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0579-0327
EXP.: XX/XX/XXXX

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

MANUFACTURER APPLICATION FOR OFFICIAL IDENTIFICATION DEVICES

Electronic Identification Devices

Please ensure that you complete a current version of the application. Contact the individual listed on page 8 if you received this application more than three months ago and have not yet completed or submitted the form.

See the Animal Disease Traceability (ADT) Website at <http://www.aphis.usda.gov/traceability/> for more information on ADT and official eartags at: http://www.aphis.usda.gov/traceability/downloads/ADT_eartags_criteria.pdf.

Date submitted by applicant:

This form is used for the following device types:

Radio Frequency Identification (RFID) Device:

Low Frequency

Device Type:

Eartag

Injectable Transponder

Ultra-High Frequency Eartag

Numbering Format:

Animal Identification Number (AIN)

National Uniform Eartagging System (NUES)

Dual (combined low and ultra-high) Frequency Eartag (AIN only)

For technologies other than RFID: Please contact ADT Program Staff at traceability@aphis.usda.gov

I. Contact Information

The manufacturer, for the purpose of Animal Identification Number (AIN) manufacturer applications, is the entity that completes the preparation of the device. In the case of injectable transponders, the manufacturer is the entity that would encode the transponder with the AIN.

A. Business Information

Company Name	Contact Person Name
Address	Contact Person Email
City, State ZIP	Primary Phone: Secondary Phone: Fax (if applicable):
Company Website (URL)	Nonproducer Participant Number (NPN): (Required) (Issued through ADT program)

B. Manufacturing Plant Information *(if different from above)*

Company Name	Contact Person Name
Address	Contact Person Email
City, State ZIP	Phone:
	Country (if other than US)

C. Information Technology (IT) Contact Information

(Designated person for USDA to contact regarding system issues)

IT Contact Person Name	Phone
IT Contact Person Email	FAX

II. Device Description

Technology Type

Select or list the technology and/or method being used as supplemental identification to the device applied for.

Radio Frequency Identification (RFID)

Low Frequency Devices (eartags): 134.2 kHz

<input type="checkbox"/> ISO 11784 (required)	<input type="checkbox"/> ISO 11785 (required)
3 digit ICAR Manufacturer Number	Transponder Read Type <input type="checkbox"/> HDX <input type="checkbox"/> FDX
ICAR Product Code (6 digits)	Activation Frequency

Ultra High Frequency* Devices: 902- 928 MHz range

*Please note that all UHF devices approved will receive conditional approval until an ISO standard has been developed for UHF. Once an international standard exists, any device submitted for approval as an official identification device using UHF technology will need to meet the standard, and be fully certified by the governing registration authority for UHF devices, to be considered for approval.

<input type="checkbox"/> ISO 18000-6C (EPC Gen 2) (required)	<input type="checkbox"/> USDA Interim Tag Data Standard (required) <i>(Request report of the interim standard if needed)</i>
Other applicable standards:	Activation Frequency

Injectable Transponder: ISO 11784/85 (required, unless other ISO or US based technology standards are applicable)

Manufacturer Number assigned by ICAR	Transponder Read Type <input type="checkbox"/> HDX <input type="checkbox"/> FDX
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ICAR Product Code (for device being applied for)	Activation Frequency
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Manufacturing

<p>What is the company's role regarding the device being applied for?</p> <p><input type="checkbox"/> Complete manufacturing and imprinting/encoding</p> <p><input type="checkbox"/> Imprinting/encoding only</p> <p>For transponders: If you encode the transponder only, who supplies the injectable transponder to your company:</p>	<p>Do you plan to be an AIN device/tag manager (AIN managers distribute the devices to producers, animal owners, etc.)</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
Manufacturer Product Name (Name used by Applicant)	Manufacturer Product Code Number (Number used by Applicant)
What is the bi-weekly production capacity for this device?	What is the anticipated inventory for this device?

Species

USDA reserves the right to approve methods of identification specific to each species.

