

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture_____

Regulation/Package Title: Dairy – Frozen Dessert Standard of Identity_____

Rule Number(s): 901:11-3-02_____

Date: September 23, 2015

Rule Type:

☐ New

☒ 5-Year Review

☒ Amended

☐ Rescinded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.

Ohio Administrative Code rule 901:11-3-02 adopts the federal standard of identity for frozen desserts outlined in Title 21 C.F.R. 135 Subpart B. These include food products such as ice cream, frozen custard, and sherbet. The rule is being amended to add an effective date to 21 C.F.R. 135 Subpart B so that the rule is compliant with the incorporation by reference standards.

The adoption of the federal standards of identity allows Ohio producers of “frozen desserts” to ship their frozen products across the United States. Standards of identity are legal definitions of food products which outline what a food must contain, often in terms of ingredients and measurements, in order to be marketed as that product. The adoption of this rule is not a federal requirement however, by adopting the federal standard Ohio producers have the flexibility needed to expand their businesses nationwide.

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 adoption of this rule is not a federal requirement however, by adopting the federal standard Ohio producers have the flexibility needed to expand their businesses 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?

Standards of identity are legal definitions of food products which outline what a food must contain, often in terms of ingredients and measurements, in order to be marketed as that product. This allows a consumer to be confident in purchasing this type of product by ensuring that the label accurately reflects what the product actually is.

Further, by adopting the federal standard, Ohio manufacturers may ship their product virtually nationwide because many other states have adopted this standard as well. Through

this mutual adoption, manufacturers do not have to vary their product in order to meet the requirements of other standards of identity.

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

All manufacturers who produce frozen desserts in the state of Ohio are inspected and any complaints regarding labeling issues 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.

This rule was reviewed by the members of the Ohio Milk Sanitation Board. 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. Rocky Volpp – United Dairy Farmers

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 reviewed the rule and the proposed amendment. During that review, the members of the Board were very supportive of the proposed changes. Further, they agreed the rule represents the best regulatory scheme at this time.

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?

Standards of identity were first adopted by Congress in the 1938 Food, Drug and Cosmetic Act. At the time of their enactment, Congress recognized the need to promote food safety and consumer protection by establishing consistent standards in commercial food products. Many

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of these standards were recognized based on the longstanding history of food safety for a particular product, the customary use of the food, and the information generally available to scientists at the time.

Since then, these standards have been updated to protect consumers from contaminated products, economic fraud, and to promote nutrition. These changes are vetted on a Federal level by the Food and Drug Administration and the United States Department of Agriculture – Food Safety Inspection Service. These two agencies utilize sixteen broad principles, many of which concentrate on the most current scientific information, to make a determination on whether or not to amend the standard of identity for any given product.

The scientific data used in developing these standards has been critical as there has been a dramatic decrease of food borne outbreaks and illnesses in the United States since that time.

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 regulating milk and/or milk products. The standards that are contained in this rule 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.

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

This rule is an example of performance based regulation. The rule outlines which products are considered “frozen desserts” and allows manufacturers to market them accordingly.

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.

This rule is 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

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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 dessert products.

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

The rule does 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.

Manufacturers of frozen desserts and like products may only identify their products as frozen desserts if they are listed in 21 CFR 135 Subpart B.

c. Quantify the expected adverse impact from the regulation.

The only adverse impact from this rule would be a situation where a manufacturer wanted to classify their product as a “frozen dessert” but their product was not listed in the CFR. This impact is difficult to quantify based on a variety of factors including, the type of product, amount potentially produced, and the price of that product.

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 rule is to give consumers the confidence of knowing what kind of product they are purchasing. This rule adopts the federal standard for “frozen desserts.” In doing so, it gives consistency across Ohio and the country on the type of product that it contains. Proper labeling also gives consumers a clear understanding of what ingredients are included in products. This promotes public safety by warning individuals that may be sensitive to certain types of ingredients and 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 this rule is public safety and consumer confidence, 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 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.