

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Pseudorabies

Rule Number(s): 901:1-11-(01-09)

Date: July 9, 2018

Rule Type:

☐ New

☐ Amended

☒ 5-Year Review

☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

The rules in this package regulate the disease known as Pseudorabies which is designated under section 901:1-21-02 of the Ohio Administrative Code (OAC) as dangerously contagious and infectious. Pursuant to authority in section 941.02 of the Ohio Revised Code, the Director of Agriculture has authority to use all proper means in the prevention and eradication of infectious and contagious diseases which pose a threat to public health or animal health.

These rules are presented as no change rules. The federal government has proposed new rules regarding pseudorabies however; these rules have been in draft form for over two years. The rules in this Chapter are up for five year rule review. Once amended by the federal government, these rules will be re-reviewed.

More specifically the rules in the chapter are as follows:

901:1-11-01 outlines the purpose of this chapter and the requirement that any test for pseudorabies be reported to the department within seven days on a form approved by the department.

901:1-11-02 sets out the definitions as used in the chapter.

901:1-11-03 prohibits the removal, alteration, or defacing of any identification applied to any animal being tested or examined for pseudorabies.

901:1-11-04 outlines requirements for the importation, possession, and use of any pseudorabies vaccine or biologic. Further, no person shall manufacture any pseudorabies vaccine unless authorized by a U.S. biologics license.

901:1-11-05 states that the department may quarantine any animals or premises where pseudorabies is known to exist or which there is good reason to suspect the presence of pseudorabies. The rule also outlines the terms for the release of quarantine.

901:1-11-06 sets the procedure for designating a herd of swine as pseudorabies free.

901:1-11-07 outlines the intrastate movement requirements for animals within certain pseudorabies areas.

901:1-11-08 states that the Department shall quarantine exposed herds and require testing of the animals within the herd.

901:1-11-09 outlines the mandatory eradication requirements of herds found to be infected with pseudorabies.

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2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

R.C. 941.03, 941.10

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

United Department of Agriculture, Animal and Plant Health Inspection Service establishes a Pseudorabies Eradication Program with which the Department participates in. The Department's participation in this program allows Ohioans to ship their swine animals across the country.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The Director of Agriculture has authority to use all proper means in the prevention and eradication of infectious and contagious diseases which pose a threat to public health or animal health. Pseudorabies is a contagious, infectious, and communicable viral disease affecting primarily swine.

In general, the virus infects the central nervous system (CNS) and the respiratory tract. Clinical signs observed depend on the age at time of infection. Young swine are very susceptible and can develop severe CNS symptoms. Mortality can reach 100 percent in piglets. Clinical signs in weaned pigs, depends on age. Few weaned pigs develop a fatal CNS disease but more often will develop a respiratory disease. Grower finishing swine typically develop only a respiratory disease component. Adult swine may have a respiratory disease component and if pregnant, depending on the trimester of pregnancy, may abort, have stillborns or give birth to weak piglets.

Through these rule and continued education to the swine communities, Ohio is pseudorabies-qualified free. Even though Ohio is currently free of the disease, the disease poses a continued risk to the animal and human populations of the state.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Success of this program is measured by the report of little or no outbreaks of pseudorabies in the state of Ohio, as well as immediate containment of any outbreaks which do occur.

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Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

On June 13, 2018, the stakeholders below were notified via email of the rules up for review.

Capitol Advocates	Rob Eshenbaugh
Capitol Consulting	Belinda Jones
Environmental Defense Fund	Katie Champan
Environmental Law & Policy Center	Madeline Fleisher
Former State Veterinarian	David Glauer
Humane Society of the United States	Corey Roscoe
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio Belgian Breeders Association	Carolyn Piergallini
Ohio Dairy Producers	Scott Higgins
Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio Farm Bureau	Adam Sharp
Ohio Farm Bureau	Jack Irvin
Ohio Farm Bureau	Larry Antosh
Ohio Farm Bureau	Tony Seegers
Ohio Farm Bureau	Yvonne Lesicko
Ohio Farm Bureau	Leah Curtis
Ohio Farmers Union	Joe Logan
Ohio Farmers Union	Linda Borton
Ohio Haflinger Association	Lucy Workman
Ohio Harness Horsemen's Association	Renee Mancino
Ohio Percheron Breeders Association	Darlana Chettle
Ohio Pork Producers Council	Bryan Humphreys
Ohio Poultry Association	Jim Chakeres
Ohio Quarter Horse Association	Scott Myers
Ohio State University	Adam Ward
Ohio Veterinarian Medical Association	Jack Advent
Ohio Veterinarian Medical Association	Michelle Holdgreve
Ohio Welsh Pony Association	Paul Hurd
Sierra Club, Ohio Chapter	Jennifer Miller
The Nature Conservancy	Anthony Sasson
The Ohio State University	Dr. Jeanette O'Quinn
USDA – APHIS	Dr. Roger Krogwold

