NAIT

NAIT GUIDELINES
ANIMAL IDENTIFICATION DEVICE APPROVAL

OSPRI

1. INTRODUCTION

ABOUT THESE GUIDELINES

1.1. These guidelines provide guidance on obtaining approval for an animal identification device to be used within the National Animal Identification and Tracing (NAIT) scheme. They provide information to help device manufacturers and distributors achieve the mandatory requirements for animal identification devices specified in the NAIT Standard: Animal Identification Devices (2019) (the Device Standard).

1.2. The guidelines should be read in association with the Device Standard.

THE NAIT SCHEME

1.3. The NAIT scheme is the mandatory system used to identify and trace livestock in New Zealand. The scheme requires all cattle and deer to be identified with an approved permanent NAIT device within 180 days of their birth or before they are moved between properties, whichever occurs first.

1.4. The NAIT organisation is the organisation designated to implement the NAIT scheme under the National Animal Identification and Tracing Act 2012 (the NAIT Act).

SCOPE

1.5. These guidelines apply to any person or organisation manufacturing, selling or preparing for sale identification devices for cattle and deer for use under the NAIT scheme.

1.6. While the guidelines relate primarily to radio frequency identification devices (RFID), they also acknowledge the potential for alternative technologies to be used in NAIT devices.

2. PRELIMINARY INFORMATION REQUIRED

2.1. Any person or organisation (applicant) applying for approval of a device for the first time, must provide the following information. Note that if an applicant already has approved NAIT devices, this preliminary information is not required.

2.2. The preliminary information required is:

- proof that the applicant is a New Zealand legal entity – either a natural person (i.e. permanent resident or citizen) or an organisation (registered New Zealand company)
- an overview of the applicant's business and services – this should include information about the full range of devices the applicant manufactures or supplies, and any other countries where the applicant supplies identification devices and for what purposes.

3. APPLYING FOR APPROVAL OF A DEVICE

APPLICATION TO BE MADE ON THE CORRECT FORM

3.1. Applicants must complete and submit the 'NAIT device approval application' form (the application form).

3.2. The application form can be found in the appendix to these guidelines. It is also available from the NAIT website and NAIT organisation, on request.

3.3. The application form must be accompanied by the mandatory and supplementary information, and product samples detailed in sections 3.7 to 3.10 of these guidelines.

REQUIREMENT FOR INTERNATIONAL CERTIFICATION

3.4. Any device submitted for approval under the NAIT scheme must already have been tested by and obtained certification from the International Committee on Animal Recording (ICAR). Certification will show that the device conforms with NZS/ISO 11784 and NZS/ISO 11785.

3.5. The device must be registered by ICAR with an approved product code.

3.6. The device manufacturer must have an ICAR manufacturer code. Where ICAR has issued a shared manufacturer code, the number range allocated to the device manufacturer must be documented in the application form.

INFORMATION TO BE PROVIDED WITH THE APPLICATION

3.7. Applicants must provide the following information with their completed application form. The information must demonstrate that their device conforms with the Device Standard.

- Information about how the device is manufactured and distributed, including:
    - the location of all sites where the device is manufactured – where a device is manufactured at a number of different sites, the location of each site must be provided individually
    - an overview of the manufacturing process for the device
    - any quality standards or certification held for manufacturing or distribution
    - an outline of the relationship between the manufacturer and the New Zealand distributor (where applicable).
- Full technical drawings and measurements for the device, including:
    - the device's dimensions and weight
    - a description and diagrams of all discrete components of the device.
- ICAR documentation relating to:
    - certification of the device
    - registration of the manufacturer.
- The results of any NZS/ISO 11784 and NZS/ISO 11785 conformance and performance tests. Tests must have been conducted in accordance with ISO 24631-1 and ISO 24631-3, and the test category should be noted.
- Laboratory test results relating to the device's physical performance, (e.g. compliance with PAS 44 [2014]), including:
    - artificial ageing (ISO 4892-2)
    - free fall (IEC 60068-2-32)
    - cold (IEC 60068-2-1)
    - dry heat (IEC 60068-2-2)
    - damp heat (ISO 4611)
    - resistance to tampering
    - tensile strength
    - acid/alkaline containment
    - visual readability
    - electronic readability (ISO 24631-1 and ISO 24631-3)
    - differential scanning calorimetry (DSC) analysis (ISO 11357)
    - spectral photometric measuring (ISO 7724)
    - any other temperature performance tests
    - any other abrasion tests.

