



# Common Sense Initiative

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Joseph Baker, Director

## Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Agriculture

Rule Contact Name and Contact Information: Renee Schmauch  
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Regulation/Package Title (a general description of the rules' substantive content):

Anthrax Control- Five Year Rule Review

Rule Number(s): 901:1-3-01

Date of Submission for CSI Review: 12/5/2023

Public Comment Period End Date: 12/27/2023

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/ 1 rule (FYR? 1)

Amended/\_\_\_ rules (FYR? \_\_\_)

Rescinded/\_\_\_ rules (FYR? \_\_\_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☐ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☐ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

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

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

Ohio Administrative Code (OAC) 901:1-3-01 outlines regulations for controlling anthrax in bone products. Anthrax is a disease caused by the bacterium *Bacillus anthracis*. The disease is generally lethal and can affect most animals. Due to the serious nature of the disease, Anthrax is listed as dangerously contagious, infectious and reportable pursuant to OAC 901:1-21-02. In order to prevent the spread of anthrax, the rule prohibits the use of bone products in animal feedstuffs unless they have been processed in a manner rendering them free from viable anthrax spores.

The rule has been reviewed in accordance with the five year rule review process and is being submitted with no changes.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

941.03

4. 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.*

Not Applicable

5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not Applicable

6. 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. A disease's inclusion on the OAC 901:1-21-02 list allows the Department to continuously monitor the disease and act swiftly should an outbreak occur. Anthrax is an extremely deadly disease whose outbreak could potentially result in the death of humans and animals alike. For these reasons, regulation is essential.

7. 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 Anthrax in the state of Ohio, as well as immediate containment of any outbreaks which do occur.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No

### **Development of the Regulation**

9. 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 September 27, 2023, the following stakeholders were emailed a copy of the proposed rules and the comment period remained open until October 11, 2023. These stakeholders represent statewide organizations and individuals with an interest in the division of Animal Health rules.

#### **Organization**

Anderholm Veterinary Clinic  
Animal Medical & Surgical Center  
Animal Welfare Institute  
Animals Unlimited Veterinary Hospital  
Barnesville-Woodsfield Veterinary Service LLC  
Byland Animal Hospital  
Celina Animal Hospital, Inc.

#### **Contact**

Anderholm, Constance  
Darr, Cathrine  
Craig, Adrienne  
Anderson, Valerie  
  
Miesse, Craig

Claremont Vet Clinic  
Coldwater Animal Clinic/ Ft Recovery  
Columbus Dog Connection  
Country Roads Veterinary Services  
Darke County Health Commissioner  
Crank and Kirkpatrick Animal Hospital  
Danville Veterinary Clinic  
Danville Veterinary Clinic  
Delaware Equine LLC  
Diamond M Veterinary Clinic  
Environmental Defense Fund  
East Holmes Vet Clinic  
East Holmes Vet Clinic  
East Holmes Vet Clinic  
Environmental Law & Policy Center  
Fayette Veterinary Hospital  
Green Camp Vet Clinic  
Healthy Pets of Wedgewood  
Hillsboro Veterinary Hospital  
Humane Society of the United States  
Karr Veterinary Clinic  
Kolehmainen Veterinary Clinic  
Lisbon Vet Clinic Inc  
Masterson Veterinary Clinic  
MedVet Columbus  
Mogadore Vet Hospital  
Mt Hope Vet Services,  
Walnut Creek Veterinary Clinic  
Northgate Animal Hospital  
Ohio Animal Welfare Federation  
Ohio Beef Council/Ohio Cattlemen's Association  
Ohio Belgian Breeders Association  
Ohio Dairy Producers  
Ohio Dairy Veterinarians  
Ohio County Dog Warden's Association  
Ohio Ecological Food and Farm Association  
Ohio Farm Bureau  
Ohio Farm Bureau  
Ohio Farm Bureau  
Ohio Farm Bureau  
Ohio Farm Bureau

