



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Agriculture

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Regulation/Package Title (a general description of the rules' substantive content):

Food Safety- Bottled Water

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

Date of Submission for CSI Review: 11/26/2024

Public Comment Period End Date: 12/18/2024

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 7 rules (FYR? yes)

Rescinded/___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **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. ODA is proposing the following amendments:

OAC 901:3-62-01 outlines the definitions as used in the chapter. The rule is being amended to correct errors based on the Legislative Service Commission's (LSC) guide on writing rules. In addition, definitions have been added pertaining to different sections of the Code of Federal Regulations and for the World Health Organization's Guidelines for Drinking Water Quality.

OAC 901:3-62-02 states that all bottled water processors must obtain a license from the Department. The rule is being amended to correct errors based on the Legislative Service Commission's (LSC) guide on writing rules and a correction to the rule number in reference. There are no substantive changes to the rule.

OAC 901:3-62-03 sets forth the nomenclature and labeling requirements. The rule establishes a bottled water "standard of identity" which outlines when a bottled water product may be called mineral water, sparkling bottled water or purified water. The rule is being amended to delete the reference to the United States Pharmacopoeia replacing it with a reference to 40 C.F.R. part 141 and the World Health Organization's Guidelines for Drinking Water Quality. In addition, the rule is being amended to specify that purified water must not contain more than

ten parts per million of total dissolved solids, deletes references to sterile water, removes effective dates of the C.F.R. because they have been defined in 901:3-62-01, adds a reference to 21 C.F.R. part 113.3e regarding commercially sterile bottled water, adds section (b) to the reference of the 21 C.F.R part 165.110 and removes a regulatory restriction.

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 food manufacturing guidelines. The rule is being amended to revise the rule that amplifies 913.28 from 913.27 to 913.41. There are no substantive changes to the 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 E.P.A. The rule is being amended to delete effective dates of the 21 C.F.R. because they have been defined in 901:3-62-01 and adds periods to the abbreviation for E.P.A. In addition, the rule is being amended to revise the rule that amplifies 913.28 from 913.27 to 913.41. There are no substantive changes to the rule.

OAC 901:3-62-06 outlines sanitary operation requirements. This rule outlines sanitation requirements for all water contact surfaces including containers, utensils, caps, and seals. The rule is being amended to revise the rule that amplifies 913.28 from 913.27 to 913.41. There are no substantive changes to the 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 delete effective dates of the 21 C.F.R. because they have been defined in 901:3-62-01. In addition, the rule is being amended to revise the rule that amplifies 913.28 from 913.27 to 913.41.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

O.R.C. 913.22, 913.23, 913.231, 913.25, 913.26, 913.28, 913.41

4. 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 manufactured food inspection program to be considered equivalent to the FDA's inspection program.

5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not Applicable

6. 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. 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.

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

The Department inspects food processing establishments and investigates complaints involving 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.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No

Development of the Regulation

9. 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.

The following stakeholders were contacted via email on October 15, 2024, for a public comment period which remained open until October 29, 2024.

Organization	Contact
Buckeye Quality Beef Association	David Hyde
Capital Advocates	Kurt Leib
Capitol Advocates	Rob Eshenbaugh
CIFT	Troy Wildermuth
Government Advantage Group	Amanda Sines
Great Lakes Community Action Partnership	Robin Richter
Greater Ohio Showmen Association	general email
Greater Ohio Showmen Association	David Drake
Greater Ohio Showmen Association	Randy Kissel

Greater Ohio Showmen Association	Russell Clements
Ice Miller	Samuel Porter
Maple Producers	Dan Brown
Mid-Ohio Growers	general email
Midwest Foods Association - Ohio group	Pat Anderson
Nation Farmers Organization	Alva Heiss
Nation Farmers Organization	Tony Bensman
Nation Farmers Organization	Bill Stachler
Ohio Agribusiness Association	Aaron Heilers
Ohio Agribusiness Association	Janice Welsheimer
Ohio Agribusiness Association	Lauren Prettyman
Ohio Agribusiness Association	Melinda Witten
Ohio Apples	general email
Ohio Association of Food Banks	Joree Novotny
Ohio Bakery Association	Lora Miller
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio Council of Retail Merchants	David Raber
Ohio Craft Brewer's Association	Ashley Rose
Ohio Craft Brewer's Association	Mary MacDonald
Ohio Dairy Producers	Scott Higgins
Ohio Ecological Food and Farm Association	Alisha Schleining
Ohio Ecological Food and Farm Association	Amber Mitchell
Ohio Farm Bureau	Adam Sharp
Ohio Farm Bureau	Jack Irvin
Ohio Farm Bureau	Leah Curtis
Ohio Farm Bureau	Roger High
Ohio Farm Bureau	Tony Seegers
Ohio Farmers Market Network	general email
Ohio Farmers Market Network	general email
Ohio Farmers Union	Joe Logan
Ohio Grocers	Kristin Mullins
Ohio Lawn Care Association	Mark Bennett
Ohio Manufacturer's Association	Ryan Augsberger
Ohio Pork Producers Council	Cheryl Day
Ohio Poultry Association	Jim Chakeres
Ohio Produce Growers Association	Lisa Schacht
Ohio Restaurant Association	John Barker
Ohio Restaurant Association	Tod Bowen
Ohio Soil and Water Conservation Commission	Jen Bowman

Ohio Soybean Association	Brandon Kern
Ohio State Grange	Mike Russell
Ohio State University	Adam Ward
Ohio State University (Farmers Markets)	Christie Welch
Ohio Veterinarian Medical Association	general email
Ohio Wine Producers	Donniella Winchell
PACA Inc.	David P. Corey
Snack Food Association – Arlington, VA	David Walsh
The Ohio State University	Peggy Hall
Wholesale Beer and Wine Association	Timothy Bechtold
Wood County Committee on Aging	Angie Bradford

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

The Department did not receive any stakeholder comments during the open comment period.

11. 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 growth of harmful bacteria to protect public safety.

12. 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?
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply

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 are in line with the federal regulations. Lack of 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.

13. 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.

14. 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

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

All bottled water processors operating within the state of Ohio.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

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.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

No

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

The prevention of food borne illnesses 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

18. 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.

19. 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.

20. 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 food manufacturers in Ohio are treated in a fair and consistent manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.