



Common Sense Initiative

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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):

Dairy Division- Ohio Manufacture Milk Rules

Rule Number(s): 901:11-2-01 to 44

Date of Submission for CSI Review: 11/17/2023

Public Comment Period End Date: 12/11/2023

Rule Type/Number of Rules:

New/___ rules

No Change/ 44 rules (FYR? yes)

Amended/___ rules (FYR? ___)

Rescinded/___ rules (FYR?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.

The rules in this package amplify the statutory authority of the Department to regulate manufacture grade milk products in the state of Ohio. These rules protect the safety, health, and well-being of Ohio consumers by ensuring that manufacture grade milk is produced in such a way that reduces the risk of bacterial contamination. Milk, which is contaminated by bad bacteria, if consumed, can cause serious health problems and in some cases can result in the death of the consumer. These rules are modeled off the Food and Drug Association's minimum standards for manufacture grade milk. While not required, virtually all states have adopted these recommended standards as a minimum, and many States regulatory agencies have adopted more stringent standards. **ODA is proposing that no changes be made to the following rules:**

901:11-2-01 sets forth the definitions for the chapter. ODA is proposing that no changes be made to this rule.

901:11-2-02 sets forth the quality requirements 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. ODA is proposing that no changes be made to this rule.

901:11-2-03 sets forth the requirements for bacterial count samples of raw milk. ODA is proposing that no changes be made to this rule.

901:11-2-04 sets forth the requirements for somatic cell count samples of raw milk. ODA is proposing that no changes be made to this rule.

901:11-2-05 sets forth the requirements for drug residue testing. ODA is proposing that no changes be made to this rule.

901:11-2-06 sets forth the requirement that samples be tested for biological significant radionuclides. ODA is proposing that no changes be made to this rule.

901:11-2-07 sets forth the requirement that samples be tested for pesticides and herbicides. ODA is proposing that no changes be made to this rule.

901:11-2-08 establishes that added water is considered an adulteration of milk and the director may suspend the producer's license for adulteration. ODA is proposing that no changes be made to this rule.

901:11-2-09 sets forth the requirements of the herd's health. ODA is proposing that no changes be made to this rule.

901:11-2-10 sets forth the conditions and requirements of a milking facility and cow yard. ODA is proposing that no changes be made to this rule.

901:11-2-11 sets forth the sanitation requirements of the milking procedure, including the cleanliness of the milker's clothing and equipment. ODA is proposing that no changes be made to this rule.

901:11-2-12 sets forth the temperatures at which milk must be stored. ODA is proposing that no changes be made to this rule.

901:11-2-13 sets forth the requirements of the milkhouse, including utensils and equipment to be stored in the milkhouse and structure of the milkhouse in order to prevent dust and contamination. ODA is proposing that no changes be made to this rule.

901:11-2-14 sets forth the requirements regarding use of drugs intended for treatment of animals and insecticides used in dairy operations, including proper labeling. ODA is proposing that no changes be made to this rule.

901:11-2-15 sets forth the condition in which utensils and equipment used in the handling of milk shall be maintained. ODA is proposing that no changes be made to this rule.

901:11-2-16 sets forth the condition, location, and quality of water used for cleaning dairy utensils and equipment. ODA is proposing that no changes be made to this rule.

901:11-2-17 sets forth the requirements for sewage disposal in the milkhouse. ODA is proposing that no changes be made to this rule.

901:11-2-18 sets forth the qualifications for a producer or processor license and requirements for a licensed dairy farm's annual inspection. ODA is proposing that no changes be made to this rule.

901:11-2-19 sets forth the conditions in which the premises of a milk plant must be kept, including an adequate drainage system. ODA is proposing that no changes be made to this rule.

901:11-2-20 sets forth the conditions in which buildings and rooms must be maintained, including adequate lighting and ventilation. ODA is proposing that no changes be made to this rule.

901:11-2-21 sets forth the requirements for the water supply for the plant, hand washing facilities, as well as other sanitary issues. ODA is proposing that no changes be made to this rule.

901:11-2-22 sets forth the requirements for the construction, use, and sanitization of equipment and utensils used in the process of milk and manufacturing of dairy products. ODA is proposing that no changes be made to this rule.

901:11-2-23 sets forth rules on the protection and transporting of raw milk and cream. ODA is proposing that no changes be made to this rule.

901:11-2-24 outlines the requirements for raw product storage. ODA is proposing that no changes be made to this rule.

901:11-2-25 sets forth the rules on the quality, composition, and wholesomeness of manufacture grade milk. ODA is proposing that no changes be made to this rule.

901:11-2-26 outlines the cleaning and sanitization of all equipment used in receiving, storing, and processing milk. ODA is proposing that no changes be made to this rule.

901:11-2-27 sets forth the cleaning and sanitizing requirements for equipment and utensils used in receiving, storing, and processing milk. ODA is proposing that no changes be made to this rule.

901:11-2-28 sets for the size, materials, and processing requirements for packaging containers used for dairy products. ODA is proposing that no changes be made to this rule.

