Animal Disease Traceability

General Standards

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UNITED STATES DEPARTMENT OF AGRICULTURE

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 in 9 CFR Part 86, Traceability for Livestock Moving Interstate. The purpose of the regulations is to improve the ability of animal health officials to trace livestock when disease is found.

This general standards document contains the ADT program standards for numbering systems, official identification devices authorized under the final rule, administration of official identification devices, and APHIS approval of official identification devices. Additional information, including listing of official identification devices, is provided at APHIS' ADT website (https://www.aphis.usda.gov/aphis/ourfocus/animal health/traceability).

Section A: Program Data Standards

Official Identification Numbers – Animals

Official identification numbering systems are fundamental to animal disease programs. Identification 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. 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 in the United States must adhere to one of the following numbering systems:

- Animal Identification Number (AIN).
- National Uniform Eartagging System (NUES).
- Location-based number system.
- Flock-based number system.
- Any other numbering system approved by the APHIS Administrator to officially identify 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 ear tags) that have an official animal number imprinted on them. Official identification devices that adhere to these numbering systems are listed in Section B of these standards. 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
Animal Identification Number (AIN)[1]	**15**	**Numeric**	**840003456789012**	
	[3][2]		840 900 (equine only)[3]	840 is the numeric country code for the United States.
	[12]		003456789012	The last 12 digits are the animal number. Start number > 003,000,000,000.
National Uniform Eartagging System (NUES)	**9 or 8**	**Alphanumeric**	**23 ELV 4574** **PA ELV 4574** **23 DX 1234** **Sheep and Goats*:** **PA DX 1234 (metal)** **PA D2 1234 or** **PA 2D 1234 (plastic)**	The 9 alphanumeric NUES format is for use in cattle and bison only. The 8 alphanumeric NUES format is for use in all other species. *Use of the State postal abbreviation for the 8 alphanumeric NUES format is reserved for use in the scrapie program.
	[2]		23 PA	Default is State or Tribe numeric code. The State postal abbreviation is optional for the 9 alphanumeric NUES format.
	[3] or [2]		ELV DX D2 or 2D	3 or 2 letters. Sheep and goats devices may also use a letter and a number.
	[4]		4574 or 1234	4 digits.
Flock-based number with a herd management number	**15 Max.**	**Alphanumeric**	**MN0456 4275**	
	[9] Max.		MN0456	See Flock Identification Number (FIN) standard below.
	[6] Max.		4275	Unique herd management number.
Location-based number with a herd management number	**14 Max.**	**Alphanumeric**	**IA123456 98765**	
	[8] Max.		IA123456	See Location Identification Number (LID) and Premises Identification Number (PIN) standard below.
	[6] Max.		98765	Unique herd management number.

[1] Beginning March 11, 2015, APHIS began recognizing only AINs beginning with numeric country codes ("840" for the United States) as defined by ISO 3166 as official. AINs with the prefix "USA" or a numeric manufacturer code assigned by the International Committee for Animal Recording (ICAR) are only considered official identification if applied to animals prior to March 11, 2015.

[2] The number in the brackets designates the sequential order of the alphanumeric characters within the numbering system.

[3] 900 manufacturer coded injectable transponders are approved official identification for equine only

Note: AINs beginning with the 840 prefix may not be applied to animals known to have been born outside the United States.

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 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 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, to number 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.

The GIN format for sheep and goats is defined in 9 CFR Part 79 Scrapie in Sheep and Goats.

Flock Identification Numbers (FINs)

The numbering system for the National Scrapie Eradication Program 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 associated with one or more locations. 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. FINs must be linked to a PIN or LID in the National Scrapie Database (see Location Numbering Systems).

The following table specifies the format for official animal group identification numbers.

Table 2. Animal Group Identification Numbers				
Data Element	**Length**	**Format**	**Example**	**Comments**
Group/Lot ID Number (GIN) - *Using a PIN*	**15**	**Alphanumeric**	**004T56711221805**	
	[7]		004T567	The first 7 characters are the PIN.
	[6]		112218	The next 6 characters are the date the lot was established: MM/DD/YY.
	[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) - *Using a LID*	**14 or 16**	**Alphanumeric**	**WA123411221805** **MN12347811221805**	
	[6] or [8]		**WA1234** **MN123478**	The first 6 or 8 characters are the location ID number.
	[6]		112218	The next 6 characters are the date the lot was established: MM/DD/YY.
	[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**	**PA723456A**	
	[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.

Location Numbering Systems

States and Tribes may elect to use location identifiers to support their animal disease traceability program. Three formats, explained below, support the administration of location identifiers that adhere to the standards defined in Table 3. PINs and non-producer participant numbers (NPN) are available through the APHIS PIN allocator, a software application that assigns a unique location identifier/number to a specific geographic location for States and Tribes electing to use it. States or Tribes may also use their own processes for administering unique State- or Tribal-issued location identifiers. In these situations, the State or Tribe has its own local system and process for issuing location numbers. To avoid confusion in presenting these options in these standards, 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, LIDs, or NPNs to administer their traceability program. However, if they choose to use location identifiers, they must ensure their information systems are compatible with other traceability and animal health databases by following the standards set forth in Table 3 below.

Location Identification Numbers

LIDs are administered through a State's or Tribe's internal system. All LIDs start with the State or Tribal code, which make the LIDs nationally unique. They consist of six or eight alphanumeric characters. The LID data standards are defined in Table 3.

Premises Identification Numbers

States and Tribes may elect to use the PIN in their traceability program. The standardized PIN, obtained through the APHIS PIN allocator, consists of seven alphanumeric characters. The last character is a check digit based on ISO/IEC 7064:2003. States may use the State's postal abbreviation as the first two of the seven characters (for example, OH341T4). Tribes may also have codes reserved for use with PINs they administer. APHIS assigns Tribal codes on 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 PIN data standards are defined in Table 3.

Non-producer Participant Numbers

Manufacturers, managers, and resellers (device distributors) are referred to as non-producer participants. Each non-producer participant obtains an NPN through the premises registration system in the State or Territory of the company's headquarters to receive and distribute AIN devices. An NPN follows the same alphanumeric format as a PIN as defined in Table 3.

Table 3. Location Identifiers

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

[1] The check digit calculation algorithm is based on ISO/IEC 7064:2003, "Data Processing – Check Character Systems."

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.

NUES State, Tribal, and Territory Codes

State, Tribal, and Territory codes used with NUES tags and location identifiers are listed below.