- Laboratory test results relating to the presence of harmful substances in the device, such as cadmium, lead, mercury and chromium. If chromium is detected, an additional analysis for carcinogenic hexavalent chromium needs to be done.
- The completed 'Self-Assessment – Conformance with Device Standard' section of the application form.
- The results and methodology for any previous field trails carried out for the device, whether in New Zealand or overseas, including details of:
    - the number of devices tested
    - the time period covered by the tests
    - results for tag retention and electronic readability.
- Details of the auditable process that the applicant, or if different, the manufacturer, uses to minimise the possibility of errors in the production of the device, in particular in relation to:
    - printing the visual identification code on the device
    - linking the visual identification code to the device number.
- Any certification or accreditation relating to the device or its manufacture obtained in other countries.

SAMPLES TO BE PROVIDED WITH THE APPLICATION

3.8. Applicants must provide 10 samples of the device with the application form.
3.9. The sample devices must not be printed with a NAIT logo. Instead, they should be printed with wording or numbering to demonstrate that both male and female portions of the device can be printed on effectively using laser printing.
3.10. Applicants must also provide a sample of the device applicator tool and the device manufacturer's associated instructions for using the tool.

4. THE ASSESSMENT PROCESS

4.1. The NAIT organisation follows a two-stage process to assess whether a device submitted for approval is suitable for use as part of the NAIT scheme.
4.2. The NAIT organisation reserves the right to set and charge the applicant a fee for either or both stages of the assessment.

FIRST STAGE: ASSESSMENT OF THE SUBMITTED INFORMATION AND DEVICE

4.3. During the first stage, the NAIT organisation will assess the application form, the accompanying documentation and the submitted device to determine whether, in the first instance, the device is likely to comply with the required physical and performance requirements detailed in the Device Standard and the NAIT Act.
4.4. Following completion of the first stage of the assessment, the NAIT organisation will provide the applicant with a report specifying whether or not the submitted device has met the required standards.
4.5. If a device hasn't met the standards, the NAIT organisation will advise the applicant in what respect it has failed.

SECOND STAGE: FIELD TRIAL

4.6. The second stage of the assessment process involves a 3-year field trial of the device's performance.
4.7. The applicant can either engage a third party to conduct the field trial or manage the trial themselves. In either instance, the trial must comply fully with the Device Standard and these guidelines.
4.8. The NAIT organisation will liaise with the applicant to determine the scope and means of conducting the trial.
4.9. The applicant must provide the NAIT organisation with a detailed protocol for how the field trial is to be conducted, and the NAIT organisation must approve the protocol in writing, before the field trial can begin. Protocols must detail the key measures of success that will apply.
4.10. The following requirements will apply to all field trials.

- Animals must be spread over a minimum of three farms, located in three geographically and climatically different areas of New Zealand.
- The trial must be conducted for at least 200 animals in each location.
- At least 1,200 tagged animals must remain in the full trial at the end of the 3-year period.
- Animals must be tagged with the device within 180 days of birth, and while tagged must adhere to all other requirements of the NAIT scheme, as set out in the NAIT Act and its regulations and standards.
- The trial must be conducted on typical New Zealand properties, under normal field conditions for each herd type. (Trials may be conducted in equivalent conditions in other countries, provided these locations are pre-approved by the NAIT organisation.)
- Applicants may apply for acceptance of results from field trials performed in other countries as long as these trials were conducted in equivalent conditions. Acceptance of results from international field trials is limited to a third of the number of tags that are to be trialled in New Zealand (i.e. reducing the number of tags to remain in the full trial in NZ from 1200 to 800).

4.11. The results of field trails must be reported to the NAIT organisation after 6, 12, 24 and 36 months, and should note the results for retention and readability of trialled devices.

