



## Common Sense Initiative

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Carrie Kuruc, Director

### Business Impact Analysis

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

Rule Contact Name and Contact Information:

Morgan Lyles – ODA Legal Counsel, [morgan.lyles@agri.ohio.gov](mailto:morgan.lyles@agri.ohio.gov), 614-728-6204

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

Food safety – Fish products

Rule Number(s): OAC 901:3-7-01

Date of Submission for CSI Review: 1/24/2020; 3/4/2020

Public Comment Period End Date: 2/14/2020

Rule Type/Number of Rules:

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? \_\_\_)

Amended rules X (FYR? 03/21/2021)

Rescinded/\_\_\_ rules (FYR?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.*

The rule in this package outlines criteria and definitions for fish and fishery products, in addition to identifying exemptions.

The amendment specifically exempts 501(c)(3) non-profit organizations that move fish or fishery products from a food processing establishment to another location under their control and serve the food to the end consumer, without charge. Pursuant to public comment, we have amended the proposed rule to include senior centers created under section 173.11 of the Revised Code.

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.**

3715.02, 3715.021

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- 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 manufacture food inspection program to be considered equivalent to the FDA's inspection program.

- 5. If the regulation 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.

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

The Department inspects and investigates complaints regarding fish processing. 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 fish products.

- 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.*

Not applicable.

### **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.*

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Wood County Committee on Aging	Angie Bradford	<a href="mailto:abradford@wccoa.net">abradford@wccoa.net</a>

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

The stakeholders' comments were supportive of the change in the rule. Many expressed their gratitude that this change was being made and expressed how this change will benefit their organizations.

**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?**

Scientific research indicates that the risks associated with the proposed exemption are low and as such support the exemption for 501(c)(3) organizations.

**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?**

As this is an exemption to an existing regulation, no alternatives were explored.

**13. 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.***

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As this is an exemption to an existing rule, performance-based regulations were not considered.

**14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

This amendment provides an exemption and therefore removes the regulatory requirement for specific organizations engaged in specific conduct.

**15. 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.**

This is an exemption to rules that are already implemented within the industry and the Department works with all manufacturers to educate and inform them on 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**

**16. 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; and**

This amendment is available 501(c)(3) organizations who serve food to the end consumer without charge.

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

The adverse impact associated with the requirements of the rule include employee time in complying with seafood HACCP rules. This amendment is an exemption to an existing rule and as such removes the adverse impact for 501(c)(3) organizations.

**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.*

This is an exemption to an existing rule and as such no adverse impact will exist to the 501(c)(3) organizations.

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

This is an exemption to an existing rule and removes the adverse impact for 501(c)(3) organizations.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

The amendment is an exemption to an existing rule. Further exemptions for small businesses would not be appropriate in light of the risk for food borne illnesses, as public protection is the primary purpose for this rule, and the exemption is narrowly defined for certain operations.

**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?**

Because this amendment exempts certain organizations from the general requirements associated with moving fish or fishery products, the same organizations will similarly be exempt with paperwork violations associated with such movement. Generally, 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 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.