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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 57 and 161

[Docket No. APHIS-2017-0002]

RIN 0579-AE39

National List of Reportable Animal Diseases

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the animal disease regulations to provide for a National List of Reportable Animal Diseases, along with reporting responsibilities for animal health professionals that encounter or suspect cases of communicable animal diseases and disease agents. These proposed changes are necessary to streamline State and Federal cooperative animal disease detection, response, and control efforts. This action would consolidate and enhance current disease reporting mechanisms, and would complement and supplement existing animal disease tracking and reporting at the State level.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0002>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0002, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments that we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0002> 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. Rebecca Jones, Strategy and Policy, Centers for Epidemiology and Animal Health, 2150 Centre Ave. Bldg. B, Fort Collins, CO 80526; (970) 494-7196.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to issue orders and promulgate regulations to prevent the introduction into the United States and the dissemination within the United States of any pest or disease of livestock. The Secretary has delegated authority to issue such orders and regulations to the Animal and Plant Health Inspection Service (APHIS).

The regulations in 9 CFR subchapter B (referred to below as the regulations) govern the cooperative control and eradication of livestock or poultry diseases within the United States. The regulations establish procedures through which Federal and State animal health authorities coordinate in their collective efforts to eradicate certain communicable animal diseases; included

provisions govern the payment of indemnities, animal identification and testing, and specific disease containment procedures.

Accurate and timely reporting of diagnosed or suspected animal diseases and disease agents to State and Federal animal health authorities is vital to preventing disease spread and protecting American agriculture. Under the AHPA, the Secretary of Agriculture has authority to respond to diseases through movement control, surveillance, and other activities including disease reporting; however, at present, the United States lacks a comprehensive nationwide approach to animal disease reporting requirements.

Reporting requirements do exist for accredited veterinarians under 9 CFR 161.4(f): Accredited veterinarians are required to immediately report to APHIS and the State Animal Health official all diagnosed suspected cases of communicable disease for which APHIS has a control or eradication program in 9 CFR chapter I, and all diagnosed and suspected cases of animal diseases not known to exist in the United States as provided in 9 CFR 71.3. (Within § 71.3, paragraph (b) lists foreign animal diseases not known to exist in the United States, and prohibits the interstate movement of animals affected with such diseases, as well as any other communicable foreign diseases.)

However, these reporting obligations do not cover all animal diseases listed by the World Organization for Animal Health (OIE), leaving critical gaps in nationwide reporting for many diseases. Not having a consistent and uniform national system for reporting animal diseases and disease agents creates challenges for the United States when fulfilling its international reporting requirements. As a Member country of the OIE, the United States must submit to the OIE reports on the status of certain diseases of livestock, poultry, aquaculture, bees and, in some instances, wild terrestrial and aquatic species. Some of these reportable diseases have the

potential for rapid spread, regardless of national borders, are of serious socioeconomic or public health consequence, and impact the international trade of animals and animal products.

Moreover, a 2015 U.S. Government Accountability Office (GAO) report¹ noted the role that gaps in animal disease reporting played in recent disease outbreaks and recommended that the United States Department of Agriculture (USDA) clarify roles and responsibilities to facilitate how the Agency responds to emerging animal diseases.

In addition to the current required disease reporting from APHIS-accredited veterinarians, States voluntarily report occurrences of monitored diseases –i.e., diseases or conditions where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence– to APHIS on a monthly basis through the National Animal Health Reporting System (NAHRS), a web-based reporting system for animal disease-related transmissions. Such voluntary reporting of monitored diseases assists in national data collection for the diseases. This data is used to monitor changes in a given population and its environment, or to report on disease occurrence. However, States are not currently required to report occurrences of monitored diseases and some diseases (such as emerging diseases) to APHIS, nor is there a Federal requirement that laboratories must report detection of these diseases to States. The proposed disease reporting requirements would help State, Federal, and industry officials to document and monitor national and State disease trends, meet travel and movement requirements, and evaluate and implement management, control, response, and prevention activities for animal disease.

