to locate at-risk animals besides the index cow:</p> <ul style="list-style-type: none"> • Two most recent progeny of the index cow • Birth cohorts of the index cow that were born and raised on the same farm (herd of origin) 1 year before and 1 year after the index cow was born.
Method of Identification	<ul style="list-style-type: none"> • No official identification • No tattoo, no management eartag, and no brand • Other alternatives used: <ul style="list-style-type: none"> – Color – Red – Age – Estimated to be 10-years-old – Sale weight when purchased by index herd
Methods of Tracing	The process of tracing the animals of interest was based on interviews with current and previous owners, stockyard sales records, phenotype, age, stage of pregnancy, and deoxyribonucleic acid (DNA) genetic matching.
Investigative Summary	<p>The positive cow had no tattoo, no eartag, and no brand. Thirty-seven farms were investigated (involving the use of DNA), to identify a herd of origin. This included two farms where the index cow resided, and 35 other farms that might have supplied the index cow to the farms where the index case resided.</p> <p>The index case did not have unique or permanent identification, and its size and color are common in the southern United States. Due to the unremarkable appearance of solid red cows, it is not easy for owners to remember individual animals. In the southern United</p>

	<p>States, it is common business practice to buy breeding age cows and keep them for several years while they produce calves. Most calves produced are sold the year they are born, whereas breeding cows are often sold when there is a lapse in breeding, which can occur multiple times in a cow's life.</p> <p>For these reasons, USDA could not locate the herd of origin and the inconclusive investigation was closed after 48 days.</p>
Cost	The estimated cost of the investigation was \$40,000. This included State and Federal field resources to conduct interviews, review records with herd owners and market operators, travel, and DNA testing.
Impact	While the overall market impact cannot be defined, this case reflects the inability of the United States to trace the movement history and herd where the animal at a young age was exposed to the disease.
Comparison with Rule on Traceability	An official identification tag from the index animal would have facilitated traceability, with minimal interviewing, to the farm of tagging within one day with cooperative participation. As described in the discussion of private sector costs of the rule, the estimated cost of an identification tag is \$0.18 per animal for producers that already tag and \$1.68 to \$4.68 for producers who do not tag their animals. This incremental cost includes all associated costs of working an animal merely for tagging purposes. Many operators already tag their cattle as part of routine management activities.

Benefits of effective traceability to producers

As discussed above, disease investigations that lack complete information and official animal identification are frequently expanded to involve more herds than will otherwise be necessary. This practice ensures the farm location that might have held the subject animal or other potentially exposed animals can be “ruled out” as being infected. More complete records and official animal identification allow investigations to focus on specific locations that are known to have had the animal of concern. In lieu of complete information, animal health officials must broadly “blanket” their herd reviews and testing to all possible locations.

As the investigation broadens in scope to ensure the disease occurrence is fully examined, more producers are required to have their herds involved in the investigation. Producers that are included in a disease investigation incur disruption to their operation and have associated costs, including:

- Time spent with animal health officials to review records needed for the investigation as well as locating historic records called for during the investigation.
- Assembling the herd for testing. This includes labor costs, time, and the inconvenience of testing when other critical farming operations need to be done.
- Costs associated with testing. These include shrinkage, injury, loss of production (especially in dairy herds), and labor. The costs are double for TB because each herd test involves handling the animals twice in a 72-hour period.

Generalized private sector costs of TB and brucellosis testing and potential cost savings due to improved traceability are summarized in table 8.

Table 8. Summary of producer costs for TB and brucellosis testing and potential savings from improved traceability

Bovine Tuberculosis		
Average number of TB trace tests per year ¹²		260,000
Average cost of producers' time, labor, etc. (per animal)		\$6.00 ¹³
Cost of TB testing		\$1,560,000
Value associated with reduced number of animals requiring testing due to improved animal disease traceability		
	25% reduction	\$390,000
	50% reduction	\$780,000
	75% reduction	\$1,170,000
Bovine Brucellosis		
Average number of brucellosis trace tests per year ¹⁴		252,000
Average cost of producers' time, labor, etc. (per animal)		\$3.00
Cost of brucellosis testing		\$756,000
Value associated with reduced number of animals requiring testing due to improved animal disease traceability		
	25% reduction	\$189,000
	50% reduction	\$378,000
	75% reduction	\$567,000

¹² USDA, APHIS, Veterinary Services data for 2010.