<p>Species for which the device is recommended by the applicant:</p> <p><input type="checkbox"/> Bison¹ <input type="checkbox"/> Cattle¹ <input type="checkbox"/> Deer/Elk <input type="checkbox"/> Horses <input type="checkbox"/> Sheep/Goats² <input type="checkbox"/> Pigs <input type="checkbox"/> Alpaca/Llama</p> <p>Note: The use of injectable transponders in food animals is subject to FDA and FSIS regulations.</p> <p>¹ Injectable transponders are not an approved official identification method for bison and cattle.</p> <p>² Official eartags used for Sheep and Goats are approved through the Scrapie eradication program. Contact Diane.L.Sutton@aphis.usda.gov for directions on how to have the tags approved for sheep and goats.</p>
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Physical Description and Characteristics of Electronic Devices


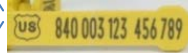
For RFID eartags please complete the section below. For RFID transponders please complete section?

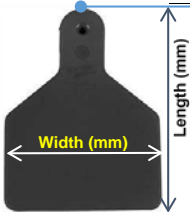
A. Physical Description and Characteristics of RFID Eartags:

✓ Plastic (2-piece tag) For RFID tags, the component that encases the transponder (or the component the transponder adheres to) is referred to as "tag piece A" and the tag component without the transponder is referred to as "tag piece B."		
Tag Piece A		
Shape <input type="checkbox"/> Strip <input type="checkbox"/> Panel (flap tag) <input type="checkbox"/> Round (button) <input type="checkbox"/> Oval	Square, rectangular, oval tags: Length (mm): Width (mm): Round tags: Diameter (mm):	
Tag Piece B		
Shape <input type="checkbox"/> Strip <input type="checkbox"/> Panel (flap tag) <input type="checkbox"/> Round (button) <input type="checkbox"/> Oval	Square, rectangular, oval tags: Length (mm): Width (mm): Round tags: Diameter (mm):	
Stem	Length (cm)	Newton value at which the stem breaks

Tag Dimensions

Be sure to list the weight and size using the units noted



Materials:

List the primary materials used to manufacture the device.

[Click here to enter explanation](#)

III. RFID Eartag Performance

Past Performance:

The manufacturer must document that they have successfully produced and marketed the identification device being applied for (or other very similar devices) with favorable results. Such documentation may include information on devices that have been approved for National identification programs in other countries and/or volumes of the device sold over the past three years. At a minimum, the device must have been approved in one other country or have been marketed for three years with a sales minimum of 10,000 for year one, 25,000 for year two and 100,000 for year three. Devices without this level of past performance data must complete Section IV. Field Test for Performance Documentation.

Official Identification for other Countries

Please list the National Identification Programs of other countries in which this tag is currently an approved tag.

Country	Date Approved	Average Tag Sold per Year	Point of Contact (Name)

Volume of Tag Sales

Please list sales history for the tag being applied for, or a very similar tag, for last three years in a least one country.

Country	Tag Name	Tags Sold	Tags Sold	Tags Sold
		YR 1:	YR 2:	YR 3:

Our records and the above information documents that the applied for tag meets or exceeds the past performance criteria.

IV. RFID Eartag Field Test for Performance Documentation

Tags without well-established past performance statistics described above must provide field test data covering a minimum of 18 months conducted in six locations with 100 animals at each that reflect both hot and cold temperatures in the United States (e.g., Arizona and Wisconsin). At least two locations must be located in the hot and cold climates.

The criteria for tag loss rates, tag deterioration and tag plasticity listed in following section must be have been met and is to be well documented in the field test report for the tag represented on this application.

I acknowledge that the applied for tag does not meet the part performance criteria and have included the results of this field testing.

V. RFID Eartag Performance and Quality Controls

Performance of the Visual Components

Clearly explain how the device being applied for meets or exceeds the following criteria. Either enter the response in the text box below (the box will automatically expand) or submit on a separate attachment. When appropriate, include other reference documentation (charts, summaries, etc.) with the application and note such explanations.

- **One Time Use - Tamper evident:** Tamper evident locking mechanism

Explain how the tag is constructed and designed for one-time use (tamper evident). Be sure to clearly explain how the tag cannot be removed from one animal and reapplied to another animal without evidence that this action has occurred.