Finally, no standard reporting requirements, guidelines, or timeframes exist under current Federal regulations for animal health professionals other than accredited veterinarians who

¹ See <https://www.gao.gov/assets/680/674174.pdf>.

encounter or suspect cases of communicable animal diseases and disease agents. For purposes of this document as well as the proposed regulations, by *animal health professional*, we mean an individual, corporate entity, or animal health organization with formal training in the diagnosis or recognition of animal diseases and/or pests of livestock.² Examples of animal health professionals include, but are not limited to, veterinary medical professionals, diagnostic laboratorians, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel with such training.

In this document, we are proposing to add a new part to 9 CFR subchapter B that would provide for a new National List of Reportable Animal Diseases (NLRAD), as well as disease reporting requirements for animal health professionals identifying or suspecting NLRAD-listed diseases or conditions. The proposed amendments for disease listing and reporting would accomplish the following:

- Establish the NLRAD with two categories: Notifiable diseases and conditions, and monitored diseases. The notifiable diseases and conditions would be subdivided into emergency incidents, emerging disease incidents, and regulated disease incidents. Monitored diseases would be diseases or conditions where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence.
- Specify reporting responsibilities for animal health professionals encountering animal diseases, disease agents, or conditions listed as monitored or notifiable.

² Please note that the AHPA, as well as this proposed rule, defines *livestock* as: “All farm-raised animals.” This includes bees, farmed aquaculture, and animals maintained in captivity on a farm.

- Indicate the existence of an NLRAD System Standards document, and provide procedures for its use.

The proposed amendments would address GAO recommendations by enhancing and clarifying national animal disease reporting guidelines for veterinarians, and by expanding reporting requirements to include other animal health professionals who may encounter such diseases – including veterinary medical professionals, diagnostic laboratorians, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel. While the vast majority of reporting of NLRAD-listed diseases and conditions is expected to be through accredited veterinarians and diagnostic laboratories, due to the serious nature of notifiable diseases and their potentially damaging impact on U.S. agriculture, immediate reporting would be required by any animal health professional with knowledge or suspicion of these diseases. To aid in identifying suspicion of disease, APHIS would maintain case definitions at the following website:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases.

The process to report diseases listed as ‘monitored’ in the NLRAD would remain largely the same as in current practice, where States track and report information on monitored diseases to APHIS. The primary differences from current practice would be that such reporting from States would become mandatory, rather than voluntary, and that laboratories encountering confirmed cases of monitored diseases would be required to report occurrence information to the State where the animal is located. Reporting of additional follow-up information by States and laboratories to APHIS – such as the number of diagnostic tests conducted, number of detections, and epidemiological information – may be requested for some monitored diseases in response to

a disease report or following consultation with stakeholders. Although the NAHRS is the current information technology system used for most monitored disease reporting from States, we are preparing to implement a new designated information technology system that would have enhanced capabilities for collecting animal disease-related data on a national scale. Once fully operational, this system would be available on the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health. The formal name for this system, once finalized, would be noted on the website and referenced in subsequent rulemakings.

Animal health professionals suspecting or diagnosing incidences of animal diseases or disease agents classified as “notifiable” in the NLRAD would be required to immediately report to both State and Federal officials. More detailed information regarding these proposed reporting requirements is included in the next section.

APHIS intends for the NLRAD to be codified as a single, nationally supported, standardized list of reportable animal diseases and disease agents that would allow for consistent disease reporting. The benefits of improving animal disease tracking and reporting on a national scale would extend to national, interstate, and international commerce, emergency disease response, and international reporting obligations to OIE as well as trading partners.

Our proposed animal disease list information and reporting requirements would be contained in a new 9 CFR part 57. Proposed § 57.1 would contain definitions related to animal health testing and diagnostics. Provisions for the NLRAD and reporting requirements would be included in proposed § 57.2. We also are proposing to amend the existing reporting requirements for APHIS-accredited veterinarians in § 161.4 to make these consistent with the new NLRAD provisions. We will address below the proposed changes in detail.