Kaeser, Donald R  
Seeger, Urban  
Defrischia, Kelly  
Brennan, David T  
Terrence Holman, DVM

Webb, L. Jarrod  
Hoxworth, Teresa  
Chase, James P  
Kearns, Earnest  
Karen Champan  
Shaver, Eric M  
Wise, Aaron  
Mierzwiak, Kristen  
Madeline Fleisher

Forshey, Melissa

Corey Roscoe  
Karr, Paul E  
Kolehmainen, William J  
Schmucker, Gordon  
Masterson, Rhonda

Whittington, David

Varga, Joseph  
Gibson, Douglas  
Colleen Evans  
Elizabeth Harsh  
Carolyn Piergallini  
Scott Higgins  
Dr. Gabe Middleton  
Barb Knapp  
Amalie Lipstreu  
Adam Sharp  
Jack Irvin  
Larry Antosh  
Leah Curtis  
Roger High

Ohio Farm Bureau  
Ohio Farm Bureau  
Ohio Farmers Union  
Ohio Farmers Union  
Ohio Forum for Companion Animals  
Ohio Haflinger Association  
Ohio Harness Horsemen's Association  
Ohio Percheron Breeders Association  
Ohio Pork Producers Council  
Ohio Poultry Association  
Ohio Quarter Horse Association  
Ohio Soil and Water Conservation Commission  
Ohio Soybean Association

Ohio State University  
Ohio Veterinarian Medical Association  
Ohio Veterinarian Medical Association  
Ohio Veterinarian Medical Association  
Ohio Welsh Pony Association  
Paw Patch Veterinary Services  
Pondview Veterinary Clinic  
Pondview Veterinary Clinic  
Shawnee Animal Clinic  
Shelby Animal Clinic  
Stonyridge Veterinary Service  
Sugarcreek Veterinary Clinic  
Sugarcreek Veterinary Clinic  
Sugarcreek Veterinary Clinic  
The Ohio State University  
The Ohio State University  
The Ohio State University  
The Ohio State University  
The Plains Veterinary Hospital, LLC  
Twin Valley Animal Hospital  
Twinsburg Vet Hospital  
USDA – APHIS VS  
Wellington Veterinary Clinic  
Westside Animal Clinic  
Wheelersburg Animal Hospital Inc.  
Willard Veterinary Clinic  
OEMA

Tony Seegers  
Yvonne Lesicko  
Joe Logan  
Linda Borton  
Leon Beachy  
Lucy Workman  
Renee Mancino  
Darlena Chettle  
Cheryl Day  
Jim Chakeres  
Scott Myers  
Tom Price  
Brandon Kern  
Dr. Tom Wittum  
Adam Ward  
Jack Advent  
R. David Frash  
  
Paul Hurd  
Hirt, Laurie  
Dougherty, Patrick  
Small, Tasha Nichole  
Sherman, Angela  
Knox, John W  
Eisenberg, Eric  
Donley, Shane  
Honigford, James  
Clay, Aimee  
Dr. Tom Wittum  
Dr. Rustin Moore  
Dr. Jeanette O'Quinn  
Peggy Hall  
Ryan, Ericka  
Twin Valley Animal Hospital  
Lozanoff, Stacy  
Dr. Roger Krogwold  
Spreng, William A  
Ayars, William  
  
Brad Schwartz

OEPA  
ODNR DOW

USDA APHIS WS  
United Producer's Inc  
DHI Cooperative, Inc  
Aquaculture  
Anderholm Veterinary Clinic  
Animal Medical & Surgical Center  
Animals Unlimited Veterinary Hospital  
ASPCA  
Barnesville-Woodsfield Veterinary Service LLC  
The Batchelder Company  
Burroughs Veterinary Services  
Byland Animal Hospital  
Capitol Advocates  
Capitol Consulting  
Celina Animal Hospital, Inc.  
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Coldwater Animal Clinic/ Ft Recovery  
Columbiana County Dog Warden  
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Danville Veterinary Clinic  
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Diamond M Veterinary Clinic  
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East Holmes Vet Clinic  
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Fayette Veterinary Hospital  
Green Camp Vet Clinic  
Greenfield Vet  
Healthy Pets of Wedgewood  
Heritage Veterinary Care  
Hillsboro Veterinary Hospital  
Hocking Hills Animal Clinic  
Holmes County Dog Warden  
Humane Society of the United States  
Karr Veterinary Clinic