¹³ Based on estimated chute costs to producers of \$1.68 to \$4.68 per head, times two because each animal must be handled twice.

¹⁴ USDA, APHIS, Veterinary Services data for 2010.

In addition, there are other costs that are difficult to value, such as the loss of revenue when there is a "hold order" in place preventing the movement of animals into or out of a herd while a test is pending. This can delay the sale of calves, breeding stock or fed cattle, resulting in additional feed costs and missed opportunities to take advantage of favorable market conditions.

Comparison to traceability for sheep and goats

The benefit of traceability, achieved primarily through official identification, is well demonstrated in the sheep and goat industry. In September 2001, the scrapie regulations were revised to require the official identification of sheep and goats not in slaughter channels (except low-risk commercial goats) and any sheep over 18 months-of-age in interstate commerce. In addition, the revision required States to implement and enforce official identification of most sheep and goats upon change of ownership in intrastate commerce.

Official identification means to apply an official identification number to an animal using an approved device or method. It also requires creating and maintaining (for 5 years) a record linking the identification number to the owner of the flock of origin/birth of the animal, if other than the person to whom the official identification numbers were issued.

APHIS maintains a database in which tag manufacturers enter the distribution records for official eartags. Most eartags are distributed directly from the tag manufacturer to the end-user. Some tags are redistributed by State or Federal offices who record the end-user in the database.

Since implementation of the Federal identification requirements for sheep and goats, only 12 percent of the positive animals identified through slaughter surveillance that did not have official identification were successfully traced to the flock of origin, whereas 94 percent of the

positive animals that were officially identified were successfully traced to the flock of origin. In FY 2010, estimates indicate that 93 percent of all mature sheep were officially identified when they arrived at slaughter establishments.

As a result of our ability to effectively traceback diseased animals, scrapie prevalence has decreased from 0.2 percent in 2002-2003 to 0.03 percent in FY 2010, a decrease of 85 percent.

Concluding observations

Official animal identification provides key information resulting in improved traceability.

Table 9. Summary of BSE Surveillance Samples			
Year	Number of Cattle Sampled	Number of Cattle with Official Identification Eartags	Percent of Cattle with Official Identification Eartags
2007	13,192	4,684	36 percent
2008	44,855	18,429	41 percent
2009	45,499	18,217	40 percent
2010	45,251	17,102	38 percent
2011	8,155	2,840	35 percent
2007-2011	156,952	61,272	39 percent

The low level of official identification in the cattle industry is well-documented. For example, 2007-2011 data from bovine spongiform encephalopathy (BSE) surveillance, summarized in table 9, show that on average less than

40 percent of the animals had an official identification eartag. These data findings are similar to those from USDA APHIS (2008) that indicate that 41 percent of beef cattle and 16 percent of beef calves are identified with an official eartag.

The current low level of official identification in the cattle sector often impedes tracing capability. In comparison, successful traceability in the sheep industry is a direct result of high levels of official identification.

The objective of the rule is to improve traceability, in particular, in the cattle industry. While the rule will only require official identification for animals moving interstate, it is likely that many livestock enterprises will routinely officially identify all of their animals in

anticipation of future, out-of-State marketing opportunities. As a result, we anticipate the level of official identification increasing significantly in the cattle sector.

Market Effects of Improved Traceability

There are also benefits to improved animal traceability if barriers to trade exist or if such barriers would be erected in the case of an animal disease outbreak contingent on there not being such traceability requirements in place. Animal diseases occur unexpectedly. This lack of predictability prevents a straightforward evaluation of the benefits of the traceability regulations.

A recent study from Kansas State University points out that export restrictions due to the discovery of a single cow with bovine spongiform encephalopathy (BSE) in 2004 resulted in losses to the U.S. beef industry ranging from \$3.2 billion to \$4.7 billion in 2004.¹⁵ They argue that cattle traceability would limit the amount of time market access is lost following an outbreak of some disease. Similar findings presented in a study by researchers at Montana State University, Kansas State University, and Colorado State University, illustrate the magnitude of the potential trade benefits by comparing hypothetical consequences of a disease outbreak under different animal identification capabilities.¹⁶ That study found that preventing the loss of exports to a large beef importing country such as South Korea (approximately 7% of U.S. beef export demand), could result in long-term losses to the beef sector of nearly \$70 million annually.