Definitions (§ 57.1)

We propose to incorporate standard definitions for terms that currently exist elsewhere in the regulations. We would define *Animal and Plant Health Inspection Service* (APHIS) as the Animal and Plant Health Inspection Service of the United States Department of Agriculture. We would define *livestock* to refer to all farm-raised animals. We also would define *State* to refer to any State, the District of Columbia, Puerto Rico, Guam, the Northern Mariana Islands, the Virgin Islands of the United States, and any other territory or possession of the United States. *United States* would refer to all of the States.

We propose to add new definitions for *animal health professional*, *monitored disease*, and *notifiable disease*, in accordance with their usage in the NLRAD and its provisions set forth in proposed § 57.2.

As noted earlier in this document, *animal health professional* would be defined as an individual, corporate entity, or animal health organization with formal training in the diagnosis or recognition of animal diseases and/or pests of livestock. The definition would further provide examples of types of professions that include *animal health professionals*: Veterinary medical professionals, diagnostic laboratorians, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel.

These examples would be illustrative, rather than exhaustive. The salient criterion in determining whether APHIS would consider the individual an animal health professional would be their formal training in the diagnosis or recognition of animal diseases and/or pests of livestock, not their profession. At a minimum, we would consider training programs administered by APHIS, a State department of agriculture, a State department of wildlife management and/or natural resources, or a licensed, accredited college or university to constitute

formal training. We request specific public comment on the types of training that should constitute *formal training*, and whether adding a definition of *formal training* to our proposed regulations would be beneficial.

Monitored disease would be defined as a disease or condition where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence. *Notifiable disease* would be defined as a disease or condition that requires immediate notification to Federal and State veterinary authorities. Notifiable diseases would be: (1) Emergency incidents (foreign animal diseases, exotic vectors, and high priority diseases); (2) emerging disease incidents (involving diseases, infections, or infestations with agents that are unknown, newly identified, or previously identified but epidemiologically changed); and (3) regulated disease incidents (involving diseases for which Federal regulations already are in place).

Finally, because we make frequent reference to the NLRAD System Standards Document – a document released with this proposed rule – we propose to include a definition for *NLRAD System Standards Document*. This document would provide specific details on the diseases and disease agents to be reported, standard operating procedures, and additional background and resources to support reporting efforts. The document would also be available on APHIS’ website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases.

National List of Reportable Animal Diseases (§ 57.2)

Section 57.2 would describe the National List of Reportable Animal Diseases (NLRAD). This section would outline the organization, as well as maintenance, of the NLRAD, and would specify new reporting requirements for animal health professionals who encounter or suspect

incidences of notifiable animal diseases and disease agents, and new reporting requirements for States and laboratories who encounter confirmed cases of monitored animal diseases.

Proposed paragraph (a) would note the location of the NLRAD on the APHIS website and specify appropriate contact information for interested parties to obtain paper copies of the list. Proposed paragraph (b) would outline the division of the NLRAD into two categories: Notifiable diseases and conditions, and monitored diseases. Notifiable diseases and conditions would be subdivided into emergency incidents (foreign animal diseases, exotic vectors, and high priority diseases), emerging disease incidents (involving diseases, infections, or infestations with agents that are unknown, newly identified, or previously identified but epidemiologically changed), and regulated disease incidents (involving diseases for which Federal regulations already are in place). Monitored diseases, as our proposed definition above indicates, are diseases where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence. A disease or condition listed as notifiable would be reportable immediately in accordance with procedures specified in proposed § 57.2(d), with additional reporting resources provided in the NLRAD System Standards Document. Monitored diseases would be the subject of required periodic summary reports, in keeping with existing practices.

