

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Division of Food Safety – Bottled Water

Rule Number(s): 901:3-62-(01-07)

Date: May 3, 2016

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☐ Rescinded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.

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

Chapter 901:3-62 of the Ohio Administrative Code regulates the bottling and processing of drinking water in the state of Ohio. The rules outline specific sanitary guidelines as they apply to bottled water processing. The rules generally comply with Federal standards to ensure that Ohio's bottled water processors do not face any undue burden when attempting to ship their products into another state. The rules as reviewed and proposed contain no substantive revisions and are being amended to comply with the incorporation by reference rules as well as to correct minor spelling and grammatical errors. The rules are more specifically explained below:

OAC 901:3-62-01 outlines the definitions as used in the chapter. The rule is being amended to correct a spelling error as well as to include dates to comply with the incorporation by reference rules. There are no substantive changes made to this rule.

OAC 901:3-62-02 states that all bottled water processors must obtain a license from the Department. The rule is being amended to make a stylistic change. There are no substantive changes to this rule.

OAC 901:3-62-03 sets forth the nomenclature and labeling requirements. The rule establishes a bottled water "standards of identity" which outline when a bottled water product may be called mineral water, sparkling bottled water, spring water, ect. The rule is being amended to include a web link to the United States Pharmacopoeia to comply with incorporation by reference standards. There are no substantive changes to the rule.

OAC 901:3-62-04 outlines the plant construction, design, and equipment standards. The rule sets out basic guidelines to ensure sanitary operations. These rules are very similar to other product manufacturing guidelines. There are no changes proposed to this rule.

OAC 901:3-62-05 outlines sanitary water requirements. Similar to OAC 901:3-62-04 this rule outlines sanitary guidelines as they apply to the water itself. This includes water testing and sampling which are required by the EPA. The rule is being amended to comply with the incorporation by reference standards. There are no substantive changes to the rule.

OAC 901:3-62-06 outlines sanitary operation requirements. This rule outlines sanitation requirements all water contact surfaces including containers, utensils, caps, and seals. There are no changes proposed to this rule.

OAC 901:3-62-07 outlines sanitary requirements for the processing and bottling operations. This includes treatment of product water, and sanitization immediately prior to bottling. The

rule is being amended to comply with the incorporation by reference standards. There are no substantive changes to the rule.

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

ORC 913.28

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, the regulation does not implement a federal requirement. However, the rules contained in this package allow the Department to participate in the Federal Drug Administration's (FDA) Manufactured Foods Regulatory Program Standards (MFRPS). This allows the Department's manufacture food inspection program to be considered equivalent to the FDA's inspection program.

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)?

Food safety regulations are essential in protecting consumers from food borne illnesses. Without these regulations, the quality and safety of food products would be dramatically decreased, likely resulting in the illness and death of consumers. When ideal conditions for bacterial growth exist, vegetative cells multiply rapidly within the product and may produce a deadly toxin within 3 to 4 days. When not properly treated, these bacteria can cause numerous health problems including but not limited to, death of the infected individual. Through these regulations, the risk for contamination and subsequently human death is dramatically decreased.

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

The Department inspects and investigates complaints regarding bottled water. The rules are judged as being successful when inspections and investigations find few violations, when there is no increase in the number of complaints filed with the Department, and when there are minimal health related outbreaks attributed to bottled water.

Development of the Regulation

7. 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.

On April 4, 2016, the Department reached out to its list of Food Safety stakeholders. The stakeholders had no suggested changes or requests regarding this rule package. The stakeholders are listed below:

Ohio Soft Drink Association	Kimberly McConville
Ohio Manufacturer's Association	Ryan Augsberger
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Department of Education/Child Nutrition	Andrea Denning
Ohio Farm Bureau	Tony Seegers
Ohio Produce Growers Association	Lisa Schacht
Ohio Dairy Producers	Scott Higgins
Snack Food Association – Arlington, VA	David Walsh
Maple Producers	Dan Brown
Ohio Bakery Association	Lora Miller
Ohio Council of Retail Merchants	David Raber
Wholesale Beer and Wine Association	Timothy Bechtold
Ohio Wine Producers	Donniella Winchell
	Belinda Jones
Ohio Restaurant Association	Joe Rosato
	John Barker
Mid-America Food Processors Association	Debra Gibson
Ohio Ecological Food and Farm Association	Amalie Lipstreu

Ohio State University (Farmers Markets)	Christie Welch
	Gwen Wolford
Ohio Beef Council	Elizabeth Harsh
Ohio Pork Producers Council	Bryan Humphreys
Ohio Farmers Union	Joe Logan
	Roger Wise
	Ron Sylvester
Ohio Grocers Association	Kristen Mullins
	Joe Ewig
Ohio Poultry Association	Jim Chakeres

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

As stated above, the stakeholders had no suggested changes or requests regarding this rule package.

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 structure 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.

Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Due to the serious 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 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 has sole regulatory authority among Ohio agencies and acts as the in-state inspector for the FDA.

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 food manufacturers, processors, and packagers to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all entities in Ohio are treated in a similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.

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 bottled water processors operating within the state of Ohio.

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

Each bottled water processor must obtain a license with the Department.

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.

There are no fines associated with this regulation. However, failure to comply with the requirements may result in the adulteration and eventual embargo or destruction of products.

c. Quantify the expected adverse impact from the regulation.

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.

The cost of a bottling license is \$200 annually.

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 prevention of the food borne illness and the protection of consumers is outweighed by the adverse impact of these regulations. The regulatory intent of these rules is considered justified due to the public safety risk.

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 small businesses 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?

There are no penalties for paperwork violations.

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

The staff members of the Division of Food Safety ensure that all manufacturers in Ohio are treated in a similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.