4.12. Devices that are identical to other trialled devices, other than the markings printed on the female portion of the device, do not need to undergo separate field-trials. Other minor variations in devices may be accepted at the discretion of the NAIT organisation.

4.13. The NAIT organisation reserves the right to audit any field trial that an applicant conducts for their device, and to observe the animals and farm sites involved in these trials at any time.

4.14. Applicants may apply to the NAIT organisation to have existing performance data for their submitted device considered in lieu of, or in addition to, the results from a field trial. The NAIT organisation may accept such data at its discretion.

4.15. The NAIT organisation reserves the right to consider the results of field trials that do not meet the specifications in this guideline as part of the assessment process.

5. LEVELS OF APPROVAL

5.1. There are three levels of approval for use of NAIT devices as part of the NAIT scheme: trial, provisional and full approval.

5.2. The approval level that a device has reached, and the uses it may be put to, will depend what point the field trails for the device have reached, and what the results show.

TRIAL APPROVAL

5.3. Trial approval enables the applicant to conduct field trials for their device, for the purpose of attaining provisional and then full approval.

5.4. Trial approval is subject to ongoing compliance with the Device Standard and these guidelines.

PROVISIONAL APPROVAL

5.5. Once the applicant has demonstrated that its device has complied with the performance requirements in the Device Standard for 1 year, the device may attain provisional approval.

5.6. An applicant may attain provisional approval for a device in one of two ways.

- The applicant has conducted 1 year of field trials in New Zealand and has provided trial reports to the NAIT organisation every 6 months. The field trail results show that the device is continuing to meet the specified retention and readability performance requirements. The applicant is responsible for analysing and reporting on these results in a way that demonstrates compliance with the Device Standard.
- The applicant has conducted at least 1 year of successful field trials in another country that has similar geographic and climatic conditions to New Zealand and has provided the data from these trials to the NAIT organisation. The

applicant is responsible for analysing and reporting on these results in a way that demonstrates compliance with the Device Standard. At its discretion, the NAIT organisation may require the applicant to provide:

- letters of endorsement or verification of accreditation or approval from the regulator or authority responsible for the animal identification and traceability scheme in the country where the trials are being conducted
- contact information for the organisations involved in the field trial to enable the NAIT organisation to confirm the trial's protocol, monitoring process and observed results.

5.7. Provisional approval will entitle the applicant to sell up to 500,000 devices each year. This limit may be extended to permit up to 750,000 devices to be sold each year (or a greater volume upon application to the NAIT Organisation for cases where there is a demonstrated benefit to the industry), if the device continues to meet the performance requirements over the first 24 months of the field trial. These limits will continue to apply until the field trails have been completed and full approval of the device attained.

FULL APPROVAL

5.8. The NAIT organisation may grant full approval for a device where, upon completion of the 3-year field trial, it has demonstrated its continuing ability to comply with the performance requirements in the Device Standard.

5.9. Full approval entitles the applicant to sell the device without any restrictions imposed.

5.10. The NAIT organisation may, at its discretion, require the field trial to be extended or the applicant to submit additional data or documentation, if it has any doubts that the performance requirements in the Device Standard have been demonstrated.

SUSPENSION AND REVOCATION OF APPROVAL

5.11. Any level of approval is subject to the ongoing compliance of the device, and of the individuals licensed to distribute and manufacture it, with the NAIT Act, and its regulations and standards.

5.12. The NAIT organisation may suspend or revoke its approval for a device where this ongoing compliance is not achieved.