Proposed paragraph (c) would specify that any changes to the NLRAD would be announced via notice in the *Federal Register*, and that updates and edits to the list would be considered when: An emerging disease is identified; changes are made to OIE-Listed diseases, infections, and infestations; changes are made in VS regulations; changes are made on the National Veterinary Stockpile (NVS) list, USDA Select Agents and Toxins list, or Centers for Disease Control and Prevention's (CDC) Category A, B, or C Bioterrorism Agents/Diseases list

(described below); or changes or additions are requested by stakeholders and adopted by APHIS. The NVS provides support to States, Tribes, and Territories responding to damaging animal disease outbreaks, and its list comprises damaging animal disease threats. The USDA Select Agents and Toxins list indicates biological agents and toxins determined to have the potential to pose a severe threat to human and animal health; and the CDC Category A, B, and C Bioterrorism Agents/Diseases list includes agents or diseases in the United States that pose a risk to national security due to ease of transmission and/or public health impact. Stakeholders who wish to request removals or additions to the NLRAD would need to submit their requests in writing in accordance with the contact information listed in proposed § 57.2(a). Written requests would require a justification for the proposed change, with examples of such justifications available in the NLRAD System Standards document.

Proposed paragraph (d) would specify reporting procedures for those who encounter or suspect notifiable or monitored diseases. For notifiable diseases, any animal health professional with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD would be required to immediately report such identification or suspicion to both APHIS and the State where the livestock is located. Animal health professionals would be required to report notifiable diseases and disease agents to APHIS as described on the NLRAD website, available at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases, or by contacting their local APHIS office.³ Reporting to the State would be to the State animal health official listed at

³ Contact information for APHIS offices can be found on the APHIS website at <https://www.aphis.usda.gov/aphis/banner/contactus>, or in the local phone directory.

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrad/ct_national_list_reportable_animal_diseases for the State in question.

We acknowledge that we would require dual reporting of notifiable diseases and disease agents: Once to APHIS, and again to the State where the animal is located. We explored alternative options that would have established a single point of contact: i.e., either the State where the animal is located or APHIS. However, not all States have a single portal for receiving reports of all notifiable diseases, and divisions of animal health or animal industry have varying staffing levels. The lack of a standardized portal, coupled with staffing constraints, could result in delays receiving reports regarding notifiable diseases, and, consequently, delays relaying these reports to APHIS. Depending on the nature of the notifiable disease reported, such a delay could have not only animal health implications, but also implications related to public health or international trade. Delays in receiving reports can directly affect trade, insofar as APHIS is required as a member of the OIE to immediately report disease occurrence to the OIE and to international trading partners for many notifiable diseases.

Conversely, State animal health personnel often serve as first responders for epidemiological investigations in response to possible animal disease outbreaks. If APHIS were the sole point of contact for notifiable diseases, any delays in relaying the report to the State where the animal is located could directly adversely impact disease response and potentially contribute to disease spread. We also took into consideration that many State regulations require veterinarians and laboratories to report notifiable diseases to the State.

Based on these considerations, we have concluded that dual reporting of notifiable diseases is warranted for the notifiable diseases in the NLRAD. That being said, we will

continue to explore means of establishing a single portal for both Federal and State personnel to receive notifiable disease reports. If this occurs, we would amend the regulations accordingly.

For monitored diseases, laboratories would be required to report occurrence information of confirmed cases of an animal disease or condition listed as monitored in the NLRAD on a monthly basis to the State where the animal is located by contacting the State animal health official listed at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health. States would be required to report occurrence information of confirmed cases of monitored diseases to APHIS on a monthly basis through the new designated information technology system portal.

The animal diseases and disease agents to be reported, standard operating procedures, and additional background and resources to support reporting efforts would be located in the supplemental NLRAD System Standards Document, a draft of which is available as a supporting document for this proposed rule (see ADDRESSES above). Updates to this document would be announced as needed via notice in the *Federal Register*. The notice would provide for a public comment period.

Finally, while we intend the regulations to be the general framework for reporting known and suspect occurrences of notifiable and monitored diseases, it is possible that APHIS could issue regulations or a Federal Order that requires an alternative reporting structure based on, for example, the epidemiology of the disease. To account for discrepancies that could arise if we were to issue such regulations or such an order, we would state that the NLRAD regulations do not supersede such a reporting structure.

