

Questions and Answers: Animal Disease Traceability Proposed Rule

Q. What is animal disease traceability?

A. Animal disease traceability, or knowing where diseased and at-risk animals are, where they've been, and when, is very important to make sure there can be a rapid response when animal disease events take place. Animal disease traceability does not prevent disease. An efficient and accurate traceability system helps reduce the number of animals involved in a disease investigation and reduces the time needed to respond. Reducing the number of animal owners impacted by an animal disease event reduces the economic strain on owners and affected communities.

Q. Why is the U.S. Department of Agriculture (USDA) issuing this proposed rule on animal disease traceability?

A. USDA is issuing this proposed rule to improve our ability to trace livestock and poultry when there is a disease event. While existing animal disease programs provide USDA and its partners with pertinent traceability information, the tracing capabilities vary widely by species. Thus, the proposed animal disease traceability regulations focus on those species, such as the cattle sector, where improved capabilities are most needed. That sector's inconsistent use of official identification coupled with the significant movement of cattle interstate warrants regulations that enhance the current traceability infrastructure. Certain other species, sheep for example, are supported with adequate traceability as a result of the current scrapie eradication program requirements. In such situations, current regulations will be maintained.

Q. How is this proposed rule any different than the National Animal Identification System (NAIS)?

A. Introduced in 2004, NAIS was a voluntary system based on registration of all premises where livestock or poultry were housed or kept. In 2009, when USDA

launched a series of efforts to assess the level of acceptance for NAIS, the findings were that many viewed NAIS as a government-imposed, "one-size-fits-all" approach to animal traceability. Producers raised serious concerns about the protection of proprietary information through premise registration and with the need for significantly more flexibility. Due to the level of opposition in the countryside, NAIS was never fully implemented and was discontinued in 2009.

The new proposed traceability approach put forward today honors the legitimate concerns of the American public and those in rural America, as well as those who have supported our past traceability efforts.

Specifically, the new approach would:

- Achieve basic, effective animal disease traceability and response to animal disease outbreaks without over-burdening producers;
- ONLY apply to animals moving interstate;
- Be owned, led, and administered by the States and Tribal Nations with Federal support focused entirely on animal disease traceability;
- Allow for maximum flexibility for States, Tribal Nations, and producers to work together to find identification solutions that meet their local needs;
- Encourage the use of low-cost technology; and
- Ensure that animal disease traceability data are owned and maintained at the discretion of the States and Tribal Nations.

Branding

Q. Why are brands not listed as official identification for cattle?

A. USDA supports the use of brands to identify animals moving interstate. USDA recognizes the value of brands and their prevalence in the western United States. However, the proposed rule requires that all States and Tribes accept all methods of official identification and since not **all** States and Tribes have brand inspection, designating brands as an official identification method for cattle would force non-brand States to establish brand inspection. To avoid this conflict, the regulation provides the flexibility to determine the use of brands at the local level. Accordingly, animal health officials in the shipping and receiving States or Tribes may agree to ship or receive cattle that are identified with brands.

Q. Are there other identification methods that States and Tribes may elect to use?

A. While official identification methods are defined for each species, the regulations allow States or Tribes to use other forms of identification, including but not limited to brands, tattoos, and breed registry certificates, when agreed upon by animal health officials in the shipping and receiving States or Tribes. In such situations, the shipping and receiving States or Tribes would determine whether a State or Tribe proposed form of animal identification meets their own traceability needs.

Benefits

Q. How does this rule benefit producers?

A. Effective animal disease traceability can help reduce the number of herds involved in a disease investigation to only those herds that are directly involved. Low levels of official identification in the cattle sector require more cattle—often thousands—to be tested than necessary and drastically increase the time required to conduct investigations. For example, bovine tuberculosis disease investigations frequently now exceed 150 days, as USDA and State investigative teams spend substantially more time and money in conducting tracebacks.

As a result of the rule, accurate traceability information will be more readily available and the amount of time required to conduct investigations will be reduced, thus the potential spread of certain diseases will be better controlled. Reducing the number of animals quarantined or disposed of and the time taken to resume interstate animal movement contribute toward making disease responses less costly for producers.

Development and Implementation of Proposal

Q. Did you gather feedback on the framework for animal disease traceability?

A. Then, in spring and summer of 2010, USDA hosted eight public meetings to discuss Secretary Vilsack's new framework for animal disease traceability. These discussions built upon the previous administration's efforts to solicit comments about the shortcomings of NAIS. These recent meetings provided a venue for USDA to provide additional details about the new framework and to learn from industry representatives and producers how best to support the States and Tribes as they move forward to develop workable traceability systems. The current proposed rule was developed not only through feedback collected from these meetings but also through input from a State-Tribal-Federal working group, Tribal consultations, and additional discussions with producers and industry.

