

September 27, 2023

Regulatory Analysis and Development
Policy and Program Development
Animal and Plant Health Inspection Service
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

RE: National List of Reportable Animal Diseases; Revising Proposed Rule, and Reopening of Comment Period

To Whom it May Concern:

The National Pork Producers Council (NPPC) appreciates the opportunity to comment on the August 28, 2023 *Federal Register* notice, “National List of Reportable Animal Diseases; Revising Proposed Rule, and Reopening of Comment Period” (Docket No. APHIS-2017-0002). NPPC is the global voice for the U.S. pork industry and consists of 43 affiliated state organizations representing America’s 66,000 pork producers who produce a demonstrably safe, wholesome, and nutritious product that is appreciated on American and international tables.

NPPC appreciates the work of the Animal and Plant Health Inspection Service (APHIS) and the opportunity to comment on this proposal to amend the animal disease regulations to provide for a National List of Reportable Animal Diseases (NLRAD) and reporting responsibilities for animal health professionals that encounter or suspect cases of communicable animal diseases and disease agents.

Overall, NPPC supports:

- the establishment of a NLRAD that consists of named animal diseases and conditions with established case definitions;
- reporting requirements for notifiable animal diseases and conditions be limited to veterinary diagnostic laboratories and veterinarians, and such reports under the federal rule should be made exclusively to the proposed NLRAD portal;
- mandated reporting of monitored animal diseases by states only enacted if states can be provided the resources needed to facilitate such reporting; and
- APHIS developing a voluntary portal separate and distinct from the NLRAD for receiving reports of suspicious animal health events.

The NLRAD has a discrete purpose: to collect and collate information concerning the diagnoses of specific named animal diseases and conditions. The pork industry also recognizes that APHIS has a legitimate need to solicit information about unusual animal health events from a wide range of stakeholders. However, we have significant concerns about conflating these two needs under one NLRAD reporting mechanism. We suggest that APHIS develop a second portal under the National Animal Health Monitoring System (NAHMS) umbrella to collect voluntary reports of suspicious animal health events. For clarity, we will address “suspicious animal health events,” “notifiable diseases and conditions,” and “monitored diseases” requirements separately.

Suspicious Animal Health Events

NPPC concurs with APHIS that under-reporting of notifiable animal diseases within the United States can have significant domestic and international ramifications. However, it must be acknowledged that false or premature reports can similarly have damaging consequences. For these reasons, animal health professionals, or indeed any individuals other than veterinarians, should not be obligated to report under the NLRAD when they are not credentialed to make a diagnosis of a specific animal disease. We also have significant concern with requiring veterinarians to report information concerning animal health events that do not meet the case definition of a disease or condition named on the NLRAD, especially since there is no defined response plan for such reports.

The pork industry appreciates APHIS’ rationale in wanting to collect information that falls under the “emerging disease” criteria in the proposed NLRAD rule. However, the proposed criteria are highly subjective—too subjective to mandate reporting. Requiring the reporting of an epidemiological change of a known (but not notifiable) animal disease, for example, creates a significant burden on veterinarians, other animal health professionals, APHIS, and state animal health agencies. For veterinarians and other animal health professionals, it removes discretion in determining the significance of clinical, diagnostic, and/or field observations. For APHIS and state animal health agencies, it will result in a significant increase of reports with no clear methodology or identified resources for analysis and response.

We strongly suggest that APHIS develop an additional portal to receive voluntary reports of suspicious animal health events. This portal could be utilized by veterinarians to report information that falls under the “emerging” classification in the proposed NLRAD rule when, in their professional judgement, they encounter an animal health event that is not classified under the NLRAD but that merits the attention of animal health officials.

Crucially, this system could also be used by other individuals—animal health professionals, producers, or other members of the public with specialized knowledge—to report suspicious animal health events.