Standards for Accredited Veterinarian Duties (§ 161.4)

We propose to amend paragraph (f) of this section to clarify reporting requirements for APHIS-accredited veterinarians. The revised requirements for veterinarians would align with the new proposed reporting responsibilities as described under § 57.2, that require any accredited veterinarian with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD to immediately report such identification or suspicion to State and Federal authorities. As we mentioned earlier in this document, we expect the vast majority of the reporting of notifiable diseases to continue to be done by accredited veterinarians; therefore, it is important that accredited veterinarians follow the reporting requirements of the NLRAD regulations.

Reporting of Notifiable Diseases of Livestock in Wildlife

Several of the diseases on our proposed list of notifiable diseases could be transmitted from wildlife to livestock, and a few have known wildlife reservoirs. To account for this, we contemplated whether to propose that notifiable diseases would need to be reported whenever they are detected in wildlife.

While such reporting would clearly assist in the aims of the NLRAD, we also acknowledge factors that could adversely impact implementation of such a reporting requirement. First, as several commenters on a proposed rule to revise and consolidate our domestic brucellosis and bovine tuberculosis programs (80 FR 78462-78520, Docket No. APHIS-2011-0044) pointed out, a number of States limit the authority of State animal health officials to livestock within the State, and effectively preclude the officials from conducting epidemiological investigations of wildlife unless livestock within the State are already known or suspected to be infected with a disease of livestock. Second, as other commenters on that

proposed rule pointed out, several States do not allow wildlife authorities to test for certain diseases of livestock, which would effectively limit reporting of disease occurrence in wildlife in those States to suspected occurrence. Finally, as several commenters on that proposed rule pointed out, wildlife populations are often itinerant, making it difficult to identify a particular infected animal within the population.

For these reasons, we elected not to propose to require reporting of notifiable diseases in wildlife within our proposed NLRAD regulations. However, we do request public comment regarding how the occurrence of notifiable diseases in wildlife should best be addressed within the NLRAD, especially when reservoirs of a notifiable disease are determined to exist in wildlife within a State.

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 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the economic effects of this proposed rule on small entities. 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).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive

analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to amend the animal disease regulations to provide for a National List of Reportable Animal Diseases (NLRAD) along with animal disease reporting responsibilities, to streamline State and Federal cooperative animal disease eradication efforts. This action would enhance and consolidate current disease reporting mechanisms, and would complement and supplement existing animal disease tracking and reporting at the State level.

The Regulatory Flexibility Act requires agencies to consider whether a rule will have a significant economic impact on a substantial number of small entities. The size of a business may have a bearing on its ability to comply with a proposed regulation and there may be unintended or unforeseen adverse impacts. Using the North American Industry Classification System (NAICS), the Small Business Administration (SBA) defines small businesses in terms of a firm's annual receipts or number of employees. It is likely that most of the entities that may be affected by the proposed rule are small.

Although the process to report diseases listed as "monitored" in the NLRAD largely would remain the same, reporting requirements would change. Currently, States track and report information on monitored diseases to APHIS. However, under the proposed rule, reporting from States would become mandatory, rather than voluntary, and laboratories encountering cases of monitored diseases would be required to report occurrence information to the State where the animal is located. Also, reporting of additional information by States and laboratories would be requested for some monitored diseases. The process to report diseases listed as "notifiable" in

the NLRAD would for the most part be new. Animal health officials suspecting or diagnosing incidences of notifiable diseases would be responsible for reporting suspected or diagnosed cases of all animal diseases or disease agents classified as notifiable in the NLRAD to both State and Federal officials.

Based on estimates from the NLRAD program, the number of laboratory reports could increase from about 6,600 to between 59,400 and 66,000 reports per year, and increase the total processing time for monitored diseases from about 3,300 hours to between 18,150 and 18,700 hours per year. In addition, the NLRAD program anticipates reports of diseases newly added to the Notifiable list, thereby increasing the annual processing time for notifiable diseases from about 3,200 hours to between 3,400 and 3,700 hours. The NLRAD program estimates potential additional public and private sector costs that may result from the proposed rule would range from \$353,000 to \$373,000 per year. Increased Federal and State administrative workloads would be resolved by reallocating program resources.

