TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

Economic Impact Statement

LSA Document #18-197

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

On June 5, 2014, the United States Department of Agriculture - APHIS (USDA-APHIS) issued a Federal Order that required mandatory reporting to USDA or state animal health officials of confirmed occurrences of porcine epidemic diarrhea virus (PEDv) and porcine deltacoronavirus (PDCoV). The novel outbreak of the PEDv virus has presented a tremendous challenge to the U.S. pork industry. Infections with these coronaviruses can cause significant mortality, particularly in young piglets. The Federal Order also required the development of herd monitoring and management plans for farms with a positive PEDv or PDCoV diagnosis.

Indiana has been working closely with the state's swine producers and veterinarians since the initial U.S. outbreak of PEDv in May of 2013, which occurred in southern Indiana. Specifically, the Indiana State Board of Animal Health (BOAH) has brought stakeholders together to share information on positive farms, discuss biosecurity practices and diagnostic capabilities, and assist with the development of an epidemiological strategy to determine the source(s) of transmission of the virus.

In addition, in late 2014 the BOAH adopted a final rule to coordinate state rules with federal action (LSA Document #14-236). This rule requires a herd owner, veterinarian, caretaker, custodian, or laboratory personnel who receives information of a presumptive positive case, confirmed positive case, or negative case of PEDv or PDCoV in a herd located in Indiana to report that information to the state veterinarian within two (2) business days. It also required an owner of a confirmed positive herd to follow and provide the state veterinarian with a copy of a herd management plan developed through a relationship with a herd veterinarian. The plan was required to be submitted no later than forty-five (45) days after the date the state veterinarian receives notice of a positive case under the rule.

On January 4, 2016, the USDA issued an amended Federal Order governing swine enteric coronavirus disease (SECD).² This Order retained the mandatory disease reporting requirement for SECD but removed the herd management plan requirement. The reporting requirement was retained because, while there were significantly fewer detections of SECD, it remained a concern for the industry. However, the USDA made a determination that herd management plans were not providing information deemed useful to the program and remuneration to accredited veterinarians for development of herd plans was not widely used. The USDA stated that its focus would shift to extending the availability of diagnostic testing that facilitates disease reporting. To align the BOAH rule with the USDA, the BOAH amended its rule to repeal the state's requirement for development and submission of a herd management plan (LSA Document #16-499).

On March 6, 2018, the USDA-APHIS issued a notice that, effective immediately, the SECD Federal Order was being rescinded. Therefore, the USDA will no longer require producers, veterinarians or laboratories to report cases to federal animal health officials. The USDA stated that they were rescinding this Order because, although the disease is now widespread, it is presently well understood by the veterinary community and tools exist to effectively manage and respond to it. The USDA further stated that the swine industry is willing and capable of working with its producers and veterinarians to address SECD without federal assistance. The rule changes being proposed by the BOAH would repeal the provisions in state law that align with the 2016 SECD Federal Order.

1. Description of Affected Industry

As stated above, the purpose of the proposed rule is to remove the SECD disease reporting requirement in order to align the state rule with federal law. If BOAH does not proceed with the proposed rule, Indiana's 2,823 pork producers would be subject to an unnecessarily burdensome state requirement that is no longer required by USDA. The estimated number of pork producers was obtained from the USDA National Agriculture Statistic Service (USDA-NASS) 2017 Census of Agriculture.³ For purposes of the Census, a "farm" is defined as any place from which \$1,000 or more of agricultural products were produced and sold, or normally would have been sold during the census year.

BOAH takes a multifaceted approach to engaging stakeholders in the rulemaking process. For example, prior to the first reading of the rule at the Board's quarterly meeting in April, BOAH included information about the proposed changes to the SECD rule on its webpage. BOAH consults with its Swine Health Advisory Committee, which is comprised of producers and veterinary practitioners from the pork production industry, regarding any changes to rules that will have an impact on this agricultural sector. BOAH maintains topic-specific interested party lists so the affected industry can receive updates by text or email that pertain to their areas of interest. The affected industry includes small businesses under the definition at IC 4-22-2.1-4.

