CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Dairy – Manufacture Milk Grade

Rule Number(s): 901:11-2-01 through 901:11-2-44 "Ohio Manufacture Milk Rules;"

Date: September 17, 2015

Rule Type:

- ☐ New
- X Amended
- X 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- ☐ Rescinded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.

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 of 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 State regulatory agencies have adopted more stringent standards.

For the most part, the rules are being amended to make stylistic and grammatical changes and to ensure compliance with incorporation by reference rules. However, there are a few substantive amendments contained in this rule package. Specifically, the rules and their amendments are as follows:

901:11-2-01 sets forth the definitions for the chapter. Amendments were made to this rule in order to provide website references to the "Official Methods of Analysis of the AOAC International" and "Standard Methods for the Examination of Dairy Products (SMEDP)."

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. This rule was stylistically amended to reformat paragraphs. For example, numbers were added to lists. However, the rule remains substantively the same.

901:11-2-03 sets forth the requirements for bacterial count samples of raw milk. This rule was stylistically amended to reformat paragraphs. For example, large paragraphs were separated into smaller paragraphs. However, the rule remains substantively the same.

901:11-2-04 sets forth the requirements for somatic cell count samples of raw milk. This rule is being amended to make reference to the Pasteurized Milk Ordinance (PMO) as well as some stylistic changes. However, the rule remains substantively the same.

901:11-2-05 sets forth the requirements for drug residue testing. This rule was amended in order to provide the website to the Association of Official Analytical Chemists.

901:11-2-06 sets forth the requirement that samples be tested for biological significant radionuclides. This rule was stylistically amended in order to comply with LSC's Drafting Manual.

901:11-2-07 sets forth the requirement that samples be tested for pesticides and herbicides. This rule was stylistically amended in order to comply with LSC's Drafting Manual.

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. This rule makes one stylistic amendment in order to comply with LSC's Drafting Manual.

901:11-2-09 sets forth the requirements of the herd's health. This rule was amended in order to correct typos and reformat paragraphs. However, this rule remains substantively the same.

901:11-2-10 sets forth the conditions and requirements of a milking facility and cowyard. Only stylistic amendments were 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. This rule was amended in order to correct a typo.

901:11-2-12 sets forth the temperatures in which milk must be stored. This rule includes minor stylistic amendments.

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. This rule includes minor grammatical amendments.

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. One amendment was made to this rule in order to remove a sentence in paragraph (A) that was repeated in paragraph (C).

901:11-2-15 sets forth the condition in which utensils and equipment used in the handling of milk shall be maintained. One amendment was made to this rule in order to update the citation to the federal regulation.

901:11-2-16 sets forth the condition, location, and quality of water used for cleaning dairy utensils and equipment. One amendment was made to this rule in order to cite the Ohio Administrative Code.

901:11-2-17 sets forth the requirements for sewage disposal in the milkhouse. This rule was stylistically amended in order to comply with LSC's Drafting Manual.

901:11-2-18 sets forth the qualifications for a producer or processor license and requirements for a licensed dairy farm's annual inspection. This rule was amended in order to correct two typos and cite an Ohio Revised Code reference.

901:11-2-19 sets forth the conditions in which the premises of a milk plant must be kept, including an adequate drainage system. This rule includes one minor grammatical amendment. However, the rule remains substantively the same.

901:11-2-20 sets forth the conditions in which buildings and rooms must be maintained, including adequate lighting and ventilation. This rule includes one minor grammatical amendment. However, the rule remains substantively the same.

901:11-2-21 sets forth the requirements for the water supply for the plant, hand washing facilities, as well as other sanitary issues. The rule is being amended to clarify references to the PMO. Substantively, the rule is being amended to remove reference to Chapter 3701-28 of the Revised Code and requires all water sources, not approved by the state regulatory authority, to be compliant with appendices D & G of the PMO.

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. The rule includes a small stylistic change, as well as, a spelling correction. However, the rule remains substantively the same.

901:11-2-23 sets forth rules on the protection and transporting of raw milk and cream. The rule includes requirements for bulk milk transport tanks as well as their cleaning and sanitization. The rule is being amended to make a small stylistic change. However, the rule remains substantively the same.

901:11-2-24 outlines the requirements for raw product storage. This includes the bacteriological levels of raw commingled milk and proper temperature conditions. The rule is being amended to make small stylistic changes. However, the rule remains substantively the same.