Benefits of the proposed rule are less quantifiable. However, the losses associated with the detection of livestock diseases in the United States can be substantial. For example, the 2003 detection of bovine spongiform encephalopathy in the United States led beef exports to fall by about \$3 billion in 1 year. The NLRAD is an important component of a comprehensive and integrated National-State foreign animal disease (FAD) surveillance system that provides key U.S. information used to complete reports about diseases as required by OIE. Early identification, detection, and control of FADs, particularly zoonotic diseases, helps maintain domestic production and export markets. FADs can result in productivity losses which may increase the cost of food products obtained from those animal sources. NLRAD information provides a historical database about occurrences of reportable diseases in the United States that

informs decision-making related to animal health issues including emerging animal health situations. The proposed expansion of FAD reporting responsibilities will enhance the ability of Federal and State authorities to promptly and effectively manage reportable animal disease occurrences.

Based on our review of available information, APHIS does not expect the proposed rule to have a significant economic impact on small entities. We have prepared this initial regulatory flexibility analysis because our understanding of possible economic effects of the rule on small entities is incomplete. In the absence of apparent significant economic impacts, we have not identified alternatives that would minimize such impacts.

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 in conflict 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.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Written

comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function." Please send a copy of your comments to: (1) Docket No. APHIS-2017-0002, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This rule would require the submission of *ad hoc* reports (for notifiable diseases) and recurring reports (for monitored diseases).

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 reporting burden for this collection of information is estimated to average 0.37362 hours per response.

Respondents: Individuals, laboratories, and States.

Estimated annual number of respondents: 2,205.

Estimated annual number of responses per respondent: 33.236.

Estimated annual number of responses: 73,285.

Estimated total annual burden on respondents: 27,381 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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 Mr. Joseph Moxey, 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 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 Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

Lists of Subjects

9 CFR Part 57

Animal diseases, Reporting and recordkeeping requirements.

9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

Accordingly, we propose to amend 9 CFR chapter I as follows:

1. Part 57 is added to subchapter B to read as follows:

PART 57 – ANIMAL HEALTH DIAGNOSTICS AND TESTING

Sec.

57.1 Definitions.

57.2 National List of Reportable Animal Diseases.

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

§ 57.1 Definitions.

As used in this part, the following terms shall have the meanings set forth in this section.

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

Animal health professional. An individual, corporate entity, or animal health organization with formal training in the diagnosis or recognition of animal diseases and/or pests of livestock. Examples of animal health professionals include, but are not limited to, veterinary medical professionals, diagnostic laboratorians, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel with such training.

Livestock. All farm-raised animals.

Monitored disease. A disease or condition where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence.

NLRAD. The list of monitored and notifiable diseases required to be reported.

NLRAD System Standards Document. A document that provides specific detail on the animal diseases to be reported, standard operating procedures, and additional background and resources to support reporting efforts. The document is available on the internet at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases.

Notifiable disease. A disease or condition that requires immediate notification to Federal and State veterinary authorities. Notifiable diseases are: (1) Emergency incidents (foreign animal diseases, exotic vectors, and high priority diseases), emerging disease incidents (involving diseases, infections, or infestations with agents that are unknown, newly identified, or previously identified but epidemiologically changed), and regulated disease incidents (involving diseases for which Federal regulations already are in place).

State. Any State, the District of Columbia, Puerto Rico, Guam, the Northern Mariana Islands, the Virgin Islands of the United States, and any other territory or possession of the United States.

United States. All of the States.

§ 57.2 National List of Reportable Animal Diseases.

(a) *National List of Reportable Animal Diseases.* A National List of Reportable Animal Diseases (NLRAD), along with disease reporting requirements, will be implemented per the provisions set forth in this section. The NLRAD will be maintained on the APHIS website at

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health. Copies of the list also will be available via postal mail or email upon request to the Center for Epidemiology and Animal Health, Veterinary Services, Animal and Plant Health Inspection Service, 2150 Centre Ave., Bldg. B, MS 2E6, Fort Collins, CO 80526. E-mail requests may be directed to NLRAD.NAHS@usda.gov.

