10.1.2 Test categories

(after C. Device Composition and Environmental Performance test (ICAR))

D. Field Validation of Animal Identification Devices

Field validation of Animal Identification Devices is a voluntary service for national Competent Authorities or other service users, other than manufacturers or their agents. The field validation service is a quality verification service to ensure that devices available in the relevant market(s) remain compliant with the appropriate ISO and ICAR test protocols. Field validation does not lead to certification of the devices. The procedures are described in Section 10.9.

Table 1. Categories for the testing of identification devices.

Test category	Test description
Application	Application *(for any kind or combination of identification devices)*
	Laboratory Test
Conformance ISO 24631-1	Transponder conformance (*granting of manufacturer code*)
Performance ISO 24631-3	Transponder performance
Composition and environmental performance	Extended laboratory test (*for any kind or combination of identification devices*)
Field validation	Reduced test (limited test for RFID devices and preliminary assessment for conventional ear tags)

10.7.4 Definitions

10.7.4.1 Certification code

Replace with 'A'

A certification code is an alpha-numeric code consisting of "~~C~~ ~~(for certified),~~ followed by three numbers. The certification code is used to identify and register an ear tag model that has successfully passed the testing procedure. This code may be embossed on all ICAR certified ear tags for official identification. The placement of the certification code on the ear tag should conform to the relevant jurisdictional requirements in whatever locality the ear tag is sold.

Delete "C" (for certified") and replace with "A".

10.7.5 ICAR testing and certification procedure

10.7.5.1 Phase 1: Manufacturer's application

To submit an ear tag for ICAR testing within the scope of the tests described in this section, the manufacturer must complete an application and email it in PDF format to the Service-ICAR secretariat. The email address of the Service-ICAR secretariat is: manufacturers@icar.org

The application must consist of:

- A letter of application.
- An Application Form (**Annex B1** or **Annex B3**).
- **Annex B1** is the application form for the certification of a new device or re-certification of an already certified device.
- **Annex B3** B2 is the application form for the certification of a device modified during its certification.* ~~A Device Change Notification (Annex B4) must accompany this application along with the initial test report of the reference tag.~~

*Add: "Please refer to section 10.7.5.3.6 for information on the Device Change Notification"

10.7.5.2.1 Manufacturer requirements

At the commencement of the Preliminary assessment the manufacturer must deliver:

1. A sample of ~~120~~ 130 ear tags marked with the reference printing applied using the same technique and style as used (or intended to be used) in the commercially marketed tags. Note: Tags used in this phase are likely to be destroyed during testing
2. ~~An additional 10 male components (pins) used to check reusability of broken and / or unfastened female ear tags.~~
3. Two pairs of tag applicators or equivalent devices supplied for the application of tags to animals.

- *Replace '120' with '130' in point 1.*
- *Delete point 2.*

10.7.5.2.3 Locking mechanism checks

The primary purpose of these tests is to verify that the male to female locking mechanism, once correctly applied using the supplied applicator, cannot be subsequently dismantled in such a way that would allow the tag to be re-used. A locked ear tag should be tamperproof so tampering with the locked tag will render the tag unusable.

'… that would allow the tag or one of the tag parts to be re-used. A locked ear tag should be tamperproof so tampering with the locked tag will render the tag unusable. …'

10.7.5.2.5 Resistance of the locking system

The 80 ear tags of Group 1 will be divided into four groups of 20 tags. These four groups will be subjected to increasing forces to determine the force required to cause breakage or unfastening of the ear tag. The forces will be applied at a speed rate of 500 mm/min. The force applied to cause breakage or unfastening of each ear tag will be recorded. ~~Broken or unfastened tags must not be re-useable.~~

- Group 1: axial test at ambient conditions (21°C ± 2°)
- Group 2: axial test at 55°C ± 2°, the forces will be applied immediately after the tags are removed from the heating or climatic chamber
- Group 3: transverse test at ambient conditions (21°C ± 2°)
- Group 4: transverse test at 55°C ± 2°, the forces will be applied immediately after the tags are removed from the heating or climatic chamber.

Requirements

- Broken or unfastened tags must not be re-useable.
- At ambient conditions, axially tested tags designed to be used in cattle shall not break ~~or unfasten~~ with the application of a force lower than 280 Newton.
- At ambient conditions, axially tested tags designed to be used in sheep and / or goats shall not break ~~or unfasten~~ with the application of a force lower than 200 Newton.
- ~~The number of tags unlocked without breakage or sustaining permanent damage during the transverse test is recorded, and broken or unfastened tags must not be re-useable.~~

Delete sentence in the first paragraph – it´s doubled to the first in "Requirements".
Delete "or unfasten" in bullet points 2 and 3.
Delete last bullet point in "Requirements".

