

Animal Disease Traceability (ADT)

Monitoring and Compliance

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Animal Disease Traceability

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Introduction

The U.S. Department of Agriculture (USDA) provides various programs that support the economic viability of animal agriculture. The Veterinary Services (VS) unit of the Animal and Plant Health Inspection Service (APHIS) works to improve health, productivity, and quality of life for animals and people and maintain and promote the safety and availability of animals, animal products, and veterinary biologics.

USDA published a final rule, “Traceability for Livestock Moving Interstate,” on January 9, 2013. The regulation establishes requirements for the official identification of livestock and documentation for certain interstate movements in title 9 of the Code of Federal Regulations (9 CFR), part 86. The requirements for official identification and movement documentation for covered livestock moving interstate improve the ability of animal health officials to trace livestock when disease is found. Covered livestock include cattle and bison; horses and other equine species; poultry; sheep and goats; swine; and captive cervids. Animals of these species, unless otherwise exempt, are required to be officially identified and accompanied by an Interstate Certificate of Veterinary Inspection (ICVI) or other movement documentation. These identification and documentation requirements provide basic information essential for traceability and are the main elements for monitoring compliance. Certain disease program requirements pertaining to traceability will be considered in monitoring compliance. In addition to APHIS regulations, the criteria and policies defined in the ADT General Standards document and guidance documents will also be considered part of the monitoring activities.

ADT must have a high level of compliance to achieve a solid infrastructure for tracing livestock. APHIS prioritizes compliance with the traceability regulations through efficient and effective use of existing resources, including field personnel. This monitoring and compliance document provides general guidelines and outlines the administrative activities needed to successfully monitor and ensure compliance with the ADT regulatory requirements. Federal, State, and Tribal animal health officials and accredited veterinarians will work with industry members to carry out various administrative activities to achieve improved traceability. The guidelines suggested in this document offer administrative processes that can be carried out by reviewing various records. Additionally, the guide recommends field activities that can support compliance monitoring.

Communication to inform stakeholders of the regulatory requirements remains the priority, as does the uniform administration of enforcement procedures. While this document does not direct outreach and education activities, these activities are critical to the successful administration of the ADT regulations.

Education and Outreach

APHIS places great importance on informing producers and other stakeholders of the ADT

program's interstate movement requirements. As States and Tribes implement local activities that support traceability, they will take the lead in providing education and outreach on the ADT program. VS offers ADT cooperative agreement funds that help support these activities.

APHIS provides various reference materials on the traceability requirements at: <http://www.aphis.usda.gov/traceability/>. These materials include:

- ADT General Standards Document
- Summary of Interstate Movement Requirements by Species
- Description of Official Identification Ear Tags
- Listing of Approved National Uniform Eartagging System (NUES) Tags
- Listing of Approved Animal Identification Number (AIN) Devices
- Interstate Movement Requirements by State

The final rule "Traceability for Livestock Moving Interstate" located at 9 CFR Part 86 can be accessed at the following link: <https://www.ecfr.gov/cgi-bin/text-idx?SID=d5ff7776f36ec735a22b3a69543d5cbb&node=pt9.1.86&rgn=div5>

APHIS has also developed Module 12: Animal Disease Traceability, a supplemental training module as part of the National Veterinary Accreditation Program; available at the following link: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/ct_aast

Administrative Functions and Activities

Administrative functions and activities for monitoring the ADT regulatory requirements and policies include reviewing records and other office procedures. These cost-effective activities will support overall compliance.

Official Identification

Administration of Official Identification Devices

Manufacturing Official Identification Devices

APHIS approves manufacturers of official identification devices and authorizes the manufacturer to imprint the Official Ear Tag Shield, which designates the tag as an official identification device as described in the *Code of Federal Regulations* and the ADT General Standards document.

Approved manufacturers are responsible for the proper administration of official identification devices. APHIS will monitor the activities below, as well as others deemed appropriate, to ensure that approved identification device manufacturers are properly administering official identification devices by:

- Imprinting official identification numbers and the Official Ear Tag Shield in accordance with printing criteria and only on approved devices.
- Maintaining the uniqueness of the official identification numbers allocated to them.
- Reporting distribution of official identification devices as prescribed, including the reporting of AIN devices to the Animal Identification Management System (AIMS).

The ADT staff oversees these activities. However, anyone who observes discrepancies should report them to a member of the ADT staff.