Such a portal would have a logical home under the Center for Epidemiology and Animal Health's Risk Identification Unit. It would provide APHIS with needed information without compromising the intent or utility of the proposed NLRAD system. APHIS must also ensure that information provided is secured, and that confidential information is fully protected. At the same time, validated reports of suspicious animal health events should be shared in summary form with animal industries and other animal health stakeholders.

Notifiable Diseases and Conditions

It is critical that APHIS implement a NLRAD system that has clear, carefully delineated reporting requirements, prevents duplicity of reporting, and that is fully resourced. As indicated above, the pork industry does not feel that this can be accomplished by folding in broader surveillance needs. These needs can be addressed by breaking down the NLRAD proposal into three components: what is to be reported, who is to report it, and how it is to be reported.

What is to be reported: Reporting should only be mandated for specific diseases or conditions explicitly listed on the NLRAD. APHIS has indicated that it will publish case definitions for each listed disease and has proposed a process to amend the list itself when new diseases or conditions need to be added. These are appropriate and needed enhancements. It is critical that there be a clear case definition for every disease or condition listed on the NLRAD. What is missing is clarity around response to the report. A veterinary diagnostic laboratory or veterinarian making report of a notifiable animal disease or condition should be provided information concerning the likely response to said report.

A response plan must be published for each and every disease or condition. The case definition document should be extended to contain this information, or a companion document created specific to each response. For diseases or conditions with extensive response plans published elsewhere, these can be referenced and succinctly summarized. If the mandated response is a foreign animal disease investigation, this should be stated. If the report is only required to satisfy national reporting requirements to the OIE, this should be clearly indicated.

In other words, the likely response (realizing that not all mitigating circumstances can be addressed) to a report should be clearly stated for everything listed on the NLRAD. The response document should also clearly state the recommended and/or required actions for the reporter to take or convey as appropriate to the attending veterinarian or owner of the affected animals.

The pork industry does not support formal sub-classification of notifiable disease and conditions into "Emergency," "Emerging," and "Regulated" categories. While we appreciate the intent of this proposal, it unnecessarily blends response and surveillance activities with reporting

requirements. As we have stated, the “emerging” category should be dealt with outside the NLRAD framework. An “emergency” categorization is irrelevant as all notifiable diseases and conditions must be immediately reported; the “regulated” category is also moot in the context of reporting requirements.

Should it be necessary, APHIS has already established under this proposal a mechanism to mandate reporting to the NLRAD for new or emerging syndromes. It can name the syndrome as a condition, establish a clear case definition, and publish it to the NLRAD. This can be accomplished rapidly and with appropriate consultation with industry and other animal health stakeholders. It will also allow for concurrent development of a response plan, and allocation of resources if needed. Again, the disease or condition should not be added to the NLRAD if a response plan has not been developed. Satisfaction of international reporting obligations is itself a response plan for endemic disease, in some cases, and this should be clearly stated if no other response is intended.

We also strongly suggest that APHIS not exclude “wildlife” from the NLRAD reporting requirements. Any disease or condition listed on the NLRAD should be reportable for any subject species, any population within that species be it wild, feral, captive or farmed.

In summary, reporting should only be mandated for specific, named diseases and conditions. Each named disease or condition should have a clear case definition. All relevant state and federal animal health authorities, as well as industry, should have common understanding of the response, if any, to the report of the disease or condition.

Who is to report it: Given the potential ramifications of a report of a notifiable disease, official reporting should be limited to both public and private veterinary diagnostic laboratories, which are credentialed to confirm the diagnosis of notifiable diseases. Veterinarians who diagnose a notifiable disease or condition without utilizing a veterinary diagnostic laboratory should also have a duty to report.

We have already suggested a mechanism by which other animal health professionals, and indeed any other individuals, can notify state and/or federal animal health officials of unusual animal health observations or events if they are not in a position to bring their concerns to the attention of a veterinarian with whom they have a relationship. This notification pathway again would be independent of that used by veterinarians to report confirmed or suspected diagnoses of discrete notifiable animal disease or conditions. Ultimately any observation of a suspicious animal health event will require the intervention of a veterinarian and/or veterinary diagnostic laboratory if

substantiated. It is the laboratory or veterinarian who should officially notify if the ultimate diagnosis is reportable.

