



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

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Regulation/Package Title (a general description of the rules' substantive content):

Brucella canis

Rule Number(s): 901:1-5-12

Date of Submission for CSI Review: 11/19/2024

Public Comment Period End Date: 12/10/2024

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 1 rules (FYR? yes)

Rescinded/___ rules (FYR?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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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 rules 901:1-5-12 has been reviewed pursuant to the Five-Year Rule Review requirements. This rule regulates the disease known as Brucella canis 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.

The Department has reviewed the rule with its stakeholders and has proposed the following amendments:

901:1-5-12 outlines testing standards of Brucella canis. The rule outlines the acceptable types of tests as well as the entities which may perform the tests. Further, the rule outlines three types of Brucella canis classification: positive, suspect, and negative. The rule requires that upon the diagnosis of either a Brucella canis positive or suspect that the animal be quarantined until further testing. Additionally, the rule outlines potential restrictions on the movement of animals which are positive or suspect.

This rule has been amended with grammatical edits to improve readability and makes changes based on the Ohio Legislative Service Commission's (LSC) rule drafting manual. In addition, the rule has been amended to revise "Approved laboratories" to the terminology used currently, "Accredited Laboratories," a definition has been added to define "Accredited Laboratory," and

further defines the criteria for a *Brucella canis* test. Also, the rule has been amended to add that further testing may be done for a reclassification at the discretion of the Ohio Department of Agriculture (ODA), adds information that needs to be included on the report to ODA as well as how to submit the report and the time frame for submitting a sample. The rule has been amended to update how veterinarians must identify a canine that is to be tested with current practices, defines a “whole kennel,” revises the language of when a *brucella canis* positive, exposed, or suspect shall be released from quarantine and adds that ODA or the National Veterinary Services Laboratory shall conduct the testing for the quarantine order to be modified or lifted. Lastly, the rule has been amended to add requirements for the sale, movement, and disposal of animals when known to be *brucella canis* exposed, suspect, or positive.

- 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.**

R.C. 941.02, 941.03, 941.22

- 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.

No

- 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. *Brucella canis* is a bacterium in the family Brucellaceae that causes brucellosis in dogs and other canids. Brucellosis is characterized by fever, lymphadenopathy, weight loss, abortion, reproductive impairment, and infertility in dogs, as well as ocular inflammation, and joint issues such as discospondylitis. A widespread outbreak of *Brucella canis* could be very costly for the canine breeding industry in the state. Due to the effects of the disease, canines that have contracted the disease produce far fewer healthy puppies than those who have not been infected. A reduced number of healthy puppies produced may result in smaller profits for much of the canine industry and the potential to force many canine producers out of business.

Additionally, this disease is zoonotic which means that it may be transmitted to humans. Studies have shown that humans infected with *Brucella canis* may see the following symptoms: fever (often periodic and nocturnal), fatigue, headache, weakness, joint pain, malaise, chills, sweats, weight loss, hepatomegaly, splenomegaly, and lymphadenopathy.

Due to this potential threat to public and animal health, this rule is necessary to track, test, and eradicate the disease in the state.

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

This rule has been in effect since 2015. Since that time the Department has seen a dramatic reduction in the number of suspect and positive animals. The Department believes that this is a result of this rule as well as the education provided to dog breeders across the state. The Department will continue to measure success by the number of suspect and positive tests.

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 October 3, 2024, the Department contacted the list of stakeholders below via email. The stakeholder comment period was open until October 17, 2024.

AABP	Fred Gingrich
AASV	Bill Minton
AAEP	Scott Myers
ANDERHOLM VETERINARY CLINIC	Anderholm, Constance
Animal Welfare Institute	Craig, Adrienne
Animal Welfare Institute	Reyes, Gwendy
ANIMALS UNLIMITED VETERINARY HOSPITAL	Anderson, Valerie
Aquaculture	Dan Longnecker
Barnesville-Woodsfield Veterinary Service LLC	general email
Buckeye Quality Beef Association	David Hyde
Burroughs Veterinary Services	Dr Brittany Erbe (Burroughs)
Burroughs Veterinary Services	Dr Mark Burroughs
BYLAND ANIMAL HOSPITAL	general email
Capital Advocates	Kurt Leib
Capitol Advocates	Rob Eshenbaugh
Capitol Consulting	Belinda Jones
CELINA ANIMAL HOSPITAL, INC.	Miesse, Craig
CLAREMONT VET CLINIC	Kaeser, Donald R
Columbiana County Dog Warden	general email
Columbus Dog Connection	DiFrischia, Kellie