901:11-2-25 sets forth the rules on the quality, composition, and wholesomeness of manufacture grade milk. The rule is being amended to make a stylistic change regarding incorporation by reference guidelines. However, the rule remains substantively the same.

901:11-2-26 outlines the cleaning and sanitization of all equipment used in receiving, storing, and processing milk. The rule is being amended to make stylistic changes to allow for easier comprehension. However, the rule remains substantively the same.

901:11-2-27 sets forth the cleaning and sanitizing requirements for equipment and utensils used in receiving, storing, and processing milk. This rule includes stylistic amendments; however, the rule remains substantively the same.

901:11-2-28 sets for the size, materials, and processing requirements for packaging containers used for dairy products. This rule includes stylistic amendments; however, the rule remains substantively the same.

901:11-2-29 sets forth the storage requirements for finished products, including processed product for shipment. This rule makes stylistic and grammatical amendments such as the deletion of repeated words. However, the rule remains substantively the same.

901:11-2-30 sets forth the requirement for drying, including the maintenance and conditions of dryers. This rule includes one stylistic amendment; however, the rule remains substantively the same.

901:11-2-31 sets forth the requirements for cooling dry products. This rule includes a stylistic amendment; however, the rule remains substantively the same.

901:11-2-32 sets for the requirements, including samples and testing, for instant nonfat dry milk. This rule includes stylistic amendments; however, the rule remains substantively the same.

901:11-2-33 sets forth the conditions and maintenance of coolers and freezers. This rule includes stylistic changes; however, the rule remains substantively the same.

901:11-2-34 sets forth the necessary precautions in a starter room in order to prevent contamination. This rule includes stylistic changes; however, the rule remains substantively the same.

901:11-2-35 sets forth the size and ventilation requirements in the room in which cheese is manufactured. This rule includes stylistic changes; however, the rule remains substantively the same.

901:11-2-36 sets forth the requirements and conditions in which equipment and utensils used for the manufacture of cheese must be maintained. This rule includes stylistic changes; however, the rule remains substantively the same.

901:11-2-37 sets forth the handling and disposal of whey. This rule amends one citation to the Ohio Administrative Code; however, the rule remains substantively the same.

901:11-2-38 sets forth the sanitary requirements for forming containers and procedures for filling containers, including sanitation and weight control. This rule includes stylistic changes; however, the rule remains substantively the same.

901:11-2-39 sets forth the requirements for maintaining records, including raw milk receipts. This rule includes stylistic amendments; however, the rule remains substantively the same.

901:11-2-40 sets forth the requirements of an insect and rodent control program. This rule includes one stylistic amendment; however, the rule remains substantively the same.

901:11-2-41 sets forth the clothing and shoe requirements for personnel cleaning the interior of the drier. This rule was stylistically amended in order to comply with LSC's Drafting Manual. However, the rule remains substantively the same.

901:11-2-42 sets forth the labeling requirements for products. This rule amends the citation for the Federal Food Drug & Cosmetic Act.

901:11-2-43 sets forth the required hygienic practices of personnel. This rule includes one minor grammatical amendment.

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. This rule replaces reference to the Ohio Administrative Code with reference to the PMO, which is defined in the first rule of this Chapter.

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.

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 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.

6. **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.

Development of the Regulation

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

   These rules were 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 rules and the proposed amendments. During their review, the Board was very supportive of the proposed rules and amendments. Further, they agreed the rules represent 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?**

   The United States Public Health Service and the Food and Drug Administration have devoted years of scientific research into establishing effective and practicable milk sanitation rules to ensure public safety. The incidence of milk-borne illness in the United States has been sharply reduced in that time. In 1938, milk borne outbreaks constituted twenty-five percent (25%) of all disease outbreaks due to infected foods and contaminated water. Through regulations such as the Pasteurized Milk Ordinance and manufacture grade milk rules, milk products continue to be associated with less than one percent (<1%) of such reported outbreaks.

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 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.

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

    As these regulations set minimum safety standards to protect the public, performance-based regulations are not appropriate.

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 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

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 or dairy operations who produce or use manufacture grade milk to produce milk products.

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

c. **Quantify the expected adverse impact from the regulation.**

The proposed rules are not expected to have any financial impact to 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.

As a whole, 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.