



Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Brucella canis Testing Package

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

Date: February 25, 2015.

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☐ Rescinded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 *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. More specifically:

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.

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.

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.

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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?

Success of this program will be measured by the report of little or no outbreaks of *Brucella canis* in the state. Additionally, the greater number of kennels that become certified as *Brucella canis* free will indicate to the Department of the diminishing presence of the disease in the state.

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.

Ohio Department of Agriculture

State Veterinarian – Dr. Tony Forshey

Assistant State Veterinarian – Dr. Melissa Simmerman

Former State Veterinarian – Dr. David Glauer

Ohio Department of Agriculture – Commercial Dog Breeder Advisory Board

Dr. Tony Forshey

Harold Dates

Matt Granito – Dog Warden, Geauga County

Dr. Michal Frederick

Dr. Patricia Haines

Linda Stickney

Federal, State, and Local Organizations

United States Department of Agriculture - Animal and Plant Health Inspection Service

National Veterinary Services Laboratories

Ohio Professional Dog Breeders Association – Abe Miller and Ervin Raber

Zoetis, a global animal health company.

Toledo Area Humane Society - Dr. Debbie Johnson

The Ohio State University, College of Veterinary Medicine – Dr. Jeanette O’Quinn

American Kennel Club – Dr. Patricia Haines

American Society for the Prevention of Cruelty to Animals – Vicki Deisner

Ohio Veterinarian Medical Association – Michelle Holdgreve and Jack Advent

Veterinarians, Clinics and Hospitals

Dr. William Lutz II

Dr. Robert McMillan

Dr. Connie Anderholm

Dr. Tara Beery Spring Meadow Vet Clinic

Carrollton Animal Hospital

Pondview Vet Clinic

Johnstown Animal Hospital

Animal Medical & Surgical Center of Coshocton

Masterson Vet. Clinic

Walnut Creek Vet Clinic

Barnesville Woodfield Vet Clinic

Country Roads Veterinary Services

Shelby Animal Clinic

East Holmes Vet Clinic

Willard Vet Clinic

Claremont Vet Clinic

Guernsey Vet Clinic

Stonyridge Vet Services

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Fort Recovery Vet Center
Westfield Vet Clinic
Sugarcreek Vet Clinic
Danville Vet Clinic
Twinsburg Vet Hospital
Horizon Animal Hospital
Kingston Vet Hospital
Wellington Vet Clinic

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

Due to the serious nature of *Brucella canis* and the potentially devastating impact on the industry, the stakeholders are very supportive of the creation of these rules. In fact, the Department and stakeholders worked together in their creation.

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 identified diseases have demonstrated what the potential environmental, health, and economic impacts of widespread infection would have on the canine industry. These identified detrimental effects support this regulation's proposal.

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 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 canine owners are treated in a similar manner. The Department has online resources and has field staff available through a 24 hour helpline to provide assistance. Training and seminars are also available.

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 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.

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:

Canine Antibody Test - \$10/animal

Indirect Fluorescent Antibody Test - \$11.50/animal

Tube Agglutination Test - \$16.50/animal

Polymerase Chain Reaction Test - \$25-35/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.