¹⁵ Shroeder, T.C. and G. T. Tonsor (2011) "Cattle Identification and Traceability: Implications for United States Beef Exports," Kansas State University Report (September, available online at <http://krex.k-state.edu/dspace/bitstream/2097/13089/1/CattleIDSchroederTonsor.pdf>).

¹⁶ Brester, G., K. Dhuyvetter, D. Pendell, T. Shroeder, and G. Tonsor. 2011. "Economic Assessment of Evolving Red Meat export Market Access Requirements for Traceability of Livestock and Meat," U.S. Meat Export Federation Report (March; available online at <http://www.usmef.org/downloads/USMEF-Final-Project-Report-Tonsor-et-al.-03.30.2011.pdf>).

Another study by some of the same authors in 2007 simulated the trade impacts of an outbreak of foot and mouth disease in Kansas.¹⁷ In this simulation, the number of animals destroyed decreased as the level of tracing and surveillance increased. The amount of time to eradicate the disease was also reduced with improved traceability. It was estimated that with 90-percent traceability, producer surplus would be \$4.5 billion (present value over 10 years) larger than if there were 30-percent traceability. The benefits primarily derive from access to beef export markets expected to become more restricted if 30-percent traceability prevailed. The study also found that consumer surplus would be less with 90-percent traceability than if there were 30-percent traceability, by about \$800 million (present value over 10 years). The reason is that under 30-percent traceability, beef that would have been exported had there not been a FMD discovery remains on the domestic market, depressing prices and increasing consumer surplus. The analysis concludes that the net benefit or societal gain of having 90-percent traceability as compared to 30-percent traceability if there were a contained FMD outbreak in Kansas, based on the model's assumptions, could total \$3.7 billion (present value over 10 years).

While such studies do not specifically model conditions that may exist under the rule, they do provide indications of the magnitude of potential trade benefits that are expected to derive from having a traceability program in place when there is a disease outbreak. As pointed out in the benefit-cost study, the benefits of a traceability system are for the most part potential benefits that rest on largely unknown probabilities of disease occurrence.

Having a traceability system in place will allow the United States to trace animal disease more quickly and efficiently, thereby minimizing not only the spread of disease but also the trade

¹⁷ Schroeder, T.C., and D.L. Pender (2007) "Value of Animal Traceability Systems in Managing Contagious Animal Diseases," Report to the Program of research on Economics of Invasive Species Management (October, available online at <http://krex.k-state.edu/dspace/bitstream/2097/4166/1/SchroederTraceability2007.pdf>).

impacts an outbreak may have. Major beef-exporting competitors of the United States, including Australia, Brazil, and Canada, have traceability systems.

The value of U.S. exports of live cattle in 2010 was \$131.8 million, and the value of U.S. beef exports totaled \$2.8 billion. The value of U.S. cattle and calf production in 2009 was \$31.8 billion.¹⁸ Annual incremental costs of the rule for cattle enterprises are estimated to be between \$14.5 million and \$34.3 million, assuming official identification will be undertaken separately from other routine management practices; or between \$10.9 million and \$23.5 million, assuming that some tagging will be combined with other routine management practices that require working cattle through a chute. The upper range of these costs represent about one-tenth of one percent of the value of domestic cattle and calf production. In other words, if there were an animal disease outbreak in the United States that affected our domestic and international beef markets, preservation of a very small proportion of these markets would justify estimated private sector costs attributable to the animal disease traceability program.

The primary benefit of the regulations will be the enhanced ability of producers, State and Tribes, and the Federal government to regionalize and compartmentalize animal health issues more quickly, minimizing losses and enabling reestablishment of foreign and domestic market access with minimum delay in the wake of an animal disease event.

Benefits Summary

The three case studies presented illustrate how the Federal government, States and Tribes, and producers can directly benefit from the animal disease traceability system. For producers affected by a disease traceback, the traceability system will mean that fewer tests will need to be carried out (and therefore fewer animals will need to be worked through a chute) and livestock

¹⁸ <http://www.ers.usda.gov/news/BSECoverage.htm>

sales and other farm operations will not be disrupted. Under the traceability system, there will be an increased likelihood that all exposed animals will be found. Tracebacks that cannot be successfully concluded because of incomplete records contribute to uncertainty about supply and prices.

