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: Proposed rule.

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

DATES: We will consider all comments that we receive on or before July 29, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0054*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0054* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

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

This proposed rule would remove the regulations governing the approval of animal diagnostic laboratories to conduct disease-specific testing, currently found in 9 CFR parts 75 (equine infectious anemia), 80 (Johne's disease), and 93 (contagious equine metritis). In their place, it would add a new section to the regulations, 9 CFR 71.22. This section, which would be titled ''Approval of laboratories to conduct official testing,'' would contain regulations describing the requirement for laboratories to perform official testing for select animal diseases in the United States.

In 2015, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) issued a concept paper suggesting consolidation of the existing diagnostic laboratory approval authorities for select animal diseases into a single regulation.

The comment period for the concept paper was 60 days. By the close of the comment period, we had received 16 comments, from State veterinary diagnostic laboratory personnel and State and Federal animal health officials. Suggestions in these comments were used in order to inform our discussions on the proposed requirements detailed below.

As parts of the regulations in 9 CFR parts 75, 80, and 93 currently do, the proposed regulations would provide a method by which animal diagnostic laboratories would be approved. Differing requirements would no longer be found in these disparate, disease-specific regulations. Rather, the consolidated regulations would provide a uniform standard, resulting in enhanced transparency and regulatory efficiency. As noted, the consolidated requirements would be added in a new § 71.22 (Approval of laboratories to conduct official testing) and the existing regulations associated with laboratory approval would be removed from the disease-specific regulations and replaced with a reference to the new section. All currently approved laboratories would maintain their approved status until the first renewal date. Any renewing or new laboratories requesting approval would be required to meet the consolidated requirements.

Definitions

In 9 CFR 71.1, we are proposing to add definitions for *approved laboratory, National Animal Health Laboratory Network (NAHLN),* and *official testing.*

The definition of *approved laboratory* would be established as ''A laboratory approved by the Administrator to conduct official testing in accordance with the regulations in § 71.22.'' The definition of *National Animal Health Laboratory Network (NAHLN)* would be established 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.'' The definition of *official testing* would be established as ''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.''

Approval of Laboratories To Conduct Official Testing

In § 71.22(a), we would establish that laboratories must obtain APHIS approval under the requirements of the section in order to conduct official testing for those diseases covered by 9 CFR subchapters B (Cooperative Control and Eradication of Livestock or Poultry Diseases), C (Interstate Transportation of Animals (Including Poultry) and Animal Products), and D (Exportation and Importation of Animals (Including Poultry) and Animal Products).

The requirements governing diseases covered by the regulations have been built up over time and are supported by our expertise and experience. They represent diseases for which required testing protocols are most effective and well understood.

Facilities

Section 71.22(b) would require that official testing 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. Approved laboratories would have to agree to periodic, unannounced inspection by APHIS personnel or other APHIS-approved inspectors following an APHIS-approved checklist. These requirements would ensure that all approved laboratories have and maintain the materials and standards we deem necessary to identify and prevent the spread of the disease or vector outside of the laboratory.

Quality System

In § 71.22(c), we would state that approved laboratories must operate

under a quality system acceptable to APHIS. A quality system is comprised of those coordinated activities that direct and control an organization to maintain a required standard.

Quality systems may be comprised of elements such as 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 could also be used to meet all or part of this requirement. Quality system records would be subject to review during facility inspections.

Those quality systems acceptable to APHIS would be determined based on criteria that would vary somewhat based on the disease testing in question, but could be comprised of Federal and international standards such as International Organization for Standardization Standard 17025—General requirements for the competence of testing and calibration laboratories and American Association of Veterinary Laboratory Diagnosticians standards. Specifics of the required quality system would be provided for each test and disease via established protocols. APHIS and APHIS-approved trainers would provide individual instruction and assistance to help laboratories meet the required standards. We have successfully used this approach elsewhere in our regulations, particularly in 9 CFR subchapter E, which concerns viruses, serums, toxins, and analogous products; organisms and vectors.

Procedures

Section 71.22(d) would require that all official testing be conducted using APHIS-approved assay methods, which may include standard operating procedures recognized by the National Veterinary Services Laboratories (NVSL) or NAHLN, and/or diagnostic test kits licensed by the USDA. A list of approved assay methods would be made available on the APHIS Laboratory Portal [1] website and in the protocols developed for individual test types. This would ensure consistency of testing over time and allow us to easily assess test results.

Training

In § 71.22(e) we would stipulate that official testing 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 would be administered annually or at an interval stipulated by APHIS. Supervisory oversight of official testing would be performed by qualified individuals, as determined by APHIS. Standardized training would be necessary to ensure that all tests are run consistently and correctly.