[Click here to enter explanation](#)

- **Unalterable printing:** The printing on the tag may not be readily altered. The transponder must have a minimum read range of 4 inches with a handheld transceiver (reader).

[Click here to enter explanation](#)

- **Readability:** The AIN or NUES must be easily and reliably readable with 20/20 vision. The printing and color contrast of the official eartag shield, lettering, and numbers are to be easily and reliably readable at a distance of 30 inches (0.75 m). (No explanation necessary. Submit sample tags as explained below.)

[Click here to enter explanation](#)

- **Tag loss rates:** On average, when applied in a manner approved by the manufacturer, no more than 1 percent of tags applied may be lost in the year following application or in any year thereafter under normal field conditions over the expected life of the tag. Provide information that documents retention.

[Click here to enter explanation](#)

- **Expected tag life:** The minimum time that a tag shall be expected to remain on an animal in a functional state (physically) is for the expected life of the animal.

[Click here to enter explanation](#)

- **Tag toxicity and animal injury:** 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.

[Click here to enter explanation](#)

- **Tag deterioration:** There may be no diffusion of colorant from tags. There may be no apparent physical deterioration (other than color) due to detrimental effects by UV light, rain, heat (45°C) and cold (-30°C) or other environmental influences such as chemicals, mud, urine, or manure for at least 5 years of wear.

[Click here to enter explanation](#)

- **Tag plasticity:** Devices may not split or crack under normal use.

[Click here to enter explanation](#)

- **Tag coupling/tensile strength:** Tag coupling/tensile strength: Evaluation standards must conform to ICAR testing standards and, at minimum, should comply with ISO standards 37 and 527.

[Click here to enter explanation](#)

- **Tag abrasion resistance:** Tag abrasion resistance: Tags shall not exhibit damage or change due to wear, may be subjected to ICAR testing standards and, at minimum, should comply with ISO standard 9352.

[Click here to enter explanation](#)

Quality Control

Explain your control measures and ability to produce the tag consistently according to the specifications. Include procedures that will ensure the uniqueness of the AIN or NUES is maintained and processes to ensure distribution records of AIN 840s are reported to AIMS. If applicable, enclose your company's quality control plan.

[Click here to enter explanation](#)

RFID Eartag Performance

For all RFID technology, please provide a written explanation in the blocks below or on a separate attachment describing how the device meets each of the following characteristic as described in Table 3 of Appendix 1.

- **Electronic Read Rates and Ranges**

Laboratory (Optional)

The applicant may provide information provided by an independent third party, documenting that the device meets or exceeds the requirements of the laboratory test as described in Table 1 in the Appendix. A minimum of 25 tags is required for this evaluation. Be sure that the test is fully documented and include the contact person of the third party that conducted the test.

[Click here to enter explanation](#)

Field Environment

The applicant must provide information provided by an independent third party, documenting that the device meets or exceeds the field environment test as described in Table 3 in the Appendix. A minimum of 300 observations using at least 100 RFID tags is required. Be sure that the test is fully documented and include the contact person of the third party that conducted the test.

[Click here to enter explanation](#)

- **Expected Tag Life:** The minimum time that a tag shall be expected to remain functional (electronically) is for the expected life of the animal.

[Click here to enter explanation](#)

- **Transponder Security:** The official number encoded within each transponder must not be able to be altered and must be contained within the tag.

[Click here to enter explanation](#)

- **Transponder Failure Rates:** The transponder within the tag shall be reliable and machine-readable for the expected lifetime of the animal.

[Click here to enter explanation](#)

II. RFID Injectable Transponder Description

A. Physical Description and Characteristics of Injectable Transponder

<input type="checkbox"/> Glass Encapsulated		
<input type="checkbox"/> Other than Glass Encapsulated <i>Please describe:</i>		
Weight (grams)	Length (mm)	Diameter (mm)

III. RFID Injectable Transponder Performance

Past Performance

The manufacturer must document that they have successfully produced and marketed the identification device being applied for (or other very similar devices) with favorable results. Such documentation may include information on devices that have been approved for National identification programs in other countries and/or volumes of the device sold over the past three years. At a minimum, the device must have been approved in one other country or have been marketed for three years with a sales minimum of 10,000 for year one, 25,000 for year two and 100,000 for year three. Devices without this level of past performance data must complete Section IV. Field Test for Performance Documentation.