901:11-2-29 sets forth the storage requirements for finished products, including processed products for shipment. ODA is proposing that no changes be made to this rule.

901:11-2-30 sets forth the requirement for drying, including the maintenance and conditions of dryers. ODA is proposing that no changes be made to this rule.

901:11-2-31 sets forth the requirements for cooling dry products. ODA is proposing that no changes be made to this rule.

901:11-2-32 sets for the requirements, including samples and testing, for instant nonfat dry milk. ODA is proposing that no changes be made to this rule.

901:11-2-33 sets forth the conditions and maintenance of coolers and freezers. ODA is proposing that no changes be made to this rule.

901:11-2-34 sets forth the necessary precautions in a starter room in order to prevent contamination. ODA is proposing that no changes be made to this rule.

901:11-2-35 sets forth the size and ventilation requirements in the room in which cheese is manufactured. ODA is proposing that no changes be made to this rule.

901:11-2-36 sets forth the requirements and conditions in which equipment and utensils used for the manufacture of cheese must be maintained. ODA is proposing that no changes be made to this rule.

901:11-2-37 sets forth the handling and disposal of whey. ODA is proposing that no changes be made to this rule.

901:11-2-38 sets forth the sanitary requirements for forming containers and procedures for filling containers, including sanitation and weight control. ODA is proposing that no changes be made to this rule.

901:11-2-39 sets forth the requirements for maintaining records, including raw milk receipts. ODA is proposing that no changes be made to this rule.

901:11-2-40 sets forth the requirements of an insect and rodent control program. ODA is proposing that no changes be made to this rule.

901:11-2-41 sets forth the clothing and shoe requirements for personnel cleaning the interior of the drier. ODA is proposing that no changes be made to this rule.

901:11-2-42 sets forth the labeling requirements for products. ODA is proposing that no changes be made to this rule.

901:11-2-43 sets forth the required hygienic practices of personnel. ODA is proposing that no changes be made to this rule.

901:11-2-44 prohibits any personnel who is afflicted with a communicable disease from being present in a room where milk is being prepared and handled. ODA is proposing that no changes be made to this rule.

- 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.**

O.R.C. 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 off the Food and Drug Administration's recommended guidelines. However, there is no specific requirement that ODA adopt those requirements.

- 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'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 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.

The 901:11-2 rule package was sent by email to members of the Ohio Milk Sanitation Board on September 19, 2023, asking for comments to be submitted to agrecommments@agri.ohio.gov by October 4, 2023. The board members include:

Mr. Lou Brown – Grade A Milk Producers

Mr. Steve Zalar- Dairy Farmers of America

Mr. Doug Soehnlen– Superior Dairy- Grade A Milk Processors

Mr. Doug Longenette – United Dairy Inc.- Grade A Milk Processors

Mr. David Burch – Pearl Valley Cheese- Manufacture Milk Processors

Mr. Matt Sall – Grade A Milk Producers

In addition, the following stakeholders were contacted via email on September 20, 2023, for a public comment period open until October 4, 2023.

Capitol Advocates

Ohio Beef Council/Ohio Cattlemen's Association

Ohio Dairy Producers

Ohio Ecological Food and Farm Association

Ohio Farm Bureau

Ohio Farm Bureau

Ohio Farm Bureau

Rob Eshenbaugh

Elizabeth Harsh

Scott Higgins

Amalie Lipstreu

Adam Sharp

Jack Irvin

Leah Curtis

Ohio Farm Bureau
Ohio Farmers Union
Ohio Poultry Association
Ohio Restaurant Association
Ohio State University
The Ohio State University

Roger High
Joe Logan
Jim Chakeres
John Barker
Adam Ward
Peggy Hall

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

ODA did not receive any comments from the Milk Sanitation Board members or the stakeholders during the 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?

The United States Public Health Service has devoted years of scientific research to establish effective and practicable milk sanitation rules to ensure public safety. The incidence of milk-borne illness in the United States has been minimal since the establishment of these standards.

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 regulating milk and/or milk products. The standards that are contained in these rules are based on scientific research and in most cases are nationally accepted. 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 is given the sole regulatory authority over milk and/or milk products through O.R.C. 917.02.

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 dairy operations to educate and inform them on the regulations. Additional education and outreach will be performed with the affected communities by the Dairy Division. The Dairy Division ensures that all dairy operations 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 manufacturers or dairy operations who produce or use manufacture grade milk to produce milk products.

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.

The proposed rules are not expected to have any financial impact on the industry in terms of changes in procedure or equipment. The regulations continue to impact all parts of the manufacture grade milk industry.

Milk haulers, dealers, producers, and processors all must meet the requirements of the rules and pay a \$15 annual licensing fee to the Department's Dairy Division. Licensees are subject to inspections and testing of their product. This minimal impact upon the industry is far 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 specifications; 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.

The rules do not have fines or penalties, although R.C. 917.02 provides for suspension or revocation of a production license and possible embargo of products that are not produced in accordance with the rules.

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 regulatory intent of the statute and rules is to protect public safety by establishing minimum sanitization 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 implications 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?

The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.