'**Requirements**

- None of the ear tags - neither male nor female part - must be re-usable. Male pin tips must break off and remain within the female caps (locking gap).
- At ambient …'

10.7.5.3.4.1.2.2 Harmful substances

Pigmented plastics may contain critical heavy metals which must be recorded. These metals are: Cadmium (Cd), lead (Pb), mercury (Hg) and chromium (Cr). If chromium is detected, an additional analysis of carcinogenic hexavalent chromium will be done. The following limit values must not be exceeded:

- Cadmium: 100 mg/kg
- Lead: 10 mg/kg
- Mercury: 1 mg/kg
- ~~Chromium: 10 mg/kg~~ (Chromate (Cr VI): < 1 mg/kg)

Delete reference to total chromium.

10.7.5.3.4.3.3 Evaluation of the resistance of the locking system

30 new, untreated ear tags, 30 artificially aged ear tags and 30 ear tags submitted to the damp heat and cold treatment will be subjected to increasing forces to determine the force required to cause breakage or unfastening of the ear tag.

The test is performed at -25°C (± 2°), 21°C (± 2°C) and 55°C (± 2°C) combined with 50% RH (when the temperature is greater than 0°C) with 10 ear tags from the three treatment variations.

The forces will be applied at a rate of 500 mm/min immediately after the tags are removed from the climatic chamber. The force applied to cause breakage or unfastening of each ear tag will be recorded. Broken or unfastened tags must not be re-useable. At 21°C (± 2°C), no breakage ~~or unfastening of an untreated ear tag~~ should occur in:

- tags designed to be used in cattle with the application of a force lower than 280 Newton
- tags designed to be used in sheep and / or goats with the application of a force lower than 200 Newton

Additionally, the distortion occurring in the ear tag at the time of breakage or unfastening will be recorded during the tensile tests as an indicator for any changes in the mechanical properties of the plastic after exposure to the artificial ageing and the damp heat/cold treatments.

Replace 'immediately' with 'within 10 seconds'
Delete half sentence as marked red.

'… will be recorded.

Requirements

- None of the ear tags – neither male nor female part – must be re-usable. Male pin tips must break off and remain within the female caps (locking gap).
- At 21°C (…), no breakage should occur in:
  - …
  - …
- The minimum breaking force applies to devices irrespective of treatments (artificial ageing, damp heat and cold).'

10.7.5.3.6 ICAR conditions for certification of conventional permanent plastic ear tags

1. Upon successful completion of the ICAR test procedures described in this Section 10.7, ICAR will grant a device certificate valid for five years and a certification reference number.
2. This certification is valid only for the specific plastic ear tag type successfully tested and certified by ICAR.
3. A manufacturer cannot utilise the ICAR certification for a plastic ear tag:
   a. Which is not manufactured by them; or
   b. Which does not comply in all respects to the ICAR certification which includes maintaining an identical tag type to the certified tag.
4. Once the ICAR certificate has been granted, the manufacturer will be responsible to:
   a. Keep an accurate and detailed log of all changes to their product and this log must be available to ICAR upon request. This log must include details of in-house performance measurements and Quality Assurance testing showing the product has maintained or enhanced its quality, performance and material composition.

   b. Submit the product for a Device Change Notification (DCN – see Annex B2) when changes are made to the device during its 5-year certification period. The modified device will have a new certification code, while the manufacturer will need to declare if the modified device will replace the existing one or if the two devices are going to co-exist. Every DCN application will be reviewed individually by ICAR and the designated laboratory, and ICAR shall decide if a partial test is applicable, or if the range of the modifications is such that a full test is required.

10.8.4 Definitions

10.8.4.1 Certification code

Replace with **"A"**

A certification code is an alpha-numeric consisting of ~~"C" (for certified)~~, followed by three numbers. The certification code is used to identify and register an RFID device that has successfully completed the testing procedure. This code may be embossed or printed on all ICAR certified RFID devices for official identification. The placement of the certification code should conform to the relevant jurisdictional requirements in whatever the locality the RFID device is sold.

Delete "C" (for certified") and replace with "A".