Distribution Records of Official Identification Devices

The ADT regulations do not require producers to report animal identification information when animals are officially identified. Therefore, the distribution records for official identification devices must be complete and accurate. These records will provide the basic information to determine where the animal was first officially identified. Additionally, the information must be retrieved quickly when responding to an animal disease event.

AIN devices

All 840 AIN device distribution records must be submitted to the AIMS. Review of compliance with this policy will include:

- Reconciling inventory reports from AIMS with the physical AIN 840 identification device inventory that animal health officials, AIN managers and resellers maintain.
- Randomly selecting 840 identification numbers from various documents (ICVIs, test charts, identification devices collected at slaughter, etc.) to review device distribution information available in AIMS.
- Identifying gaps in the reporting of AIN distribution records (“broken events” in AIMS), informing individuals of discrepancies in reporting distribution of AINs and overseeing corrections.

The Area Veterinarian in Charge should assign personnel to review AIN device inventory reports with actual inventories at State and Tribal offices. Animal health officials should work together to monitor and check compliance of AIN device inventory and distribution records of AIN managers and resellers.

NUES tags

Federal and State officials have primary responsibility for administering NUES tags. States may provide NUES tags directly to producers. Activities to monitor proper administration of NUES tags include:

- Reviewing the process for properly recording NUES tag distribution to animal owners.
- Randomly selecting NUES tag numbers that are either attached or likely to be attached to an animal and reviewing availability and completeness of tag distribution records.

The VS Area Veterinarian in Charge should assign personnel from their offices to visit State offices to review completeness of these administrative functions and to perform tests with random numbers from issued NUES tags.

Movement Documentation

Administration of Interstate Certificates of Veterinary Inspection

The ICVI is one type of movement document frequently used to meet the requirements established in 9 CFR part 86. While the ICVI is typically listed as the movement document, the exemptions to the ICVI allow for other movement documentation. The Summary of General Requirements by Species document summarizes those movement documents.

Activities to assure compliance with the requirements for administering ICVIs or other movement documents must include a review of randomly selected documents obtained by the shipping and receiving States. The actions to be reviewed include:

- Submission of the ICVI by the accredited veterinarian to the shipping State within the number of days specified in the *Code of Federal Regulations*.
- Submission of the ICVI by the shipping State to the State of destination within the number of days specified in the *Code of Federal Regulations*.
- Listing the following required information on the ICVI by the accredited veterinarian:
 - Species of animals covered by the ICVI.
 - Number of animals covered by the ICVI.
 - Purpose for which the animals are to be moved.
 - Address where the animals were loaded for interstate movement.
 - Address where the animals are destined.
 - Names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address where the animals are destined.
 - Official identification number of each animal, unless the species-specific requirements for ICVIs provide an exception:
 - If the animals are not required to be officially identified, the ICVI must state the exemption that applies.
 - 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.

The State animal health official should assign personnel to review compliance with these requirements for ICVIs received. Additionally, the Area Veterinarian in Charge will assign personnel from the local VS Field Office to visit State offices to review completeness of these administrative functions. Accredited veterinarians who have not properly completed the ICVIs will be notified as described in the Guidelines for Noncompliance section (below).

Field Functions and Activities

APHIS will monitor compliance of traceability field functions and activities. The States will also monitor compliance based on how their State regulations align with the Federal regulation. Some field functions and activities may be supported by sectors of the industry, other industry programs, law enforcement agencies, and State departments of transportation.

The primary focus will be to ensure that animals are officially identified as required; that they move interstate with required documentation; and that the identification devices are removed at termination points (slaughter or rendering facilities) as required.

The official identification and movement documentation requirements for livestock moved interstate are summarized by species at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/SA_Traceability. States and Tribes should monitor compliance with these requirements to help realize tracing capabilities. APHIS expects compliance with all types of movements; thus, States and Tribes should use a random monitoring process to include all aspects of interstate movement.

While Animals are in Transit

Illegal animal movements can spread disease. Law enforcement agencies are often the first line of defense in detecting illegal movement of livestock and often have the authority to stop livestock vehicles for inspection. State departments of transportation already inspect trucks as part of their mission to prevent commercial motor vehicle-related fatalities and injuries. State police units may conduct truck stops at highway rest areas.

To use existing resources and not duplicate effort, VS Field Office personnel, State and local law enforcement agencies, State departments of transportation, State departments of agriculture or livestock, APHIS Investigative and Enforcement Services, the motor carrier industry, labor safety interest groups, and others need to work together. These partnerships will increase awareness of and compliance with interstate animal movement regulations.