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8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Department emailed the stakeholders listed above a copy of the rules and gave them an opportunity to comment. Stakeholders agreed that proceeding with a no-change rule package would be best at this time.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The testing requirements of this rule have been developed for over 40 years. Adherence to this schedule of testing has dramatically reduced the number of reported cases of pseudorabies.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The Department is statutorily tasked with the control and eradication of contagious and infectious diseases to protect the animals of the state under Chapter 941. The status of these diseases identified on this list as dangerously contagious and infectious are based on scientific research supporting this designation. In addition, the identification of these diseases as dangerously contagious and infectious diseases is generally nationally accepted. Stakeholder participation in this rule package has indicated to the Department that this is the best regulatory scheme at this time. For those reasons, no other regulatory alternatives were considered.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

The rules in this chapter are not performance based due to the nature of what is being regulated, which is providing the framework for those diseases which are designated dangerously contagious or infectious. Upon diagnosis of pseudorabies in an animal, the rule provides the authority to immediately quarantine the animal and a requirement that the disease is reported to Department

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Department is given sole regulatory authority to designate dangerously contagious or infectious diseases in R.C. 941.03.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

These rules are already implemented within the industry and the Department works with all livestock dealers and those involved in animal industries to educate and inform them on the safety regulations. Additional education and outreach will be performed with the affected communities of the changes by the Animal Health Division. The staff members of the Animal Health Division ensure that all swine owners are treated in a similar manner.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

All swine owners and producers.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Currently, Ohio is a free state for pseudorabies. This removes the testing requirements for these animals as they have originated from a free state. However, should Ohio have an outbreak of this disease, livestock owners and producers could be subject to the testing requirements as outlined in this rule.

In the event that an animal is classified as suspect or positive for pseudorabies, the breeder or producer will be subject to immediate quarantine of their animal and potentially their facility or farm. They will also be subject to the reporting requirement of the presence of the disease in their facility or farm which may take time during normal business hours.

c. Quantify the expected adverse impact from the regulation.

Tests for pseudorabies are approximately \$1.40 or \$2.25 per animal, plus any veterinarian fees which will vary from veterinarian to veterinarian.

In the event an animal in their possession does receive a diagnosis of pseudorabies, they will be obligated to use business time to notify the Department of the presence of the disease, which should not exceed more than a half hour after discovery of the disease. They also cannot sell or otherwise move the animal, and potentially may not

be able to move, transfer, or otherwise sell any other animal on the premises until it is determine the animal has recovered, the remaining animals are disease-free, or other containment takes place. The breeder or producer will likely be subject to veterinarian costs for diagnosis and treatment, which will vary on the location and the individual veterinarian providing the services. In the event that the animal does not recover, the breeder or producer may be subject to losing the animal to prevent the spread of the disease.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Department acknowledges that there will be an adverse impact on the business community. However, the Department is also directed by statute to protect the health and safety of Ohio's animals and Ohio's consumers. As an outbreak of the disease could significantly impact the livestock industry, the adverse impact is considered justified.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Due to the health and safety nature of the rule, different standards based on the size of the business would be inappropriate.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Due to the potential to cause serious harm to public and animal health, the Department does not waive penalties or fines for first time violators.

18. What resources are available to assist small businesses with compliance of the regulation?

These rules are already implemented within the industry and the Department works with all stakeholders in order to educate and inform them on the regulations.