

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Food Safety – Produce Safety

Rule Number(s): 901:3-12-(01-06)

Date: September 6, 2017

Rule Type:

☒ New

☐ Amended

☐ 5-Year Review

☐ Rescinded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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

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.

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. The rules below have been reviewed in accordance with Chapter 119 of the Ohio Revised Code and are being proposed as being as follows:

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

901:3-12-02 amends the code of federal regulations adopted in OAC 901:3-12-01 to ensure that the proper terminology is used state wide. Specifically, we amend terminology used in the CFR to ensure that the terminology matches what is used other Ohio Revised Code sections.

901:3-12-03 sets forth the regulations housed in 21 C.F.R. part 112 which are deleted under the rules. The deleted portions relate to enforcement procedures which only apply to FDA and do not apply to the Department.

901:3-12-04 sets forth the regulations which are amended under the rules. Many of the amendments have been made to ensure that the correct terminology is accurate for the state of Ohio.

901:3-12-05 outlines the compliance dates associated with this rule. These dates correspond with the timeline for implementation as directed by the federal government.

901:3-12-06 establishes a voluntary registration. At the request of several farms, ODA has created a voluntary registration which would allow farms that are otherwise exempt to be inspected and regulated by ODA. These farms have indicated to ODA that their clients are requesting that they be inspected pursuant to these laws. ODA will work with these farms to ensure that they are properly regulated and thereby opening their businesses to a larger marketplace

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

ORC 925.26, 3715.02, and 3715.021

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- 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, the regulation does not implement a federal requirement. However, the rules contained in this package allow the Department to participate in the Federal Drug Administration's (FDA) Manufactured Foods Regulatory Program Standards (MFRPS). This allows the Department's manufacture food inspection program to be considered equivalent to the FDA's inspection program.

- 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 Ohio Department of Agriculture is tasked with ensuring that all food products produced in the state of Ohio are produced and stored in a safe, sanitary establishment. Without these regulations, food could be produced or stored in a facility that is filthy, unclean, with a high potential of food borne 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 food producers. 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 juice products.

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 August 8, 2017, the Department sent the rule to the stakeholders listed below:

Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio Department of Education/Child Nutrition	Andrea Denning
Ohio Pork Producers Council	Bryan Humphreys
Ohio State University (Farmers Markets)	Christie Welch

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Maple Producers	Dan Brown
Ohio Council of Retail Merchants	David Raber
Snack Food Association – Arlington, VA	David Walsh
Mid-America Food Processors Association	Debra Gibson
Ohio Beef Council/Ohio Cattlemen’s Association	Elizabeth Harsh
Ohio State University (Farmers Markets)	Gwen Wolford
Ohio Farm Bureau	Jack Irvin
Ohio Produce Growers Association	Jennifer Kennedy
Ohio Poultry Association	Jim Chakeres
Ohio Grocers Association	Joe Ewig
Ohio Farmers Union	Joe Logan
Ohio Restaurant Association	Joe Rosato
Ohio Restaurant Association	John Barker
Ohio Soft Drink Association	Kimberly McConville
Ohio Grocers Association	Kristen Mullins
Ohio Farmers Union	Linda Borton
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Produce Growers Association	Lisa Schacht
Ohio Bakery Association	Lora Miller
Environmental Law & Policy Center	Madeline Fleisher
Ohio Lawn Care Association	Mark Bennett
Ohio Manufacturer’s Association	Ryan Augsberger
Ohio Dairy Producers	Scott Higgins
Wholesale Beer and Wine Association	Timothy Bechtold
Ohio Farm Bureau	Tony Seegers
Ohio Farm Bureau	Yvonne Lesicko

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

On August 23, 2017, the Ohio Ecological Food and Farm Association (OEFFA) provided written comments and request for clarifications to the proposed rules. Specifically, OEFFA stated, “The exemptions contained in the federal produce safety rule statute were included specifically to limit the burden on small producers that are selling into local markets and for whom the risk is considered insignificant.” The federal rule does exempt these producers from being regulated under this rule. However, ODA has spoken with numerous otherwise exempt farms that wish to be regulated under these rules. These farms have indicated that failure to be regulated under these rules may cause their clients to turn to other regulated entities. To ensure that these small produce growers remain competitive in an already

competitive market, ODA has established a voluntary program which otherwise exempt farms may voluntarily subject themselves to. As the program is voluntary there is no requirement to be a part of this program.

