

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: *Brucella canis* Testing Five Year Review

Rule Number(s): 901:1-5-12 and 13.

Date: July 30, 2018

Rule Type:

<input type="checkbox"/> New	<input checked="" type="checkbox"/> 5-Year Review
<input checked="" type="checkbox"/> Amended	<input type="checkbox"/> Rescinded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.

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.

Ohio Administrative Code rules 901:1-5-12 and 13 have been reviewed pursuant to the Five-Year Rule Review requirements. The rules in this package regulate 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 rules set forth in this package create testing standards as well as standards recognizing dog kennels as *Brucella canis* free. The Department has reviewed the rules with its stakeholders and have 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.

The rule has been amended to remove the canine antibody test (more commonly referred to as the “card test”) and the polymerase chain reaction test (PCR) as accepted tests for *Brucella canis*. Through independent verification by the Department these tests have been found to be unreliable in the testing of *Brucella canis*. In addition, the rule has been amended to update the process from being released from quarantine. Animals which successively test negative to a brucella canis test at least sixty days apart can be properly determined to be free of brucella canis.

901:1-5-13 sets forth the procedures for a kennel licensed under chapter 956 of the Revised Code to become certified as a *Brucella canis* free kennel. A kennel may be awarded that designation if the kennel has had two successive whole kennel negative tests, continues required testing, and ensures that all additions to the kennels comply with the rules. This certification is currently voluntary and has been requested by the industry as an opportunity to show consumers that their facility is a clean, safe, and reputable business.

The rule has been amended to use consistent terminology with OAC 901:1-5-12. Further, clarifications have been made to the rule to ensure proper enforcement.

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

R.C. 941.02, 941.03

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.

No.

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. *Brucella canis* is form of brucellosis which is characterized by abortion, reproductive impairment, and infertility in dogs, as well as ocular inflammation. A wide spread 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 whom 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, malaise, chills, sweats, weight loss, hepatomegaly, splenomegaly, and lymphadenopathy.

Due to this potential threat to public and animal health, these rules are necessary to track, test, and eradicate the disease in the state.

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

These rules have 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 these rules 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.

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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 20, 2018, the Department contacted the list of stakeholders below via email. The stakeholder comment period was open until July 6, 2018.

Capitol Advocates	Rob Eshenbaugh
Capitol Consulting	Belinda Jones
Environmental Defense Fund	Katie Champan
Environmental Law & Policy Center	Madeline Fleisher
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 Professional Dog Breeders Association	Ervin Raber
Ohio Professional Dog Breeders Association	Abe Miller
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
The Nature Conservancy	Anthony Sasson
The Ohio State University	Dr. Jeanette O'Quinn

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USDA – APHIS	Dr. Roger Krogwold
USDA – APHIS	Dr. Susan Skorupski
ANDERHOLM VETERINARY CLINIC	Anderholm, Constance
Animal Medical & Surgical Center	Darr, Cathrine
ANIMALS UNLIMITED VETERINARY HOSPITAL	Anderson, Valerie
Barnesville-Woodsfield Veterinary Service LLC	
Burroughs Veterinary Services	Burroughs, Mark Steven
BYLAND ANIMAL HOSPITAL	
CELINA ANIMAL HOSPITAL, INC.	Miese, Craig
CLAREMONT VET CLINIC	Kaeser, Donald R
COLDWATER ANIMAL CLINIC/ Ft Recovery	Seeger, Urban
COUNTRY ROADS VETERINARY SERVICES	Brennan, David T
CRANK AND KIRKPATRICK ANIMAL HOSPITAL	
DANVILLE VETERINARY CLINIC	Webb, L. Jarrod
DANVILLE VETERINARY CLINIC	Hoxworth, Teresa
Delaware Equine LLC	Chase, James P
DIAMOND M VETERINARY CLINIC	Kearns, Earnest
East Holmes Vet Clinic	Shaver, Eric M
East Holmes Vet Clinic	Wise, Aaron
East Holmes Vet Clinic	Mierzwiak, Kristen
FAYETTE VETERINARY HOSPITAL	
GREEN CAMP VET CLINIC	Forshey, Melissa
HEALTHY PETS OF WEDGEWOOD	
Hillsboro Veterinary Hospital	
Karr Veterinary Clinic	Karr, Paul E
KOLEHMAINEN VETERINARY CLINIC	Kolehmainen, William J
LISBON VET CLINIC INC	Schmucker, Gordon
MASTERTSON VETERINARY CLINIC	Masterson, Rhonda
MedVet Columbus	
Mogadore Vet Hospital	Whittington, David
Mt Hope Vet Services,	
Walnut Creek Veterinary Clinic	Varga, Joseph
NAPOLEON VETERINARY CLINIC	
Northgate Animal Hospital	Gibson, Douglas
Paw Patch Veterinary Services	Hirt, Laurie
PONDVIEW VETERINARY CLINIC	Dougherty, Patrick
PONDVIEW VETERINARY CLINIC	Small, Tasha Nichole
SHAWNEE ANIMAL CLINIC	Sherman, Angela
SHELBY ANIMAL CLINIC	Knox, John W
STONYRIDGE VETERINARY SERVICE	Eisenberg, Eric

