

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 901:3-1-09
Rule Type: Rescission
Rule Title/Tagline: Manufacturing operations.
Agency Name: Department of Agriculture
Division: Food Safety
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I. Rule Summary

- 1. Is this a five year rule review? Yes**
 - A. What is the rule's five year review date? 8/8/2018**
- 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? 3715.021, 3715.02**
- 5. What statute(s) does the rule implement or amplify? 3715.03, 3715.59, 3715.62**
- 6. What are the reasons for proposing the rule?**

The rule is up for five year rule review.

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

The rules contained in Chapter 901:3-1 of the Ohio Administrative Code mirror the regulations found in 21 CFR 110. Effective September 17, 2018, these provisions will be rescinded from the CFR. The regulations will be replaced by 21 CFR 117. These standards were adopted in the OAC in October of 2017. Upon the rescission of 21 CFR

110, the rules found in 901:3-1 shall no longer be necessary. Therefore, the rules in OAC Chapter 901:3-1 are proposed to be rescinded.

8. Does the rule incorporate material by reference? No
9. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.

Not Applicable

10. 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

11. As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.

This will have no impact on revenues or expenditures.

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There will be no impact on the expenditures or revenues of the Department. The rules are being rescinded and replaced with the new OAC 901:3-17.

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

There is no cost of compliance as the rules are being rescinded.

13. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No

14. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No

III. Common Sense Initiative (CSI) Questions

15. Was this rule filed with the Common Sense Initiative Office? Yes

16. 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? No

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

Current GMPs have been updated and clarified. 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.

C. Does this rule require specific expenditures or the report of information as a condition of compliance? No