

Rule Summary and Fiscal Analysis (Part A)**Department of Agriculture**

Agency Name

Food Safety

Division

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901:3-17-01

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Incorporation by reference.**RULE SUMMARY**

1. Is the rule being filed for five year review (FYR)? **No**
2. Are you proposing this rule as a result of recent legislation? **No**
3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**
4. Statute(s) authorizing agency to adopt the rule: **3715.02, 3715.021**
5. Statute(s) the rule, as filed, amplifies or implements: **3715.59, 3715.60, 3715.62**
6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

The rules in this package adopt the Preventive Control processes as set forth in Title 21 of the Code of Federal Regulations part 117. 21 CFR 117 is more commonly referred to as the #Preventive Controls for Human Food rule# which is a part of the FDA Food Safety Modernization Act (FSMA). FSMA was signed into law on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system and recognizes the need for a global approach to food safety. All food processing establishments shall

comply with the rules established in this package to ensure that the food has been manufactured under such conditions that render the food safe, unadulterated, and not misbranded. These rules contained in this package mirror federal regulations in order to allow Ohio's food manufacturers to be able to ship all across the country.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; if the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

901:3-17-01 incorporates by reference all the food safety regulations housed in 21 CFR 117.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

Pursuant to section 121.76 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.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Not applicable.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. Five Year Review (FYR) Date:

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

0.00

Not applicable.

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable.

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

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.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

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? **Yes**

Records must be made available to the Department upon request.