Official Identification for other Countries

Please list the National Identification Programs of other countries in which this transponder is currently an approved device.

Country	Date Approved	Average Tag Sold per Year	Point of Contact (Name)

Volume of Transponder Sales

Please list sales history for the transponder being applied for, or a very similar transponder, for last three years in a least one country.

Country	Tag Name	<u>Tags Sold</u>	<u>Tags Sold</u>	<u>Tags Sold</u>
		YR 1:	YR 2:	YR 3:

Our records and the above information documents that the applied for tag meets or exceeds the past performance criteria.

A. Performance

Clearly explain how the device being applied for meets or exceeds the following criteria (either enter the response in the text box below or submit on a separate attachment). When appropriate, include other reference documentation (charts, summaries, etc.) with the application and note such explanations.

- **Read Range:** The transponder must have a minimum read range of 4 inches with a handheld transceiver (reader).
- **Anti-migration:** The transponder shall be constructed to prevent migration after implantation.
- **Transponder security:** The AIN encoded within each transponder shall not be alterable (changed to represent a different AIN than what was initially encoded in the transponder).
- **Expected transponder life:** The minimum time that a transponder shall be expected to remain functional (electronically) is for the expected life of the animal. (20 years for horses)
- **Transponder failure rates:** The transponder shall be reliable and machine-readable for the expected lifetime of the animal with a failure rate of less than 1% per annum.
- **Breakage:** The transponder, under normal animal husbandry conditions, shall not break.
- **Harmless to the animal:** The implant, when injected and maintained as an implanted device, shall not cause harm to the animal.

B. Quality Control

Explain your quality control measures and ability to produce the transponder consistently according to the specifications. Include procedures that will ensure the uniqueness of the AIN is maintained. If applicable, enclose your company's quality control plan.

VII. Application Packet for Submission

■ Application and supporting documents

- Ship one hard copy set of the entire application and supporting materials to the address listed below.

- On the date the hard copy application is submitted, email a Portable Document Format (PDF) version of the entire hard copy set to the email addresses listed below. This email provides an alert to ADT staff that your application packet has been shipped.
- Photograph of tag: Submit a close up view of a sample tag (similar picture) as a digital photo in JPG format with the email containing of the application. If the tag is approved, the photo will be used in official eartags. (See: <http://www.aphis.usda.gov/traceability/devices.shtml>).



to the adjacent the pdf version the listing of

■ Samples and Packaging:

A. RFID Eartags

- Provide in the submission packet at least 20 samples of the applied for tag imprinted as defined in Table 2 of the Appendix with the following numbers used for test:
 - AIN tags: 840003123456770 - 840003123456789
 - NUES tags: 60ABC0001 – 60ABC0020
- If the tag application is for a 2-piece tag, provide at least 5 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.
- **Tag applicators**
 - Provide three applicators used to apply the tag being applied for. Indicate if the tagger functions with other devices that your company is applying for AIN tag authorization. List those tags by your product name. (You will not be required to forward additional taggers for those tags.)

