

## Rule Summary and Fiscal Analysis

### Part A - General Questions

**Rule Number:** 901:3-7-01

**Rule Type:** New

**Rule Title/Tagline:** Incorporated by reference- fish and fishery products.

**Agency Name:** Department of Agriculture

**Division:** Food Safety

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#### I. Rule Summary

1. **Is this a five year rule review?** No
  - A. **What is the rule's five year review date?**
2. **Is this rule the result of recent legislation?** No
3. **What statute is this rule being promulgated under?** 119.03
4. **What statute(s) grant rule writing authority?** 3715.02, 3715.021
5. **What statute(s) does the rule implement or amplify?** 3715.59, 913.41, 3715.03, 3715.04, 3715.52, 3715.551, 3715.60
6. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** No
  - A. **If so, what is the citation to the federal law or rule?** Not Applicable
7. **What are the reasons for proposing the rule?**

This rule package is being amended as part of the five year rule review process. 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."

**8. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

Rule 901:3-7-01 is 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.

**9. Does the rule incorporate material by reference? Yes**

**10. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

Pursuant to section 121.75 of the Revised Code, the code sections incorporated into this rule are exempt from compliance with sections 121.71 to 121.74 of the Revised Code.

A copy of the 21 C.F.R. chapter 1, subchapter b, part 123 (2015) is available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=123>.

**11. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

*Not Applicable*

## **II. Fiscal Analysis**

**12. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

0.00

Not Applicable

**13. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

This rule is being updated to match the Code of Federal Regulations. The updates do not add any costs to applicable businesses. The estimated cost of compliance

regarding these rules includes employee time in complying with HACCP rules. Failure to comply with the requirements may result in the adulteration and eventual embargo or destruction of products.

14. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B).** No
15. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C).** No
16. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

While this rule does not have a regulation fee, all establishments processing fish and fishery products must have a food processing establishment registration in order to engage in production. The registration cost is based on the square footage of the food processing establishment that ranges from \$50 to \$300. The registration fee goes into a rotary fund that is used to administer the program.

### **III. Common Sense Initiative (CSI) Questions**

17. **Was this rule filed with the Common Sense Initiative Office?** Yes
18. **Does this rule have an adverse impact on business?** Yes
  - A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business?** Yes

All establishments processing fish and fishery products must have a food processing establishment registration in order to engage in that production.
  - B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms?** Yes

Failure to comply with the requirements may result in the adulteration and eventual embargo or destruction of products.
  - C. **Does this rule require specific expenditures or the report of information as a condition of compliance?** Yes

All food processing establishments regulated under this chapter must have a HACCP plan prior to production.

- D. **Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? Yes**

The estimated cost of compliance regarding these rules includes employee time in complying with HAACP rules.

**IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).**

19. **Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? Yes**

- A. **How many new regulatory restrictions do you propose adding to this rule? 1**

OAC 901:3-7-01 second independent paragraph adds the requirement that all food processing establishments as defined in section 3715.021 of the Revised Code shall comply with the rules of this chapter to determine that food has been manufactured under such conditions that render the food safe, unadulterated, and not misbranded.

- B. **How many existing regulatory restrictions do you propose removing from this rule? 0**

- C. **If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.**

901:3-7-01 Rescind

- D. **Please justify the adoption of the new regulatory restriction(s).**

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."