(b) *List organization.* Diseases and conditions in the NLRAD are categorized as either notifiable or monitored.

(1) Diseases and conditions categorized as notifiable are further subdivided into:

(i) Emergency incidents (foreign animal diseases, exotic vectors, and high priority diseases);

(ii) Emerging disease incidents (involving diseases, infections, or infestations with agents that are unknown, newly identified, or previously identified but epidemiologically changed); and

(iii) Regulated disease incidents (involving diseases for which Federal regulations already are in place).

(2) Diseases and conditions categorized as monitored are diseases where occurrence is routinely tracked by APHIS and data are used to monitor changes in a given population and its environment, or to report on disease occurrence.

(c) *Updates and edits.* Changes to the NLRAD will be announced via the publication of a notice in the **Federal Register**. Updates and edits to the NLRAD will be considered when:

(1) An emerging disease is identified.

(2) Changes are made to the World Organization for Animal Health (OIE)-Listed diseases, infections, and infestations.

(3) Changes are made in Veterinary Services (VS) regulations.

(4) Changes are made on the National Veterinary Stockpile (NVS) list, USDA Select Agents and Toxins List, or Centers for Disease Control and Prevention (CDC) Category A, B, or C Bioterrorism Agents/Diseases list.

(5) Changes or additions are requested by stakeholders. Stakeholders must submit change requests in writing via postal mail or e-mail using the contact information provided in paragraph (a) of this section. Written requests must include a justification for the proposed change. Examples of justifications can be found in the NLRAD System Standards Document, available on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrad/ct_national_list_reportable_animal_diseases.

(d) *Reporting*. The following reporting procedures will be required:

(1) *Notifiable diseases*. Any animal health professional with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD must immediately report such identification or suspicion to both APHIS and the State where the livestock is located. Reporting to APHIS may be accomplished as described on the NLRAD website available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrad/ct_national_list_reportable_animal_diseases, or by contacting a local APHIS office.¹ Reporting to the State should be to the State animal health official listed at

¹ Contact information for APHIS offices can be found on the APHIS website at <https://www.aphis.usda.gov/aphis/banner/contactus>, or in the local phone directory (listed under Animal and Plant Health Inspection Service (APHIS), Veterinary Services).

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health for the State in question.

(2) *Monitored diseases.* (i) Laboratories must report occurrence information of confirmed cases of an animal disease or condition listed as monitored in the NLRAD on a monthly basis to the State where the animal is located by contacting the State animal health official listed at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health.

(ii) States must report information of confirmed cases of an animal disease or condition listed as monitored in the NLRAD on a monthly basis to APHIS through the Designated Information Technology System available on the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health.

(3) *Additional guidance.* Additional reporting information, including background and resources to support reporting efforts, can be found in the NLRAD System Standards Document available on the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases. Revisions to the NLRAD System Standards Document, other than updates to the NLRAD described in paragraph (c) of this section, will be announced to the public as needed through the publication of a notice in the **Federal Register**. The notice will also provide for a public comment period.

(4) *Alternative reporting structures.* The regulations in this paragraph (d) do not supersede any alternative reporting structure that APHIS may require through issuance of a general regulation or Federal Order.

PART 161 – REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS
AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

2. The authority for part 161 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

3. In § 161.4, paragraph (f) is revised to read as follows:

§ 161.4 Standards for accredited veterinarian duties.

* * * * *

(f) An accredited veterinarian shall immediately report all diagnosed or suspected cases of any animal disease, disease agent, or condition classified as notifiable in the National List of Reportable Animal Diseases (NLRAD) in accordance with reporting provisions set forth in § 57.2 of this chapter. The NLRAD can be viewed on the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health.

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Done in Washington, DC, this 26th day of March 2020 .

Mark Davidson

Acting Administrator, Animal and Plant Health Inspection Service.

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