

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 901:3-17-01
Rule Type: Amendment
Rule Title/Tagline: Incorporation by reference.
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?** 1/31/2024
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, 3715.60, 3715.62
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 has been reviewed in accordance with the five year rule review process.
8. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

901:3-17-01 incorporates by reference all the food safety regulations housed in 21 CFR 117. This rule is being amended to update the revision of 21 CFR 117 from 2017 to 2022.

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 according to section 121.75 (A)(1) of the Revised Code.

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?**

Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. 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.

The adverse impact from these rules is difficult to quantify. The amount of work required depends greatly on the product, the amount of product produced, and the size and layout of the facility. Many manufacturer's already have a food safety plan in place. Smaller manufacturers may choose to draft the food safety plan themselves and thereby reduce costs - or - hire an outside company to complete the necessary plan.

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.**

Not Applicable

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? 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**

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**

Records must be made available to the Department upon request. 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.

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**

These are federal requirements for all food processing establishments in the country. The adverse impact from these rules is difficult to quantify. The amount of work required depends greatly on the product, the amount of product produced, and the size and layout of the facility. Many manufacturer's already have a food safety plan in place. Smaller manufacturers may choose to

draft the food safety plan themselves and thereby reduce costs – or – hire an outside company to complete the necessary plan.

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? No

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

Not Applicable

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

Not Applicable

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

Not Applicable

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

Not Applicable