Commercial Dog Breeding Advisory Committee	Dr. Patricia Haines
Commercial Dog Breeding Advisory Committee	Linda Stickney
Commercial Dog Breeding Advisory Committee	Lori Carlson
Commercial Dog Breeding Advisory Committee	Matt Granito
Commercial Dog Breeding Advisory Committee	Linda Stickney
Commercial Dog Breeding Advisory Committee	April Burnside
Commercial Dog Breeding Advisory Committee	Suzanne Wilcox
COUNTRY ROADS VETERINARY SERVICES	Brennan, David T
CRANK AND KIRKPATRICK ANIMAL HOSPITAL	general email
DANVILLE VETERINARY CLINIC	Hoxworth, Teresa
DANVILLE VETERINARY CLINIC	Webb, L. Jarrod
Delaware Equine LLC	Chase, James P
DHI Cooperative, Inc	Brian Winters
DIAMOND M VETERINARY CLINIC	Kearns, Earnest
East Holmes Vet Clinic	Mierzwiak, Kristen
East Holmes Vet Clinic	Shaver, Eric M
East Holmes Vet Clinic	Wise, Aaron
FAYETTE VETERINARY HOSPITAL	general email
GREEN CAMP VET CLINIC	Forshey, Melissa
Greenfield Vet	Sims, Michael
HEALTHY PETS OF WEDGEWOOD	general email
Heritage Veterinary Care	general email
Hillsboro Veterinary Hospital	general email
Hocking Hills Animal Clinic	Shannon Moore
Holmes County Dog Warden	general email
Humane Society of the United States	Corey Roscoe
Humane Society of the United States	Mark Finneran
Ice Miller	Samuel Porter
Karr Veterinary Clinic	Karr, Paul E
Knox County Dog Warden	John Carhart
KOLEHMAINEN VETERINARY CLINIC	Kolehmainen, William J
LISBON VET CLINIC INC	Schmucker, Gordon
Little Puppies Online LLC	Nathan Bazler
MASTERSON VETERINARY CLINIC	Masterson, Rhonda
MedVet Columbus	Eric Schertel
Mogadore Vet Hospital	Whittington, David
Mt Hope Vet Services, Walnut Creek Veterinary Clinic	Varga, Joseph
Napoleon Veterinary Clinic	general email
Nation Farmers Organization	Alva Heiss
Northgate Animal Hospital	Gibson, Douglas

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Northview Vet Clinic	Dr. Hutchinson
ODNR DOW	Kendra Wecker
OEPA	Alison Shockley
Ohio Fair Managers Association	Meg Noah
Ohio Ag Council	Janice Welsheimer
Ohio Agribusiness Association	Aaron Heilers
Ohio Agribusiness Association	Janice Welsheimer
Ohio Agribusiness Association	Lauren Prettyman
Ohio Agribusiness Association	Melinda Witten
Ohio Animal Welfare Federation	Colleen Evans
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio Belgian Breeders Association	Carolyn Piergallini
OEMA	Collin Campbell
OEPA	Alison Shockley
Ohio Dairy Producers	Scott Higgins
Ohio Dairy Veterinarians	Dr. Gabe Middleton
Ohio Dairy Veterinarians	general email
ODNR DOW	Kendra Wecker
Ohio Farm Bureau	Adam Sharp
Ohio Farm Bureau	Jack Irvin
Ohio Farm Bureau	Leah Curtis
Ohio Farm Bureau	Roger High
Ohio Farm Bureau	Tony Seegers
Ohio Farm Bureau	Jordan Hoewischer
Ohio Farmers Union	Joe Logan
Ohio Forum for Companion Animals	Leon Beachy
Ohio Forum for Companion Animals	general email
Ohio Forum for Companion Animals	Daniel Schlabach
Ohio Forum for Companion Animals	Joseph Miller
Ohio Haflinger Association	Lucy Workman
Ohio Harness Horsemen's Association	Kim Poma
Ohio Percheron Breeders Association	Darlana Chettle
Ohio Pork Producers Council	Cheryl Day
Ohio Poultry Association	Jim Chakeres
Ohio Quarter Horse Association	Scott Myers
Ohio Soil and Water Conservation Commission	Tom Price
Ohio Soybean Association	Brandon Kern
Ohio State Grange	Mike Russell
Ohio Veterinarian Medical Association	general email
Ohio Veterinarian Medical Association	Jack Advent
Ohio Veterinarian Medical Association	Chris Henney