The Area Veterinarian in Charge and State animal health officials may train various enforcement authorities that already inspect trucks. The training would prepare authorities to inspect livestock vehicles for interstate movement violations and to understand required identification and movement documentation.

To document progress, States and Tribes can also review and document the following information at least annually:

- The number of livestock vehicle inspections.
- The number and type of interstate movement violations noted during inspections.

Livestock Concentration Points

Markets and Buying Stations

Monitoring and enforcing compliance at livestock markets and buying stations is important due to the tremendous volume of livestock they handle and the various points of origin for the livestock. The commingling of livestock at these locations, while necessary for commerce, increases the risk of transmission of livestock diseases.

To ensure compliance, APHIS and State animal health officials will work with livestock markets and buying stations to develop a plan to monitor compliance. Each plan will ensure that:

- On entering the livestock facility:

- Personnel query consignors to determine if animals have moved interstate to the facility.
- Animals are officially identified as required.
- Required movement documentation is presented.
- While at the livestock facility:
 - There is proper determination of which animals need to be identified.
 - There is proper determination of when animals need to be identified.
- When leaving the livestock facility:
 - There is proper determination of which animals need to be identified.
 - There is proper determination of which animals need to be accompanied by an ICVI.
 - There is proper determination of which animals need to have the official identification number listed on the ICVI.

Not all livestock facilities are the same. There is no “one size fits all” plan for monitoring and compliance. Each livestock facility will need to identify points in its market system where things may go wrong, develop a plan to monitor those points, and provide appropriate corrective action. State or Federal animal health officials will conduct routine inspections of livestock facilities to track progress and specify additional corrective actions that may be warranted.

During routine inspections Federal officials will review the monitoring and compliance records and report their findings. When agreed to by State and Federal animal health officials, State officials may conduct the review.

Livestock Sales

Private treaty, Production Sales and Online Auctions

Monitoring the private sale of covered livestock between individuals for compliance with the traceability requirements for official identification and movement documentation can be challenging. As mentioned in the transit section above illegal animal movements can spread disease and States will need to work with law enforcement agencies to maximize resources to conduct truck and trailer stops as feasible. In addition, the Area Veterinarian in Charge and State animal health officials should provide training to various enforcement authorities that already inspect trucks for interstate movement violations to understand required identification and movement documentation and to assess if compliance is being achieved.

Regulatory personnel have the ability to provide outreach and education to operators of production sales and online auctions regarding the traceability regulations for covered livestock sold through these venues in order to promote compliance. Review of regional agricultural publications and online search engines for livestock production sales and online auction advertisements provide local authorities with opportunities for monitoring compliance of these livestock sales.

VS and State animal health officials should discuss and implement other opportunities for monitoring private treaty, production sales and online auctions of livestock locally as resources permit.

Livestock Termination Points

Slaughter Plants

The Food Safety and Inspection Service (FSIS) requires the collection and linking of identification devices to the carcass at slaughter. To expedite the traceability of diseased animals found at slaughter, APHIS included a similar requirement in the traceability rule. The traceability regulation includes the following requirement:

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.

APHIS and FSIS must work collaboratively to review compliance with these requirements. The VS Area Veterinarian in Charge shall ensure that all federally- approved slaughter plants are inspected quarterly (at a minimum) by APHIS personnel. APHIS personnel must observe and report compliance with these requirements during site inspections including:

- The plants process for the collection of identification including ensuring that sufficient tissue remains on the device for DNA matching if needed and mechanism for maintaining traceability for animals presented for slaughter without identification
- The plants mechanism for maintaining correlation of identification to the carcass through final disposition
- The plants process for retrieval of identification for inclusion with samples to be submitted for laboratory testing
- Ensuring the plant has adequate and demonstrable record keeping

Rendering Plants

The collection of livestock identification devices at rendering plants is as important as collection at slaughter.

