

Mike DeWine, Governor Jon Husted, Lt. Governor Joseph Baker, Director

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):		
Commercial Feeds		
Rule Number(s): 901:5-7-01, 01.1, 02, 03, 04, 05, 06, 07, 08, 09, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25		
Date of Submission for CSI Review: 12/4/2023	<u> </u>	
Public Comment Period End Date: 12/26/2023	<u> </u>	
Rule Type/Number of Rules:		
New/ <u>2</u> rules	No Change/ rules (FYR?)	
Amended/ <u>5</u> rules (FYR? <u>Y</u>)	Rescinded/ 20 rules (FYR? Y)	

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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Common Sense Initiative

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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. \square 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.

The rules in this chapter amplify the statutory authority that the Department will inspect commercial animal feeds for adulteration and mislabeling. The rules regulate the naming and labeling of feed to ensure that feeds contain the products they claim and that no unsubstantiated claims as to the feed are made on the label.

Pursuant to the Legislative Service Commission's guide on administrative rule drafting, the Department has proposed to incorporate by reference the Association of American Feed Control Officials (AAFCO) Model Bill which is a voluntary membership association of local, state and federal agencies charged by law to regulate the sale and distribution of animal feeds and animal drug remedies.

OAC 901:5-7-01 sets forth definitions as used in the chapter. Rule 901:3-8-01 will be rescinded and replaced with a new rule setting forth that The Ohio Department of Agriculture will incorporate by reference the "Association of American Feed Control Officials" (AAFCO), Chapter 4 to Chapter 6 and the AAFCO Feed Inspector's Manual.

OAC 901:5-7-01.1 is an appendix that sets forth requirements for product names. This rule will be rescinded.

OAC 901:5-7-02 sets forth label guarantees for drugs, minerals, vitamins, and moisture. This rule will be rescinded and replaced with a new rule setting forth the commodities which are exempt.

OAC 901:5-7-03 this rule sets forth the requirements for ingredient statements. This rule will be rescinded.

OAC 901:5-7-04 this rule sets forth the requirements regarding minerals. This rule will be rescinded.

OAC 901:5-7-05 sets forth the maintenance requirements. This rule is being amended to add clarification on the maintenance of scales that are used for the manufacture of feed.

OAC 901:5-7-06 this rule sets forth the requirements for the labeling of feeds containing non-protein nitrogen. This rule will be rescinded.

OAC 901:5-7-07 sets forth the requirements of labels. This rule is being amended to update sections of the Revised Code referenced and to clarify the rule that labels are to be clearly visible.

OAC 901:5-7-08 sets forth the requirements related to exempt buyers. This rule is being amended to remove the word major from feed manufacturers, adds clarifying language to the requirements of an exempt buyer and adds that the director may exempt those who apply and qualify.

OAC 901:5-7-09 this rule sets forth the requirements for labeling feeds containing drugs. This rule will be rescinded.

OAC 901:5-7-10 sets forth the requirements of labeling bulk storage. This rule is being amended to revise the title for a better description of the rule, adds a reference to ORC 923.43 for the labeling requirements which allows the removal of the list from the rule, and the rule adds a requirement that transport vehicles shall provide a label.

OAC 901:5-7-12 addresses the guaranteed analysis of commercial feed distributed in the state. This rule will be rescinded.

OAC 901:5-7-13 addresses the use of precautionary statements on the labeling of all commercial feed. This rule will be rescinded.

OAC 901:5-7-14 sets forth the requirements for adulterants. This rule will be rescinded.

OAC 901:5-7-15 addresses good manufacturing practices and federal food and drug administration guidelines. This rule will be rescinded.

OAC 901:5-7-16 addresses the use and restriction of using animal waste products in animal feeds. This rule will be rescinded.

OAC 901:5-7-17 the rule sets forth the labeling requirements for all pet food and specialty pet food. This rule will be rescinded.

OAC 901:5-7-18 the rule regulates brand and product names for pet food and specialty pet food. This rule will be rescinded.