In addition to the direct benefits to producers, the traceability system will provide added assurance that APHIS has the capability to respond to a foreign animal disease outbreak such as foot and mouth disease quickly and efficiently. As described in the foregoing example, effects for producers due to changes in prices and international market access could be dramatic, in this scenario resulting in a \$3.7 billion net benefit to society because of improved animal disease traceability.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their final rules on small businesses, small organizations and small governmental jurisdictions. Section 603 of the Act requires agencies to prepare and make available for public comment a final regulatory flexibility analysis that describes expected impacts of a rule on small entities.

Reason Action is Being Considered

APHIS enacts regulations to prevent, control, and eradicate diseases of livestock (including poultry), thereby increasing foreign and domestic confidence in the safety of U.S. farm-raised animals and their products. Many animal disease program regulations, such as those for bovine tuberculosis and brucellosis, contain components of a traceability program, e.g., requirements for certain animals moving interstate to be officially identified and accompanied by documents recording, among other things, the animals' official identification numbers and the locations from and to which they are being moved. However, the United States does not

currently have an overarching animal disease traceability program integrated to meet the needs of all species and disease programs. This rulemaking is intended to address animal disease traceability gaps in the regulations and enhance our ability to safeguard animal health.

Objective of and Legal Basis for the Rule

This rule will establish minimum traceability requirements, namely, official identification of livestock moved interstate unless specifically exempted and issuance of an interstate certificate of veterinary inspection (ICVI) or other acceptable movement documentation. The rule reflects a flexible yet coordinated approach that will enable States, Tribes, and livestock producers to use means of traceability that work best for them. The objective is to improve APHIS' ability to trace livestock in the event disease is found.

In accordance with the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Secretary of Agriculture has the authority to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

Potentially Affected Small Entities

As explained in the Supplemental Information for this rule, APHIS expects the cattle industry will be the livestock sector principally affected by this rule. Cattle enterprises that move cattle interstate will be directly affected.

Existing animal identification requirements for the interstate movement of farm-raised animals largely satisfy the official animal identification and ICVI requirements. Cattle moving interstate are often required to be accompanied by a health certificate under current regulations. Some diseases require specific statements and tests as part of the certificate. In addition, nearly all States require a certificate of veterinary inspection for breeder and feeder cattle entering from another State.

Table 10 shows cattle industries that will be affected by the rule, as categorized by the North American Industry Classification System, and sales and employment information that underscores the prevalence of small entities among establishments that comprise these industries. We note that numbers of establishments shown include ones that may not be directly affected by the rule, in particular, those that do not move cattle interstate.

Table 10. Small-entity representation in cattle sector industries that may be affected by the rule, 2007

Industry (NAICS code)	Number of Establishments	SBA Small-Entity Size Standard	Average Value of Establishments' Annual Sales ¹	Number of Establishments with fewer than 100 Employees
Beef cattle ranching and farming (112111)	656,475	≤ \$750,000 annual receipts	\$43,197	
Dairy cattle and milk production (112120)	57,318	≤ \$750,000 annual receipts	\$611,773	
Cattle feedlots (112112)	31,065	≤ \$2,500,000 annual receipts	\$977,048	
Animal (except poultry) slaughtering (311611)	1,597	≤ 500 employees		1,466
Rendering and meat byproduct processing (311613)	228	≤ 500 employees		208

Sources: USDA NASS, 2007 Census of Agriculture, http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_1_US/st99_1_062_062.pdf; U.S. Census Bureau, 2007 Economic Census, http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0731I1&-lang=en.

¹Includes government payments.

The Census of Agriculture allows further examination of small entities that could be affected by the rule, namely, small family cattle enterprises and cattle enterprises for which one or more of the principal operators belong to a socially disadvantaged group. Small family farms are defined by USDA as family farms with gross sales of less than \$250,000 (USDA ERS 2010). (Any farm where the operator and persons related to the operator own a majority of the business is considered a family farm.) In 2007, nearly 88 percent of farms with cattle and calf inventories were small family farms.