The traceability regulation requires all official identification devices affixed to covered livestock carcasses moved interstate for rendering to be removed at the rendering facility and that the devices be made available to APHIS. The VS Area Veterinarian in Charge shall ensure that all federally- approved rendering plants are inspected quarterly (at a minimum) by APHIS personnel. APHIS personnel must observe and report compliance with these requirements during site inspections including:

- Evaluation of the rendering plants process for collection and storage of identification
- The plants process for retrieval of identification for inclusion with samples to be submitted for laboratory testing

- Ensuring the plant has adequate and demonstrable record keeping

Overview and Guidelines for Noncompliance

The Animal Health Protection Act of 2002 authorizes the assessment of civil penalties for violations of the Act. It also authorizes criminal penalties, under Title 18 of the United States Code, for violations that are “knowingly” committed under the Act. The Act provides the following maximum civil penalties:

- \$1,100 for an individual who is a first-time violator and whose action was not for monetary gain.
- \$60,000 per violation for other individuals.
- \$300,000 per violation for other legal entities, such as corporations.¹

Criminal penalties include fines, imprisonment, or both.

The following explains violations and related actions.

- **Alleged Violation.** A claim of fact by APHIS, which, if proven, will constitute a violation of a VS-administered statute or regulation.
- **Enforcement Actions.** Options available for resolving alleged violations of VS-administered statutes and regulations, including:
 - “Official Warning, Violation of Federal Regulations” (APHIS Form 7060). An official warning of an alleged violation of a VS-administered statute or regulation. It also notifies the subject that APHIS may seek civil or criminal penalties for the alleged violation if the subject again violates APHIS-administered statutes and regulations. APHIS generally issues Form 7060s to resolve minor to moderate alleged violations or alleged violations that are not appropriate to pursue through the Office of General Counsel (OGC) or the U.S. Department of Justice (DOJ).
 - Stipulation. A pre-litigation monetary settlement between APHIS and the subject. The stipulation gives the subject notice of the alleged violation, lets the subject ask for an administrative hearing, and allows the subject to waive the hearing and pay (generally within 30 days) a monetary penalty calculated in accordance with

¹Effective May 7, 2010, the Secretary of Agriculture, pursuant to the Federal Civil Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 *et seq.*), adjusted the civil penalty that may be assessed under the Animal Health Protection Act for each violation of the Act and the regulations issued thereunder, pursuant to 7 U.S.C. 8313(b)(1), occurring after May 7, 2010. The adjustment increases the statutory maximums from \$1,000 to \$1,100 for an individual who is a first-time violator and whose action was not for monetary gain; from \$50,000 to \$60,000 for other individuals; and from \$250,000 to \$300,000 per violation for other legal entities (9 CFR 3.91(b)(2)(vi)). The Secretary of Agriculture also adjusted the statutory maximums under other VS-administered statutes, including the Swine Health Protection Act, the Agricultural Bioterrorism Protection Act of 2002, and the Twenty-Eight Hour Law, for violations occurring after May 7, 2010.

the VS Civil Penalty Guidelines. APHIS generally issues stipulations in connection with moderate to serious alleged violations that are appropriate for referral to OGC or DOJ, if unpaid.

- Administrative Enforcement Action. A referral to OGC recommending that OGC file, on behalf of APHIS, a formal administrative complaint alleging violations of VS-administered statutes and regulations, and requesting appropriate penalties in accordance with the VS Civil Penalties Guidelines. A referral may also recommend that OGC refer the matter to DOJ for criminal or civil prosecution.
- Letter of Information. An official letter or notice that informs the subject of the relevant regulatory requirements and is used as a means of education in cases of minor violations. A Letter of Information is not considered an enforcement action.

Initial Evaluation of an Alleged Violation

When a VS program official first learns of a possible violation, he or she must clearly define which regulation he or she believes has been violated. VS sends a number of cases to APHIS' Investigative and Enforcement Services (IES) annually, only to find that the alleged act is not specifically prohibited by the regulations. If there is any question about regulatory authority to pursue a case, the program official should confer with IES and VS District or Headquarters staff.

Next, the program official must determine whether to request an IES investigation. An IES investigation may not be necessary if VS obtains sufficient information to show that an alleged violation occurred or is likely to have occurred and that the violation is minor. These cases may be resolved by educating the subject, through a Letter of Information along with verbal counseling, without the need to expend IES resources. The criteria for such cases include:

- Little or no risk of disease spread.
- No evidence of inhumane treatment of animals.
- No evidence of fraud.
- No prior history of violations (i.e., no prior enforcement actions).
- The subject has cooperated with the Agency in good faith.
- The alleged violation involves only paperwork violations (i.e., errors or omissions but not intentional falsifications).