OAC 901:5-7-19 this rule sets forth requirements for the expression of guarantees for pet food and specialty pet food. This rule will be rescinded.

OAC 901:5-7-20 this rule sets forth requirements for ingredient labeling on pet food and specialty pet food packaging. This rule will be rescinded.

OAC 901:5-7-21 this rule sets forth requirements regarding drug and food additives for pet food and specialty pet foods. This rule will be rescinded.

OAC 901:5-7-22 sets forth the requirements regarding glucosamine; chondroitin; hyaluronan, methylsulfonylmethane in animal feed. This rule is being amended to add cannabidiol to the title, adds the requirement that feeds containing cannabidiols must be labeled according to Ohio commercial feed law labeling requirements and adds the requirement that the amount of cannabidiols must be stated in milligrams per serving on the product label.

OAC 901:5-7-23 this rule outlines the nutritional adequacy requirements of pet food and specialty pet food. This rule will be rescinded.

OAC 901:5-7-24 this rule sets forth the requirements regarding feeding directions on all pet food and specialty pet food products. This rule will be rescinded.

OAC 901:5-7-25 sets forth the requirements regarding the statements of calorie content for pet food and specialty pet food. This rule will be rescinded.

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.

ORC 923.50 923.41 923.44

- 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 Department is statutorily tasked under Chapter 923 with protecting the commercial feed supply and the health and safety of animals and humans. These rules provide quality assurance, truth-in-labeling and ensure safe and approved ingredients are used in manufacturing commercial feed to protect Ohio consumers.

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

The Department inspects and investigates complaints regarding the commercial feed industry. The rules are judged as being successful when inspections and investigations find few violations, when feeds are registered with the Department, and when there is no increase in the number of complaints filed with the Department.

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?

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.

The following stakeholders comprise a list of the leaders of several agricultural organizations found within the state of Ohio. The following stakeholders were contacted via email on October 27, 2023, for a public comment period open until November 10, 2023.

Organization	Contact
AmericanHort	Meagan Nace
AmericanHort	Craig Regelbrugge
Capital Advocates	Kurt Leib
Capitol Advocates	Rob Eshenbaugh
NPMA SPAR	Kurt Scherzinger
Ohio Aggregates & Industrial Minerals	Patrick Jacomet
Ohio Agribusiness Assoc.	Chris Henney
Ohio Agribusiness Assoc.	Aaron Heilers
Ohio Association of Meat Processors	Valerie Parks Graham
Ohio Christmas Tree Association	Valerie Graham
Ohio Corn & Wheat	Tadd Nicholson
Ohio Corn & Wheat Growers Assoc.	Luke Crumley
Ohio Dairy Producers	Scott Higgins
Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio Environmental Council	Trent Dougherty
Ohio Environmental Council (OEC)	Pete Bucher
Ohio Environmental Council (OEC)	Chris Tavenor
Ohio Farm Bureau	Adam Sharp

Ohio Farm Bureau
Ohio Farm Bureau Federation (OFBF)
Ohio Farm Bureau Federation (OFBF)
Ohio Farm Bureau Fereration (OFBF)
Ohio Farmers Union
Ohio Forestry Association

Ohio Farmers Union
Ohio Forestry Association
Ohio Green Industry Association
Ohio Green Industry Association
Ohio Invasive Plants Council
Ohio Invasive Plants Council
Ohio Lawn Care Association
Ohio P.L.A.N.T.

