

ICAR Sub-Committee for Animal Identification

Validation of animal identification devices for national Competent Authorities

DRAFT protocol

Concept

ID device validation is a voluntary service for national Competent Authorities or other service users, other than manufacturers or their agents. The 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. Validation does not lead to certification of the devices.

Principles

1. The validation service request should document for ICAR:
 - a. Identity of the requester and contact within the organisation making the request.
 - b. Name of device manufacturer.
 - c. Name and type of product (e.g. bolus, injectable, visual ear tag, RFID ear tag, etc.).
 - d. Species
 - e. Product code (if it exists, as originally granted by ICAR & published on ICAR website).
 - f. Commercial name of the product (as assigned by manufacturer, e.g. in sales catalogue, etc.).
 - g. Country and/or Region this product is being used/obtained.
 - h. The plant(s) or factory(s) in which the product was produced (if known).
 - i. Method of selling to market:
 - i) "Direct" from manufacturer to farmer
 - ii) Via "Local Authority" to farmer
 - iii) Via "Local Dealer" (who is not an appointed representative of the manufacturer)For methods (ii) and (iii) local contacts should obtain the samples of the product(s) to be tested (see 'Sampling Protocols' below).
2. ICAR will maintain a database with the following information:
 - a. Manufacturer
 - b. Product name
 - c. Product type
 - d. Product code
 - e. Country
 - f. Region
 - g. Plant
 - h. Selling method
 - i. Last test
3. Sampling Protocols
 - a. Products should be collected by the service user, organisation or body making the request. It is a basic requirement that the product samples are obtained by the service user from the market and not from the manufacturer.
 - b. The number of product samples required to be submitted for testing can be determined by reference to the appropriate test protocol documents.
 - c. After receipt of the samples but before the test begins, ICAR must notify the respective manufacturer about the validation request and seek confirmation from the manufacturer that the product obtained for validation from the specific country or market, is indeed a product that the manufacturer recognises as being or having been marketed in that country.

- d. Also after receipt of the samples but before the test begins, ICAR must get permission from the manufacturer to allow the contracted test laboratory to access the original test report for this device when last certified by ICAR (if the original test report was not produced by the same laboratory).

4. Testing

- a. The service user or national Competent Authority making each request is responsible for the intervals at which they require validation to be carried out.
- b. Product(s) will be tested against the current ICAR standards and the results compared with original or earlier results for the same product(s) by a certified laboratory designated by ICAR.
- c. Basic Tests: A basic device validation test will be carried out by using the Limited Test protocol for the RFID conformance tested devices and/or the Preliminary Assessment protocol for the material performance of the tested devices.
- d. Additional Testing: The service user may also request or specify additional 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.

5. Ownership, publication and reporting of results

- a. 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.
- b. Ownership of the reports:
 - Service user: Owns the 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 validation test report upon agreement with the service user.
 - Laboratory: Issues the validation test report. Needs the manufacturer's permission to access any previous reports, if these were not produced by the same laboratory.
- c. Test results relating to the same product(s), but submitted in requests from different applicants may be compared by Service-ICAR or its designated laboratories acting on its behalf. In cases where the test results reveal differences between samples of the same product(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 ICAR device certification protocols, then the case must be reported to Service-ICAR. ICAR has an existing established procedure for the handling of misuse cases.

6. Costs

- a. Service-ICAR is the responsible body for the contracting of tests under the various ICAR standards for ID devices. Service-ICAR will bill each device validation test, including the cost of any additional test protocols mentioned above on the principle that the service user pays, based on the laboratory test fee plus any applicable Service-ICAR administrative fee.

7. Confidentiality

- a. Neither ICAR nor Service-ICAR will publish the names of the Competent Authorities and/or service users using their ID device 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.

- b. ICAR will not disclose information about which products are being or have been tested from which countries/markets.
- c. 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 products mentioned under 'Publication and Reporting of Results'. Specific test results are returned only to the authority making the request(s) and providing the specific samples.