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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 75, 80, and 93

[Docket No. APHIS-2016-0054]

RIN 0579-AE46

Approval of Laboratories to Conduct Official Testing; Consolidation of Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are consolidating the regulations governing diagnostic laboratory approval authorities for select animal diseases into a single regulation and establishing a set of standard procedures that we will use to conduct future diagnostic laboratory approvals. These consolidated regulations will provide for consistent inspection protocols, proficiency testing methods, quality system guidelines, and definitions and will facilitate the approval of additional laboratories in emergency situations. The consolidated regulations will serve to simplify regulatory oversight and compliance.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Randall L. Levings, Scientific Advisor, Diagnostics and Biologics, VS, APHIS, 1920 Dayton Ave., Ames, IA 50010-9602; (515) 337-7601.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR subchapters B, C, and D pertain to the cooperative control and eradication of livestock or poultry diseases (subchapter B), the interstate transportation of animals (including poultry) and animal products (subchapter C), and the exportation and importation of animals (including poultry) and animal products (subchapter D).

In a proposed rule¹ published in the *Federal Register* on May 30, 2019 (84 FR 25013-25018, Docket No. APHIS-2016-0054), we proposed to consolidate the regulations governing diagnostic laboratory approval authorities for animal diseases covered by 9 CFR subchapters B through D into a single regulation and establish a set of standard procedures that we would use to conduct future diagnostic laboratory approvals. The consolidated regulations are intended to provide for consistent inspection protocols, proficiency testing methods, quality system guidelines, and definitions; facilitate the approval of additional laboratories in emergency situations; and simplify regulatory oversight and compliance.

We solicited comments for 60 days ending on July 29, 2019. We received six comments by that date, from private citizens and a State animal health commission. All the commenters generally supported the proposed rule. One commenter did raise a few questions, which are discussed below.

As part of the proposed rule, we proposed to remove the specific laboratory approval provisions found in our regulations regarding equine infectious anemia, Johne's disease, and contagious equine metritis. One commenter noted that the scope of the proposed regulations

¹ To view the proposed rule, supporting documents, and the comments we received, go to <https://www.regulations.gov/docket?D=APHIS-2016-0054>.

could appear to be limited to those three diseases, but stated they favored a more expansive interpretation that would include all the diseases cited in 9 CFR subchapters B, C, and D.

The commenter's more expansive interpretation is correct. As stated in proposed § 71.22(a), State, university, and private laboratories must obtain Animal and Plant Health Inspection Service (APHIS) approval to conduct official testing for those diseases covered by subchapters B, C, and D and must meet the requirements of § 71.22 in order to obtain and maintain that approval.

The same commenter stated that it should be clear that regulations also apply to laboratories that test for other communicable diseases of livestock or poultry that the Secretary may determine constitute an emergency and pose a threat to animal health. In that vein, the commenter also encouraged APHIS to continue to develop regulations for a national list of reportable animal diseases.

As anticipated by the commenter, the regulations will serve as the framework for the approval of laboratories that test for new or emerging communicable diseases of livestock or poultry for which tests are available should there be a need for those laboratories. We continue our work on developing regulations for a national list of reportable animal diseases.

Finally, the commenter asked for clarity as to whether or not there are any potential user fees for laboratory approvals and inspections by APHIS personnel.

User fees currently do apply with respect to some inspections conducted in connection with new or continuing approvals of laboratories, and those existing fees are not affected by this rule. Any new fees or adjustments to existing fees would be the subject of a separate regulatory action.

Revision to the Proposed Definition of National Animal Health Laboratory Network

In the proposed rule, we proposed to define the term *National Animal Health Laboratory Network (NAHLN)* as “a nationally coordinated network and partnership of Federal, State, and university-associated animal health laboratories that provide animal health diagnostic testing, methods research and development, and expertise for education and extension to detect biological threats to the nation’s animal agriculture, thus protecting animal health, public health, and the nation’s food supply.” In this final rule, we are revising this proposed definition to indicate that the NAHLN is primarily composed of Federal, State, and university-associated animal health laboratories. This is because, on a case-by-case basis, private laboratories may be used in the NAHLN based on needed capabilities.

Clarification Regarding Laboratory Facility Approval

In the proposed rule, proposed paragraph (b) of § 71.22 provided that official testing would have to be performed in laboratory facilities with controlled conditions, instrumentation appropriate for the testing being conducted, and biosecurity measures commensurate with the disease of diagnostic concern, but neglected to specify that each of these facility requirements must be acceptable to APHIS. In this final rule, we are clarifying that the determinations that the requirements have been met must be made by APHIS, rather than the facility itself.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This rule

is not an Executive Order 13771 regulatory action because it is not significant under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov website (see footnote 1 above for a link to Regulations.gov).