B. RFID Injectable Transponder

- Provide at least 10 samples of the applied for transponder in the planned package for distribution (individual sterile packaging with transponder and injection device) encoded the following AIN range: 840003123456770 - 840003123456779 (these *numbers have been designated for use in sample AIN devices.*)
- Manufacturer's recommendation for sterile handling and administration of Injectable transponder with the application.
- When the device is being applied for use in food animals the manufacturer's recommendations regarding FSIS and FDA guidelines/requirements for removal at harvest or rendering in accordance with above (Section IV, footnote 1).
- **Copy of FDA and FSIS Approval Letters:** Applications for USDA APHIS approval for use of injectable transponders as official identification devices using the 840 numbering standard must include a copy of the FDA approval letter for use of the specific injectable transponder for the food animal species to which the application is being submitted. Based upon the January 17, 1996 FDA Center for Veterinary Medicine Update, concurrence from USDA FSIS must also be obtained and a copy of the FSIS approval letter must also be submitted as a matter of record with this application.
- **Acknowledgement of FSIS and FDA Policies and Guidelines**
 - By submission of this application for injectable transponders in animals for official identification by USDA APHIS, applicants are fully informed and aware that all requirements of FDA and USDA FSIS are separate and distinct from those regarding use of official identification by USDA APHIS. USDA APHIS approval does not substitute for, convey or confer any assurances or assumptions that FDA and FSIS approvals have been made or maintained with regard to use of injectable transponders in animals designated within this application. Any violations of FDA and FSIS guidelines, requirements, or policy subsequent to USDA APHIS approval are strictly a matter involving the applicant, FDA and/or FSIS, and the offending individual/entity.

X _____
Signature of Applicant

Date: _____

Submit Original Application (hard copy), Samples and Applicators to:

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

Email PDF Application and Digital Photo to:

(Please send the email on the date the application packet is shipped.)

traceability@aphis.usda.gov

Direct Questions To:

Email: traceability@aphis.usda.gov

Phone: Daisy M. Witherspoon: 301-851-3496

Appendix 1

Table 1. RFID Eartag Performance Requirements and Description

Performance Requirements	
One-time use – Tamper evident	The tag must be designed for one-time use (tamper evident), making it impossible to remove and reapply the tag without visual evidence of tampering
Unalterable	The printing on the tag may not be readily altered.
Readability	The AIN must be easily and reliably readable with 20/20 vision. The printing and color contrast of official eartag shield, lettering, and numbers are to be easily and reliably readable at a distance of 30 inches (0.75 m). The percent of data matrix read on new tags being shipped from the manufacturing plant must be at 100% when read with a camera based image reader (barcode reader).
Tag loss rates	On average, when applied in a manner approved by the manufacturer, not more than 1 percent of tags applied may be lost in the year following application or in any year thereafter under normal field conditions over the expected life of the tag.
Expected tag life	The minimum time that a tag shall be expected to remain on an animal in a functional state (physically) is for the expected life of the animal.
Tag toxicity and animal injury	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. There may be no apparent physical deterioration (other than color) due to detrimental effects by UV light, rain, heat (45C) and cold (-30C) or other environmental influences such as chemicals, mud, urine, or manure for at least 5 years of wear.
Tag plasticity	Devices may not split or crack under normal use.

Tag coupling/tensile strength	Tag coupling/tensile strength: Evaluation standards must conform to ICAR testing standards and, at minimum, should comply with ISO standards 37 and 527.
Tag abrasion resistance	Tag abrasion resistance: Tags shall not exhibit damage or change due to wear, may be subjected to ICAR testing standards and, at minimum, should comply with ISO standard 9352.

Table 2. — RFID Eartags – Printing Standards and Description for Eartags

Printing Description
<ul style="list-style-type: none"> • The tag must have the official eartag shield imprinted on its surface¹ imprinted at a minimum height of 5 mm (0.2 inches). • The tag must bear the entire official animal number and imprinted at a minimum height of 5 mm (0.2 inches). For AIN tags a space must be inserted between each 3rd 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 or, if different, approved by APHIS. • The text “UNLAWFUL TO REMOVE” must be imprinted on the tag.² and must be a minimum height of 3 mm (0.12 inches).² • All NUES and AIN characters that are part of the official number format must be 5mm (3/16 of an inch) high and easily readable with 20/20 vision at a distance of 30 inches (0.75 m). <p>Note: Exception may be made for small size tags, in particular RFID tags, that do not allow the printing of the official identification number at 5mm but are clearly read at the required distance</p> <ul style="list-style-type: none"> • 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. • Printing of other information may be authorized if it does not compromise the readability of the required information. • Visual only tags must be imprinted with a 2D Data Matrix that conforms with the ECC200 Data Matrix protocol. The data matrix is to be printed on the device in a square approximately 5mm x 5mm and should be a two dimensional representation of the official animal number printed on the tag. The data matrix must be imprinted on any part of the tag containing official animal identification number. Readability (percent of data matrix read) on new tags being shipped from the manufacturing plant must be at 100% when read with a camera based image reader (barcode reader). • AIN tags that contain RFID technology must have the 2D Data Matrix described above imprinted on the tag piece that contains the official animal number unless waived by USDA.