Table 4. State, Tribal, 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
COLORADO	CO	84	NEW YORK	NY	21
COMMONWEALTH OF THE NORTHERN MARIANAS	MP	98	NEW JERSEY	NJ	22
CONNECTICUT	CT	16	PENNSYLVANIA	PA	23
DELAWARE	DE	50	OHIO	OH	31
EASTERN CHEROKEE NATION	EC	80	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	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	WESTERN CHEROKEE NATION	CN	79
OKLAHOMA	OK	73	EASTERN CHEROKEE NATION	EC	80
OREGON	OR	92	MONTANA	MT	81
PENNSYLVANIA	PA	23	IDAHO	ID	82
PUERTO RICO	PR	94	WYOMING	WY	83
RHODE ISLAND	RI	15	COLORADO	CO	84
SOUTH CAROLINA	SC	56	NEW MEXICO	NM	85
SOUTH DAKOTA	SD	46	ARIZONA	AZ	86
TENNESSEE	TN	63	UTAH	UT	87
TEXAS	TX	74	NEVADA	NV	88
UTAH	UT	87	WASHINGTON	WA	91
VERMONT	VT	13	OREGON	OR	92
VIRGIN ISLANDS	VI	59	CALIFORNIA	CA	93
VIRGINIA	VA	52	PUERTO RICO	PR	94
WASHINGTON	WA	91	HAWAII	HI	95
WEST VIRGINIA	WV	54	ALASKA	AK	96
WESTERN CHEROKEE NATION	CN	79	GUAM	GU	97
WISCONSIN	WI	35	COMMONWEALTH OF THE NORTHERN MARIANAS	MP	98
WYOMING	WY	83	AMERICAN SAMOA	AS	99

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 either the 840 prefix or 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.

Table 5. Country Codes for U.S. Territories

Territory	Code	Territory	Code
America 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 Identification Methods and Devices for Animals

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 these standards list official animal numbering systems for livestock.

Official identification devices and methods are listed in title 9, *Code of Federal Regulations* (9 CFR) part 86 by species, and include radio frequency identification (RFID) ear tags, visual ear tags, and RFID injectable transponders.

Official Ear Tag Specifications

Official ear tags approved for certain species are APHIS-approved tags that provide official identification numbers for individual animals. APHIS must approve the tag before a manufacturer can produce and sell ear tags bearing the official ear tag shield (see Section C, Approval of Official Identification Methods and Devices for Animals)[1]. APHIS has posted a description of the types of official ear tags with the specifications and options as well as lists of currently approved official ear tags on the ADT website at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/SA_Traceability.

Official ear tags must:

- Be imprinted with an official identification number (see Table 1).
- Be imprinted with the official ear tag shield.
- Be tamper evident with high retention.
- Have other characteristics specified in Appendix 2.

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

Distribution of Official Identification Devices

Official identification devices must be properly administered to support animal disease traceability. State and Tribal animal health officials may provide official identification devices to accredited veterinarians who wish to use them as official identification for specific disease control programs (e.g., brucellosis calfhood vaccination or official disease testing). In addition, State and Tribal animal health officials may provide official identification devices to accredited veterinarians, approved tagging sites[2], or directly to producers for other purposes (e.g., to meet the requirements for interstate movement). In either case, the State or Tribal animal health officials will maintain complete oversight for the integrity of official identification device distribution information.

[1] See definition of Official eartag at 9 CFR Part 86.1 Definitions
[2] See "Approved Tagging Sites" description on p. 12.

Distribution records and records of official identification devices applied are to be administered as explained below with the exception of sheep and goats. Requirements for administering official Scrapie Program identification tags are explained in the Scrapie Program Standards Volume 1: National Scrapie Eradication Program, here (or https://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/nsep-program-standards-final-rule.pdf.)

Animal Identification Number Devices

APHIS, through an application and approval process, approves AIN devices that meet established standards (see Section C, Approval of Official Animal Identification Methods and Devices). Approved AIN manufacturers are allocated the 840 numbers through the Animal Identification Management System (AIMS) and are authorized to encode and/or imprint the AIN only on their approved devices. AIN device manufacturers distribute AIN devices through AIN device managers, or may act as AIN device managers themselves. AIN device managers and resellers distribute AIN devices to producers and accredited veterinarians.

All distribution records of 840 and 900 (equine injectable transponders only) AIN devices administered by AIN manufacturers, device managers, resellers (e.g., accredited veterinarian, online retailer, feed store, etc.), and Federal animal health officials must be reported to AIMS by the person possessing the device when distributing the device to the next individual, whether it is a producer or another reseller. AIN device recipients must have a PIN, LID, or NPN as defined in Section A and provide that number to the person distributing the devices. The record includes the AINs, date of distribution, and PIN, LID, or NPN where the devices were distributed. The AIN Management System User Guide provides details of the processes available for completing these distribution records. The Guide can be found under the Public Tools – Help section at the following link: https://vsapps.aphis.usda.gov/aims/

APHIS does not require State or Tribal animal health officials to be AIN device managers if they maintain complete distribution records of 840 AIN devices. A State or Tribe may use AIMS as the information system of record to meet this requirement or may use their internal animal health information system if it is searchable and supports tag distribution recording and electronic data sharing.

Producers electing to use AIN devices may acquire them from local or online resellers or directly from manufacturers. The complete listing of AIN devices and the AIN device manufacturer's information is at https://www.aphis.usda.gov/traceability/downloads/ADT_device_ain.pdf.

When accredited veterinarians obtain 840 AIN devices direct from an AIN device manufacturer or device manager for further distribution or application to animals, they must report the device distribution or application records in AIMS. In this case, they are acting as AIN device managers and must establish a marketing arrangement with the device manufacturer.

When accredited veterinarians obtain 840 AIN devices or 900 manufacturer coded injectable transponders for equine from a State or Tribal or Federal animal health official they must report records of devices applied or distributed as directed by the animal health official who provided the tags.

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.

Animal health officials are responsible for ensuring that sufficient contact information is collected and maintained by accredited veterinarians applying NUES tags directly to animals to qualify for interstate movement or specific disease control programs, or when distributing NUES tags directly to producers who wish to use them for official identification and purposes other than through a specific disease control program. At a minimum, tag 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.

Manufacturers and resellers distributing NUES tags directly to producers must report the records of NUES tags distributed as directed by the State or Federal Animal Health Official. Animal Health Officials must ensure the NUES number sequence is carefully coordinated with the manufacturer to avoid duplicate tag numbers.

States and Tribes may use the 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.

More specific details on the administration of NUES ear tags are available in Veterinary Services (VS) Guidance 10000.1: Distribution and Use of Official Identification Ear Tags with Numbers Conforming to the National Uniform Eartagging System (4/13/2014).

Producers and accredited veterinarians should contact their State or Tribal animal health officials regarding the availability of NUES tags.

Premises Identification Number Ear 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 back tag 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 at slaughter. If a PIN tag includes a manufacturer imprinted number unique within a herd, the tag would also qualify as an official ear tag for interstate movement of individual animals.