Small family farms are further divided into retirement farms (operators reporting they are retired), residential/ lifestyle farms (operators reporting a major occupation other than farming), and farming-occupation farms (operators reporting farming as their major occupation). Farming-occupation farms are classified as low-sales small family farms (sales less than \$100,000) and high-sales small family farms (sales between \$100,000 and \$249,999). A fifth category of small family farms are limited resource farms, which have sales of not more than \$100,000 and a total household income at or below the national poverty level for a family of four, or less than 50 percent of county median household income.

The Census of Agriculture indicates that in 2007, 40 percent of small family cattle operations were residential/lifestyle farms. With regard to the other categories of small family cattle enterprises, over one-fourth of the owners reported that they had already retired, limited resource farms and the low-sales farming-occupation farms each comprised about 15 percent of the operations, and about 6 percent were high-sales farming-occupation farms.

Socially disadvantaged groups are ones that historically have been subjected to bias and prejudice. They include women, persons of Hispanic origin, American Indians or Alaska Natives, Asians, African Americans, and Native Hawaiians or other Pacific Islanders. These

farm operators, themselves, may not have experienced bias or prejudice, but they identify with one or more of these gender, ethnic, and racial groups.

For more than 8 percent of cattle operations in 2007, the principal operator was a woman. About 5 percent of cattle operations had a person of Hispanic heritage and/or an American Indian or Alaskan native as one of their top-three operators. Fewer than 2 percent of cattle operations have an African-American as a top-three operator.

Most cattle enterprises are small family farms. As is true for other cattle operations, incremental costs of the rule for these farms will depend upon whether official animal identification will be incorporated into ongoing, routine management practices, and whether the enterprise is already moving cattle interstate other than for immediate slaughter.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Reporting and recordkeeping requirements associated with the rule are discussed in the rule under the heading "Paperwork Reduction Act." APHIS will require that any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices maintain for a minimum of 5 years a record of the names and addresses of anyone to whom the devices were distributed. APHIS will also require that approved livestock facilities keep for a minimum of 5 years paper or electronic records of any ICVIs or alternate documentation used in lieu of an ICVI for livestock that enter the facility on or after the effective date of this rule. If an animal loses an official identification device and needs a new one, the person applying the new one will have to record information about the event and maintain the record for 5 years.

Duplication, Overlap, or Conflict with Existing Rules and Regulations

APHIS has not identified any duplication, overlap, or conflict of the rule with other Federal rules.

Alternatives to minimize Significant Economic Impacts of the Rule

APHIS has developed this rule intent on minimizing costs that the private sector may bear. Incremental costs of official animal identification will be minimal for many cattle operations that will incorporate this activity into current herd management practices involving eartagging. Similarly, current movement documentation required by nearly all States for inshipments of breeding and feeder cattle is much the same as the ICVI; incremental costs for operations that already move cattle interstate other than for immediate slaughter will be minimal. The collaborative manner in which the rule's implementation is intended to advance, with representatives from States, Tribes, and the affected industries advising APHIS on the effectiveness of various elements of the traceability program, is also expected to help minimize operational burdens.

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Select List of Tests Performed on Beef Cattle at CAHFS