APPENDIX: NAIT ANIMAL IDENTIFICATION DEVICE APPROVAL APPLICATION FORM

ORGANISATION DETAILS	
Organisation name	
Application details	☐ This organisation is applying for approval of an RFID for the first time. ☐ This organisation already has an approved RFID with NAIT (complete organisation name and other details if they have changed, then skip to RFID details).
Physical address	
Postal address	
Phone number	
Email address	
Website	
Regular business operating days	☐ Mon ☐ Tues ☐ Wed ☐ Thu ☐ Fri ☐ Sat ☐ Sun ☐ Public holidays
RADIO FREQUENCY IDENTIFICATION DEVICE DETAILS	
This application is for	☐ New device ☐ Change to existing approved NAIT device (please advise which component is being changed)
Tag type	☐ Button ☐ Other (please describe)
Transponder type	☐ HDX ☐ FDX
Seeking approval for use on	☐ Cattle ☐ Deer
MANUFACTURER DETAILS	
Manufacturer of transponder used in the device	
Manufacturer of remainder of device	
Manufacturing sites	Provide details separately of: • Sites where the device is manufactured • Overview of manufacturing process • Quality standards held for manufacturing and distribution • Relationship between the manufacturer and NZ distributor (if applicable)
Printing on tag is completed by	
Description of device	Provide details separately of: • Plastics used • RFID ID / supplier information

Technical drawings	Provide separately technical drawings and measurements (dimension and weight). Provide a description and diagrams of all discrete components of the RFID device.
ICAR approval letters	Provide copies: • ICAR number • Compliance with ISO 11784 and ISO 11785

Additional information	• Laboratory test results (e.g. compliance with PAS 44, 2014)
	  ○ Resistance to tampering
	  ○ Tensile strength
	  ○ Acid/alkaline
	  ○ Temperature performance of EID
	  ○ Abrasion test
	  ○ Copies of laboratory certificates
	• Any previous field test results
	  ○ Tag retention
	  ○ Electronic readability
	  ○ Details to cover time period of observations and numbers or devices tested
	• Certifications for the device in other regions

SELF-ASSESSMENT – CONFORMANCE WITH DEVICE STANDARD		
Required physical standards (cattle)		
Requirement	**Criteria met?**	**Comments**
3.1 The NAIT device must be in the form of a NAIT approved ear tag.	☐ Yes ☐ No	
3.2 The female electronic portion of NAIT devices for cattle, housing the transponder must be white.	☐ Yes ☐ No	
3.3 The centre of the female electronic portion, not housing the transponder, may be black, white or yellow.	☐ Yes ☐ No	
3.7 The male portion of NAIT devices for cattle must be white and in the form of a button type tag.	☐ Yes ☐ No	
Required physical standards (deer)		
Requirement	**Criteria met?**	**Comments**
3.1 The NAIT device must be in the form of a NAIT approved ear tag.	☐ Yes ☐ No	
3.2 The female portion of NAIT devices for deer must be orange.	☐ Yes ☐ No	
3.3 The male portion of NAIT devices for deer may be any colour other than white.	☐ Yes ☐ No	
Required physical standards (cattle and deer)		
Requirement	**Criteria met?**	**Comments**
3.8 The NAIT device shall contain a half-duplex (HDX) transponder or full duplex (FDX) transponder.	☐ Yes ☐ No	
3.9 The transponder shall be low frequency.	☐ Yes ☐ No	

3.10 The transponder must comply with NZ/ISO 11784:2001 and 11785:2001.	☐ Yes ☐ No	
3.11 The unique number encoded within each transponder must be non-reprogrammable.	☐ Yes ☐ No	
3.12 Devices must be encoded with the relevant manufacturer's code and have Conformance and Performance certification issued by the International Committee on Animal Recording (ICAR).	☐ Yes ☐ No	
3.13 The NAIT device must not contain recycled components, including transponders. 3.14 The NAIT device must be electronically readable on the female portion of the device.	☐ Yes ☐ No ☐ Yes ☐ No	
3.15 The NAIT device shall not be capable of causing chemical contamination of meat or edible offal, damage to the hide, or be capable of adversely affecting the health and well-being of cattle or deer following application.	☐ Yes ☐ No	
3.16 It must be possible to apply the NAIT device on animals from birth. Loss rates are to be determined from the time of application of the NAIT device.	☐ Yes ☐ No	
3.17 NAIT devices must be designed to prevent unauthorised removal and reuse and be tamper-evident (tamper-proof).	☐ Yes ☐ No	

SIGNATURE	
Signed for and on behalf of (entity)	
Signature	
Full name	
Position (owner, director, CEO)	
Date	