Manufacturers distributing swine PIN tags directly to producers must report the records of PIN tags distributed as directed by the State or Federal Animal Health Official.

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 move interstate to an approved tagging site for the application of official identification.

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 accurately maintain the animals' identity until tagging. This will ensure the official identification numbers correlate to the owner of the animals (or person responsible) when the animals are shipped to the tagging site. For example, a livestock market, acting as an approved tagging site, may use back tags to temporarily identify the animal on unloading. The approved tagging site, at a minimum, must:

- Obtain official identification devices 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 ear tags were applied.
- Submit the records of tags applied in an acceptable electronic format to the designated animal health official as directed by APHIS, State, or Tribal animal health officials within 7 days of application.
- Ensure the security of official identification devices and distribution records by:
  - Maintaining a record of all official identification devices 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, Tribal, or Federal animal health official.
- Tag all animals in accordance with 9 CFR part 86:
  - Tag all animals required to be identified.
  - Only tag animals not already officially identified. Do not apply additional official ear tags except as provided in 9 CFR 86.4(c).
  - Remove and/or replace official identification devices in accordance with 9 CFR 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 identification devices are to be applied at an approved tagging site along with the name and complete address of the tagging site. States will provide public lists of tagging sites.

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

Use of More Than One Official Identification Device

After March 13, 2013, no animal should have more than one official identification device, except in the following circumstances:

- The animal may have a second official identification device if device bears the same official identification number as the existing one.
- In specific cases when the need to maintain the identity of an animal is intensified (e.g., 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 identification device to an animal that already has one or more.
- An ear tag with an 840 AIN may be applied to an animal already officially identified with one or more NUES tags and/or an official vaccination ear tag used for brucellosis.
- A brucellosis vaccination ear tag with a NUES number may be applied to an animal already officially identified with one or more official ear tags.

The person applying the second official identification device must record the date the device is added, the official identification numbers of both the existing official identification device and the new official identification device, and must maintain those records for 5 years.

Replacement of Official Identification Devices

Replacement official identification devices (for applying a new identification number to animals that lose their official identification device) are defined in 9 CFR 86.4 (d), Removal or loss of official identification devices.

Issuance of Duplicate Official Identification Ear Tags

Duplicate official identification ear tags may only be obtained from approved manufacturers by an organization authorized (e.g., breed registries or genetic companies) to order reissued tags when an official ear tag is lost and the owner or person responsible for the animal needs to retag the animal with the official identification number of the lost ear tag. For AIN ear tags, the manufacturer submits a record to AIMS with the information on the reissuance and distribution of the duplicate ear tag. Additionally, the ear tag manufacturer imprints the designated symbol on the ear tag to reflect that the tag is a duplicate of a previously issued tag. When the duplicate ear tag contains RFID technology, the manufacturer encodes the number in accordance with the existing ISO or the existing APHIS-approved standard for administering transponders.

Section C: Approval of Official Identification Methods and Devices for Animals

An official identification device or method is a means approved by the Administrator for:

- Applying an official identification number to an animal of a specific species.
- Associating an official identification number with an animal or group of animals of a specific species.
- Otherwise officially identifying an animal or group of animals.

APHIS must approve an official identification device before a manufacturer can produce and sell it.

APHIS provides species-specific approval of RFID, visual ear tags, and injectable transponders as official identification devices (see 9 CFR 86.4 (a), Official identification devices and methods approved for covered species). The appendices following this section provide detailed information on the requirements for approving official identification devices.

Beginning December 31, 2018, APHIS will no longer approve applications for visual-only identification devices as official identification for bovine species. Manufacturers may still request approval of paired visual and RFID devices.

Non-U.S. manufacturers seeking approval of an identification device must have a representative within the United States who can serve as a device manager in accordance with Distribution of Official Identification Devices in Section B: Administration of Official Identification Methods and Devices for Animals and the AIN Management System User Guide.

Overview of Device Approval Process

Manufacturers seeking approval of a new device or modification of an existing approved official identification device will need to follow the process outlined below:

- Perform required ICAR conformance and performance testing.
- Submit initial device application including, results of ICAR testing and certification, device approval and sales data from other countries or proposed field trial protocol for APHIS approval, sample devices, and device applicator to APHIS.
- After receiving APHIS approval produce devices for field trial according to the specifications provided in these standards.
- Initiate field trials and complete required assessments.
- Request APHIS approval for controlled device sales if the device meets all specifications and performance standards at assessments according to the field trial protocol timelines outlined in Appendix 1.
- Complete field trials with successful results and submit final application with compiled field trial data for APHIS review.
- APHIS reviews data and determines if the device meets the criteria for full approval.

APHIS will place a hold on field trials and sales (if applicable) of devices failing to meet acceptable performance criteria at any point in the approval process or post approval if the device fails to perform as expected, until the manufacturer resolves performance issues, APHIS terminates the approval process, or revokes approval.

Application for Approval of Official Identification Devices

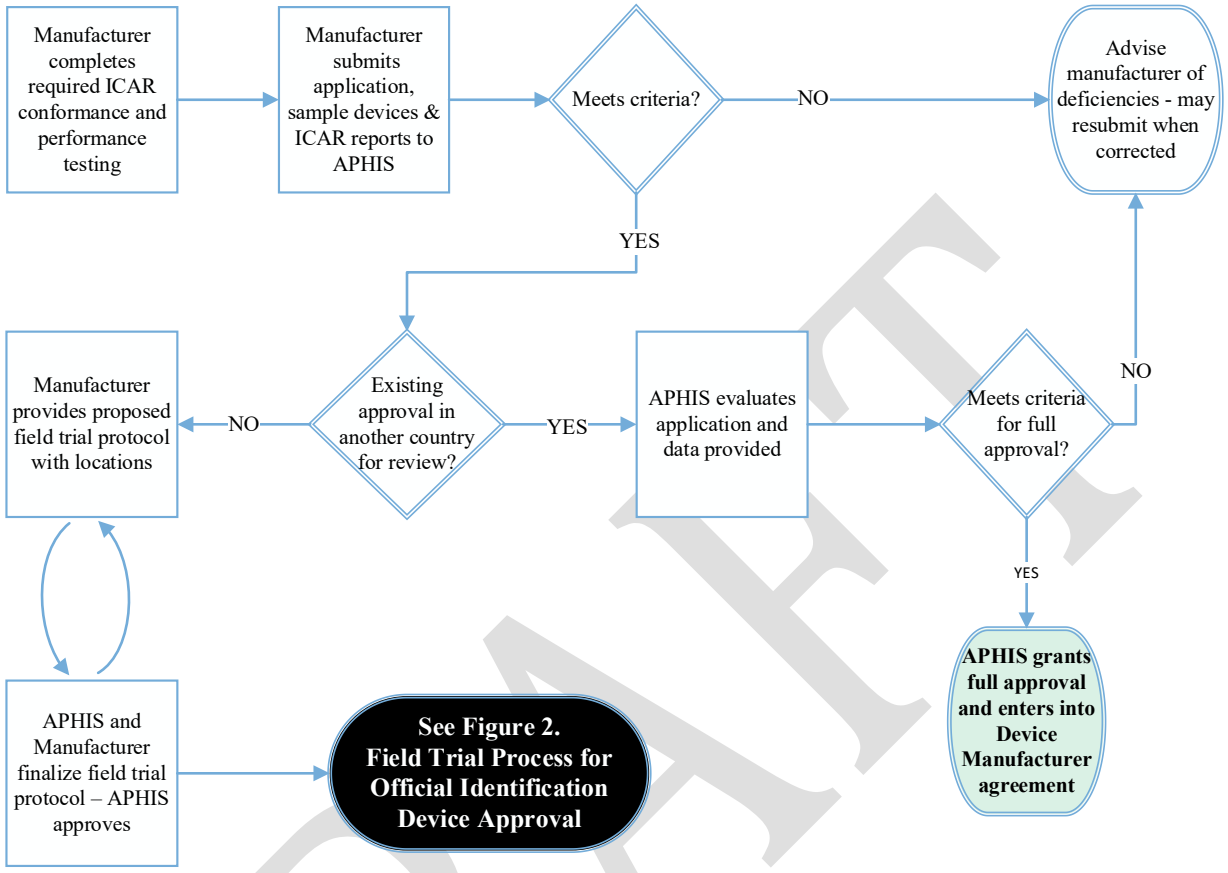
Manufacturers seeking APHIS approval of an identification device must document that they have successfully tested, produced, and marketed the identification device submitted for approval with favorable results. Such documentation must show at a minimum that the device has been either:

- Approved for a national identification program in at least one other country with comparable or more stringent requirements than the performance criteria outlined in these standards (APHIS will review the approval documentation and sales data provided to determine equivalency); or
- Tested in field trials in accordance with the protocol outlined in Appendix 1. The device must also meet the criteria for conformance and performance listed in Appendix 2. The manufacturer must document how the criteria have been met in the device field test report presented with the application for approval.

APHIS may consider requests for approval of alternative field testing or previously generated data. Alternative field testing must provide verifiable data and demonstrate that the outcome conclusions are at minimum equivalent to the field trial protocols and standards described in this document. Requests will be evaluated on a case by case basis.

Modification of approved devices may require new field trials or laboratory testing depending on the type of modification requested. Manufacturers seeking to modify an approved device should contact ADT staff at traceability@usda.gov.

Figure 1. Initial - Official Identification Device Approval Process



Appendix 1: Field Trial Protocol

Identification devices without approval in another country with comparable or more stringent standards must undergo field trials for 3 years in covered species[3] with the exception of 2.5 years in swine before APHIS will consider fully approving the device. The field trials help ensure the devices are of high quality and meet industry needs while providing traceability; and provide data on the device's physical performance (application, durability, and retention) and transponder performance (if applicable). Field trials must be supervised by an independent third party who knows the management practices for the species used to test the trial device, and who has no conflict of interest with the trial locations or manufacturer. Field trial supervisors must be on site to monitor each assessment and certify results, and ensure that field trials comply with all State, Tribal, and Territory regulations.

While APHIS is committed to only approving identification devices with a proven history of retention and durability, we also want to encourage new identification devices meeting preliminary standards to enter a controlled marketplace until the remaining requirements are met for full approval. Therefore, the field trial protocol provides for preliminary device approval after 12 months to promote the introduction of new devices and technologies into the market. APHIS reserves the right to terminate or extend a field trial with 30 days' written notice if the approved device fails to meet the minimum performance requirements contained in these standards.

Manufacturers must submit the proposed identification device field trial protocol outlined in this Appendix, receive approval of the protocol from APHIS, and enter into a Field Trial Device Manufacturer Agreement with APHIS prior to commencing the field trials. The Field Trial Device Manufacturer Agreement certifies that manufacturers will adhere to the responsibilities regarding the production and distribution of official identification devices for animals to support the implementation of animal disease traceability activities.

APHIS may consider requests to assess field trials currently in progress that do not fully conform to the protocol contained in this document and/or existing field trial data, and approve or disapprove the identification device based on our assessment of the data provided.

Field Trial Timeline

Devices undergoing the approval process must first complete initial field trials, which include successfully meeting all required performance standards. Upon completing the initial field trials, device manufacturers may request preliminary approval status with the ability to sell a limited number of devices to the public. Subsequently, manufacturers with devices assessed for a minimum of 24 months and meeting the required performance standards in the preliminary status period may request conditional APHIS approval and the ability to sell unlimited devices to the public for the remainder of the required field trial period if they maintain acceptable performance.

[3] Cattle and bison, sheep and goats, captive cervids, equine and swine per 9 CFR Part 86. While swine are covered under the traceability regulation the field trial timeline is limited to 2.5 years to account for the shorter production life in relation to the other species.

Table 6 below outlines the process devices must undergo during the 3-year approval process.

Table 6. Field Trial Timeline		
Timeline	**Approval Status**	**Number of Devices Approved for Sale as Official Identification**
0-12 months	Trial	NONE
12-24 months (limited sales)	Preliminary	500,000
24-36 months (unlimited sales)	Conditional	Unlimited
Full approval upon successful completion of 36-month field trial (30-month for swine)		

Manufacturers must ensure that all field trial devices are assessed at application and at 6, 12, 18, 24, 30, and 36 months (the 36 month assessment is not applicable in swine). Devices must meet the minimum performance standards at each assessment to advance in the field trial. APHIS encourages manufacturers to conduct performance assessments beyond 36 months (30 months in swine) and report results to APHIS.

Trial devices will be evaluated in a variety of livestock management systems and environmental settings for the appropriate species; e.g., beef/dairy/wool, confinement/grazing, hot/cold climate. Field trials must be practical and incorporate trial device assessment into normal management practices.

Field trial locations must represent the variety of livestock management systems and environmental settings found in the United States. Select at least six locations that represent both hot and cold climates in the United States (e.g., Arizona and Wisconsin). At least two trial locations will be in hot climates and at least two in cold climates. If a location needs to be excused from the field trial, APHIS will consider the inclusion of additional locations at the manufacturer's request.

The manufacturer must evaluate trial devices in each species for which device approval is requested according to Table 7 below. Select field trial production settings and number of animals per location to ensure sufficient animals remain available to assess device performance over the field trial period.