In summary, mandated reporting under the NLRAD should be limited to veterinary diagnostic laboratories that have confirmed the diagnosis of a reportable disease or condition. Veterinarians who have arrived at a confirmed or presumed diagnosis that falls under an established case definition without utilizing a veterinary diagnostic laboratory should also have a duty to report. Alternative mechanisms, distinct from NLRAD, should be developed and/or promoted for laypersons to notify animal health officials of suspicious events.

How it is to be reported: NPPC appreciates that APHIS explored a single portal for reporting, and that not all states have equally robust animal health agencies. We support that APHIS require all veterinary diagnostic laboratories, or veterinarians operating independent of such, report notifiable animal diseases and conditions to the NLRAD electronic portal as proposed upon diagnosis. APHIS should ensure that the state is immediately and automatically notified of a report to the NLRAD portal.

We understand, and support that many states do in fact have a reporting requirement for certain animal diseases or conditions. These should stand. Many veterinarians will prefer to notify their state animal health officials of their diagnosis as well as report to the NLRAD. This should also remain a viable option. The federal regulation should dictate federal reporting requirements; state regulations and accepted practice should dictate state reporting requirements.

As with the proposed portal for reporting suspicious animal health events, APHIS should ensure that the reporting system is secure and that confidential and identifying information is protected from public release. Reports should be summarized and provided to the animal industries and other animal health stakeholders promptly—especially if they concern non-endemic diseases or conditions.

In summary, the NLRAD should only mandate reporting to the proposed federal NLRAD portal. APHIS should ensure that the appropriate state agency is immediately notified upon receipt of a report. APHIS should let states determine their own direct reporting requirements for diagnostic laboratories, veterinarians and other animal health professionals under their jurisdiction, as is current practice.

NPPC supports the establishment of a NLRAD for notifiable animal diseases and conditions. The NLRAD should consist of a discrete list of named animal diseases and conditions, each with a published case definition and response plan. Reporting requirements should be limited to veterinarians who have a

confirmed or presumed diagnosis of a disease or condition named on the NLRAD. The report should be made to the federal NLRAD portal as proposed, with states reserving the right to establish their own reporting requirements. The NLRAD should inform but not replace robust animal health monitoring and surveillance programs.


Monitored Animal Diseases

NPPC can only support mandating state reporting of monitored animal diseases if both APHIS and states have the necessary resources to compile and transmit this information electronically, and if APHIS has the resources to analyze and contextualize this information when making it publicly available or reporting it to the OIE. In proposing the NLRAD, APHIS indicates that it expects up to a tenfold increase in reported data. While this does support the assertion that it will provide a clearer picture of the status of monitored diseases, it will be more resource intensive to manage this amount of data. APHIS should ensure that it can accomplish this without compromising other animal health programs. It also suggests that many, if not most, states are not currently voluntarily providing this information. It is even more critical that states not have to divert resources from other animal health programs to fulfill this reporting requirement. If APHIS is not in position to provide states with funding and other needed resources required to fulfill this mandate, it should not be enacted at this time.

In summary, NPPC supports the establishment of a NLRAD that consists of named animal diseases and conditions with established case definitions. Reporting requirements for notifiable animal diseases and conditions should be limited to veterinary diagnostic laboratories and veterinarians, and such reports under the federal rule should be made exclusively to the proposed NLRAD portal. Mandated reporting of monitored animal diseases by states should only be enacted if states can be provided the resources needed to facilitate such reporting. APHIS should develop a voluntary portal separate and distinct from the NLRAD for receiving reports of suspicious animal health events.

Thank you for the opportunity to comment on this important topic.

Sincerely,



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Submitted electronically.