10.8.5.1 Manufacturer's Application

To submit an external RFID device for ICAR testing within the scope of the tests described in this section, the manufacturer must complete an application and email it in PDF format to the Service-ICAR secretariat. The email address of the Service-ICAR secretariat is: manufacturers@icar.org

The application must consist of:

- A letter of application
- An Application Form (**Annex C1** or **Annex C2**), and
- **Annex C1** form is the application form for the certification of a new device.
- **Annex C2** is the application form for the certification of a device that has been modified during its certification period. ~~A Device Change Notification (**Annex C3**) must accompany this application along with the initial test report of the reference tag.~~

• Add: "Please refer to section 10.8.5.3.7 for information on the Device Change Notification"

10.8.5.2.1 Manufacturer requirements

At the commencement of the Preliminary Assessment the manufacturer must deliver:

1. A sample of ~~120~~ 130 RFID devices programmed with the reference ID codes and the reference printing. The printing must be applied using the same technique and style as used (or intended to be used) in the commercially marketed devices. Note: Devices used in this phase are likely to be destroyed during testing.
2. ~~An additional 10 male components (pins) used to check reusability of broken and / or unfastened female devices.~~
3. Two pairs of device applicators or equivalent devices supplied for the application of devices to animals.

- *Replace '120' with '130' in point 1.*
- *Delete point 2.*

10.8.5.2.2.1.3 Locking mechanism checks

The primary purpose of these tests is to verify that the male to female locking mechanism, once correctly applied using the supplied applicator, cannot be subsequently dismantled in such a way that would allow the tag to be re-used. A locked ear tag should be tamperproof so tampering with the locked tag will render the tag unusable.

'… that would allow the tag or one of the tag parts to be re-used. A locked ear tag should be tamperproof so tampering with the locked tag will render the tag unusable. …'

10.8.5.2.2.1.5.1 Flag Tags

The 80 RFID ear tags of Group 1 will be divided into four sub-groups of 20 tags. Those four sub-groups will be subjected to increasing forces to determine the force required to cause breakage or unfastening of the ear tag. The forces will be applied at a speed rate of 500 mm/min. The force applied to cause breakage or unfastening of each ear tag will be recorded. ~~Broken or unfastened tags must not be re-useable.~~

- Group 1: axial test at ambient conditions 21°C (± 2°).
- Group 2: axial test at 55°C (± 2°); the forces will be applied immediately after the tags are removed from the heating or climatic chamber.
- Group 3: transverse test at ambient conditions 21°C (± 2°).
- Group 4: transverse test at 55 °C (± 2°)..

Requirements

- Broken or unfastened tags must not be re-useable.
- At ambient conditions, axially tested tags designed to be used in cattle shall not break ~~or unfasten~~ with the application of a force lower than 280 Newton.
- At ambient conditions, axially tested tags designed to be used in sheep and / or goats shall not break ~~or unfasten~~ with the application of a force lower than 200 Newton.
- ~~The number of tags unlocked without breakage or sustaining permanent damage during the transverse test is recorded, and broken or unfastened tags must not be re-usable.~~

Delete sentence in the first paragraph – it´s doubled to the first in "Requirements".
Delete "or unfasten" in bullet points 2 and 3.
Delete last bullet point in "Requirements".

'**Requirements**

- None of the ear tags - neither male nor female part - must be re-usable. Male pin tips must break off and remain within the female caps (locking gap).
- At ambient …'

10.8.5.2.2.1.5.2 Ear tags not classified as flag tags

The 40 RFID ear tags of Group 1 will be divided into two sub-groups of 20 tags. Those two sub-groups will be subjected to increasing forces to determine the force required to cause breakage or unfastening of the ear tag. The forces will be applied at a speed rate of 500 mm/min. The force applied to cause breakage or unfastening of each ear tag will be recorded. ~~Broken or unfastened tags must not be re-useable.~~

- Group 1: axial test at ambient conditions 21°C (± 2°).
- Group 2: axial test at 55°C (± 2°); the forces will be applied immediately after the tags are removed from the heating or climatic chamber.

Requirements

- Broken or unfastened tags must not be re-useable.
- At ambient conditions, axially tested tags designed to be used in cattle shall not break ~~or unfasten~~ with the application of a force lower than 280 Newton.
- At ambient conditions, axially tested tags designed to be used in sheep and / or goats shall not break ~~or unfasten~~ with the application of a force lower than 200 Newton.