¹ The above printing standards are for visual identification, and the visual eartag is the animal's official identifier. Radio frequency identification technology (RFID) may be incorporated in the visual tag when the above printing criteria is met. Such technology is considered supplemental identification. Tags with RFID technology must have all 15 digits of the AIN printed on the portion of the tag that contains the transponder which is coded with the identical 15 digit AIN. Imprinting the AIN on the portion of the tag that does not contain the transponder is optional, but when this is the case, the tag set is packaged in containers or trays so that the two pieces are maintained as a pair until they are applied.

² In order for producers, market operators, and animal health officials, etc., to recognize eartags as "Official", it is essential that the official eartag shield be visible on the animal after it is tagged. Similarly, in order to emphasize the need to maintain this identification for the life of the animal, it is necessary to have the text, "UNLAWFUL TO REMOVE" clearly visible. Therefore, the official eartag shield must be printed on both parts of a two part tag, and the text, "UNLAWFUL TO REMOVE" must be printed on the portion of the eartag that is most visible following application.

For small button tags, the "UNLAWFUL TO REMOVE" text must be printed on the back piece of the tag (outside of ear). For panel tags, the text must be printed on the back piece (outside of ear), but may also be printed on the front piece (inside of ear).

Table 3 — Radio Frequency Technical Standards

RFID Low Frequency Devices	All transponders must have ICAR Full Certification.
Ultra High Frequency Devices	Devices must comply with: ISO 18000-6C (EPC Gen 2) and USDA Interim Tag Data Standard Once ISO UHF Standards are approved, all UHF identification devices must be fully certified by the governing registration authority for UHF devices.
Electronic Read Rates and Ranges	In a laboratory with a neutral electromagnetic environment: Transponders must have a 100 percent read rate in best orientation at 24 inches (60 cm) in a stationary test and a moving test of 1 m/sec over a passage length of at least 20 inches (50 cm). Note: This test information is optional. <u>Low frequency tags:</u> In a field test environment: Transponders must be reliably machine read at a rate of 95 percent without regard to orientation by a standardized dual HDX/FDX reader, as cattle (or other species) move by in a single file passage at 4 mph (1m/sec). <u>High frequency tags:</u> In a field test environment: Transponders must be reliably machine read at a rate of 95 percent without regard to orientation by a compatible reader at the read distance designated by the applicant.
Expected tag life	The minimum time that a tag shall be expected to remain functional (electronically) is for the expected life of the animal.
Transponder security	The official number encoded within each transponder must not be able to be altered and must be contained within the tag. Tags will be tamper-evident and impossible to unseal without visible evidence of tampering.
Transponder failure rates	The transponder within the tag shall be reliable and machine-readable for the expected lifetime of the animal.

Table 4 — AIN/RF Implants Performance Criteria and Characteristics

Read Range	The transponder must have a minimum read range of 4 inches with a handheld transceiver (reader). <i>Note: USDA APHIS will use an inventoried transceiver that reads ISO compliant transponders to test the read distance. Applicants submitting non-ISO transponders must also provide a reader with their application.</i>
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Anti-migration	The transponder shall be constructed to prevent migration after implantation.
Transponder security	The AIN encoded within each transponder shall not be alterable (changed to represent a different AIN than what was initially encoded in the transponder).
Expected transponder life	The minimum time that a transponder shall be expected to remain functional (electronically) is for the expected life of the animal. (20 years for horses)
Transponder failure rates	The transponder shall be reliable and machine-readable for the expected lifetime of the animal with a failure rate of less than 1% per annum.
Breakage	The transponder, under normal animal husbandry conditions, shall not break.
Harmless to the animal	The implant, when injected and maintained as an implanted device, shall not cause harm to the animal.