Test Name	Specimen Type	Container/ Shipping	Fee (in state)
Bacteriology			
Aerobic culture (abscess, pinkeye, BRD, etc.)	swab, fluid, tissue	Culturette (at lab in 24 hr. for pinkeye)	15.90
Anaerobic culture panel (with Gram stain)	tissue, fluid	Sealed, cool (no air)	45.10
<i>Clostridium septicum</i> and <i>chauvoei</i> FA (blackleg, malignant edema)	affected muscle	Sealed, cool (no air)	26.40
K99 <i>E. coli</i> antigen ELISA	feces, 1gm	Cool	10.60
<i>M. paratuberculosis</i> (Johne's disease) PCR	feces, 10gm	Cool	25.30
Mycoplasma culture	milk, swab, fluid	Cool	15.10
Salmonella PCR and/or culture	feces	Cool	14.70
Biotechnology/ Virology			
	(^a = not cotton type)		
Bluetongue virus rRT PCR (fluids)	1ml whole blood	Purple stopper EDTA tube, cool	24.80
Bovine coronavirus PCR on calf feces	0.5ml of feces	Cool	Contact lab
Bovine viral diarrhea rRT PCR (fluid)	1ml whole blood, Swab ^a of ulcer	Purple stopper EDTA tube-blood, cool	23.70
Bovine viral diarrhea antigen ELISA	ear notch, 1x1cm	Tube (no fluid), cool	5.50
Infectious bovine rhinotracheitis (IBR) rt PCR	swab ^a (nasal, eye, vagina), lung	Cool (swab in RTT)	23.70
Respiratory virus PCR panel (IBR, BVD, BRSV, coronavirus)	nasal swab ^a , lung	Cool	55.00
Rotavirus antigen ELISA	feces, 1ml or gm	Cool	13.20
Parasitology			
Cryptosporidia fecal exam	feces, 1ml	Cool	8.80
Fecal exam for flukes	feces, 5-10gm	Cool	14.30
Fecal exam for lungworm larvae (arrival cool at lab on Mon-Thurs)	fresh feces, 15gm	<24 hr old fecal and Refrig within 1hr.	14.30
Fecal exam for coccidia and worm eggs	feces, 10gm	Cool	10.50
Trichomonas culture or pouch read (see web site or call lab for special shipping and official forms)	uterine wash, preputial scraping	Saline/lactated ringer, In pouch	9.90
Trichomonas PCR (see above)	see above	InPouch	27.50
Pathology			
Histopathology (only)	tissue in formalin	Sealed container	39.50
Necropsy (<3 months old and fetuses) - up to 3 animals for one fee	carcass		120.00
Necropsy (>3 months old) - 1 each	carcass		120.00

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Table 11. Cattle and Calves – Inventory and Sales: 2012 and 2007

[For meaning of abbreviations and symbols, see introductory text.]