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Sugarcreek Veterinary Clinic	ANGEL, JONATHAN
Sugarcreek Veterinary Clinic	Donley, Shane
Sugarcreek Veterinary Clinic	Honigford, James
Sugarcreek Veterinary Clinic	Sugarcreek Veterinary Clinic
Sugarcreek Veterinary Clinic	Clay, Aimee
THE PLAINS VETERINARY HOSPITAL, LLC	Ryan, Ericka
Twin Valley Animal Hospital	Twin Valley Animal Hospital
Twinsburg Vet Hospital	Lozanoff, Stacy
WELLINGTON VETERINARY CLINIC	Spreng, William A
Westside Animal Clinic	Ayars, William
WHEELERSBURG ANIMAL HOSPITAL INC.	
WILLARD VETERINARY CLINIC	

On July 19, 2018, the Department met with the following groups to discuss a variety of topics, including review of the proposed rules:

- Ohio Professional Dog Breeders Association (OPDBA) board members & kennel evaluation team
- USDA Animal Care personnel
- Holmes County dog wardens
- Coshocton County dog warden
- Dr. Aaron Wise of East Holmes Veterinary Clinic

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

The Department did not receive any comments from the original email sent on June 20, 2018. The Department believes the lack of comment is due to how well the *Brucella canis* testing has been implemented by the Department.

During the July 19th meeting, OPDBA members expressed their support of the rule package. Specifically, the members were encouraged with the amendments made to the *Brucella canis* certification process. Additionally, potential future changes of the rules were discussed should the amendments to the certification process be successful.

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?

Recent outbreaks of the disease has 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.

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. Additionally, 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 any of these diseases 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 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

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;

The rules in this package will have an impact on dog owners and licensed kennels under chapter 956 of the Revised Code.

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

There is no requirement for mandatory testing of *Brucella canis* at this time. However, in accordance with chapter 941 of the Revised Code and section 901:1-21-02 of the OAC, any canine that is diagnosed as *Brucella canis* suspect or positive will be subject to immediate quarantine. Further, there is a possibility that their facility or farm also be quarantined. Additionally, should an animal be suspect or positive, it may result in further costs associated with treatment or euthanasia.

There is also no direct cost for a kennel to become designated as a *Brucella canis* free. However, in order to be designated, a kennel must perform tests on its animals to comply with the requirements. Additionally, they must fill out a *Brucella canis* certification form and send it to the Department.

c. Quantify the expected adverse impact from the regulation.

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 ORC 941.03 and OAC 901:1-21-02 the owner of any animal which receives a diagnosis of *Brucella canis*, 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. 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 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.

As the program is voluntary, there are no mandatory costs. However, in order to gain the certification, they owners must test their canines regularly pursuant to the rules. Costs for *Brucella canis* testing, vary on the location and individual veterinarian. However, at a minimum the costs for approved *Brucella canis* tests are as follows:

Indirect Fluorescent Antibody Test - \$11.50/animal

Tube Agglutination Test - \$16.50/animal

Brucella canis Culture Test - \$25-35/animal

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. Due to the danger to both public and animal health these rules are deemed necessary. The Department has worked closely with members of the regulated business community and at this time the rules as set forth represent the best balance of public health and adverse business impact.

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 serious impact *Brucella canis* may have on Ohio's animal industry, individuals who bring animals into the state in violation of these rules are subject to immediate quarantine.

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

The Department has established a Commercial Dog Breeders office and the Animal Health division, which is available to work with any business that needs help with educational materials.

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