In addition, Secretary Vilsack established the Secretary's Advisory Committee on Animal Health, which has representation from States, Tribes, and industry. The committee has already met twice and offered feedback on the new framework. Additionally, USDA plans to work with a separate advisory group to offer advice and recommendations on the phase-in of official identification requirements for cattle and bison under 18 months of age and to provide feedback on the effectiveness of various elements of the traceability program.

Q. What role will States and Tribes play in the implementation of the proposed rule?

A. States and Tribes will be the primary administrators of the program under the proposed rule. The proposed approach to improving animal disease traceability will allow States and Tribes to develop their own systems for tracing animals, designing what works best for them and for producers and others in their jurisdiction.

Interstate Movement

Q. What will I need in order to move my animal interstate under this proposed rule?

A. Under this proposed rule, unless specifically exempted, livestock moved interstate would have to be officially identified and accompanied by an interstate certificate of veterinary inspection (ICVI) or other documentation, such as an owner-shipper statement or a brand certificate. The proposed regulations specify approved forms of official identification for each species, but would also allow livestock to be moved between the shipping and receiving States or Tribes with another form of identification, such as brands, as agreed upon by animal health officials in the two jurisdictions.

Q. What is an interstate certificate of veterinary inspection or ICVI?

A. An ICVI, often referred to as a health certificate, is an official document issued by a Federal, State, or accredited veterinarian at the location from which animals are shipped interstate. If the animal is not required to be officially identified, the ICVI would specify the exemption that applies.

Under specific circumstances and for certain classes of livestock, the traceability regulation provides options other than ICVIs for the interstate movement of livestock. For example, cattle and bison under 18 months of age may be moved between any two States or Tribes with documentation other than an ICVI, such as an owner-shipper statement or a brand certificate, as agreed upon by animal health officials in those two States or Tribes.

Q. Why is there a 5-year recordkeeping requirement for ICVIs for approved livestock facilities?

A. We would require that approved livestock facilities keep for a minimum of 5 years any ICVIs, or alternate documentation used in lieu of an ICVI, for livestock that enter the facility on or after the effective date of the final rule stemming from this proposal. We propose to define approved livestock facility as a stockyard, livestock market, buying station, concentration point, or any other premises under State or Federal veterinary inspection where livestock are assembled. This requirement is based on the fact that livestock animals, especially breeding cattle, typically live to be 5 or more years old. Therefore, traceability information that fully supports disease control, eradication, and surveillance needs to be maintained for at least 5 years.

Exemptions

Q. Are there any exceptions for animals moving interstate that are uniformly applied to all species?

A. There are two circumstances when traceability requirements would not apply to interstate movement of livestock of any species:

- 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 it's lands are located; or
- The movement is to a custom slaughter facility in accordance with Federal and State regulations for preparation of meat for personal consumption.

Q. Are there any exemptions directed at individual producers?

A. There are exemptions for producers when moving animals interstate to custom slaughter facilities for processing for their own consumption.

Q. Will the size of my herd have any relation to the standards I must meet and who must participate?

A. The only threshold for participation is whether the producer has animals moving interstate. Producers who raise animals and move them within a State, Tribal Nation, and others that may move their animals interstate to a custom slaughter facility for processing for their own consumption are exempt.

Q. Are producers who only market or sell animals locally required to participate?

A. Only producers whose animals move interstate will be covered by the Federal animal disease traceability framework.

Q. Can you explain more about the movement of livestock on Tribal land?

A. Under this rulemaking, Tribal lands, whether entirely within a State or straddling State lines, would be covered by the same traceability system as the State or States within which they are contained, unless the Tribal representatives choose to have their own traceability system separate from the State(s). If a tribal land straddling a State line does not have in place a separate traceability system from the State within which it is contained, then, because of Tribal sovereignty, livestock movements taking place entirely within that Tribal land, even across State lines, would not be regarded as interstate movement. Therefore, the proposed traceability requirements for interstate movement would not apply.

Official Identification

Q. What is an official identification number?

A. The rule defines an official identification number as a nationally unique number permanently associated with an animal or group of animals. The official identification number would have to adhere to one of the following systems, most of which are already in use:

- National Uniform Eartagging System (NUES) (typically, metal eartags such as silver USDA tag);
- Animal Identification number (AIN);
- Location-based number system (e.g., sheep scrapie tags); or
- Any other numbering system approved by the Administrator for the official identification of animals.