Delete sentence in the first paragraph – it´s doubled to the first in "Requirements".
Delete "or unfasten" in bullet points 2 and 3.

'**Requirements**

- None of the ear tags - neither male nor female part - must be re-usable. Male pin tips must break off and remain within the female caps (locking gap).
- At ambient …'

10.8.5.3.4.2.2 Harmful substances

Pigmented plastics may contain critical heavy metals which must be recorded. These metals are: Cadmium (Cd), lead (Pb), mercury (Hg) and chromium (Cr). If chromium is detected, an additional analysis of carcinogenic hexavalent chromium will be done. The following limit values must not be exceeded:

- Cadmium: 100 mg/kg
- Lead: 10 mg/kg
- Mercury: 1 mg/kg
- ~~Chromium: 10 mg/kg~~ (Chromate (Cr VI): < 1 mg/kg)

Delete reference to total chromium.

10.8.5.3.5.3 Resistance to tensile loading

This test applies to RFID ear tags only.

This test is done using 30 new ear tags, 30 artificially aged tags and 30 tags submitted to damp heat treatment. The test is performed at -25°C (± 2°), 21°C (± 2°) and 55°C (± 2°) combined with 50% RH (when the temperature is greater than 0°C) with every 10 ear tags from the three treatment variations.

To test the tensile strength of the locking mechanism the ear tag is affixed to a test jig simulating its application and attempts are made to remove the ear tag by subjecting it to increasing forces. The class 1 tensile test machine shall operate at a speed rate of 500 mm/min and be capable of generating loads of up to 1,000 N.

An increasing load will be applied in axial direction. The maximum load and the effect(s) of the tensile force on the appearance and/or efficacy of the ear tags will be recorded. ~~Broken or unfastened tags must not be re useable.~~

Requirements

- At ambient conditions (21°C ± 2°), ear tags designed to be used in cattle shall not break ~~or unfasten~~ with application of a force lower than 280 Newton.
- At ambient conditions (21°C ± 2°), ear tags designed to be used in sheep and / or goats shall not break ~~or unfasten~~ with the application of a force lower than 200 Newton.
- The minimum breaking force applies to devices irrespective of treatments (artificial aging, damp heat, etc.)

'… will be recorded.

Requirements

- None of the ear tags – neither male nor female part – must be re-usable. Male pin tips must break off and remain within the female caps (locking gap).
- At ambient conditions (21°C … '

Delete "or unfasten" within the bullet points 1 and 2.

10.8.5.3.7 ICAR conditions for certification of permanent external RFID devices

1. Upon successful completion of the ICAR test procedures described in this Section 10.8, ICAR will grant a device certificate valid for five years and a certification reference number.
2. The certification is valid only for the specific external RFID device type successfully tested and certified by ICAR.
3. A manufacturer cannot utilise the ICAR certification for an RFID device:
   a. Which is not manufactured by them; or
   b. Which does not comply in all respects to the ICAR certification (but not limited to):
      i. Maintaining identical technology and the manufacturer of the certified tag;
      ii. Maintaining an identical RFID device to the certified tag;
4. Once the ICAR certification has been granted, the manufacturer will be responsible to:
   a. Keep an accurate and detailed log of all changes to their product and this log must be available to ICAR upon request. This log must include details of in-house performance measurements and Quality Assurance testing showing the product has maintained or enhanced its quality, performance and material composition.

b. Submit the product for a Device Change Notification (DCN) when changes are made to the composition and environmental performance characteristics of the device* during its 5-year certification period. The modified device will have a new conventional product code, while the manufacturer will need to declare if the modified device will replace the existing one or if the two devices are going to co-exist. Every DCN application will be reviewed individually by ICAR and the designated laboratory, and ICAR shall decide if a partial test is applicable, or if the range of the modifications is such that a full test is required. *Note: if changes are made to the electronic (RFID) part of the device, a full or limited test will be required, based on the type of changes.*

(New section)

SECTION 10.9 – FIELD VALIDATION OF ANIMAL IDENTIFICATION DEVICES

10.9.1. Introduction

ID device field validation is a voluntary service for national Competent Authorities or other service users, other than manufacturers or their agents. The field validation service is a quality ~~verification~~ service to ensure that devices available in the relevant market(s) remain compliant with the appropriate ISO and ICAR test protocols. Field validation does not lead to certification of the devices.