Alison Shockley  
Kendra Wecker  
Mike Tonkovich  
Andy Montenev  
Mike Bumgarner  
Brian Winters  
Dan Longnecker  
Anderholm, Constance  
Darr, Cathrine  
Anderson, Valerie

Judy, Troy  
Burroughs, Mark Steven

Rob Eshenbaugh  
Belinda Jones  
Miesse, Craig  
Kaeser, Donald R  
Seger, Urban

Brennan, David T

Hoxworth, Teresa  
Chase, James P  
Kearns, Earnest  
Karen Champan  
Shaver, Eric M  
Wise, Aaron  
Mierzwiak, Kristen  
Madeline Fleisher

Forshey, Melissa  
Sims, Michael

Shannon Moore

Corey Roscoe  
Karr, Paul E

Knox County Dog Warden  
Kolehmainen Veterinary Clinic  
Lisbon Vet Clinic Inc  
Little Puppies Online LLC  
Masterson Veterinary Clinic  
MedVet Columbus  
Mogadore Vet Hospital  
Mt Hope Vet Services,  
Walnut Creek Veterinary Clinic  
Napoleon Veterinary Clinic  
Northgate Animal Hospital  
Ohio Animal Welfare Federation  
Ohio Beef Council/Ohio Cattlemen's Association  
Ohio Belgian Breeders Association  
Ohio Dairy Producers  
Ohio County Dog Warden's Association  
Ohio Ecological Food and Farm Association  
Ohio Farm Bureau  
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Ohio Forum for Companion Animals  
Ohio Haflinger Association  
Ohio Harness Horsemen's Association  
Ohio Percheron Breeders Association  
Ohio Pork Producers Council  
Ohio Poultry Association  
Ohio Quarter Horse Association  
Ohio State University  
Ohio Veterinarian Medical Association  
Ohio Veterinarian Medical Association  
Ohio Welsh Pony Association  
Paw Patch Veterinary Services  
Petco  
Pondview Veterinary Clinic  
Pondview Veterinary Clinic  
Premier Pups LLC

John Carhart  
Kolehmainen, William J  
Schmucker, Gordon  
Nathan Bazler  
Masterson, Rhonda  
  
Whittington, David  
  
Varga, Joseph  
  
Gibson, Douglas  
Colleen Evans  
Elizabeth Harsh  
Carolyn Piergallini  
Scott Higgins  
Barb Knapp  
Amalie Lipstreu  
Adam Sharp  
Jack Irvin  
Larry Antosh  
Leah Curtis  
Roger High  
Tony Seegers  
Joe Logan  
Linda Borton  
Leon Beachy  
Lucy Workman  
Renee Mancino  
Darlena Chettle  
Bryan Humphreys  
Jim Chakeres  
Scott Myers  
Adam Ward  
Jack Advent  
R. David Frash  
Paul Hurd  
Hirt, Laurie  
Mike Gonidakis  
Dougherty, Patrick  
Small, Tasha Nichole  
Michael Schoeff

