

Business Impact Analysis

Agency Name: Department of Agriculture	
Regulation/Package Title: Manufacture Milk and Frozen Dessert Rules Review	
Rule Number(s): 901:11-2-01, 02,03,04,05,06,07,09,11,12,13, 15, 18, 20, 21, 22, 23, 24, 25, 26,	
27, 29, 32, 33, 37, 38, 39, 40, 42, 43, and 44. 901:11-3-01 and 03 through 11,	
Date: 8/8/12	_
Rule Type:	
□ New	X 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☐ Amended	□ Rescinded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.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117 <u>CSIOhio@governor.ohio.gov</u>

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Chapter 901:11-2 regulates the manufacture milk industry and Chapter 901:11-3 regulates the frozen dessert industry. Both are separate from the Grade A milk regulations found in Chapter 901:11-1 and the Federal Grade A Pasteurized Milk Ordinance. The rules set forth the proper handling, sanitation, and safety procedures for the manufacture milk and frozen dessert industries.

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? If yes, please briefly explain the source and substance of the federal requirement. No.
- 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 (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The regulations provide uniform health and safety standards for these components of the dairy industry.

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

The Dairy Division will measure success by adherence to the safety standards and the continued wholesomeness of the products of these industries.

Development of the Regulation

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.
 - The Manufacture Milk Committee and the Frozen Dessert Committee were convened in the 1990's. These rules have been unchanged for over 10 years.
- 8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

- The stakeholders had great input into these rules. Rules were written and presented and discussed one by one with consensus.
- 9. What scientific data was used to develop the rule or the measurable outcomes of the rule?
 - Industry standards were used, either FDA or USDA recommendations were employed in the development of these applicable rules.
- 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?
 - ODA adopted rules as developed in conjunction with industry advisory committees, alternatives were discussed at the time but the existing rules are a consensus agreement and the industry has found no need to request changes.
- 11. Did the Agency specifically consider a performance-based regulation? Please explain. Yes, the Frozen Dessert Rules are based on HACCP, a performance based regulation model.
- 12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?
 - The regulation of the manufacture milk and frozen dessert industries were consolidated under ODA in the 1990's, and the Department remains the sole regulator of those industries.
- 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.
 - As there is no change for the regulated community, there will be a continuality of services that industry has come to rely on to move milk across state lines.

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;

The Manufacture Grade community consists of 700 dairy producers, 34 processors. The Frozen Dessert industry is made up 44 licensed entities.

b. Identify the nature of the adverse impact.

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

c. Quantify the expected adverse impact from the regulation.

No new adverse impact is expected. These rules have remained unchanged for years, and all producers are familiar with them.

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

The continued safety of the food supply as assured by compliance with these rules outweighs any cost savings the industry might realize without the regulations.

Regulatory Flexibility

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

Not applicable, as it is not possible to maintain food safety standards otherwise.

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?

The Department does work with all producers and will waive fines when circumstances warrant.

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

We have experienced field sanitarians that work closely with the licensees and have a network of extension personnel that we can recommend.