Determination of the Seriousness of Alleged Violations and Subsequent Enforcement and Compliance Action

A program official may request an investigation through an IES investigator or the VS District Office. If an investigation results in insufficient evidence to prove an alleged violation or the determination that no violation occurred, the VS program official, with input from the IES Area Manager, will close the investigation at the field level (that is, the case will not be submitted to the Animal Health and Horse Protection Enforcement Branch (AHHPEB)). For investigations that result in substantiated alleged violations, the VS program official and the chief of AHHPEB (or the IES specialist assigned to the case) will evaluate the seriousness of

the alleged violations using the guidelines below and determine the appropriate enforcement action.

The guidelines below provide a framework for determining the seriousness of violations, but are not intended to replace the judgment of the VS program official and the chief of AHHPEB when determining the seriousness of the alleged violations documented in an investigation.

- **Serious Alleged Violations**

A serious alleged violation may involve one of the following issues:

- Actual or potential disease introduction or transmission, such as the unapproved interstate shipment of diseased animals (for example, movement of a known equine infectious anemia-positive equine), quarantined animals, or feral swine; or mishandling of biologics or biological materials (for example, select agents or marketing of unlicensed biologics).
- Criminal and fraudulent activities under VS-administered statutes and regulations, such as counterfeiting import or export documents, or assaulting a Federal officer (these cases are handled by other authorities, with IES and OGC in a supporting role).
- Inhumane treatment of animals: for example, shipments of blind or lame horses going to slaughter; animals for export that are unfit for travel; or alleged violations of the Twenty-Eight Hour Law.

- **Moderate Alleged Violations**

A moderate alleged violation may involve one of the following issues:

- Individuals or legal entities with several alleged violations, prior enforcement actions, or who demonstrate willfulness or blatant disregard for the regulations.
- Repeated interstate or international movement of animals or animal products without a valid permit or health certificate.
- Repeated violations of the Commercial Transportation of Equines to Slaughter Act that do not involve the inhumane treatment of animals.
- The animals or products in the violation have been confiscated, destroyed, or returned to the point of origin.

- **Minor Alleged Violations**

Minor alleged violations may involve one of the following issues:

- A first-time violator or subject.
- An alleged violation that does not increase risks of disease transmission or negatively affect animal health (for example, not completing forms correctly, incorrectly moving animals that are not diseased, confiscating unlawful products or animals).
- The alleged violation does not involve commercial quantities of product (where commercial quantity is defined as an amount reasonably believed to be in excess of that needed for personal use or consumption).
- Improper movement of unprocessed noncommercial trophies and hides from an area with low disease risk.

- A determination has been or can be made that any stipulation issued in the case would be less than \$1,000.

Enforcement and Compliance Actions

- Serious violations: IES will confer with VS management to determine which cases involving serious alleged violations should be referred to OGC for an administrative enforcement action, referred to DOJ for criminal or civil prosecution, or offered a settlement agreement.
- Moderate violations: IES will generally issue a stipulation or an official warning (Form 7060) for cases involving moderate violations. If the subject accepts the terms of the stipulation and pays the monetary penalty, IES will close the case. If the subject does not accept the terms of the stipulation or wishes to exercise his or her opportunity for a hearing, IES with concurrence from the program official will refer the case to OGC for an administrative enforcement action.
- Minor violations: IES will generally issue an official warning (Form 7060) for cases involving minor violations. The VS program official and chief of AHHPEB (or the IES specialist assigned to the case) may also deem it appropriate to pursue no enforcement action for minor alleged violations. In instances where APHIS pursues no enforcement action, the VS program official may elect to send the subject a Letter of Information that excerpts or attaches the relevant regulatory provisions. VS will use standard correspondence for any such notices, and will confer with IES if additional assistance on developing appropriate language is needed. For purposes of any future investigation, IES will not consider a Letter of Information a prior enforcement action or a prior violation.

Documentation and Communication

In all cases, IES will update its database to indicate the enforcement action imposed and inform the VS program official of the case's resolution. If the case is related to a National Veterinary Accreditation Program (NVAP) regulation, the NVAP coordinator at the appropriate VS District or Field office will enter the violation data in the Veterinary Services Process Streamlining data storage system. For cases where a Letter of Information is issued by a VS program official, the program official should document the issuance of the letter so that VS can track, report, and analyze such letters for trends.

VS program officials must notify appropriate parties (i.e., the State veterinarian and other State and Federal officials involved in the case) of the disposition of each case. In many cases the State veterinarian should be notified before taking enforcement action because a case might also have pending State enforcement actions.