Table 7. Field Trial Requirements by Species		
Species	**Minimum Total Number of devices/animals (minimum per trial location)**	**Management Settings**
Cattle and Bison	1500 (250)	At least one commercial dairy
Sheep and Goats	300 (150 sheep and 150 goats) (50) at least 50 sheep and 50 goats must be < 8 weeks of age at device application. Breeding replacement lambs/kids and 1-2 year old breeding animals are the preferred animals for the trial. 150 sheep and 150 goats and 50 sheep and 50 goats < 8 weeks of age at device application will need to complete the trial so additional animals will be required at the outset.	At least one commercial goat dairy, one commercial meat goat herd and one commercial sheep flock. In addition, devices must be assessed in settings with 4" woven wire fence, regular use of feed bunks or hay bunks for at least 3 months of the year, and moderate to high levels of brush a minimum of 50 goats and 50 sheep in each of these environments, same animal may be exposed to more than one of these conditions.
Captive Cervids	600 white-tailed deer and elk (65% white-tailed deer and 35% elk distribution if possible) (40)	Properties representative of typical production settings
Swine	1,000 sows and boars (250)	Assess devices in the following settings: Outdoor in low-density pens (pasture), outdoor in high-density pens (concrete feeding floor), and indoor in confined pens (groups of 25+).
Equine	200 equids (horses, mules, and donkeys) (20)	Properties representative of typical production settings
Llamas and Alpacas	Field trials in sheep, goats or captive cervids suffice for testing of devices to be approved for use on llamas, and alpacas	
Manufacturers requesting approval of identification devices for species not listed above should contact traceability@usda.gov		

Manufacturers must submit an initial device application form (VS Form 1-64) to initiate the approval process (see Appendix 3)[4]. Once APHIS initially approves the application and device, the manufacturer needs to enter into an APHIS Field Trial Identification Device Manufacturer Agreement certifying that it will adhere to the responsibilities regarding the production and distribution of official identification devices for animals to support the implementation of animal disease traceability activities during the field trial period. APHIS will assign the manufacturer a product code for use in AIMS when the manufacturer produces the devices for field trials and for any devices produced during the field trial period. APHIS will provide a permanent product code once it fully approves a device.

APHIS will authorize devices applied to animals included in the field trials and those marketed during the approval period as official identification for the life of the animal. These devices must

[4] For sheep and goats also provide manufacturers agreement.

meet the performance and quality control standards detailed in Appendix 2. AIN devices must be encoded and/or imprinted using the 840 numbers allocated to the manufacturer through AIMS.

To distinguish devices used in field trials from fully approved official identification devices, all devices produced for use in field trials must be imprinted with "US Trial" on the portion of the tag containing the wording "Unlawful to Remove" and be green in color (R:120 G:180 B:50) with black print.

Devices marketed during the approval period must be imprinted with "US Trial" as described for field trial devices, but may be manufactured using colors determined by the manufacturer. However, devices imprinted with the "US Trial" may not be applied for the purpose of identifying animals for disease control programs; i.e., brucellosis testing and vaccination.

The maximum number of devices that may be produced for field trials is 5000 per device application.

All devices to be used in the trials must be produced before the trials start and manufacturers must submit the identification numbers to APHIS in an Excel spreadsheet. In the case of non-840 tags or in the case of companies that are not currently approved device manufacturers the company must use numbers assigned by APHIS to avoid duplicating existing official ID numbers.

Application and Assessment of Trial Devices

Manufacturers must notify APHIS at least 5 working days before applying the devices to animals in the trial and each scheduled performance assessment during which devices will be read. An APHIS representative may be present for application and performance assessment and if present shall be given access to monitor the process.

Individuals applying trial devices shall apply them according to the manufacturer instructions using the recommended applicator. Each animal to which a trial device is applied must also be tagged with a secondary device for use as a reference if a trial device is lost. The secondary device can be either an approved official identification device, or a premises unique identification device or tattoo present prior to or applied at the same time as the trial device, but must remain in the animal for the duration of the field trial. Tattoos may be used as reference identification but are not required in the case of field trials for injectable transponders in equine.

Trial devices may be applied in either ear; however, all trial devices shall be applied in the same ear for all animals at a field trial location. For injectable transponders in equine, trial devices shall be placed in the nuchal ligament on the left side of the neck.

When applying electronic identification devices for the field trials all devices will be electronically read after application to ensure they are functioning. Any electronic identification device not functioning immediately following application will be documented as failed during application. For all trial devices difficulty or failure of proper application of devices must also be documented (e.g. device breakage, failure of the locking mechanism, excessive application force needed to penetrate ear, etc.) Failed ear tags shall be removed and a new device can then be applied to the animal. For injectable transponders a new device may be implanted in the same or a replacement animal.

For electronic identification devices, conduct at least one assessment using a stationary reader (excluding injectable transponders) and one assessment using a handheld reader at each trial location. All readers used in the field trials must be commercially available in the United States.

Each device included in the field trial will be evaluated for device retention, durability, and readability (electronic and visual) at each assessment. APHIS calculates retention rates based on all remaining animals presented for assessment. If animals are removed from the trial (sold or died), read their devices on exiting the trial and report them at the next scheduled assessment. Approved trial devices may not be removed once applied, as they are official identification.

After initial device application and each assessment, manufacturers must submit their results and high-resolution photographs of at least 10 trial devices that have been applied to animals in the trial clearly demonstrating the information imprinted on the device. The manufacturer must provide USDA with representative samples of recovered trial devices that did not remain attached to the animal throughout the field trial.

