



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Food Safety Chapter 8

Rule Number(s): 901:3-8-01 to 901:3-8-07

Date of Submission for CSI Review: 4/28/23

Public Comment Period End Date: 5/19/23

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ 6 rules (FYR? 6)

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

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

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

The rules located in Chapter 901:3-8 define the criteria for processing shellfish.

Pursuant to the Legislative Service Commission's guide on administrative rule drafting, the Department has proposed to rescind the existing rules found in Chapter 901:3-8 and replace with a new rule setting forth that Food Safety Chapter 8 regarding shellfish processing will incorporate by reference the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish."

Rule 901:3-8-01 sets forth definitions as used in the chapter. Rule 901:3-8-01 will be replaced with a new rule setting forth that Food Safety Chapter 8 regarding shellfish processing will incorporate by reference the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish."

Rule 901:3-8-02 sets standards for transportation. This rule will be rescinded.

Rule 901:3-8-03 sets general requirements for dealers. This rule will be rescinded.

Rule 901:3-8-04 sets standards for shucking and packing. This rule will be rescinded.

Rule 901:3-8-05 sets standards for repacking of shucked shellfish. This rule will be rescinded.

Rule 901:3-8-06 sets standards for shellstock shipping. This rule will be rescinded.

Rule 901:3-8-07 sets standards for reshipping. This rule will be rescinded.

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2. 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.

ORC 3715.02, 3715.021

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.

Yes, the NSSP is a requirement for facilities that wish to ship shellfish interstate.

4. 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

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 shellfish and shellstock producers. 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 shellfish and shellstock products.

7. 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

8. 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 February 10, 2023, for a public comment period open until February 24, 2023.

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Capitol Advocates – Rob Eshenbaugh
Maple Producers – Dan Brown
Ohio Association of Food Banks – Lisa Hamler-Fugit
Ohio Bakery Association- Lora Miller
Ohio Beef Council / Ohio Cattlemen’s Association – Elizabeth Harsh
Ohio Council of Retail Merchants – David Raber
Ohio Dairy Producers – Scott Higgins
Ohio Ecological Food and Farm Association – Amalie Lipstreu
Ohio Farm Bureau – Adam Sharp, Jack Irvin, Leah Curtis, Roger High, and Tony Seegers
Ohio Farmers Union – Joe Logan
Ohio Lawn Care Association – Mark Bennett
Ohio Manufacturer’s Association – Ryan Augsberger
Ohio Pork Producer’s Council – Bryan Humphreys
Ohio Poultry Association – Jim Chakeres
Ohio Produce Growers Association – Lisa Schacht
Ohio State University – Peggy Hall, Adam Ward, Christie Welch, and Gwen Wolford
Snack Food Association (Arlington, VA) – David Walsh
Wholesale Beer and Wine Association – Timothy Bechtold
Great Lakes Community Action Partnership – Robin Richter
PACA Inc. – David P. Corey
Wood County Committee on Aging – Angie Bradford

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

During the public comment period, no comments were received.

10. 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 that are nationally accepted. 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.

11. 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.*

Chapter 901:3-8 Shellfish Processing was developed many years back and served as the basis for the shellfish inspections conducted by Food Safety. The department now feels that it would be beneficial for industry, without sacrificing public health, to simply adopt rules that are nationally accepted and in line with the federal regulations as opposed to having our own rules.

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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 manufacturers to educate and inform them of the requirements and regulations. 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.

Adverse Impact to Business

14. 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 shellfish and shellstock product manufacturers operate 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.

Each shellfish and shellstock product manufacturer must register as a food processing establishment under Ohio Revised Code 3715.041.

There are many factors to determine the cost of complying with this regulation. The facility must be maintained in acceptable condition and equipment must be in working order and calibrated correctly. Records must be maintained to demonstrate that the filed process is being followed to produce safe food. Records must then be reviewed before the 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 adulteration and eventual embargo or destruction of products.

15. 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*).

The department feels that adopting the shellfish rules by reference instead of continuing with the rules as written will ease the burden for industry because Ohio will be following the nationally

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recognized rules. Additionally, many of the firms in Ohio that are certified shellfish dealers have facilities that are outside the state of Ohio. Adopting the nationally recognized rules means these firms won't have to adhere to separate rules.

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

The regulated industry has been inspected against very similar requirements since the development of 901:3-8, so the department doesn't feel there will be any adverse impact to the regulated community. The prevention of 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

17. 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.

18. 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. When violations are found during an inspection a facility is given time to come into compliance (a minimum of 10 days) before legal remedy is sought.

19. 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.