

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 901:1-11-04
Rule Type: No Change
Rule Title/Tagline: Vaccination.
Agency Name: Department of Agriculture
Division: Animal Industry
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I. Rule Summary

1. **Is this a five year rule review?** Yes
 - A. **What is the rule's five year review date?** 9/4/2018 and 09/04/2023
2. **Is this rule the result of recent legislation?** No
3. **What statute is this rule being promulgated under?** 119.03
4. **What statute(s) grant rule writing authority?** 941.03, 941.09
5. **What statute(s) does the rule implement or amplify?** 941.09
6. **What are the reasons for proposing the rule?**

The rule is up for five year rule review.

7. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

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.

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.

8. **Does the rule incorporate material by reference? Yes**
9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.**

Pursuant to section 121.76 of the Revised Code, the code sections incorporated into this rule are exempt from compliance with sections 121.71 to 121.74 of the Revised Code.
10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

II. Fiscal Analysis

11. **As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.**

This will have no impact on revenues or expenditures.

0.00

Not applicable.

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

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 determined 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.

13. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B).** No
14. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C).** No

III. Common Sense Initiative (CSI) Questions

15. **Was this rule filed with the Common Sense Initiative Office?** Yes
16. **Does this rule have an adverse impact on business?** Yes
 - A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business?** No
 - B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms?** Yes

Failure to comply may result in criminal or civil penalties being issued against the violator.
 - C. **Does this rule require specific expenditures or the report of information as a condition of compliance?** Yes

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