Ohio Pest Management Association
Ohio Pest Mgmt Assoc. (OPMA)
Ohio Pest Mgmt.Assoc. (OPMA)
Ohio Pork Producers Council
Ohio Poultry Association

Ohio Produce Growers & Marketers
Ohio Seed Improvement Assoc
Ohio Soybean Association
Ohio Soybean Council
Ohio State Beekeepers Assoc. (OSBA)

Ohio State University
Ohio Turfgrass Foundation
Ohio Turfgrass Foundation
Ohio Turfgrass Foundation
Pesticide Applicator for Responsible Reg

The Nature Conservancy

The Ohio State University
Ohio Beef Council/Ohio Cattlemen's Association

Jack Irvin
Larry Antosh
Leah Curtis
Roger High
Adam Sharp
Jack Irvin
Larry Antosch
Joe Logan
Jenna Reese
Tracy Schiefferle
Roni Peterson
Jennifer Windus
Gary Conley
Mark Bennett

Molly Mash
Sheri Maskow
Cheryl Day
Jim Chakeres
Valerie Graham
John Armstrong
Brandon Kern
Kirk Merritt
Peggy Garnes
Adam Ward

Tony Seegars

Melinda Howells

Adam Ward Mark Bennett Troy Judy Mark Bennett Mike Grace

Jessica D'Ambrosio

Peggy Hall Elizabeth Harsh

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

No comments were received during the stakeholder outreach comment period.

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?

These rules are based on the standards from the Association of American Feed Control Officials (AAFCO) which utilizes years of scientific research on the nutrition and health of animals in developing rules.

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 stakeolders must use to comply.

The department is statutorily tasked with regulating commercial feeds in order to provide a reliable and trustworthy marketplace for the Ohio consumer. The AAFCO Model Bill standards that are contained in this rule are based on scientific research and have been adopted by most of United States and Canada. The lack of 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.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Department has sole regulatory authority for commercial animal feeds in Ohio.

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.

These rules are already implemented within the industry and the Department works with all registered feed manufacturers and distributors to educate and inform them on the requirements of labeling regulations. The staff members of the Commercial Feed Division ensure that all permit holders in Ohio are treated in a similar manner.

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 All commercial animal feed manufacturers and distributors in Ohio.
 - 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.

As the rules are currently implemented, all companies that manufacture, ships into, or distribute commercial animal feed within the state must register with the Department.

There is no monetary cost for the application or registration. There is negligible time for compliance with the application process.

Manufacturers must apply labels to all of their products indicating the contents of the feeds. Labeling costs vary and usually depend on the design and marketing decisions of the manufacturer. Manufacturers can satisfy the labeling requirements of these rules with a simple computer-generated label which usually costs less than ten cents.

Manufacturers must submit semi-annual reports of their sales. These tonnage reports indicate to the Department how many tons of feed they have sold in the past six months. For every ton reported sold in the past six months, the manufacturers shall pay twenty-five cents. There is a 100-ton minimum every report. This results in a \$25 minimum semi-annual payment to the Department.

As already implemented, these rules provide that failure to comply with the rules and regulations of the chapter may result in product being withdrawn from distribution until the manufacturer comes into compliance. The amendments to the rules do not require any additional fees, fines, or time for employer compliance and should not have any additional adverse impact upon any manufacturers.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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)

Exemptions have been added that reduce the regulatory burden for certain commodities.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The minimal impact of proper labeling of products outweighs the risk to the animals that could be malnourished or sickened if feeds are mislabeled or adulterated. Label requirements ensure that feed is safe and effective for use. Consumer confidence and knowledge that the feed is regulated for animal and consumer safety helps to protect the industry. In an unregulated industry, deceptive practices of a few will hurt consumer confidence in the industry. Therefore, the adverse impact is justified.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Smaller firms can self-attest with the FDA and become a Qualified Firm which would exempt them from some of the regulations outlined within 21 CFR 507, which are referenced in the AAFCO Model Bill as adopted in this rule package. This would exempt those firms from having a Hazard Analysis and Food Safety Plan.

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 public health implications of an improperly labeled feed product the Department does not waive penalties for first-time offenders. The penalty for a mislabeled product is prohibiting the sale and distribution of the product.

Usually, violations are corrected by simply applying a corrected sticker to the product. In the case of failure to submit their tonnage fees, the Department usually provides the offender significant opportunity to come into compliance prior to withdrawing their registration.

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

The staff members of the Division of Plant Health ensure that all covered businesses in Ohio are treated in a similar manner. The Department has online resources and has field staff available to help. Training and seminars are also available.