

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 901:3-12-01

Rule Type: New

Rule Title/Tagline: Produce safety.

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?** 925.26, 3715.02, 3715.021
5. **What statute(s) does the rule implement or amplify?** 925.26, 3715.02, 3715.021
6. **What are the reasons for proposing the rule?**

The rules in this package adopt the produce safety processes as set forth in Title 21 of the Code of Federal Regulations part 112. These regulations focus on setting standards for the production, harvest, and handling of fruits and vegetables, in an effort to reduce foodborne illnesses and to prevent microbial contamination associated with fresh produce. These rules contained in this package mirror federal regulations in order to allow Ohio's producer growers to be able to ship all across the country

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

901:3-12-01 incorporates by reference all the food safety regulations housed in 21 CFR 112.

8. **Does the rule incorporate material by reference? Yes**
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.**
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.
10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

There was an error contained in the original public hearing notice.

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 increase expenditures.

\$500,000.00

The cost to implement this program will be \$500,000. However, the Ohio Department of Agriculture received a grant from the Food and Drug Administration. Therefore, the costs will be entirely offset.

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

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 produce growers already have plans in place that meet these standards. Establish qualification and training requirements for all personnel who handle covered produce or food contact surfaces and their supervisors; require documentation of required training; and establish hygienic practices and other

measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance.

Establish qualification and training requirements for all personnel who handle covered produce or food contact surfaces and their supervisors; require documentation of required training; and establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance. Farm operators are required to exclude any person with applicable health conditions from working in operations that may result in contamination of covered produce. The applicable health conditions include communicable illnesses, or infectious diseases, infections, open lesions, vomiting, or diarrhea. Farms must tell these workers not to come to work. Therefore, these farms may experience either slower production or have to hire additional staff in order to meet their processing needs. Further, all farm workers who handle covered produce are required to follow hygienic practices in order to prevent contamination of covered produce including, maintaining adequate personal cleanliness, washing hands and drying hands thoroughly at certain times, keeping gloves in an intact and sanitary condition and replacing gloves when it is no longer possible to do so, and avoiding contact with animals other than working animals and minimizing contact with covered produce when in direct contact with working animals. Farm workers are required to wash their hands before work, before putting on gloves, after using the toilet, after a break or other absence from the work station, as soon as practical after touching an animal or animal waste, and at any other time when the hands could have become contaminated

Require that all agricultural water must be of safe and sanitary quality for its intended use. The agricultural water quality rules are not effective until at the earliest 2020. There has been significant discussion on the federal level or amending these rules and/or pushing the timeline further back. Regardless, the Department is adopting these rules and will amend these rules should a change be made. The proposed rule requires a review of agricultural water sources, distribution systems, facilities and equipment under a farm's control at the beginning of the growing season, and the regular inspection and maintenance of agricultural water sources and distribution systems and equipment under the farm's control. The proposed quality criteria includes the assurance that there is no detectable E. coli per 100 ml sample of water that is intended for harvest, packing and holding uses that directly contact covered produce. It is estimate that the farms will regularly inspect their water sources at least twice during the production cycle.

Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-

washing and toilet facilities, sewage, trash, plumbing, and animal excreta; and Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities.

Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing; Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements; Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards; Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin; and Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements. With regards to the biological soil rules, the FDA has estimated that nationwide 820 farms will have to change their practices related to the use of soil amendments as a result of the proposed rule. Farms that use untreated raw manure will likely switch to the lowest cost alternative in order to meet the requirements of the rule. There are several options available including compost and/or fertilizer. The quantified costs vary widely by the type of product, the rate of application, and the amount of acres.

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? Yes**

There is no prior authorization required however, entities which are regulated by these rules must register with the Department.

- 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 rules of this Chapter could result in action taken against the entity.

- C. Does this rule require specific expenditures or the report of information as a condition of compliance? Yes**

Yes. Records must be kept and made available to the Department upon request.