Further, OEFFA requested that an individual be appointed as an ombudsman to mediate the process of the implementation of these rules. ODA understands the necessity for producer education and clarity when it comes to these adopted regulations. ODA has already conducted several trainings and outreach sessions and will continue to do so. Therefore, ODA did not adopt OEFFA's suggestion of establishing an ombudsman.

On August 23, 2017, the Ohio Farm Bureau Federation (OFBF) provided written comments to the proposed rule. OFBF stated that "we appreciate the clarification in 901:3-12-04(D) stating that the withdrawal of qualified exemptions would be administered by FDA. This important clarification ensures producers understand that if a qualified exemption is withdrawn, that process will go through the FDA rather than our state agency."

Further, OFBF requested a formalized procedure for addressing variance requests. ODA declined to adopt such a procedure. As stated above, ODA understands the necessity for producer education and clarity when it comes to these adopted regulations and therefore, ODA has already conducted several trainings and outreach sessions and will continue to do so. The products, procedures, and operations of Ohio's producers are incredibly diverse. Rather than placing one size fits all constraints on this process, ODA will be reviewing all variance requests on a case by case basis. This procedure will ensure that each variance request is properly researched, reviewed, and given the consideration it deserves. For those reasons, ODA chose not to adopt a formalized procedure in rules.

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?

The rules contained in the package mirror standards set forth by the FDA. The rules were developed over years of scientific research. The rules present the best scientific approach to limiting the spread of harmful bacteria in order to protect public safety.

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?

The department is statutorily tasked with developing and establishing standards for this industry. The standards that are contained in this rule are based on scientific research and in are in line with the federal regulations. Stakeholder participation in this rule package has indicated to the Department that this is the best regulatory scheme at this time as it allows

Ohio food producers to ship their products across the country. For those reasons, no other regulatory alternatives 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.

Due to the serious public health risks, the Department did not consider a performance based regulation. The regulations dictate the process in order to ensure safety by establishing science-based minimum standards for safe production and harvesting of fresh fruits and vegetables. Further, the process allows individual producers the flexibility to create a process based on their own production methods. The critical control points along with the requirements of the regulation must be followed to protect against *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, and other organisms.

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 among Ohio agencies and acts as the in-state inspector for the FDA.

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.

ODA understands the necessity for producer education and clarity when it comes to these adopted regulations. ODA has already conducted several trainings and outreach sessions and will continue to do so. The staff members of the Division of Food Safety ensure that all producers 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 entities which grow, pack, process or sell fresh produce are subject to these rules. The rules however contain several exemptions and exclusions. In particular, the rules do not apply to commodities which are rarely consumed raw. Further, the rules do not cover farms that have a three year average annual value of \$25,000 or less. There are several more exemptions and exclusions not mentioned here.

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

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.

Require that all agricultural water must be of safe and sanitary quality for its intended use.

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.

c. Quantify the expected adverse impact from the regulation.

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.

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

The agricultural water quality rules are not effective until at the earliest 2020. There has been significant discussion on the federal level of 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 estimated that the farms will regularly inspect their water sources at least twice during the production cycle.

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.

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

The primary benefit of the provisions in this rule would be an expected decrease in the incidence of illnesses relating to produce from microbial contamination. The FDA states that there are an estimated 2.68 million illnesses per year associated with produce. Nationwide the costs associated with these illnesses are \$1.6 billion annually. The prevention of the food borne illness and the protection of consumers is outweighed by the adverse impact of these regulations.

Regulatory Flexibility

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

The rule provides for exemptions based on the size of the business. Should a small business comply with the exception they would be exempt from the rules.

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?

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.

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 producers 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.