This rule consolidates existing diagnostic laboratory approval authorities for certain animal diseases into a single regulation and establishes a framework that we will use to conduct future diagnostic laboratory approvals. The consolidated regulations will serve to simplify regulatory oversight and compliance, saving time and resources. For both the laboratories and APHIS, consolidating and standardizing the process will create an easier-to-understand and more user-friendly approval process; improve efficiency in obtaining approvals to conduct testing for single or multiple diseases; reduce the administrative burden associated with obtaining and tracking laboratory approvals; and simplify the steps required to renew an existing approval.

There are over 400 APHIS-approved laboratories. The laboratories range widely in size, from one-person practices to large, State-wide systems. They are classified within the Veterinary Services industry, for which the Small Business Administration's small-entity standard is annual receipts of not more than \$7.5 million. For the industry overall in 2012, there were 27,939 establishments that operated throughout the year. Ninety-nine percent (27,605 establishments) had receipts of less than \$5 million. Thus, most of these entities are small.

Cost savings because of this rule would be realized mainly by approximately 50 larger laboratories due to the multiple tests they perform. In accordance with guidance on complying

with Executive Order 13771, the single primary estimate of the yearly savings that would be provided by this proposed rule is \$1.1 million, the mid-point estimate annualized in perpetuity using a 7 percent discount rate.

This rule will lessen the administrative burden for affected laboratories, benefiting rather than having any negative impact on them. Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting and recordkeeping requirements included in this final rule, which

were filed under 0579-0472, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects

9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 75

Animal diseases, Horses, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 80

Animal diseases, Livestock, Transportation.

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 71, 75, 80, and 93 as follows:

PART 71—GENERAL PROVISIONS

1. The authority citation for part 71 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 71.1 is amended by adding in alphabetical order definitions for “Approved laboratory]”, “National Animal Health Laboratory Network (NAHLN)”, and “Official testing” to read as follows:

§ 71.1 Definitions.

* * * * *

Approved laboratory. A laboratory approved by the Administrator to conduct official testing in accordance with the regulations in § 71.22.

* * * * *

National Animal Health Laboratory Network (NAHLN). The NAHLN is a nationally coordinated network and partnership of primarily Federal, State, and university-associated animal health laboratories that provide animal health diagnostic testing, methods research and development, and expertise for education and extension to detect biological threats to the nation’s animal agriculture, thus protecting animal health, public health, and the nation’s food supply.

* * * * *

Official testing. Testing to determine the disease status of animals for use in State-Federal programs. Tests are approved by the Administrator and conducted by qualified analysts in an approved laboratory.

* * * * *

§ 71.20 [Amended]

3. Section 71.20 is amended by redesignating footnote 7 as footnote 1.

§ 71.21 [Amended]

4. Section 71.21 is amended by redesignating footnotes 8 and 9 as footnotes 2 and 3, respectively.

5. Section 71.22 is added to read as follows:

§ 71.22 Approval of laboratories to conduct official testing.

(a) *Approvals.* State, university, and private laboratories must obtain APHIS approval to conduct official testing for those diseases covered by subchapters B, C, and D of this chapter. Laboratories seeking approval must meet the requirements of this section.

(b) *Facilities.* Official testing must be performed in laboratory facilities with controlled conditions, instrumentation appropriate for the testing being conducted, and biosecurity measures commensurate with the disease of diagnostic concern; each of these facility requirements must be acceptable to APHIS. Approved laboratories must agree to periodic, unannounced inspection by APHIS personnel or other APHIS-approved inspectors following an APHIS-approved checklist.

(c) *Quality system.* Laboratories must operate under a quality system acceptable to APHIS. Components of such systems include acceptable documentation of procedures, recordkeeping, training, reporting, and corrective actions taken if standards and procedures are not reached or maintained. Adherence to certain nationally or internationally established quality systems recognized by APHIS may be used to meet all or part of this requirement.⁴ Quality system records are subject to review during facility inspections.

⁴ A list of established quality systems recognized by APHIS is available on the internet at <https://www.nahln.org>.

(d) *Procedures.* All official testing must be conducted using APHIS-approved assay methods,⁵ which may include standard operating procedures recognized by the National Veterinary Services Laboratories (NVSL) or National Animal Health Laboratory Network, and/or diagnostic test kits licensed by the USDA.

(e) *Training.* Official testing must be conducted only by those individuals who have completed APHIS-approved training and have passed proficiency tests administered by APHIS or its official designee. These tests will be administered annually or as necessary at an interval stipulated by APHIS. Supervisory oversight of official testing must be performed by qualified individuals, as determined by APHIS.

(f) *Reporting.* Approved laboratories must report test results to APHIS and State animal health officials using an individualized (by disease) timeline established by APHIS at the time of laboratory approval.

(g) *Applications for approval.* (1) Laboratories must use APHIS application forms, including an agreement to meet the obligations to APHIS listed in this section, and submit completed forms to the NVSL Director. The Director will make a preliminary determination of the application's acceptability, based on initial review of submitted materials and, when appropriate, a needs assessment for diagnostic capacity. These determinations are made on an annual basis, or as needed based on the number of applications received.