Shawnee Animal Clinic  
 Shelby Animal Clinic  
 Sierra Club, Ohio Chapter  
 Stonyridge Veterinary Service  
 Sugarcreek Veterinary Clinic  
 Sugarcreek Veterinary Clinic  
 Sugarcreek Veterinary Clinic  
 Sugarcreek Veterinary Clinic  
 The Ohio State University  
 The Ohio State University  
 The Plains Veterinary Hospital, LLC  
 Tuscarawas County Dog Warden  
 Twin Valley Animal Hospital  
 Twinsburg Vet Hospital  
 USDA – APHIS  
 USDA – APHIS  
 Walnut Hills Vet  
 Wayne County Dog Warden  
 Wellington Veterinary Clinic  
 Westside Animal Clinic  
 Wheelersburg Animal Hospital Inc.  
 Willard Veterinary Clinic  
 Your New Puppy  
 Hocking Hills Animal Clinic  
 Commercial Dog Breeder Advisory Board  
 Commercial Dog Breeder Advisory Board  
 Commercial Dog Breeder Advisory Board  
 Commercial Dog Breeder Advisory Board  
 Commercial Dog Breeder Advisory Board  
 Commercial Dog Breeder Advisory Board  
 Country Road Veterinary Services  
 Town and Country Veterinary Clinic  
 Orrville Veterinary Clinic

Sherman, Angela  
 Knox, John W  
 Adam Rissien  
 Eisenberg, Eric  
 Daugherty, Rick  
 Donley, Shane  
 Honigford, James  
 Sugarcreek Veterinary Clinic  
 Dr. Jeanette O'Quinn  
 Peggy Hall  
 Ryan, Ericka  
  
 Lozanoff, Stacy  
 Dr. Roger Crogwold  
 Dr. Susan Skorupski  
 Mark Parker  
  
 Spreng, William A  
 Ayars, William  
  
 Mark Johnson  
 Shannon Moore  
 Matt Granito  
 Linda Stickney  
 Lisa Zimmerman  
 Lori Carlson  
 Dr. Micheal Frederick  
 Dr. Patricia Haynes  
 Dr. Dennis Trautwein  
 Dr. Greg Price  
 Dr. Gabe Middleton

**10. 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. No comments were received.

**11. 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?**



Anthrax generally ceased to be an environmental issue during the 1930's with the development of an anthrax vaccine. However, outbreaks of the disease in the late 1970's and early 1980's indicated that the disease is still naturally occurring and a danger to humans and animals. Further, use of the bacteria *Bacillus anthracis* in the early 2000's as biological weapons continued to show the risk of Anthrax. The World Health Organization has commissioned several studies of Anthrax and *Bacillus anthracis* over the last several decades. The terms of our rule are consistent with those findings.

- 12. 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?**  
*Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

In accordance with R.C. Chapter 941, the Department is statutorily tasked with the control and eradication of contagious and infectious diseases to protect the animals of the state. The status of the diseases identified in OAC 901:1-21-02 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. For those reasons, no other regulatory alternatives were considered.

- 13. 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 animal diseases in R.C. 941.03.

- 14. 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.**

This rule is already implemented within the industry and the Department works with all stakeholders in order to educate and inform them on the safety regulations.

### **Adverse Impact to Business**

- 15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community, and**  
The rule in this package will have an impact on the processing of animal feed stuffs.
- b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**  
*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.*

All bone products intended for use as animal feed stuffs must be processed in a manner which renders them free of viable Anthrax spores. This generally requires a heat process which steams or degelantizes the bone.

If a product is found or suspected to be contaminated with anthrax spores, the product shall either be sterilized or destroyed immediately.

There exists a potential for loss of product should anthrax spores exist in a food product. The quantified impact of this loss depends on the amount of product lost. Further, there is an additional processing step that must occur in all animal feed stuff processing. However, this is already been incorporated as a general industry practice to free animal bones of all bacteria and organisms, not just anthrax spores.

- 16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

No

- 17. 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 directed by statute to protect the health and safety of Ohio's animals and Ohio's consumers. The potential health implications of an anthrax outbreak are far greater than the adverse impact on business in this situation. Further, the practices already taken by industry in order to comply with the rule are standard industry practice. Therefore, the adverse business impact is considered justified.

### **Regulatory Flexibility**

- 18. 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.

- 19. 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.

- 20. What resources are available to assist small businesses with compliance of the regulation?**

This rule is already implemented within the industry and the Department works with all stakeholders in order to educate and inform them on the regulations.