

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

Agency Name

**Food Safety**

Division

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**901:3-23-09**

Rule Number

**NO CHANGE**

TYPE of rule filing

Rule Title/Tag Line

**Process controls and verification.****RULE SUMMARY**

1. Is the rule being filed for five year review (FYR)? **Yes**
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: **3715.27**
6. State the reason(s) for proposing (i.e., why are you filing,) this rule:  
This rule is up for five year rule review.
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:

The rules in this package regulate the processing of juice products in the state of Ohio. Without proper safeguards, juice manufacturing process can result in the

growth of highly dangerous pathogens such as *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, and *Listeria monocytogenes*. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting, and in some cases can result in the death of the infected individual. Due to this high level of risk there is significant regulation to monitor the juice production industry which is designed to prevent illness and protect consumers. These rules contained in this package mirror federal regulations in order to allow Ohio's juice processors to be able to ship all across the country.

901:3-23-09 requires that all juice processors subject to these rules must show in their HACCP plan that their processes will consistently produce juice that has undergone a five-log reduction for pertinent microorganisms. A five-log reduction is a process which achieves at least a 100,000 decrease in the micro-organisms present in the juice. This process is akin to pasteurization however, other methods may be utilized to meet this requirement. These organisms include *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, and *Listeria monocytogenes*. This process can be obtained through a process whereby the juice is heated to a level that eradicates the bacteria present in the juice.

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: **5/18/2017** and **05/18/2022**

(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:

The cost to register as a food processing establishment depends on the square footage of the facility. A majority of Ohio's juice processors who register as a food processing establishment fall under the smallest category which is below 5000 square feet. The cost of this registration is \$50 annually. The largest facilities, over 100,000 square feet, must pay \$300 annually to register as a food processing

establishment.

The adverse impact of these regulations is difficult to quantify as it is hard to separate production practices from regulation. The regulations dictate some equipment specifications; however equipment manufacturers specifically tailor their machinery to meet the regulations. Additionally, there are record keeping requirements which require time for employer compliance however; for the most part the machinery used in this industry automatically records this information.

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? **Yes**

Each juice processor must register as a food processing establishment under Ohio Administrative Code 901:3-21-02.

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**

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**