(2) Applicants will be informed of the preliminary determination. If positive, applicants will then be able to request a facility inspection and personnel training, conducted in accordance

⁵ A list of approved assay methods is available on the APHIS Laboratory Portal website at <https://www.nahln.org> and at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information>.

with this section. If negative, APHIS will provide a rationale for the denial. Denied applicants may appeal any denials in accordance with the regulations in paragraph (j) of this section;

(3) When all requirements in this section have been met, the NVSL Director will issue a final approval. Approvals are specific to those lab personnel working at the inspected, approved laboratory who have met the eligibility and proficiency requirements. Denied applicants may appeal any denials in accordance with the regulations in paragraph (j) of this section.

(h) *Maintenance of approved status.* (1) Previously approved laboratories that wish to maintain their approved status must reapply for APHIS approval at least 1 month before their approval term expires, or at least every 2 years, whichever comes first. Laboratories wishing to maintain approved status must submit a renewal application form, as supplied by APHIS, to the NVSL Director.

(2) Approved laboratories must have at least one individual with the required training and unexpired proficiency certification in their employ at all times.

(3) Approved laboratories must perform the minimum number of tests to maintain proficiency, as stipulated by APHIS in the guidance documents developed for individual test types.

(i) *Probation, suspension, and rescission of laboratory approval.* (1) Laboratories not conducting the minimum number of tests as required by paragraph (h)(3) of this section during a single reporting period will be assigned probationary status. A reporting period is less than or equal to the time for which the laboratory has been approved to conduct testing by APHIS. Laboratories on probation may continue to conduct official testing. If the minimum required number of tests are not performed during two consecutive reporting periods, the laboratory will

not be eligible for renewal of APHIS approval. Exceptions to this requirement may be granted by the NVSL Director upon request.

(2) Approval to conduct official testing will be suspended in the event that a laboratory experiences changes that may impact its ability to provide quality testing services. These changes include: No longer employing an individual approved to conduct official testing, a move to different facilities, or a natural disaster that impacts power or water systems. Laboratories with suspended status will not be approved to conduct official testing. Laboratories will be restored to approved status upon training and/or testing new personnel, successful inspection of new facilities, and/or correction of noncompliance issues. Reapproval will involve resubmitting those sections of the application materials required by the NVSL Director.

(3) Approval may be rescinded at any time, at the discretion of the NVSL Director, if a laboratory fails to meet its obligations to APHIS, as listed in the agreement signed by the laboratory during the application process. The NVSL Director will issue a notice to the laboratory, providing the justification for the proposed removal. Laboratories will have 30 days to respond in writing to the concerns provided before the NVSL Director finalizes the removal decision.

(j) *Appeals.* Appeal of any denial, probation, suspension, or rescission of laboratory approval must be made in writing to the APHIS Administrator or the Administrator's official designee within 30 days of the laboratory's receipt of the NVSL Director's decision. Responses to these appeals will be provided within 60 days of receipt by APHIS.

(Approved by the Office of Management and Budget under control number 0579-0472)

PART 75—COMMUNICABLE DISEASES IN HORSES, ASSES, PONIES, MULES, AND ZEBRAS

6. The authority citation for part 75 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

7. Section 75.4 is amended as follows:

a. By revising the section heading;

b. In paragraph (a), by removing the definition of *Official test* and by revising the definition of *Reactor*; and

c. By removing paragraphs (c) and (d).

The revisions read as follows:

§ 75.4 Interstate movement of equine infectious anemia reactors.

(a) * * *

Reactor. Any horse, ass, mule, pony or zebra which is subjected to an official test in accordance with the regulations in § 71.22 of this subchapter and found positive.

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PART 80—JOHNE'S DISEASE IN DOMESTIC ANIMALS

8. The authority citation for part 80 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

9. In § 80.1, the definition of “Official Johne’s disease test” is revised to read as follows:

§ 80.1 Definitions.

* * * * *

Official Johne's disease test. An organism detection test approved by the Administrator and conducted in a laboratory approved by the Administrator.¹

* * * * *

¹The list of approved laboratories is available on the internet at <https://www.nahln.org> or upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Veterinary Services Laboratories, P.O. Box 844, Ames, IA 50010-0844.

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

10. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 93.301 [Amended]

11. Section 93.301 is amended as follows:

a. In paragraphs (e)(2)(iii) and (e)(5)(i), by removing the words “paragraph (i) of this section” and adding the words “§ 71.22 of this chapter” in their place; and

b. By removing and reserving paragraph (i).

§ 93.303 [Amended]

12. Section 93.303 is amended by redesignating footnote 12 as footnote 10.

§ 93.308 [Amended]

13. Section 93.308 is amended by redesignating footnotes 13, 14, and 15 as footnotes 11, 12, and 13, respectively.

Done in Washington, DC, this 17th day of January 2020.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.
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