Guidelines for Manufacturing, Selling, and Distributing USDA-Approved Official Identification Devices

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Are you a tag manufacturer interested in producing USDAapproved official identification?

Below is an overview of the process for seeking official identification device approval:

Step 1: Review the Official Animal Identification Device Standards (OAIDS) document in its entirety.

Section C of the OAIDS describes the approval process.

See Figure 1 on page 15 of the OAIDS for a simplified flow chart outlining the process.

Step 2: Gather evidence that all the requirements as outlined in the <u>OAIDS</u> are met. This includes results of the International Committee for Animal Recording (ICAR) or equivalent testing of materials for performance and conformance of any visual and electronic components. Note that any identification methods for cattle and bison must be both visually and electronically readable to be considered for approval.

- Pass the required <u>ICAR testing</u> or equivalent testing.
- If the device has already been approved in another country with comparable or more stringent standards, please fully complete the device application (VS Form 1-64), as outlined in the OAIDS Appendix 3 and send the application and all supporting documentation, including a quality control plan, an overview of the approval process completed in the country(ies) in which the device is already approved, and all sales and retention data available, to traceability@usda.gov.
- If you are seeking to conduct field trials, please review the standards for field trials and then contact traceability@usda.gov with a proposed field trial plan.

Step 3: Submit the final application to traceability@usda.gov and send the required device samples and applicators to the USDA office address listed in the OAIDS. Please note that devices intended for use

in sheep and goats require an additional approval process from <u>Sheep and Goat</u> staff for use in the Scrapie Program.

Step 4: If the device is approved for official use, the manufacturer must enter into a Memorandum of Understanding, as known as an AIN Tag Manufacturer Agreement, with USDA APHIS, agreeing to follow the terms and conditions set forth by APHIS regarding tag manufacture, distribution, and recordkeeping (see **Section B** of the OAIDS to ensure that manufacturer is able to meet these requirements).

Step 5: Approved tag manufacturer distributes devices and maintains records in accordance with 9 CFR Part 86 and Section B: Administration of Official Identification Methods and Devices for Animals of the OAIDS.

Are you a tag distributor interested in selling or distributing USDA-approved official identification devices?

Below is an overview of the requirements for any person or entity who distributes official identification devices.

Step 1: Review all requirements outlined in 9 CFR Part 86 and the OAIDS (see Section B: Administration of Official Identification Methods and Devices for Animals). Pay special attention to the following language:

§ 86.3 Recordkeeping requirements.

(a) Any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices must maintain for 5 years a record of the names and addresses of anyone to whom the devices were distributed. Official identification device distribution records must be entered by the person distributing the devices into the Tribal, State, Federal, or other database acceptable to each government entity. Additional guidance on meeting these recordkeeping requirements is found in the OAIDS.

Step 2: Become an AIN Device Manager. Review "How to Become an AIN Device Manager" document and follow the instructions provided in the document.

Have questions or concerns not addressed after reviewing the above?

Please reach out to traceability@usda.gov.