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Ohio Veterinarian Medical Association	R. David Frash
Ohio Welsh Pony Association	Paul Hurd
Paw Patch Veterinary Services	Hirt, Laurie
Petco	Mike Gonidakis
PONDVIEW VETERINARY CLINIC	Dougherty, Patrick
PONDVIEW VETERINARY CLINIC	Small, Tasha Nichole
Premier Pups LLC	Michael Schoeff
Sierra Club, Ohio Chapter	Adam Rissien
STONYRIDGE VETERINARY SERVICE	Eisenberg, Eric
Sugarcreek Veterinary Clinic	Daugherty, Rick
Sugarcreek Veterinary Clinic	Donley, Shane
Sugarcreek Veterinary Clinic	Honigford, James
Sugarcreek Veterinary Clinic	Sugarcreek Veterinary Clinic
The Batchelder Company	Judy, Troy
The Ohio State University	Dr. Jeanette O'Quinn
The Ohio State University	Dr. Rustin Moore
The Ohio State University	Dr. Tom Wittum
The Ohio State University	Peggy Hall
Ohio State University	Adam Ward
THE PLAINS VETERINARY HOSPITAL, LLC	Ryan, Ericka
Tuscarawas County Dog Warden	general email
Twin Valley Animal Hospital	Twin Valley Animal Hospital
Twinsburg Vet Hospital	Stacy Lozanoff
United Producer's Inc	Mike Bumgarner
USDA-APHIS-AC	Dana Miller
USDA – APHIS VS	Dr. Leeza Bercaw
USDA – APHIS VS	Dr. Jamie Davis
USDA APHIS WS	Andy Montenev
Wayne County Dog Warden	general email
WHEELERSBURG ANIMAL HOSPITAL INC.	general email
WILLARD VETERINARY CLINIC	general email
Veterinarian	Dr. Dennis Trautwein
Veterinarian	Dr. Gabe Middleton
Veterinarian	Dr. Greg Price
Veterinarian	Hoxworth, Teresa
Veterinarian	Mike Tonkovich
Veterinarian	Meghan Provo
Veterinarian	Dr. Micheal Frederick
Member of the public	Zharon VanMeter
Member of the public	Vicki Deisner
Member of the public	Lisa Zimmerman

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

The Department received two comments during the stakeholder comment period. One from Dr. Shaver, a veterinarian in the state of Ohio, supporting the proposed rule and Zaron VanMeter whose comment brings awareness to the evaluation of a new vaccine for canine brucellosis which does not affect the revision of this rule currently.

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?

Recent outbreaks of the disease have demonstrated what the potential environmental, health, and economic impacts of widespread infection would have on the canine industry. Further, the Department conducted an independent study of the effectiveness of the available *Brucella canis* tests. The Department determined that the canine antibody test (more commonly referred to as the “card test”) and the polymerase chain reaction test (PCR) were not effective tests for the disease in kennel settings.

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.

The Department is statutorily tasked with the control and eradication of contagious and infectious diseases to protect the animals of the state under R.C. Chapter 941. Additionally, lack of stakeholder participation for this rule indicates to the Department that this is the best regulatory scheme at this time. 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 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 high-volume dog breeders to educate them about the disease, biosecurity measures, and testing requirements. 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 canine owners are treated in a similar manner. The Department has online resources and has field staff available to provide assistance.

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 rules in this package will have an impact on dog owners and high-volume dog breeders licensed under chapter 956 of the Revised Code.

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.

Pursuant to R.C. 941.03 and OAC 901:1-5-12 the accredited veterinarians who conduct brucella canis testing or submit samples for brucella canis testing will be obligated to use business time to report to the Department the presence of the disease along with required information within seven days. Owners 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 the Department has conducted an epidemiological investigation, the remaining animals are classified as disease-free, or other containment and conditions takes place. The breeder is 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 an animal is classified as positive, the breeder may be subject to losing the animal to prevent the spread of the disease.

Indirect Fluorescent Antibody Test - \$15.00 per test; 5 pooled samples

Tube Agglutination Test - \$19.10 per test

Brucella canis Culture Test - \$40.10 per test

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 also directed by statute to protect the health and safety of Ohio's animals and Ohio's consumers. Due to the danger to both public and animal health

this rule is deemed necessary. The Department has worked closely with members of the regulated business community and Ohio's veterinarians and at this time the rules as set forth represent the best balance of animal and public health and adverse business impact.

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?

The Department has an established Commercial Dog Breeding office within the Animal Health division, which is available to work with any business that needs assistance with educational materials.