2. Estimated Annual Reporting, Record Keeping, and Other Administrative Costs

The proposed rule reduces reporting, record keeping and other administrative costs of regulated entities. It benefits the regulated community by eliminating the possibility that swine producers who elect to test for this

disease must pay increased testing costs as a result of the laboratory having to follow reporting protocols.

3. Estimated Total Annual Economic Impact on Small Businesses

This rule reduces compliance costs for regulated entities. The current SECD rule does not mandate testing of swine, but BOAH estimates the cost to conduct a SECD test to be approximately \$40. Specifically, the Purdue University Animal Disease Diagnostic Laboratory (ADDL) fee schedule is as follows:

Accession Fee - \$10.00 (This fee is charged for every case submitted to ADDL).

Porcine Delta Corona virus (Non Surveillance) - \$30.00

Porcine Epidemic Diarrhea virus (Non Surveillance) -\$30.00

Disease testing for SECD is voluntary as a result of a consultation between a veterinarian and his or her client. However, when a result is received, the rule imposes a duty upon a herd owner, veterinarian, caretaker, custodian, or laboratory personnel to report it. It is important to emphasize that, if the samples are submitted to a National Animal Health Laboratory Network (NAHLN) laboratory for testing, duplicate reporting by the herd owner, veterinarian, caretaker, or custodian is not required.

The duty to report in Indiana also applies in the case of a negative SECD diagnosis, which extends beyond the Federal Order. However, in the midst of the initial outbreak of the disease in 2013, the additional state requirement was included because it served as an important piece of epidemiological information for Indiana swine producers. The repeal of this requirement will ensure that a producer does not have to incur additional costs in order for the NAHLN laboratory, and possibly their veterinarian, to verify compliance with a state requirement that is no longer required by federal law. BOAH estimates that the total estimated impact (cost) will be less than \$500,000.

4. Justification of Requirements

a. Compliance with Federal and State Law

If the BOAH does not proceed with this proposed rule, it would have negative consequences with regard to economic development. It is a statutory duty of the BOAH to develop programs and work cooperatively with appropriate agencies to prevent, detect, and control diseases. IC 15-17-3-13. State law also requires an owner, veterinarian, or custodian of an animal that knows or has reason to suspect that a dangerous, contagious, or infectious disease exists in an animal to report the existence of disease to the state veterinarian within forty-eight (48) hours after discovering or having reason to suspect the disease exists. IC 15-17-10-1.

The private sector relies upon Indiana to have reporting rules in place that are consistent with federal law in order to move their products throughout the U.S. and internationally. BOAH is requesting approval to repeal this disease reporting requirement because the agency agrees with the USDA's position that resources formerly devoted to disease reporting can be more effectively used by focusing on transmission research in order to mitigate the devastating effects of this virus.

b. Justification of Requirements not Mandated by Federal or State Law

The proposed rule does not impose a requirement or cost beyond what is expressly required by federal or state law.

5. Regulatory Flexibility Analysis

Because the purpose of the proposed rule is to repeal state requirements to ensure the BOAH is no more restrictive than federal law, BOAH did not consider alternatives to the repeal. The repeal of this rule furthers a market-oriented approach by allowing state resources to be focused on providing the industry with critical information and analysis to assist them in making individualized production decisions for their farm.

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¹ USDA-APHIS Federal Order, Reporting, Herd Monitoring and Management of Novel Swine Enteric Coronavirus Diseases, June 5, 2014.

² USDA-APHIS Federal Order, *Reporting, Herd Monitoring and Management of Novel Swine Enteric Coronavirus Diseases*, January 4, 2016.

United States Department of Agriculture – 2017 Census of Agriculture, https://www.agcensus.usda.gov/