



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Dairy Division 5-Year Review / Corrections Rule Package

Rule Number(s): 901:11-1-06, 901:11-2-02, 901:11-2-26, and 901:11-3-04.

Date of Submission for CSI Review: 12/17/2020

Public Comment Period End Date: 1/13/2021

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 4 rules (FYR? 2)

Rescinded/___ rules (FYR?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.

Rule 901:11-1-06 sets forth the meetings of the Milk Sanitation Board. The rule is being amended to remove the exact publishing of the meetings and specific URL address.

Rule 901:11-2-02 sets forth the quality requirement for milk, including the sediment content of milk and quality testing of milk from new producers, producers whose license has been suspended, or transfer producers. The rule is being amended to correct LSC manual requirements and clarify areas of rule language.

Rule 901:11-2-26 outlines the cleaning and sanitization of all equipment used in receiving, storing, and processing milk. The rule is being amended to correct LSC manual requirements and remove temperature requirements.

Rule 901:11-3-04 outlines the chemical, bacteriological, and temperature standards for frozen desserts. The rule is being amended to correct a typographical error.

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.**

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Revised Code 917.02.

- 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. The rules are modeled from the Food and Drug Administration's recommended guidelines. However, there is no specific requirement that ODA adopt those requirements, but Ohio's adoption of the rules allows Ohio manufacturers that flexibility to ship their products nationwide.

- 5. If the regulation 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's purpose for these regulations is to ensure continued public safety by establishing minimum sanitization and bacteriological standards of milk and/or milk products.

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

All manufacturers who produce milk products or frozen dessert products in the state of Ohio are inspected and any complaints regarding unsafe operations are investigated. The rules are judged as being successful when inspections find few violations 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?**

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.

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The rules were sent to the following stakeholders on September 24, 2020 via email and posted to the Ohio Department of Agriculture's website.

Capitol Advocates - Rob Eshenbaugh
Ohio Beef Council/Ohio Cattlemen's Association - Elizabeth Harsh
Ohio Council of Retail Merchants - David Raber
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 - Leah Curtis
Ohio Farm Bureau - Roger High
Ohio Farm Bureau - Tony Seegers
Ohio Farmers Union - Joe Logan
Ohio Grocers Association - Joe Ewig
Ohio Grocers Association - Kristen Mullins
Ohio Pork Producers Council - Bryan Humphreys
Ohio Poultry Association - Jim Chakeres
Ohio Restaurant Association - John Barker
Ohio State University - Adam Ward
The Ohio State University - Peggy Hall
Milk Sanitation Board Member - James Stockert
Milk Sanitation Board Member - Lou Brown
Milk Sanitation Board Member - Doug Longenette
Milk Sanitation Board Member - Doug Blacksten
Milk Sanitation Board Member - Robert Troyer
Milk Sanitation Board Member - Dennis Sidle

10. 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 stakeholder comments during the open 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?

The rules contained in the package mirror standards set forth by the FDA. The rules were developed over years of scientific research. The rules present the best scientific approach to limiting the spread of harmful bacteria to protect public safety.

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?

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The department is statutorily tasked with developing and establishing standards for this industry. The standards that are contained in the rules are based on scientific research and are constituent with the federal regulations. Stakeholder participation in the rules has indicated that this is the best regulatory scheme as it allows Ohio manufacturers to ship their products across the country. For those reasons, no other regulatory alternatives were considered.

13. 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.

Due to the public health risks, the department did not consider a performance-based regulation. The regulations dictate the process in order to ensure safety and allows the manufacturer to be able to ship their products across the country.

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

The department is given the sole authority over milk and/or milk products through Revised Code 917.02.

15. 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.

The rules are already implemented within the industry and the department works with all dairy operations to educate and inform them on the regulations. The staff members of the Dairy Division ensure that all manufacturers in Ohio are treated in a similar manner.

Adverse Impact to Business

16. 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; and

All manufacturers or dairy operations who produce or use manufacture grade milk to produce milk products and all manufacturers of frozen desserts.

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

All manufacturers of frozen desserts must obtain a milk processor license and are subject to monthly inspection fees by the department. All producers of milk must obtain a license from the department.

The rules do not have fines or penalties, although Revised Code 917.02 provides for suspension or revocation of production licenses for violations of these rules and a possible embargo of product that is not produced in accordance with the rules.

c. Quantify the expected adverse impact from the regulation.

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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.

The proposed rules are not expected to have any financial impact to the industry in terms of changes in procedure or equipment.

Milk hauler, dealers, producers, and processors all must meet the requirements of the rules and pay a \$15 annual licensing fee to the Dairy Division. Licensees are subject to inspections and testing of their product. This minimal impact upon the industry is outweighed by the health benefits of a safe and wholesome milk supply to the consumer and industry.

The adverse impact of these regulations is difficult to quantify as it is hard to separate production practices from regulation. The regulations dictate some equipment; however, equipment manufacturers specifically tailor their machinery to meet the regulations. Additionally, there are record keeping requirements which require time for employer compliance; however, for the most part the machinery used in this industry automatically records this information.

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

The regulatory intent of the statute and rules is to protect public safety by establishing minimum sanitation and bacteriological standards of milk and/or milk products. Due to the nature of the risk, the adverse impact is considered to be justified.

Regulatory Flexibility

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

As the primary purpose of these rules is public safety, exemptions for smaller operations would not be applicable.

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 implication of adulterated milk or milk products, the department does not waive penalties for first-time offenders. However, the department works with the violators to educate them on how to correct any potential future violations.

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

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The department has online resources and staff available to provide assistance.

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