Reporting Field Trial Assessment Results

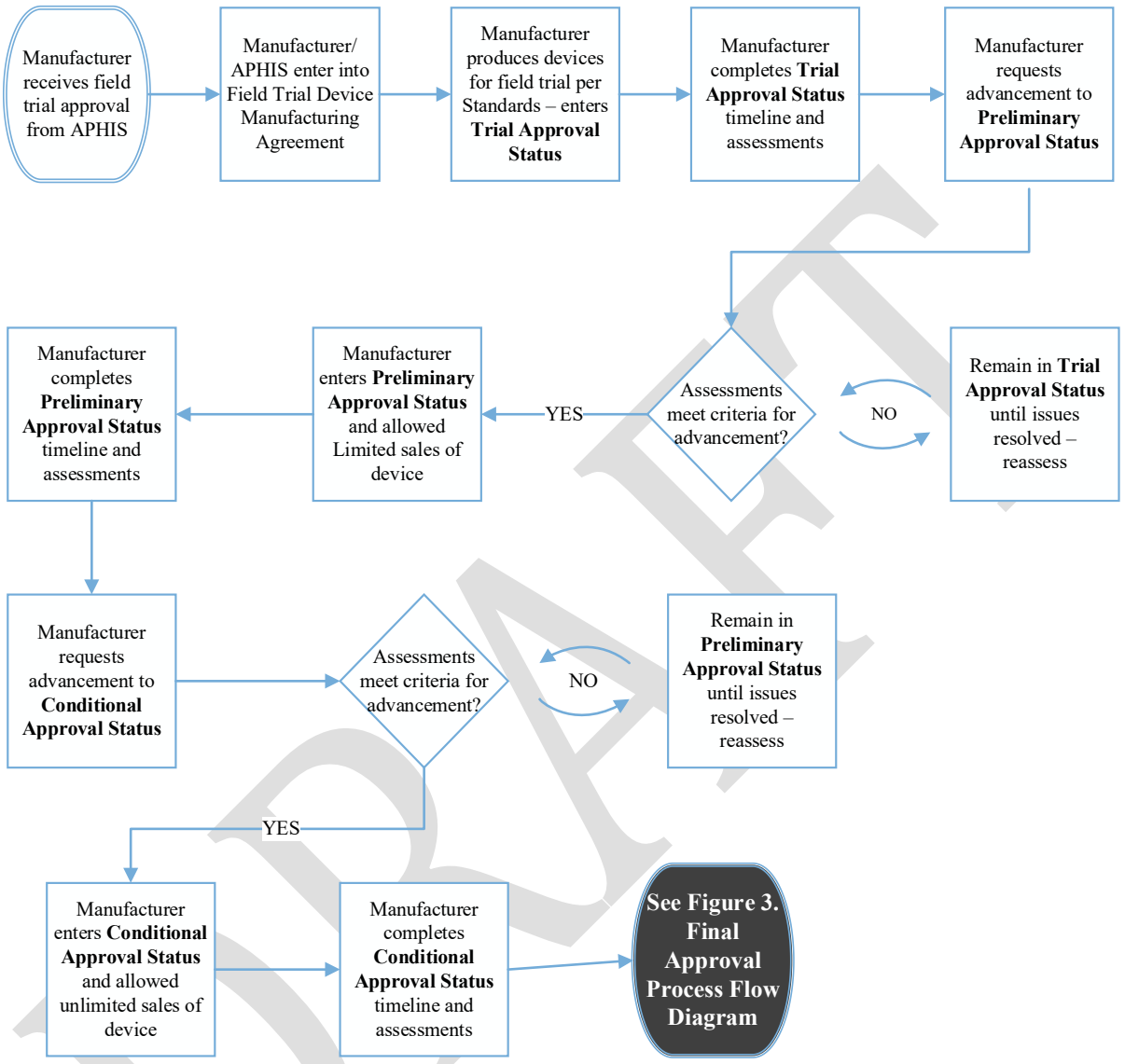
The manufacturer will ensure APHIS receives results within 10 days of each assessment. Include an electronic file in Excel (.xlsx) format detailing the:

- Device name and product code.
- Date, location, and production type of the facility where the assessment was conducted.
- Identification numbers of the trial devices initially applied and the corresponding reference tags (all trial devices initially applied must be accounted for at each assessment).
- Age, sex, species and breed of animals associated with each trial device.
- Identification numbers and total number of trial devices that:
  - Fail to be successfully applied.
  - Read at each assessment.
  - Are not retained (device loss determined using remaining reference device).
  - Demonstrate visible damage affecting legibility.
  - Experience transponder failure (RFID only).
  - The imprinted identification number does not match the encoded AIN (RFID only).
  - Experienced transponder migration or breakage.
- RFID reader used (if applicable).
- Disposition of animals not presented at each assessment, including reason not presented.

Manufacturers must maintain all assessment results throughout the field trial and submit a final summary report of all assessment results and final VS Form 1-64 to APHIS at traceability@usda.gov at the end of the field trial period to be considered for full approval of the trial device. Include a brief description of the field trial locations, design, and any deviations from the protocol in the final summary report.

APHIS will share performance, conformance and field trial data for trial devices with other countries upon request.

Figure 2. Field Trial Process for Official Identification Device Approval



APHIS Review for Approval

APHIS will notify the applicant in writing of the approval review outcome within 4 weeks of receiving the completed application and field trial summary report. APHIS reserves the right to assess field trial results, including those that do not fully conform to this protocol, and approve or disapprove trial devices based on our assessment of the data provided.

Once APHIS fully approves a device, the manufacturer needs to enter into an APHIS Approved Official Identification Device Manufacturer Agreement recertifying that it will adhere to the responsibilities regarding the production and distribution of official identification devices for animals to support the implementation of animal disease traceability activities.

APHIS may withdraw approval of any device that fails to meet the performance criteria specified

in this Standard at any time with 30 days' written notice[5]. Upon termination of approval, the manufacturer will provide APHIS copies of all records regarding the production and distribution of the approved identification device. APHIS will direct the disposition of any formerly approved identification devices marked with the U.S. shield in the possession of the manufacturer and resellers on the date of termination.

[5] 60 days written notice to withdraw approval for sheep and goat devices. Revocation of approval of a sheep or goat device may be appealed by following the procedures in Scrapie Program Standards Volume 1: National Scrapie Eradication Program.

Appendix 2: Animal Identification Device Performance and Quality Controls

Printing Standards and Description for All Official Ear Tags

Official Ear Tag Shield and "UNLAWFUL TO REMOVE":

- For producers, market operators, and animal health officials to recognize ear tags as "Official," the official ear tag shield must be visible on the animal after it is tagged.
    - For PIN ear tags for slaughter swine: The official ear tag shield must be a minimum of 33 percent larger than the PIN print size (see Printing Standards and Description for Swine PIN tags, below). The shield must be at least 0.33 inches (8 mm) high and wide.
    - For all other ear tags: The official ear tag shield must be must be visibly imprinted on the surface of the tag at a minimum height of 5 mm (0.2 inches) and must be visibly imprinted on both parts of a two-part tag, and on the back portion of the tag (outside the ear) for a one-piece tag.
    - For a copy of the official shield please contact traceability@usda.gov.
- To emphasize the need to maintain this identification for the life of the animal, the text, "UNLAWFUL TO REMOVE" must be clearly visible on the tag. The text must be imprinted:
    - For small button tags: On the back piece of the tag (outside of ear).
    - For panel tags: On the back piece (outside of ear), but may also be printed on the front piece (inside of ear). The text must be imprinted on the tag at a minimum height of 3 mm (0.12 inches).
    - For one-piece tags: On the back portion of the tag (outside of the ear).
    - For PIN ear tags for slaughter swine: On the back piece (outside of ear), but may also be imprinted on the front piece (inside of ear).
    - For sheep and goats "UNLAWFUL TO REMOVE is not required on very small tags.

