



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 Frozen Dessert Rules

Rule Number(s): 901:11-3-01 to 11

Date of Submission for CSI Review: 5/7/24

Public Comment Period End Date: 5/29/24

Rule Type/Number of Rules:

New/ 4 rules

No Change/ rules (FYR?)

Amended/ 5 rules (FYR? 5)

Rescinded/ 6 rules (FYR? 6)

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.

Chapter 901:11-3 of the Ohio Administrative Code regulates the production of frozen desserts in the state of Ohio. Frozen desserts are defined in OAC 901:11-3-02 but generally includes products such as ice cream and frozen custard. Without proper safeguards, the manufacturing process can result in the growth of highly dangerous pathogens such as *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, and *Listeria monocytogenes*. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting, and in some cases can result in the death of the infected individual. Due to this high level of risk, there is significant regulation to monitor the frozen dessert production industry which is designed to prevent illness and protect consumers.

These rules contained in this package mirror federal regulations in order to allow Ohio's frozen dessert processors to be able to ship all across the country. The rules below have been reviewed in accordance with Chapter 119 of the Ohio Revised Code and are being proposed as follows:

OAC 901:11-3-01 outlines the definitions as used in the chapter. The rule is being amended to delete definitions that are already defined in 21 CFR part 117 due to the division incorporating by reference and adds definitions for the 21 C.F.R., Federal Food Drug and Cosmetic Act, Nutrition Labeling and Education Act and Officially Designated Laboratory. Further the amendments include revising definitions for clarity, adds/updates revision dates of references and makes stylistic changes according to the Legislative Service Commission's (LSC) Guide to Rulemaking Manual.

OAC 901:11-3-02 states the term “frozen desserts” means the articles of food listed in Title 21 C.F.R. 135 Subpart B. The adoption of this standard of identity ensures that consumers are confident in purchasing frozen dessert products by ensuring that the label accurately reflects what the product is. The amendments include deleting the edition of the 21 CFR 135 Subpart B because it is now defined in 901:11-3-01 and deletes, in its entirety, 21 CFR 135.160.

OAC 901:11-3-03 outlines the labeling requirements for frozen desserts. The rule requires that both commercial bulk packages and retail packages be legibly labeled with certain information. The rule is being amended to remove the requirement of labeling the retail packaged frozen dessert with the federal information processing standards (FIPS) number, adds the option of labeling the frozen dessert with volume rather than just net weight, and makes stylistic changes according to LSC’s Guide to Rulemaking Manual.

OAC 901:11-3-04 outlines the chemical, bacteriological, and temperature standards for frozen desserts. The rule has been amended to reformat the rule for easier reading and comprehension, adds the name of the standard methods and the official methods to be used as “Appendix N of the PMO”. Further, language has been added to clarify how often the type of products will be collected for examination to determine bacterial, coliform counts and drug residue and what will be done to identify the source of a positive result.

OAC 901:11-3-05 outlines the pasteurization requirements for frozen dessert products. The rule has been amended to clarify what section of the PMO the equipment shall comply with, deletes the shorthand of water activity, adds an option to use containers in addition to totes and deletes the edition date of the 21 C.F.R. because it is defined in 901:11-3-01.

OAC 901:11-3-06 requires all frozen dessert manufacturers develop a written Hazard Analysis and Critical Control Point plan, otherwise known as a HACCP plan. This rule is being rescinded and replaced with a new rule. The new rule incorporates by reference 21 C.F.R. part 117 in its entirety with the exception of provisions that have been amended or deleted in this chapter. The 21 C.F.R. part 117 sets forth the requirements for good manufacturing practices, hazard analysis and risk-based preventive controls for human food.

OAC 901:11-3-07 outlines the process for taking corrective actions when a deviation from a critical limit occurs. This rule is being rescinded and replaced with a new rule. The new rule sets forth the definitions which are amended or replaced in 21 C.F.R. part 117.

OAC 901:11-3-08 requires all frozen dessert manufacturers to verify and validate that their HACCP plan is being implemented according to its design. This rule is being rescinded and replaced with a new rule. The new rule sets forth the regulations in 21 C.F.R. part 117 which are being deleted and shall not become rules of the Department.

OAC 901:11-3-09 requires that all frozen dessert manufacturers maintain records which document the processor’s HACCP plan. This rule is being rescinded and replaced with a new rule. The new rule sets forth modifications that shall be made to 21 C.F.R. part 117.

OAC 901:11-3-10 states that all frozen dessert manufacturers shall have and implement a sanitation standard operating procedure. This rule is being rescinded because the Department has incorporated by reference 21 C.F.R. part 117.

OAC 901:11-3-11 outlines the training and education necessary to apply HACCP principles. This rule is being rescinded because the Department has incorporated by reference 21 C.F.R. part 117.

- 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, 917.01, 917.11,

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

- 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)?**

Without proper safeguards, the manufacturing process can result in the growth of highly dangerous pathogens such as Clostridium botulinum, E. coli 0157:H7, Salmonella, and Listeria monocytogenes. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting, and in some cases can result in the death of the infected individual. Due to this high level of risk, there is significant regulation to monitor the frozen dessert production industry which is designed to prevent illness and protect consumers.

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

All manufacturers who produce 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.

The 901:11-3 rule package was sent by email to members of the Ohio Milk Sanitation Board on March 13, 2024, asking for comments to be submitted to agrecomments@agri.ohio.gov by April 4, 2024. The board members include:

Mr. Lou Brown – Grade A Milk Producers

Mr. Steve Zalar- Dairy Farmers of America – Milk Haulers

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. Zach Steiner – Grade A Milk Producers

In addition, the following stakeholders were contacted via email on April 4, 2024, for a public comment period open until April 18, 2024.

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 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 Poultry Association	Jim Chakeres
Ohio Restaurant Association	John Barker
Ohio State University	Adam Ward
The Ohio State University	Peggy Hall
Milk Sanitation Board Member	Lou Brown
Milk Sanitation Board Member	Doug Longenette
Milk Sanitation Board Member	Steve Zalar
Milk Sanitation Board Member	Doug Soehnlen
Milk Sanitation Board Member	David Burch
Milk Sanitation Board Member	Zach Steiner

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

The Milk Sanitation Board members were supportive of the proposed changes and approved sending the rules for additional stakeholder outreach and to the Common Sense Initiative at the April 4, 2024, Milk Sanitation Board Meeting.

ODA did not receive any comments 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?

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?
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 developing and establishing standards for this industry. The standards that are contained in this rule are based on scientific research and are in line with the federal regulations. Lack of stakeholder opposition in this rule package has indicated to the Department that this is the best regulatory scheme at this time as it allows Ohio manufacturers to ship their products across the country. 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 manufacturers to educate and inform them on the requirements and regulations. The staff members of the Dairy Division ensure that all manufacturers 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 of frozen desserts in the state of 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.

All manufacturers of frozen desserts must obtain a milk processor license through the Department. Further, manufacturers of frozen desserts are subject to monthly inspection fees by the Department. 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.

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. As outlined in 917.031, the inspection fees for the Dairy Division shall not exceed 63% of the estimated cost of administering and enforcing Chapter 917 of the Revised Code. Currently, this fee breaks down to \$146,000 monthly paid by industry. This figure is then broken down to a per-pound fee which is sent to manufacturers based on their usage of dairy products.

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.

- 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.