Q. How do I know what eartags are official? What types of eartags are recognized as "official" under this proposed rule?

A. Official eartags are a common method of official identification of several species. Official eartags have one of the following official identification numbers imprinted on the tag:

- National Uniform Eartagging System (NUES).
- Animal Identification Number (AIN).
- Location-based number system.
- Flock-based number system.

The new regulation also requires that the U.S. Shield is imprinted on the tag.

Q. How does this proposed rule support the use of low-cost technology as a form of official identification?

A. Official identification is defined for each species. For cattle, the low-cost NUES (metal eartag) may be used. To encourage its use, USDA plans to provide these eartags at no cost to producers to the extent funds are available. While other producers may elect to use official eartags with radio frequency (RF) eartags, no State or Tribe may require official RF

eartags for cattle moving into their jurisdiction. This ensures that all producers using the low cost official eartags may move their cattle to any other State or Tribal land using that method of official identification. This is a change to current regulations in that a State or Tribe could currently require RF tags as the official identification method for livestock entering their jurisdiction.

Q. What happens if my animal loses its official identification eartag or other device?

A. If an animal loses its official eartag and needs a new one, the person applying the new one would have to record the following information and maintain the following information for five years:

- Date the new official identification device was added;
- Official identification number on the new device; and
- Official identification number on the old device, if known.

This proposed recordkeeping requirement would aid State, Tribal, and Federal officials when it is necessary to trace animals.

Q. How do official eartags enhance traceability?

A. Official identification associates an official identification number with a distribution record. By doing so, it provides animal health officials with a specific starting point from which to trace diseased or potentially diseased animals, such as a traceforward. Without official identification, i.e., only traceback potential, arriving at that starting point can take months or may never be achieved. Official eartags provide the opportunity to conduct a disease investigation from two points of reference rather than just one.

The sheep industry has had tremendous success with official identification expediting traceability for scrapie. As part of the National Scrapie Eradication Program (NSEP), a cooperative State-Federal-industry program, 92 percent of cull breeding sheep bear an official identification tag at slaughter, primarily using flock identification eartags applied at the farm of origin. This identification made it possible in 2010 for USDA, as part of the scrapie surveillance program, to trace scrapie-positive sheep from slaughter to the flock of origin or birth 96 percent of the time, typically in a matter of minutes.

Q. How is the lack of official identification in the cattle sector hurting us?

A. Simply, low levels of official identification in the cattle sector require more cattle—often thousands—to be tested than necessary and drastically increase the time required to conduct investigations. For example, bovine tuberculosis disease investigations

frequently now exceed 150 days, as USDA and State investigative teams spend substantially more time and money in conducting tracebacks. When animals cannot be traced to specific locations, epidemiologists often need to expand herd testing to ensure that cattle with any potential for exposure are tested. Also, expanded timeframes for tracebacks may cause longer, more encompassing quarantines and/or imposed limitations on animal movement. At the same time, the potential for disease spread increases.

Q. How will the traceability approach described in this proposed rule help fix these problems?

A. Increasing the levels of official identification will help State and Federal animal health official to more quickly identify which animals do not need to be held and tested during an animal disease investigation. This information will reduce the number of locations included in the testing and the numbers of animals tested, thereby decreasing the length of the investigation and the cost to producers and the government.

Q. How does this proposed rule work with existing USDA disease programs, for example tuberculosis and brucellosis?

A. In a new section of the *Code of Federal Regulations*, USDA compiled species-specific identification requirements and revised them as necessary to be consistent with the proposed rule. These revisions recognize the different animal disease traceability needs of various animal species and build upon the animal disease traceability successes. These revisions also clarify how our new framework for animal disease traceability works with existing disease control programs. While this proposed rule would establish minimum traceability requirements, the disease program regulations may contain additional, or more specific, requirements necessary to control or eliminate livestock diseases. For instance, the traceability requirements of suspect, exposed, or reactor animals will be contained in the program regulations, not in the new traceability section.

Cost

Q. What is compliance with the proposed rule going to cost the individual producer?

A. One of USDA's priorities when it began to design the new framework for animal disease traceability was to ensure that producers were not adversely impacted by the cost of the program by focusing on low-cost technologies. USDA plans to provide the NUES tags (metal eartags) available at no cost to producer to the extent funds are available. The proposed rule also meets this goal by allowing for a variety of official identification methods, including tags, to be used for

herd management, minimizing the need for multiple tags.

The costs of the program are expected to vary by both operation preference and whether traceability would be by individual animal or by lot or group. The proposed rule specifically addresses the expected costs for cattle enterprises, States and Tribes, and the Federal government in the “Summary of Traceability Economic Analysis.”

