

**AIN DEVICE MANUFACTURER AGREEMENT  
BETWEEN THE  
UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)  
And  
Company Name**

This **Agreement** is made effective on the 29th day of October, 2007 between **United States Department of Agriculture, Animal Health Plant Inspection Service, Veterinary Services**, 4700 River Road, Riverdale MD 20737 hereinafter referred to as "APHIS" and **Company Name and address**, hereinafter referred to as "Manufacturer."

**ARTICLE 1 – PURPOSE**

This Agreement identifies and sets forth the joint and individual responsibilities and procedures of APHIS and the manufacturer regarding the production of official animal identification devices to be used to support the implementation of the National Animal Identification System (NAIS). This agreement is part of an evolving "voluntary" program which is designed to:

1. Safeguard animal health and provide a viable option to producers who want to use identification devices authorized for use in the NAIS.
2. Ensure an accurate record of Animal Identification Number Devices (AIN Devices) distributed to a production premises is achieved to aid in the determination of an animal's origin.
3. Ensure that AIN Device Manufacturers maintain accurate records of all official devices produced and distributed.
4. Minimize the risk of the production of fraudulent AIN Devices.

While participation in the NAIS is voluntary at the Federal level, strict adherence to the terms and conditions of this agreement is required for the Manufacturer to receive and maintain the status of an authorized AIN Device Manufacturer.

**ARTICLE 2 - BACKGROUND**

As part of its ongoing efforts to safeguard U.S. animal health, the USDA initiated the implementation of the NAIS in 2004. The NAIS is a cooperative State-Federal-industry program administered by USDA's APHIS. The main objective is to develop and implement a comprehensive information system which will:

- Support ongoing animal disease monitoring, surveillance, detection, and response capabilities in order to complete current eradication programs;
- Enable State and Federal animal health officials to respond rapidly and effectively to animal health emergencies such as foreign animal disease outbreaks or emerging domestic diseases with significant economic, social, or public health consequences;

Partnerships among all stakeholders are the foundation for achieving this tremendously important and extremely challenging goal. The NAIS is a voluntary program. Producers and other stakeholders can now participate in the program to test the system and offer feedback to help

ensure that practical solutions evolve. The NAIS establishes standards for producers to identify their animals and to report their movements that will support the needs of animal health officials to track animals for the purposes of managing animal diseases. Animal movement information will be maintained by the industry and will provide the traceback and trace forward information for animal health officials while, at the same time, maintaining other information the industry deems necessary for marketing purposes.

#### ***Premises ID/Registration***

Premises registration involves assigning a unique premises identification number, or PIN, to a location where livestock are housed or kept and recording contact information for that location. The goal is to establish a complete record of all locations, or premises, in the United States that manage or hold livestock. This information will allow animal health officials to notify producers quickly when a disease outbreak might impact their area(s) or the species of animals they have.

#### ***Animal Identification***

The second component of NAIS involves assigning each reportable animal or group/lot of reportable animals a unique identification number. The number is assigned at the animal's birthplace and is linked to the premises of origin. This information gives animal health officials a "starting point" for epidemiologic investigations when necessary. Only animals that enter commerce or commingle with animals at other premises (e.g., salesyards; State or national exhibits/shows) would be identified.

#### ***Animal Tracing***

The final component of NAIS involves the work of private and State databases to collect and maintain animal movement records. These records will be securely held in animal tracking databases owned, managed, and controlled by the private sector and the States, for the Federal Government. The data held in these numerous and separately held databases will provide traceback and traceforward information for animal health officials only during an animal disease event.

### ARTICLE 3 - AUTHORITIES

The Animal Health Protection Act (AHPA) authorizes the Secretary of Agriculture to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (7 USC 8308). Sections 10404 - 10406 authorizes the Secretary to prohibit or restrict the importation, entry, exportation, or interstate movement of any animal or other article if the Secretary determines that the prohibition is necessary to prevent the dissemination of any pest or disease of livestock (7 USC 8303 -8305). Section 10416 of the AHPA authorizes the Secretary to promulgate such regulations, and issue such orders, as the Secretary determines necessary to carry out the provisions of the AHPA. Section 10411 authorizes the Secretary to cooperate with other Federal agencies, States or political subdivisions of states, national or local governments of foreign countries, domestic or international organizations or associations, Indian tribes and other persons (7 USC 8310). Additionally, the Secretary is authorized to use cooperative agreements to reflect a relationship with a cooperator to carry out programs to protect the nation's animal and plant resources (7 USC 2279g).

Under these authorities APHIS has implemented cooperative disease control programs and has issued regulations to detect, control and eradicate diseases of livestock. These regulations are found in Title 9 of the Code of Federal Regulations, parts 1 to 199 and in many of the disease control programs there are requirements for the identification, under certain circumstances, of specified animals.

## ARTICLE 4 - MUTUAL RESPONSIBILITIES

The Manufacturer and APHIS mutually agree/understand that the accuracy of recording the AIN to a premises is imperative to the success of the NAIS and agree that every effort will be taken to maintain the accuracy of the AIN distribution system.