Printing Standards and Description for Plastic AIN and NUES Ear Tags

- For RFID tags the entire official identification number must be imprinted on the portion of the tag containing the transponder encoded with the identical official identification number. Two-piece tags may have the official identification number imprinted on the portion of the tag that does not contain the transponder. When this is the case, the tag set must be packaged in containers or trays so that the two pieces are maintained as a pair until they are applied.
- For visual-only tags the entire official identification number must be imprinted on the portion of the tag inside the animal's ear. The official identification number may also be imprinted on the portion of the tag on the outside of the animal's ear.
- All official identification numbers must be imprinted at a minimum height of 5 mm (0.2 inches) and easily readable with 20/20 vision at a distance of 30 inches (0.75 m). An exception may be made for small RFID ear tags that do not allow the imprinting of the official identification number at 5 mm but are clearly read at the required distance. For AIN tags a space must be inserted after each third digit of the AIN imprinted on the AIN tag (e.g., 840 003 123 456 789.
- The font for all characters for required information imprinted on the tag must be Arial.

APHIS must approve any different font.
- An indentation of the manufacturer's unique, copyrighted logo or trademark must be clearly visible on the tag. Having such information permanently imprinted on the tag is also acceptable.
- APHIS may approve printing of other information if it does not compromise the readability of the required information. Manufacturers should include requests for additional print specifications with their applications.
- AIN tags that contain RFID technology must have the 2D Data Matrix that conforms with the ECC200 Data Matrix protocol imprinted on the portion of the tag that contains the transponder unless APHIS waives this requirement at the manufacturer's request. The data matrix is to be imprinted on the device in a square approximately 5mm x 5mm and should be a two-dimensional representation of the official animal number imprinted on the tag. Readability (percent of data matrix read) on new tags being shipped from the manufacturing plant must be at 100 percent when read with a camera-based image reader (bar code reader).

Printing Standards and Description for Swine PIN Ear Tags

The portion of the ear tag most visible to animal handlers and used as the primary identifier of the animal **must**:

- Be at least 2 square inches in size.
- Bear the entire 7-digit PIN of the premises.
- Bear the official ear tag shield.
- Bear the PIN and corresponding bar code on the reverse side (APHIS prefers Code 128 symbology).

The portion of the ear tag most visible to animal handlers and used as the primary identifier of the animal **may**:

- Include a management number. If a management number is applied by the manufacturer or at the premises, the PIN and management number must be imprinted on separate lines.
- Include a management number in the bar code if the first seven alphanumeric characters of the bar code correspond to the PIN.

All characters must be imprinted on the tag in Arial font. APHIS must approve any different font. Ear tag print size must be a minimum height of 0.25 inches (6 mm) for PIN numbers and letters.

An indentation of the manufacturer's unique, copyrighted logo or trademark must be easily observed on the tag. Having such information permanently imprinted on the tag is also acceptable if the print is on the back of the visual portion of the tag. APHIS may authorize printing of other information if it does not compromise the readability of required information.

Performance of the Visual Components

Visual-only identification devices must have ICAR Conformance and Performance Certification in accordance with Procedure 4 of Section 10 of ICAR Guidelines – Testing of Conventional Plastic Ear Tags. The manufacturer must document that the device submitted for approval meets or exceeds the following criteria:

- **One-time use - tamper evident:** The device contains a tamper-evident locking mechanism designed for one-time use, and cannot be removed from one animal and reapplied to another animal without evidence that this action has occurred.
- **Tag coupling/tensile strength:** Evaluation standards must conform to ICAR testing standards and, at a minimum, with ISO standards 37 and 527.
- **Unalterable printing:** The imprinting on the tag may not be readily altered.
- **Readability:** The imprinted device must be easily and reliably readable with 20/20 vision. The printing and color contrast of the official ear tag shield, lettering, and numbers are to be easily and reliably readable at a distance of 30 inches (0.75 m). Submission of sample tags suffices for documentation of readability.
- **Tag loss rates:** When ear tags are applied in a manner approved by the manufacturer, on average the maximum tag loss rates per species may not exceed the values listed in Table 8 below:

Table 8. Device Retention by Species

Species	Maximum Device Loss Rates
Cattle and Bison	No more than 1 percent annually or 3 percent in a 3-year period
Sheep and Goats	No more than 2.7 percent annually or 8 percent in a 3-year period
Captive Cervids	No more than 2 percent annually or 6 percent in a 3-year period
Swine	No more than 5 percent annually when applied just prior to entering and no more than 1 percent while swine are in slaughter channels, or no more than 12.5 percent when applied prior to entering and 2.5 percent while swine are in slaughter channels in a 2.5 year period respectively

- **Expected tag life:** The tag is expected to remain on the animal in a physically functional state for the animal's expected lifetime.[6]
- **Tag toxicity and animal injury:** In accordance with Appendix B5 of Section 10 part 1.2.2 of the ICAR Guidelines – Laboratory Test for Conventional Plastic Ear Tags, tags may do no harm to an animal or affect its health or well-being. Tags may not cause chemical contamination of meat or edible offal or damage the hide.
- **Tag deterioration:** There may be no diffusion of colorant from tags in accordance with Appendix B5 of Section 10 part 3.2 of the ICAR Guidelines – Laboratory Test for Conventional Plastic Ear Tags. There may be no apparent physical deterioration (other than color) due to detrimental effects by UV light, rain, heat (113°F/45°C) and cold (-22°F/-30°C) or other environmental influences such as chemicals, mud, urine, or manure for at least 5 years of wear.
- **Tag plasticity:** Tags may not split or crack under normal use.
- **Tag abrasion resistance:** Tags shall not exhibit damage or change due to wear, and at a minimum, shall comply with ISO standard 9352.

[6] 15 years for cattle, bison, sheep, goats and captive cervids, 3 years for swine and 25 years for equine.

RFID Transponder Performance

RFID Ear Tag Performance

The manufacturer must document that the RFID ear tag submitted for approval meets or exceeds the following criteria:

- **Low Frequency devices:**
  - Transponders must conform to ISO 11784 and ISO 11785 and must have ICAR Conformance and Performance Certification in accordance with Procedure 5 of Section 10 of ICAR Guidelines – Testing of External RFID Devices.
- **Ultra High Frequency devices must comply with:**
  - ISO 18000-6C (EPC Gen 2) and the USDA Interim Tag Data Standard available on the ADT website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/traceability.
  - Ear tags must have ICAR device composition and environmental performance testing in accordance with Appendix B4 of Section 10 of the ICAR Guidelines – Preliminary Test of Conventional Plastic Ear Tags and Appendix B5 of Section 10 of the ICAR Guidelines – Laboratory Test of Conventional Plastic Ear Tags.
  - ISO UHF conformance and performance standards once approved. All UHF identification devices will be required to be fully certified by the governing registration authority for UHF devices.
- **Electronic Read Rates and Ranges:**
  - Low frequency devices: Transponders must be reliably machine read at a rate of 95 percent without regard to orientation by a compatible reader commercially available in the United States, as cattle (or other species) move by in a single file passage at 4 mph (1.8 meters/second).
  - Ultra-high frequency devices: Transponders must be reliably machine read at a rate of 95 percent without regard to orientation by a compatible reader commercially available in the United States at the read distance designated by the device manufacturer.
- **Expected transponder life:** The transponder within the tag shall be reliable and machine-readable for the animal's expected lifetime[6] with a failure rate of less than 0.2 percent annually and no more than 0.5 percent in 3 years.
- **Transponder security:** The unique official identification number encoded within each transponder must be one-time programmable and must be identical to the number imprinted on the device.