Reporting

In § 71.22(f) we would require approved laboratories to 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. Timelines would be determined by the urgency of necessary actions in light of a positive test result for the disease in question and/or APHIS' reporting obligations. Approved laboratories would benefit from a clear and consistent testing and reporting timeline.

Applications for Approval

Section 71.22(g) would establish the procedures by which laboratories would request APHIS approval to conduct official testing and the notification process APHIS would follow as a result of those requests. The application and approval process would be as follows:

- Laboratories would be required to use APHIS application forms, including an agreement to meet the obligations to APHIS listed in the section, and submit completed forms to the NVSL Director. The Director would 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 would be made on an annual basis, or as needed based on the number of applications received;
- Applicants would be informed of the preliminary determination. If positive, applicants would then be able to request a facility inspection and personnel training, conducted in accordance with the section. If negative, APHIS would provide a rationale for the denial. Denied applicants would be able to appeal any such denials in accordance with proposed § 71.22(j);
- When all approval requirements have been met, the NVSL Director would issue a final approval. Approvals would be specific to those lab personnel working at the inspected, approved laboratory who have met the eligibility and proficiency requirements. Denied applicants would be able to appeal any such denials in accordance with proposed § 71.22(j).

This process would improve efficiency of inspections and approvals by establishing the need for inspection only for those laboratories that meet established planning requirements. It would also provide entities whose applications were initially denied with the information necessary to improve their chances of future approval.

Maintenance of Approved Status

In § 71.22(h), we would stipulate that any previously approved laboratories that wish to maintain their approved status would be required to 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 would have to submit a renewal application form, as supplied by APHIS, to the NVSL Director. This would allow laboratories with existing approvals to transition more slowly to the new, streamlined approval process and avoid creating unnecessary burden for currently approved facilities. Laboratories not electing to renew their approvals would be removed by the NVSL Director when their current approvals expire.

Approved laboratories would also be required to have at least one individual with the required training and unexpired proficiency certification in their employ at all times. This would allow for uninterrupted consistency and competency in testing.

Finally, the minimum number of tests to maintain proficiency, as stipulated by APHIS in the protocols developed for individual test types, would have to be performed. This would be necessary to ensure that approved laboratories maintain familiarity with required testing procedures over the course of time to guarantee testing accuracy.

Probation, Suspension, and Rescission of Laboratory Approval

Paragraph (i) of § 71.22 would outline the conditions under which approved laboratories would enter probation or have their approvals suspended or removed.

Laboratories not conducting the minimum number of tests as required in proposed § 71.22(h)(3) during a single reporting period would be assigned probationary status. A reporting period would be less than or equal to the time for which the laboratory has been approved to conduct testing by APHIS. Laboratories on probation could continue to conduct official testing. If the minimum number of tests are not performed during two consecutive reporting periods, the laboratory would not be eligible for renewal of APHIS

[1] You may view the APHIS Laboratory Portal on the internet at *https://www.nahln.org.*

approval. Exceptions to this requirement may be granted by the NVSL Director upon request. This would allow us to deal with laboratories on a more individualized basis as well as allowing those laboratories with probationary status to regain full status without having to reapply. A tiered system of approval, probation, and suspension would establish needed flexibility in the process while maintaining APHIS oversight.

Approval to conduct official testing would be suspended in the event that a laboratory experiences changes that may impact the ability to provide quality testing services. These changes include, but are not limited to, 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 would no longer be approved to conduct official testing. Laboratories would be restored to approved status upon training and/or testing new personnel, successful inspection of new facilities, and/or correction of noncompliance issues. Reapproval would involve resubmitting those sections of the application materials required by the NVSL Director. This would allow us to quickly address noncompliant laboratories, while giving affected entities opportunity to take necessary steps to retain their approved status without having to go through full reapplication.

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 detailed by the agreement signed by the laboratory during the application process. The NVSL Director would issue a notice to the laboratory, providing the justification for the proposed removal. Laboratories would have 30 days to respond in writing to the concerns provided before the NVSL Director finalizes the removal decision. While we anticipate that most issues with approved laboratories that arise would be resolved through the suspension process, it is also important to codify our policy concerning approval removal. The decision about whether to carry out a suspension or a removal would be made on a case-by-case basis after full consideration of the individual issues of concern.

Appeals

Finally, § 71.22(j) would describe the process by which laboratories would be able to appeal the decision of the NVSL Director with regard to denials, probations, suspensions, or rescissions.

Appeals would have to 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 would be provided within 60 days of receipt by APHIS. The appeals process would provide clarity concerning roles and responsibilities for APHIS and the approved laboratory.

Other Changes

In addition to removing the regulations governing the approval of animal diagnostic laboratories to conduct disease-specific testing as previously explained, we are also proposing to make other changes to the regulations in parts 75, 80, and 93 in response to the proposed addition of § 71.22.

