

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture _____

Regulation/Package Title: Dairy – Frozen Dessert Rules 2017 FYR

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

Date: December 28, 2017

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☒ Rescinded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.

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 make small stylistic changes which do not impact the substance of the rule.

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. There are no changes proposed to this rule.

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 make a stylistic change which should improve reader comprehension. Further, the rule is being amended to ensure that frozen desserts whose ingredients are not from either a goat or a cow are labeled properly.

OAC 901:11-3-04 outlines the chemical, bacteriological, and temperature standards for frozen desserts. Due to the Legislative Service Commission's rule on administrative rule drafting the rule has been rescinded and replaced in order to make this rule easier to comprehend. No substantive changes have been made to this rule.

OAC 901:11-3-05 outlines the pasteurization requirements for frozen dessert products. The rule has been amended to simplify external references. Further, the rule has been amended to allow dairy products to be included in the frozen dessert after pasteurization when these products and the processor demonstrates to the director's satisfaction that the addition of these products post-pasteurization will not negatively impact the ability to produce a safe, sanitary, and quality product.

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 is required whenever the hazard analysis performed reveals one or more food hazards are likely to occur during production. This plan outlines critical control points where food hazards are likely to occur and critical limits which, when operating within these limits, allows the processor to decrease the likelihood of product contamination. Additionally, the HACCP plan outlines how manufacturers will monitor these critical control points and requires the development and implementation of corrective action plans should a deviation from the critical limits occur. There are no changes proposed to this rule.

OAC 901:11-3-07 outlines the process for taking corrective actions when a deviation from a critical limit occurs. The rule states that all corrective action plans shall ensure that no product which may be injurious to consumer health or otherwise adulterated enter the stream of commerce. The rule also requires that the cause of this deviation be corrected. There are no changes proposed to this rule.

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. A manufacturer verifies and validates their HACCP plan by reviewing any consumer complaints, calibrating instruments, and recording any deviation that may occur. This validation must take place at least once every twelve months. There are no changes proposed to this rule.

OAC 901:11-3-09 requires that all frozen dessert manufacturers maintain records which document the processor's HACCP plan. In particular, the manufacturer must maintain records documenting that the processor continues to monitor the critical control points and their critical limits. There are no changes proposed to this rule.

OAC 901:11-3-10 states that all frozen dessert manufacturers shall have and implement a sanitation standard operating procedure. This procedure addresses sanitation controls at all points in the production line including, water sanitation, cross contamination of other insanitary objects (ie. utensils, food packaging material, gloves, and clothing), and control of employee health conditions. There are no changes proposed to this rule.

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OAC 901:11-3-11 outlines the training and education necessary to apply HACCP principles. There are no changes proposed to this rule.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

R.C. 917.02

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?

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.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not Applicable.

5. What is the public purpose for this regulation?

The purpose of this rule is to ensure that both dairy producers and dairy dealers have accurate records should a financial emergency arise. However, as these records are being kept in the dairy industry's normal course of business the administrative requirement was not considered necessary.

6. 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.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

On December 7, 2017, these rules were reviewed by the members of the Ohio Milk Sanitation Board. The Milk Sanitation Board is the statutory stakeholder group for the Department regarding rules promulgated under Chapter 917 of the Ohio Revised Code. ORC

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917.031 states that the board is to advise and consult with the Director regarding rules. Members of the Milk Sanitation Board include:

Mr. Gene Phillips – Director of Health - Ex-Officio, Ohio Department of Health

Mr. Amos D. Miller – Manufacture Milk Producers

Mr. James P. Stockert

Mr. Tim Shipley – Shipley Farms

Mr. Doug Longenette – United Dairy Inc.

Mr. Bob Troyer – Bunker Hill Cheese

Mr. Doug Blacksten – Tamarack Farm's Dairy

Mr. Dennis Sidle – Sidle Transport Inc.

8. 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 were supportive of the proposed changes and approved sending the rules to the Common Sense Initiative.

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?

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.

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 developing and establishing standards for this industry. The standards that are contained in this rule are based on scientific research and in are in line with the federal regulations. Stakeholder participation 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.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

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. This process is recognized nationally and allows manufacturer to be able to ship their products across the country. Further, the process allows individual producers the flexibility to create a process based on their own production methods. These processes are based on the size of the food, the ingredients in the finished product and the process time. The critical control points along

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with the requirements of the regulation must be followed to protect against *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, and other organisms.

12. 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 R.C. 917.02.

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 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

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;

All manufacturers of frozen desserts in the state of Ohio.

b. Identify the nature of the adverse impact; and

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.

There are many factors to determining the cost of complying with this regulation. The equipment must be in working order and calibrated correctly and then records must be maintained to demonstrate that the filed process is being followed to produce a safe food. Records must then be reviewed before product is allowed to go into commerce.

c. Quantify the expected adverse impact from the regulation.

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.

15. 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

16. 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.

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 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.

18. 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.