



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- 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Rescinded/ 11 rules (FYR?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

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

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.