In several places we propose to replace references to those parts of the regulations that contained disease-specific laboratory approval requirements with references to the consolidated regulations in § 71.22. We are also updating references to the locations where stakeholders can access a list of approved laboratories.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This proposed 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 proposed rule is not expected to be an Executive Order 13771 regulatory action because this proposed rule 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 **ADDRESSES** above for instructions for accessing *Regulations.gov*).

This proposed rule would consolidate existing diagnostic laboratory approval authorities for select animal diseases into a single regulation and establish a set of standard procedures we may use to conduct future diagnostic laboratory approvals. The consolidated regulations would serve to simplify regulatory oversight and compliance, saving time and resources. For both the laboratories and APHIS, consolidating and standardizing the process would 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 proposed rule would 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 would 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), reporting and

recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send comments on the Information Collection Request (ICR) to OMB's Office of Information and Regulatory Affairs via email to *oira_submissions@omb.eop.gov,* Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2016–0054. Please send a copy of your comments to the USDA using one of the methods described under **ADDRESSES** at the beginning of this document.

The Animal Health Protection Act is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the ability of U.S. producers to compete in the global market of animal and animal product trade.

The regulations require APHIS approval or certification for laboratories conducting tests for disease management as well as live animal interstate movement, import, and export. To facilitate the approval or certification of laboratories, APHIS will require information collection activities such as notifications for intent to request approval; applications for APHIS approval; inspections; checklists and agreements; documentation of accreditation status; documentation of implemented quality system; quality document verifications; quality assurance/control plans; notifications of proposed changes to assay protocols; test exemptions; submission of sample copies of diagnostic reports; requests for removal of approved status; appeal of approval denial, suspension, or removal; reporting; and recordkeeping.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of burden: Public burden for this collection of information is estimated to average 7.1 hours per response.

Respondents: State animal health officials and laboratory directors.

Estimated annual number of respondents: 402.

Estimated annual number of responses per respondent: 13.

Estimated annual number of responses: 5,306.

Estimated total annual burden on respondents: 37,697 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the estimate of burden.)

A copy of the information collection may be viewed on the *Regulations.gov* website or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

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 proposed rule, please contact Ms. Kimberly Hardy, 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 propose to amend 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 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. 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 and 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.

(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 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.

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:

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

[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.*

§ 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.

* * * * *

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]

* * * * *

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.

CANADA [Amended]

■ 14. The undesignated center heading ''CANADA'' immediately preceding § 93.315 is amended by redesignating footnote 16 as footnote 14.

CENTRAL AMERICA AND THE WEST INDIES [Amended]

■ 15. The undesignated center heading ''CENTRAL AMERICA AND THE WEST INDIES'' immediately preceding § 93.319 is amended by redesignating footnote 17 as footnote 15.

MEXICO [Amended]

■ 16. The undesignated center heading ''MEXICO'' immediately preceding § 93.321 is amended by redesignating footnote 18 as footnote 16.

§ 93.324 [Amended]

■ 17. Section 93.324 is amended by redesignating footnote 19 as footnote 17.

Done in Washington, DC, this 24th day of May 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–11278 Filed 5–29–19; 8:45 am]

BILLING CODE 3410–34–P

[1]The 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.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701 and 741

RIN 3313–AF00

Public Unit and Nonmember Shares

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is proposing to amend the NCUA's public unit and nonmember share rule to allow Federal credit unions (FCU) to receive public unit and nonmember shares up to 50 percent of the credit union's paid-in and unimpaired capital and surplus less any public unit and nonmember shares.

DATES: Comments must be received by July 29, 2019.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *NCUA website: http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html*. Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov*. Include ''[Your name] Comments on Public Unit and Nonmember Shares Proposed Rule'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public inspection: All public comments are available on the agency's website at *http://www.ncua.gov/RegulationsOpinionsLaws/comments* as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library, at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6540 or send an email to *OGCMail@ncua.gov*.

FOR FURTHER INFORMATION CONTACT: Benjamin M. Litchfield, Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, Virginia 22314, or by telephone at (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background

Section 107(6) of the Federal Credit Union Act (FCU Act) permits an FCU to receive payment on shares from nonmembers under certain circumstances.[1] An FCU may receive payment on shares from nonmember credit unions.[2] An FCU may also receive payment on shares from nonmember public units and their political subdivisions.[3] The term ''public unit'' generally refers to ''the United States, any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Panama Canal Zone, any territory or possession of the United States, any county, municipality, or political subdivision thereof, or any Indian tribe as defined in section 3(c) of the Indian Financing Act of 1974.'' [4]

Moreover, an FCU that predominantly serves low-income members may

[1] 12 U.S.C. 1757(6).

[2] *Id.*

[3] *Id.*

[4] 12 CFR 745.1(c).