Q. Will USDA provide funding to States and Tribal Nations to develop their animal disease traceability approaches?

A. It is USDA's intent that animal disease traceability not be an unfunded mandate. As such, if available, USDA would provide Federal funding to assist States and Tribes to carry out activities that align with the scope of the new framework. Certain animal disease traceability requirements would be implemented in stages, thereby lowering near-term costs of the program.

Performance Standards

Q. Will the new traceability approach require States and Tribes to meet certain performance standards?

A. Under the proposed rule, USDA is not prescribing the methods or systems that States and Tribes must use in order to trace animals. This outcome-based approach to improving traceability allows States and Tribes to develop systems for tracing animals that work best for them and for producers and others in their jurisdictions.

Q. What is the current thinking on the performance standards?

A. USDA currently envisions the States and Tribes being required to accomplish four activities—necessary components of a trace investigation—within a specified timeframe for any species covered under the traceability regulations. The four activities are:

- State or Tribe that received a reference animal can determine the State or Tribe in which the animal was officially identified and notifies that State or Tribe of the animal's official identification number.
- State or Tribe where reference animal was officially identified confirms that it has the documentation that the official identification number was issued in its jurisdiction and has the contact information for the person who received that number.
- State or Tribe that received a reference animal determines which State or Tribe the animal was directly shipped from and notifies that State or Tribe of the animal's official identification number.
- State or Tribe that receives notification that a reference animal moved interstate from its jurisdiction

determines the address from which the reference animal was directly shipped.

USDA intends to conduct baseline studies by collecting information on States' and Tribes' abilities to carry out these four activities. The data we collect will enable us to establish firm measurements by which we could evaluate performance of States and Tribes.

Q. What is the General Standards Document?

A. In this proposed rule, frequent reference is made to the Animal Disease Traceability General Standards Document. It is a document released with the proposed rule that provides specific detail on, among other things, numbering systems, official identification devices, and ICVIs and other animal movement documents. The document is available online and can be found at www.aphis.usda.gov/traceability/.

Confidentiality

Q. Who will hold the information needed to conduct traces? How will USDA gain access to this information when a disease event occurs?

A. Under the new framework traceability information is maintained at the discretion of the States and Tribal Nations, though USDA will stand ready to assist States and Tribal Nations as requested. The information systems used to support animal disease traceability follow secure data standards to ensure compatibility of databases so information can be provided to USDA and other States/Tribes when needed for animal disease programs.

Q. How will animal disease traceability information be maintained?

A. Animal disease traceability information will be maintained at the discretion of the State and Tribal Nations.

Q. What will USDA do to keep my information confidential?

A. These proposed regulations uphold and build on existing disease program regulations, wherein information has always maintained confidentiality. USDA believes that producer information gathered through animal disease traceability efforts should be treated as information maintained under existing disease program regulations and, therefore, is exempt from provisions of the Freedom of Information Act.

Food Safety

Q. How does the proposed USDA rule relate to food safety?

A. The proposed rule is specifically focused on controlling animal diseases; it is not a food safety initiative. USDA's proposed rule for traceability will

assist animal health officials in quickly finding out where diseased animals have been and identify other at-risk animals.

Q. Will animal disease traceability allow USDA to trace an animal back to a package of meat?

A. No. USDA's Animal and Plant Health Inspection Service (APHIS) is the lead Federal agency for animal disease traceability. This type of pre-harvest traceability is focused on animal health and allows for the tracing of an animal's movements during its lifespan. Currently, animal disease traceability ends when an animal is slaughtered. USDA's Food Safety and Inspection Service (FSIS) is the lead agency dealing with food safety in meat and poultry. They have a wide range of programs designed to ensure food safety.

Q. How will the proposed traceability protect consumers?

A. Food security involves dependability in terms of supply and quality, among other attributes. Should there be an animal disease event, including zoonotic disease concerns, animal disease traceability as outlined in the proposed rule would allow for efficient traceback of infected animals and the rapid quarantine of potentially exposed animals. This ensures that healthy animals can continue to move freely to processing facilities, providing a dependable and affordable source for consumers as well as protecting producer's livelihoods. At that point, FSIS' methods for quality assurance take over and assure further safety and security of the food supply.

Next Steps

Q. How can I submit my comments on the proposed rule?

A. This notice is published in today's Aug. 11 *Federal Register*. Consideration will be given to comments received on or before Nov. 9. You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov/#!documentDetail;D=APHIS-2009-0091.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2009-0091, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

we receive on this docket may be viewed at www.regulations.gov/#!docketDetail;D=APHIS-2009-0091 or in our reading room, which is located in Room 1141 of the USDA South Building, 14th St. and Independence Ave., SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, excluding holidays. To facilitate entry into the comment reading room, please call (202) 690-2817.

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Supporting documents and any comments