Item	United States	Alabama	Alaska	Arizona	Arkansas	California	
INVENTORY							
Cattle and calves	farms, 2012	913,246	21,149	134	6,029	25,866	16,764
	2007	983,689	23,970	130	7,716	28,292	16,638
	number, 2012	89,994,614	1,236,467	10,667	911,334	1,615,774	5,370,531
	2007	96,347,858	1,187,171	14,823	1,000,038	1,802,653	5,498,025
Farms by inventory:							
1 to 9	farms, 2012	243,071	3,815	67	2,961	5,075	7,396
	2007	233,078	5,978	67	4,416	5,396	6,106
10 to 19	number, 2012	1,179,625	21,451	250	11,652	26,551	31,252
	2007	1,155,984	31,680	280	16,285	28,275	27,344
20 to 49	farms, 2012	171,675	4,583	27	1,109	5,167	2,451
	2007	174,518	5,486	20	1,368	5,518	2,681
50 to 99	number, 2012	2,350,565	63,663	(D)	14,877	71,502	32,475
	2007	2,392,813	75,792	(D)	18,218	76,266	35,601
100 to 199	farms, 2012	222,547	6,832	19	966	7,892	2,236
	2007	240,975	6,847	20	1,004	8,593	2,719
200 to 499	number, 2012	6,907,696	212,072	611	28,028	248,014	67,476
	2007	7,518,194	210,409	541	29,473	269,610	81,339
500 or more	farms, 2012	118,394	3,211	7	331	4,124	1,128
	2007	135,117	3,091	6	337	4,669	1,187
100 to 199	number, 2012	8,161,882	218,500	486	22,160	286,032	78,554
	2007	9,344,247	209,929	450	22,546	319,154	81,470
200 to 499	farms, 2012	76,729	1,654	6	207	2,155	914
	2007	91,193	1,540	10	204	2,548	942
500 or more	number, 2012	10,456,310	224,808	790	28,606	289,841	126,681
	2007	12,434,470	208,739	1,431	28,016	343,102	129,392
200 to 499	farms, 2012	52,878	812	3	266	1,070	896
	2007	59,234	791	1	183	1,152	1,049
500 or more	number, 2012	15,851,268	235,261	(D)	73,586	308,951	283,466
	2007	17,697,011	232,532	(D)	55,191	335,958	338,760
500 or more	farms, 2012	27,952	242	5	189	393	1,743
	2007	29,554	237	6	204	416	1,954
500 or more	number, 2012	45,087,268	260,712	7,473	732,425	384,883	4,750,627
	2007	45,805,139	218,090	11,654	830,329	430,288	4,804,119
Cows and heifers that calved	farms, 2012	777,943	19,771	110	4,966	23,442	12,566
	2007	818,992	21,496	110	5,375	25,517	13,544
	number, 2012	38,208,825	731,903	5,373	391,522	822,222	2,399,249
	2007	42,101,375	691,911	7,045	380,604	964,483	2,503,153
Beef cows	farms, 2012	727,906	19,685	98	4,851	23,385	10,925
	2007	764,984	21,415	98	5,246	25,361	11,827
	number, 2012	28,956,553	722,787	(D)	197,901	813,250	583,594
	2007	32,834,801	678,949	6,468	197,060	947,765	662,423
2012 farms by inventory:							
1 to 9	farms	261,017	5,130	57	2,570	6,343	6,173
	number	1,201,766	26,992	182	9,841	31,617	22,566
10 to 19	farms	155,549	4,707	18	890	5,339	1,280
	number	2,090,980	63,685	(D)	11,681	72,551	16,727
20 to 49	farms	177,656	6,128	12	688	7,324	1,424
	number	5,332,440	184,420	347	19,926	219,605	43,410
50 to 99	farms	71,184	2,232	4	250	2,809	801
	number	4,744,396	148,168	(D)	16,648	186,255	54,765
100 to 199	farms	36,428	1,038	2	226	1,122	542
	number	4,796,037	133,950	(D)	31,601	143,617	73,119
200 to 499	farms	20,564	364	3	167	369	479
	number	5,853,297	100,626	1,150	46,001	105,334	141,855
500 or more	farms	5,508	86	2	60	79	226
	number	4,937,637	64,946	(D)	62,203	54,271	231,152
Milk cows	farms, 2012	64,098	219	28	239	100	1,931
	2007	69,890	157	28	182	339	2,165
	number, 2012	9,252,272	9,116	(D)	193,621	8,972	1,815,655
	2007	9,266,574	12,962	577	183,744	16,718	1,840,730
2012 farms by inventory:							
1 to 9	farms	18,483	140	24	160	10	457
	number	40,899	560	53	318	(D)	954
10 to 19	farms	3,782	16	-	1	2	26
	number	51,906	193	-	(D)	(D)	305
20 to 49	farms	14,107	14	-	6	26	36
	number	488,801	530	-	(D)	896	1,158
50 to 99	farms	15,351	27	2	-	31	52
	number	1,029,386	1,935	(D)	-	1,982	3,558
100 to 199	farms	7,359	8	2	-	21	110
	number	977,416	1,132	(D)	-	2,835	15,428
200 to 499	farms	3,712	11	-	3	10	258
	number	1,109,975	2,915	-	1,032	3,174	84,334
500 or more	farms	3,344	3	-	69	-	992
	number	5,553,789	1,851	-	192,079	-	1,709,918
Other cattle (see text)	farms, 2012	742,665	16,904	110	3,860	22,119	13,380
	2007	788,633	19,164	91	5,472	23,489	13,149
	number, 2012	51,785,789	504,564	5,294	519,812	793,552	2,971,282
	2007	54,246,483	495,260	7,778	619,234	838,170	2,994,872
2012 farms by inventory:							
1 to 9	farms	328,947	7,576	66	2,306	9,217	6,751
	number	1,367,194	33,125	227	8,051	39,978	25,859
10 to 19	farms	136,483	3,927	17	563	4,991	1,793
	number	1,817,394	51,494	229	7,400	67,025	23,273
20 to 49	farms	136,133	3,414	15	525	4,892	1,668
	number	4,096,942	100,482	(D)	15,115	144,646	49,083
50 to 99	farms	62,088	1,126	7	172	1,711	790
	number	4,185,311	73,509	490	11,468	114,745	53,830
100 to 199	farms	36,795	516	1	129	704	591
	number	4,912,616	66,439	(D)	17,327	90,973	79,732
200 to 499	farms	27,072	243	3	79	384	711
	number	8,060,158	68,983	1,050	23,152	119,676	219,260
500 or more	farms	15,167	102	1	86	220	1,076
	number	27,346,176	110,532	(D)	437,299	216,509	2,520,245

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