

Business Impact Analysis

Agency Name: <u>Ohio Department of Agriculture</u>		
Regulation/Package Title: <u>Division of Food Safety – Farm Markets</u>		
Rule Number(s): <u>901:3-6-(01-08)</u>		
Date: June 2, 2016		
Rule Type:		
□ New	X 5-Year Review	
X Amended	Rescinded	

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. Please briefly describe the draft regulation in plain language. Please include the key provisions of the regulation as well as any proposed amendments.

Chapter 901:3-6 of the Ohio Administrative Code regulates farm markets, farmers' markets, and farm product auctions which have registered with the Ohio Department of Agriculture. Pursuant to Ohio Revised Code 3717.22, these regulated areas are exempt from the general retail food establishment requirement so long as they register with the Department. This registration is voluntary however, only through registration is an entity exempt from the retail food establishment licensure. In order to meet this exemption, the regulated areas are only allowed to sell foods that are not potentially hazardous. Specifically, the rules outline sanitation requirements for these entities and are being amended as follows:

OAC 901:3-6-01 outlines the terms as defined in the chapter. Specifically the rule is being amended to make stylistic changes to the rules which do not impact the substance of the rule. Additionally, code reference changes have been made to match amended Revised Code sections.

OAC 901:3-6-02 outlines sanitation rules and prohibitions regarding food articles at farm markets, farmer's markets, and farm product auctions. The rule is being amended to make a grammatical change which does not affect the substance of the rule.

OAC 901:3-6-03 outlines requirements for equipment and facilities for the regulated areas. More specifically, the rule outlines basic sanitation requirements for equipment as well as refrigeration and restroom requirements. The rule is being amended to make a grammatical change which does not affect the substance of the rule.

OAC 901:3-6-04 outlines the wash, rinse, and bactericidal treatment for utilizes and food contact surfaces at the regulated areas. The rule is being amended to make a stylistic change which should allow for easier comprehension by the regulated community. There are no substantive changes proposed.

OAC 901:3-6-05 outlines the handwashing requirements for the regulated areas. The rule is being amended to make a small grammatical change which does not affect the substance of the rule.

OAC 901:3-6-06 outlines the water supply requirements for the regulated areas. As a general rule, water provided for handwashing and cleaning must be from a municipal water supply. However, water from a non-municipal water supply may be used however it must be tested annually to determine if it is negative for coliform. No substantive changes have been made.

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OAC 901:3-6-07 establishes that the Department has authorization to inspect the regulated areas. Only stylistic changes which do not impact the substance of the rule have been made.

OAC 901:3-6-08 states that when a regulated entity exceeds the scope permitted in OAC 901:3-6-01, the Department may refer the establishment to the local board of health. No changes have been made to this rule.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

ORC 3715.221

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? *If yes, please briefly explain the source and substance of the federal requirement.*

No.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The purpose for these rules is to protect consumers by establishing basic sanitation requirements. The regulated areas under this rule are permitted to sell foods which are not potentially hazardous. Establishments which sell potentially hazardous foods are required to license as a retail food establishment. These establishments are inspected by local health districts to ensure that they are meeting strict health standards. The regulated areas under this rule do not rise to the level of inspection as retail food establishments. Regardless as these regulated areas are offering food for sale to the public, basic sanitation requirements are necessary. These requirements help to limit consumers from foodborne illnesses.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Department inspects and investigates complaints regarding farm markets, farmer's markets, and farm product auctions. The rules are judged as being successful when inspections and investigations find few violations, when there is no increase in the number of complaints filed with the Department, and when there are minimal health related outbreaks attributed to these regulated areas.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

On April 4, 2016, the Department reached out to its list of Food Safety stakeholders. The stakeholders had no suggested changes or requests regarding this rule package. The stakeholders are listed below:

Ohio Soft Drink Association	Kimberly McConville
Ohio Manufacturer's Association	Ryan Augsberger
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Department of Education/Child Nutrition	Andrea Denning
Ohio Farm Bureau	Tony Seegers
Ohio Produce Growers Association	Lisa Schacht
Ohio Dairy Producers	Scott Higgins
Snack Food Association – Arlington, VA	David Walsh
Maple Producers	Dan Brown
Ohio Bakery Association	Lora Miller
Ohio Council of Retail Merchants	David Raber
Wholesale Beer and Wine Association	Timothy Bechtold
Ohio Wine Producers	Donniella Winchell
	Belinda Jones
Ohio Restaurant Association	Joe Rosato
	John Barker
Mid-America Food Processors Association	Debra Gibson
Ohio Ecological Food and Farm Association	Amalie Lipstreu

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Ohio State University (Farmers Markets)	Christie Welch
	Gwen Wolford
Ohio Beef Council	Elizabeth Harsh
Ohio Pork Producers Council	Bryan Humphreys
Ohio Farmers Union	Joe Logan
	Roger Wise
	Ron Sylvester
Ohio Grocers Association	Kristen Mullins
	Joe Ewig
Ohio Poultry Association	Jim Chakeres

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Ms. Lisa Schacht of the Ohio Produce Growers Association voiced her support for this rule p package. No other stakeholders made comments with respect to this rule package.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

These rules are based on widely accepted basic sanitation practices. These practices have been developed over the past several decades to ensure that products are handled in a safe, clean manner which limits the potential for foodborne illness.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Based on the comments submitted by the stakeholders, the Department believes that the rules as established help to ensure that general sanitation practices are utilized by these regulated areas. As the stakeholders had no specific suggestions, no other alternative regulations were considered.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117 CSIOhio@governor.ohio.gov When human health is concerned performance-based regulations are often inadequate in ensuring that food products are produced in a safe, wholesome environment. The rules in this chapter are very basic however they describe that certain actions must be taken and certain facilities must be available. This level of specificity is needed in order to limit the possibility of foodborne illness.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Department has sole regulatory authority pursuant to ORC 3717.221.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

These rules are already implemented within the industry and the Department works with all food manufacturers, processors, and packagers to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all entities in Ohio are treated in a similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

All food manufacturers, processors, and packagers operating within the state of Ohio.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

All food manufacturers, processors, and packagers who wish to be exempted from licensure as a retail food establishment must register with the Department. This registration is voluntary but does take time to complete the one page registration application. The registration is required to be update annually.

Entities which register must comply with the sanitation requirements outlined in the rules of this package. They include having proper refrigeration for their products, as well as having facilities to clean and sanitize their utensils and food contact surfaces. This generally requires either a two or three compartment sink.

There is no cost of registration.

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c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

The regulated areas must have access to running water in order to sanitize their equipment, hands, and food contact surfaces. This usually requires access to a dedicated water line. This may limit the number of locations available for the regulated areas.

The regulated areas must have sanitization agents such as soap, bleach, or other cleaning agent. These products are widely available and offered for a minimum cost.

There is no cost of registration.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The prevention of the food borne illness and the protection of consumers is outweighed by the adverse impact of these regulations. The regulatory intent of these rules is considered justified due to the public safety risk.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

As the primary purpose of this rule is the protection of consumers and the prevention of foodborne illnesses, exemptions for small businesses would be inappropriate.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

There are no penalties for paperwork violations.

18. What resources are available to assist small businesses with compliance of the regulation?

The staff members of the Division of Food Safety ensure that all manufacturers in Ohio are treated in a similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.