## ARTICLE 5 - MANUFACTURER RESPONSIBILITIES

The Manufacturer agrees to:

1. Abide by the terms and conditions set forth in this AIN Device Manufacturer agreement;
2. Complete the AIN Device Manufacturer training program provided by USDA;
3. Imprint the “840” AIN allocated to him/her with the U.S. Shield only on identification devices approved by APHIS;
4. Maintain the uniqueness of the AINs allocated to them;
5. Imprint approved devices according to the specifications listed in the AIN Management System Procedures and Guidelines document (provided on [www.usda.gov/nais](http://www.usda.gov/nais));
6. Report the shipment of all AIN Devices to the AIN Management System according to established protocols prescribed in the NAIS Technical Supplement (provided on [www.usda.gov/nais](http://www.usda.gov/nais)) within 24 hours of shipment;
7. Have an operational computerized system that communicates with the AIN Management System and is compatible with NAIS standards to maintain the necessary information, including a database of the manufacturer product code for all devices that contain an AIN;
8. Furnish official identification devices to AIN Device Managers as prescribed in the AIN Management System Procedures and Guidelines document;
9. Have a means to support the distribution of AIN devices through marketing agreements with AIN Device Managers or being an AIN Device Manager himself/herself;
10. Provide a record (if applicable) to APHIS of all “transitional” AINs produced with leading “USA” and their International Committee on Animal Recording (ICAR) Manufacturer number;
11. Agree to discontinue the printing of any identification numbering system as prescribed by USDA if the numbering system is terminated and phased-out as an official numbering system by USDA;
12. Complete the application for AIN Device Manufacturer and submit to USDA;
13. Maintain a record of inventoried AIN Devices and have such records available to the USDA upon their request; and
14. Enter the names of Nonproducer Participants that he/she wishes to utilize as AIN Managers into the AIN Management System advising them that such designation requires participation in AIN Manager training provided by USDA.

## ARTICLE 6 - APHIS RESPONSIBILITIES

APHIS agrees to:

1. Provide the specifications and requirements for the production of “authorized” identification devices;
2. Designate the manufacturer’s identification devices that meet the performance requirements and technology standards as “USDA Approval Pending” which authorizes their use in the voluntary phase of NAIS;
3. Provide access to and training and support for the use of the AIN Management System;
4. Provide the communication protocols for submitting distribution records of the AIN to the AIN Management System; and
5. Provide AINs to the manufacturer for the production of authorized AIN Devices.

## ARTICLE 7 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this AGREEMENT does not constitute a financial obligation on the part of APHIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this agreement. Transfers of funds or items of value are not authorized under this agreement.

## ARTICLE 8 - LIMITATIONS OF COMMITMENT

This agreement and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this AGREEMENT shall be expended in accordance with its terms and the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

## ARTICLE 9 - CONGRESSIONAL RESTRICTION

Under 41 U.S.C. 22, no member of, or delegate to, Congress shall be admitted to any share or part of the agreement or to any benefit to arise therefrom.

## ARTICLE 10 - LIABILITIES

APHIS will hold the Manufacturer harmless from any liability arising from the negligent act or omission of the APHIS officer or employee acting within the scope of his or her employment to the extent compensation is available pursuant to the Federal Tort Claims Act (FTCA), 28 U.S.C. 2671 et seq., except to the extent that aforesaid liability arises from the negligent acts or omissions of the Manufacturer, its employees, agents or subcontractor, and employees or agents of the subcontractor(s). Such relief shall be provided pursuant to the procedures set for in the FTCA and applicable regulations.

ARTICLE 11 - AMENDMENTS

This agreement may be amended by mutual agreement of the parties upon submission of a written request for consideration no less than sixty (60) days prior to the proposed date of amendment.

ARTICLE 12 - TERMINATION

This agreement may be terminated by either party upon sixty (60) days written notice to the other party.

This agreement may be suspended or terminated by APHIS at any time if any of the requirements listed above are not met. **Company Name** may be subject to civil or criminal penalties for any false statements knowing or willfully submitted to APHIS regarding this agreement and/or the production and distribution of AIN Devices covered under this agreement. Additionally, if a manufacturer's AIN Devices do not meet the performance requirements for retention and durability, APHIS may withdraw approval with 60 days written notice.

Upon termination of the agreement, the AIN Device Manufacturer will provide copies of all records to APHIS regarding AIN Devices produced and/or distributed under this agreement. Any AIN Devices marked with the U.S. shield that are in the possession of the Device Manufacturer on the date of termination shall be disposed of as directed by APHIS.

ARTICLE 13 - EFFECTIVE DATE AND DURATION

This agreement will be in effect upon date of final signature and will continue for one year from date of final signature. This agreement may be renewed for up to five years by written request and subsequent approval by APHIS.

**Company Name**

\_\_\_\_\_  
**Company Representative  
Title**

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Dr. Adam Grow  
Director, Surveillance and Identification

\_\_\_\_\_  
Date

## Amendment

This Amendment to the AIN Manufacturer Agreement (“Agreement”) made and entered into as of **Date** by and between **Company Name** and United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (“APHIS”) is effective as of the date executed by the final signatory and is an integral part of the Agreement. Except as amended herein, the Agreement remains in full force and effect, subject to all remaining terms and conditions.

APHIS has reviewed the AIN Device Manufacturer application and has evaluated the identification device of the manufacturer and authorizes the following device to be used in NAIS as “USDA Approval Pending.”

Manufacturer Product Name	<b>XXXX</b>
Manufacturer Product Code Number	<b>XXXX</b>
APHIS Product Code Number	<b>XXXX</b>

### **Company Name**

\_\_\_\_\_  
**Company Representative**  
**Title**

\_\_\_\_\_  
Date

UNITED STATES DEPARTMENT OF AGRICULTURE  
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