10.9.2 Steps for the field validation of animal identification devices

- The applicant (Competent Authority or other service user) fills in the application form (Annex ~~B5/C4~~ D1), signs it and sends it to icar@icar.org.
- The sample devices are collected from the local market stock by the applicant – not by the manufacturer.
- After receipt of the samples by the test laboratory, ICAR ~~notifies~~ informs the respective manufacturer about the field validation request.
- Devices are tested against the current ICAR standards and the results compared with original or earlier results for the same devices by a ~~certified~~ laboratory designated by ICAR. The applicant may also request or specify additional field validation test protocols, provided these are defined in other existing ISO or ICAR higher level test protocols.
- The test results are compiled into a confidential report, which is property of the applicant.
- ICAR will not disclose information about which devices are being or have been tested from which countries/markets.

10.9.3 Sampling protocol

- Devices ~~should~~ shall be collected by the service user, organisation or body making the request. It is a basic requirement that the device samples are obtained from the local market stock, with batch ID details given, and not from the manufacturer or his local agent.
- The number of device samples required to be submitted for testing are as follows*:
  - For RFID devices (testing of transponder): 10 transponders
  - For conventional ear tags or external RFID devices (testing of external material): 130 ear tags.
  - Two pairs of tag applicators or equivalent devices supplied for application of tags to animals.

  (* or as differently specified by Service-ICAR)
- After receipt of the samples by the test laboratory but before the test begins, ICAR will ~~notify~~ inform the respective manufacturer about the field validation request and seek confirmation from the manufacturer that the device obtained for field validation from the specific country or market, is indeed a device that the manufacturer recognises as being or having been marketed in that country.

10.9.4 Testing protocol

- The Competent Authority or service user making each request is responsible for the intervals at which they require field validation to be carried out.
- Device(s) will be tested against the current ICAR ~~standards~~ Guidelines and the results compared with original or earlier results for the same device(s) by a ~~certified~~ laboratory designated by ICAR.
- A basic device field validation test will be carried out by using:
  - The Limited Test protocol for the RFID conformance tested devices. (Section 10.2.4 Procedures for verifying the ISO conformance of transponders transponders)
  - The Preliminary Assessment protocol for the material performance of the tested devices. (Section 10.7.5.2 Preliminary assessment)

- Additional Testing: The service user may also request or specify additional field validation test protocols, beyond those specified in the Limited Test protocol or Preliminary Assessment protocol, provided those additional test(s) are defined in other existing ISO or ICAR higher level test protocols. The designated test laboratory will then quote the additional cost(s) in the test plan they submit to Service-ICAR. Service-ICAR will then pass on those additional costs to the service user making the request.

10.9.5 Ownership, publication and reporting of results

- The test results will be compiled into a confidential report, a copy of which will then be transmitted to the service user(s) who signed the application. The service user or applicant then becomes the owner of that report. Service-ICAR will retain a confidential copy of the report for reference and comparison purposes.
- Ownership of the reports:
  - Service user: Owns the field validation test report. Should not access any previous reports or reports owned by other service users.
  - Manufacturer: Owns the original or previous test report(s). Can obtain the field validation test report upon agreement with the service user.
  - Laboratory: Issues the field validation test report. Needs the manufacturer's permission to access any previous reports, if these were not produced by the same laboratory.
- Test results relating to the same device(s), but submitted in requests from different applicants may be compared by Service-ICAR or the designated laboratories acting on its behalf. In cases where the test results reveal differences between samples of the same device(s) between tests from different applicants or service users, the test report will detail those differences and their implications. It will then become the responsibility of the respective Competent Authority who submitted the request(s) to take any initiative they require to resolve or explain those differences with the relevant manufacturer, to the mutual satisfaction of those parties. If the case reveals ~~a misuse of~~ non-compliance with ICAR device certification protocols, then the case must be reported to Service-ICAR. ~~ICAR has an established procedure for the handling of misuse cases.~~

10.9.6 Confidentiality

- Neither ICAR nor Service-ICAR will publish the names of the Competent Authorities and/or service users using their ID device field validation services. Nor share the results of tests requested by independent authorities directly with the relevant device manufacturers unless the authority's permission is asked and given.
- ICAR will not disclose information about which devices are being or have been tested from which countries/markets.
- All test results shall be kept confidential between ICAR and the authority making the request, with the exception of comparisons between tests of the same devices mentioned under 'Ownership, publication and reporting of results'. Specific test results are returned only to the authority making the request(s) and providing the specific samples.