

§ 54.11

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evaluation by APHIS and, when appropriate, outside scientists, of:

(1) A standardized test protocol that must include a description of the test, a description of the reagents, materials, and equipment used for the test, the test methodology, and any control or quality assurance procedures;

(2) Data to support reproducibility, that is, the ability to reproduce the same result repeatedly on a given sample;

(3) Data to support suitability, that is, data to show that similar results can be produced when the test is run at other laboratories;

(4) Data to support the sensitivity and specificity of the test; and

(5) Any other data requested by the Administrator to determine the suitability of the test for program use.

(b) To be approved, a scrapie test must be able to be replicated at the National Veterinary Services Laboratories, or another reliable, timely, and cost effective method of check testing must be available to APHIS.

(c) A test or combination of tests may be approved for the identification of suspect animals, for the identification of scrapie-positive animals, or for other purposes such as flock certification. For a test to be approved for the identification of scrapie-positive animals, the test must have a specificity comparable to the specificity of the currently approved tests. For a test to be approved as a live animal screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(d) Specific guidelines for use of approved scrapie tests within the Scrapie Eradication Program or Scrapie Flock Certification Program will be added to this part as tests are approved and will also be contained in the Scrapie Eradication UM&R and the Scrapie Flock Certification Program standards based on the characteristics of the test, including specificity, sensitivity, and predictive value.

(e) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a

test, the animal will be designated a suspect animal, unless:

(1) The test was run as part of a bona fide research protocol designed to evaluate an unapproved test in which the owner is not informed of the test result; or

(2) The test protocol includes appropriate measures to prevent the spread of scrapie.

§ 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.

(a) State, Federal, and university laboratories, or in the case of genotype tests, private laboratories will be approved by the Administrator when he or she determines that the laboratory:

(1) Employs personnel assigned to supervise the testing who are qualified to conduct the test based on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

(2) Has adequate facilities and equipment to conduct the test;

(3) Follows standard test protocols;

(4) Meets check test proficiency requirements;

(5) Meets recordkeeping requirements;

(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases for 5 years;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours; and

(8) Will report all test results to State and Federal animal health officials within agreed timeframes. An inspection may include, but is not limited to, review and copying of records, examination of slides, observation of the test being conducted, and interviewing of personnel.

(b) A laboratory may request approval to conduct one or more types of scrapie test or genotype test on one or more types of tissue. To be approved, a laboratory must meet the requirements in paragraph (a) of this section for each type of test and for each type of tissue for which they request approval.

(c) The Administrator may withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give written notice of the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing will be held to resolve the conflicts.

Subpart B—Scrapie Flock Certification Program

§ 54.20 Administration.

The Scrapie Flock Certification Program is a cooperative effort between APHIS; members of the sheep and goat industry, including owners of flocks, slaughtering and rendering establishments, and breed associations and registries; accredited veterinarians; and State governments. APHIS coordinates with State scrapie certification boards and State animal health agencies to encourage flock owners to certify their flocks as free of scrapie by being in continuous compliance with the Scrapie Flock Certification Program standards.

§ 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Flock Certification Program by sending a written request to a State scrapie certification board or to the area veterinarian in charge. A notice containing a current list of flocks participating in the Scrapie Flock Certification Program, and the certification status of each flock, may be obtained from the APHIS web site at URL <http://www.aphis.usda.gov/vs/scrapie>. A list of noncompliant flocks may also be obtained from this site, and either list may be obtained by writing to the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

(Approved by the Office of Management and Budget under control number 0579-0101)

§ 54.22 State scrapie certification boards.

An area veterinarian in charge, after consulting with a State representative and industry representatives, may appoint a State scrapie certification board for the purpose of coordinating activities for the Scrapie Flock Certification Program, including making decisions to admit flocks to the Scrapie Flock Certification Program and to change flock status in accordance with the Scrapie Flock Certification Program standards. These boards are not appointed for the purpose of providing APHIS with consensus advice or policy recommendations. No more than one State scrapie certification board may be formed in each State. Each State scrapie certification board shall include as members the area veterinarian in charge, one or more State representatives, one or more accredited veterinarians, when possible, and one or more owners of flocks, and, at the discretion of the area veterinarian in charge, may include other members.

PART 55—CONTROL OF CHRONIC WASTING DISEASE

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55.1 Definitions.

Subpart A—Chronic Wasting Disease Indemnification Program

- 55.2 Payment of indemnity.
- 55.3 Appraisal and destruction of captive cervids.
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- 55.8 Official CWD tests and approval of laboratories to conduct official CWD tests.

Subpart B [Reserved]

AUTHORITY: 21 U.S.C. 111-113, 114, 114a, 114a-1, 120, 121, 125, and 134b; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 67 FR 5931, Feb. 8, 2002, unless otherwise noted.

§ 55.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any other employee of the