

must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(d) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

(e) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47.

(f) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

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AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 73 FR 60479, Oct. 10, 2008, unless otherwise noted.

§ 149.0 Purpose and scope.

The Trichinae Certification Program described in this part is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to foreign markets.

§ 149.1 Definitions.

Accredited veterinarian. A veterinarian approved by the APHIS Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, D, and G of this chapter.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

AMS Administrator. The Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator.

AMS representative. Any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform services required by this part.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Animal disposal plan. A written document that describes methods for the removal and disposal of dead swine or swine remains from a pork production site.

Animal movement record. A written record of the movement of swine into or from a pork production site.

APHIS Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator.

APHIS representative. Any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized by the APHIS Administrator to perform the services required by this part.

Approved laboratory. A non-Federal laboratory approved by the Agricultural Marketing Service and recognized by the APHIS Administrator or