



# Common Sense Initiative

Mike DeWine, Governor  
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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- Fish and Fishery Products

Rule Number(s): 901:3-7-01 through 11

Date of Submission for CSI Review: 1/24/2024

Public Comment Period End Date: 2/8/2024

**Rule Type/Number of Rules:**

New/ 4 rules

Amended/     rules (FYR?    )

No Change/     rules (FYR?    )

Rescinded/ 11 rules (FYR? yes)

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.

Pursuant to the Legislative Service Commission's guide on administrative rule drafting, the Department has proposed to rescind the existing rules found in Chapter 901:3-7 and replace with a new rule setting forth that Food Safety Chapter 7 regarding fish and fishery products will incorporate by reference the 21 C.F.R. Chapter 1, Subchapter B, Part 123 "Fish and Fishery Products."

**Rule 901:3-7-01** rule sets forth criteria and definitions as used in the chapter. Rule 901:3-7-01 will be replaced with a new rule setting forth that Food Safety Chapter 7 regarding fish and fishery products will incorporate by reference 21 C.F.R. Chapter 1, Subchapter B, Part 123.

**Rule 901:3-7-02** sets forth the requirements for a Hazard Analysis and Hazard Analysis Critical Control Point Plan (HACCP). Rule 901:3-7-02 will be replaced with a new rule which amends definitions adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 123. This allows for the crossover of the rule to meet definitions used in Ohio.

**Rule 901:3-7-03** sets forth the requirements regarding corrective actions. 901:3-7-03 will be replaced with a new rule which deletes certain regulations adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 123. These sections address public disclosure and special requirements for

imported products. These are removed because the department has its own public disclosure protocols and imported products are regulated by the US Food and Drug Administration.

**Rule 901:3-7-04** sets forth criteria for verification. 901:3-7-04 will be replaced with a new rule which modifies regulations adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 123. This section addresses adulterated food. This rule is modified to clarify that failure of a processor to have and implement a HACCP plan shall render the fish or fishery products of that processor adulterated.

**Rule 901:3-7-05** sets forth the criteria for records. ODA is proposing to rescind this rule.

**Rule 901:3-7-06** sets forth the criteria for training. ODA is proposing to rescind this rule.

**Rule 901:3-7-07** sets forth sanitation control procedures. ODA is proposing to rescind this rule.

**Rule 901:3-7-08** sets forth the process controls for smoked and smoke-flavored fishery products. ODA is proposing to rescind this rule.

**Rule 901:3-7-09** sets forth the source controls for raw molluscan shellfish. ODA is proposing to rescind this rule.

**Rule 901:3-7-10** sets forth the criteria for raw molluscan shellfish tags. ODA is proposing to rescind this rule.

**Rule 901:3-7-11** sets forth the criteria for adulteration of fish and fishery products. ODA is proposing to rescind this rule.

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.**

ORC 3715.02, 3715.021, 3715.52, and 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.*

Yes, these are federal requirements for all food processing establishments that intend on processing fish or fishery products in the country. This chapter incorporates by reference the fish and fishery product regulations housed in 21 CFR Chapter 1, Subchapter B, Part 123. A few amendments have been made to ensure definitions and terminology in the CFR matches what is used in Ohio. Also, the rule deletes portions that are related to public disclosure, for which the Department has its own protocols and imported products as the US Food and Drug Administration regulates imported products. Further, the rule modifies the portion of the CFR that outlines the criteria for adulterated food.

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 and injury. Without these regulations, the quality and safety of food products would be dramatically decreased, likely resulting in the illness, injury or 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 possible 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 and investigates complaints regarding food manufacturers. The rules are judged as being successful when inspections and investigations find only minor 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 and fishery 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.*

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 December 8, 2023, for a public comment period which remained open until December 22, 2023.

|  |                  |
|--|------------------|
| 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        |

|  |                    |
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| Mid-Ohio Growers                               | General email      |
| Midwest Foods Association - Ohio group         | Pat Anderson       |
| Ohio Ag Council                                | Chris Henney       |
| Ohio Agribusiness Assoc.                       | Chris Henney       |
| Ohio Apples                                    | General email      |
| Ohio Aquaculture Association                   | Matthew A. Smith   |
| Ohio Association of Food Banks                 | Lisa Hamler-Fugitt |
| 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      | Amalie Lipstreu    |
| 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                    | Laura Morrison     |
| 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          | Jack Advent        |
| Ohio Veterinarian Medical Association          | General email      |

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|--|-------------------|
| PACA Inc.                              | Gary Conley       |
| 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    |
| Area Agency on Aging Region 9          | General email     |
| Area Agency on Aging District 7        | General email     |
| Western Reserve Area Agency on Aging   | General email     |
| AVI Food Systems                       | Lucy DUHAIME      |
| AVI Food Systems                       | Colin COBBERLY    |
| AVI Food Systems                       | Cathy Burden      |
| AVI Food Systems                       | Anthony PAYIAVLAS |

**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 that are nationally accepted. The rules were developed over years of research by the FDA utilizing the industry and other public entities. The rules represent the best approach to limiting physical, biological and chemical hazards in the regulated products 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 department has determined 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. 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 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**

**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 producers of fish and fishery products 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 adverse impact from these rules includes employee time in complying with HACCP rules. 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 injury 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.**

No, all processors of fish and fishery products must comply with the rule to ensure they are producing safe food.

**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. 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.

**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.