RFID Injectable Transponder Performance

All transponders must have ICAR Conformance Certification and performance testing according to Procedure 1 of Section 10 of the ICAR Guidelines – Conformance of Transponders with ISO Standards. The manufacturer must document that the injectable transponder submitted for approval meets or exceeds the following criteria:

- **Read range:** The transponder must have a minimum read range of 4 inches with a handheld transceiver (reader).

- **Anti-migration:** The transponder must be constructed to prevent migration after implantation. No more than 1 percent of transponders may exhibit migration annually and no more than 3 percent in 3 years.
- **Expected transponder life:** The transponder shall be reliable and machine-readable for the animal's expected lifetime[6] with a failure rate of less than 0.2 percent annually and no more than 0.5 percent in 3 years.
- **Transponder security:** The unique official identification number encoded within each transponder must be one-time programmable.
- **Breakage:** The transponder must not break under normal animal husbandry conditions. No more than 1 percent breakage may occur annually and no more than 3 percent in 3 years.
- **Harmless to the animal:** The implant, when injected and maintained as an implanted device, must not harm the animal.

Quality control

The manufacturer must have documented quality control measures in place to ensure the ability to produce the device consistently according to specification including, a full quality control plan and flow diagram for the identification device from manufacturing of all components, through encoding and/or imprinting, shipment and addressing consumer complaints. Procedures must ensure the uniqueness of the AIN or NUES is maintained, that only AINs allocated to the manufacturer are encoded in devices, and that processes to ensure distribution records of 840 AIN devices are reported to AIMS. If more than one company is involved with the manufacturing of device components a full quality control plan is required for each entity.

Appendix 3. Application Packet for Submission

Manufacturers applying for device approval must mail one hard copy of the VS Form 1-64 application and supporting materials to:

USDA APHIS Veterinary Services
c/o Animal Traceability Staff
4700 River Road, Unit 200
Riverdale, MD 20737

On the date they submit the hard copy application, manufacturers must also email a Portable Document Format (PDF) version of the VS Form 1-64 and a high-quality digital photograph of the device in JPG format to traceability@usda.gov including a photo of each number format and color for which approval is requested if applicable. The device photo will be used in the listing of devices on the ADT website. (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/traceability). This email alerts ADT staff that the manufacturer's application packet has been shipped.

Supporting Materials

Initial application and supporting materials:

- Submit documentation demonstrating approval in another country with comparable or more stringent standards, and sales data OR proposed field trial protocol.

- Ear tags:
  - Include in the submission packet at least 20 samples of the trial device submitted for approval (marked with "US Trial" on the portion of the tag containing the wording "Unlawful to Remove" and green in color (R:120 G:180 B:50) with black print). In addition, include at least 20 samples of the trial device in a color and package intended for retail sale for APHIS review of print specifications and encoding validation for RFID (if applicable). Imprint/encode devices with the following numbers (examples shown):
    - AIN RFID tags: 840003123456770 – 840003123456789
    - NUES RFID tags: 60ABC0001 – 60ABC0020
    - PIN tags: Premises Number: ABC1234; State abbreviation: IA
    - For sheep and goat tags the numbering systems for which approval is being requested:
      - Serial metal (NUES): STAA0001 – STAA0020
      - Serial plastic (NUES): STA10001 – STA10020
      - Slaughter only serial (NUES): STAA0001 – STAA0020 must be medium blue tag and include "Slaughter Only" or for small tags "MEAT"
      - Flock ID: ST1234567 123456 to ST1234567 123476
      - AIN RFID tags: 840003123456770 – 840003123456789
      - NUES RFID tags: STAA0001 – STAA0020
      - AIN RFID tags with Flock ID: ST1234567 and 840003123456770 – 840003123456789
  - If the device application is for a two-piece tag or a pair set, provide at least five tag sets in one container or package in the numerical sequence being used to reflect how the male tag and female tag will be distributed as a matched pair. For

one or two-piece visual only tags provide at least five tags in the packaging they will be provided in. Packaging must maintain the tags in sequential order.
- Provide three applicators used to apply the device submitted for approval. If the applicator functions with other devices for which the company is applying for AIN tag authorization, list those tags by product name (additional taggers will not be required for those tags).

- RFID injectable transponder:
  - Provide at least 10 samples of the injectable transponder submitted for approval in the package intended for retail sale encoded with the following AIN range: 840003123456770 – 840003123456779 (these numbers have been designated for use in sample AIN devices.) The sample retail package must include individually packaged sterile transponder with injection device and instructions for compliant use of the injectable transponders.
  - The instructions provided in the retail package must include:
    - The manufacturer's recommendation for sterile handling and administration of the injectable transponder.
    - Any VS program guidelines/requirements for the species involved.
    - The FDA guidelines/requirements regarding the use of injectable transponders in food animals in the packaging of all AIN injectable transponder shipments. Recommendations regarding the disclosure of the injectable transponder at the time of harvest or rendering and the recommendations for removal at the time of harvest must be in bold print on the enclosed product packaging directions insert.
    - When the device is intended for use in food animals, the manufacturer must include a copy of the U.S. Food and Drug Administration (FDA) approval letter for use of the specific injectable transponder in the food animal species addressed in the manufacturer's application.

<u>Modification of an existing approved official identification device:</u>

- Submit detailed information regarding both the original official identification device or component and the proposed modification including complete specifications (composition, diagrams, schematics, etc.). For ear tags, explain any impacts the proposed modification would have on the use of existing recommended tag applicator(s). Include field trial data or device approval and sales data of the modified device or component from other countries as applicable.
- Provide 10 sample devices that incorporate the proposed modification and 10 devices representing the existing approved device. If the modification requires a new applicator, submit three new applicators with the sample devices.

<u>Final application and supporting materials:</u>

- Submit the field trial summary report, including all assessment results and a brief description of the field trial locations, design, and any deviations from the protocol.
- Submit 20 sample devices in the format and package intended for retail sale. For sheep and goat ear tags, if multiple colors and print formats will be offered provide one sample of each color and print format. For AIN devices, encode and/or imprint the sample official identification devices with numbers allocated to the manufacturer

in AIMS. Manufacturers or their device manager must record shipment of the 20 devices to NPN 0034P2K in AIMS.

Direct questions regarding the application process to traceability@usda.gov.