

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Food Safety – Good Manufacturing Practices

Rule Number(s): 901:3-1-(01-10); 901:3-5-01; 901:3-6-02; 901:3-7-(01, 07);

901:3-23-(01, 02, 09); 901:3-62-01.

Date: February 27, 2018

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☒ Rescinded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.

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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.

Ohio Revised Code 3715.021 states that the Ohio Department of Agriculture shall adopt rules that establish standards and good manufacturing practices for food processing establishments which conform to the standards established by the United States Food and Drug Administration in Title 21 of the Code of Federal Regulations.

The rules contained in Chapter 901:3-1 of the Ohio Administrative Code mirror the regulations found in 21 CFR 110. Effective September 17, 2018, these provisions will be rescinded from the CFR. The regulations will be replaced by 21 CFR 117. These standards were adopted in the OAC in October of 2017. Upon the rescission of 21 CFR 110, the rules found in 901:3-1 shall no longer be necessary. Therefore, the rules in OAC Chapter 901:3-1 are proposed to be rescinded.

Further, all code references to 901:3-1 have been amended to read 901:3-17. Please note that the amendments exclude OAC 901:3-1-01, OAC 901:3-8-01, and OAC 901:3-8-03. These rules are going through a separate review and will be amended respectively.

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

ORC 3715.02, 3715.021

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.

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 manufactured foods 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 manufactured 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, or with a high potential of food borne illnesses. Further, ORC 3715.021 requires the Department to adopt standards which meet the federal standards.

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 manufacturers. 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 food 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 January 22, 2018, the Department sent the rule to the stakeholders listed below:

| | |
|--|--------------------|
| Capitol Advocates | Rob Eshenbaugh |
| Environmental Law & Policy Center | Madeline Fleisher |
| Maple Producers | Dan Brown |
| Mid-America Food Processors Association | Debra Gibson |
| Ohio Association of Food Banks | Lisa Hamler-Fugitt |
| Ohio Bakery Association | Lora Miller |
| Ohio Beef Council/Ohio Cattlemen's Association | Elizabeth Harsh |
| Ohio Council of Retail Merchants | David Raber |
| Ohio Dairy Producers | Scott Higgins |
| Ohio Department of Education/Child Nutrition | Andrea Denning |
| Ohio Ecological Food and Farm Association | Amalie Lipstreu |
| Ohio Farm Bureau | Jack Irvin |
| Ohio Farm Bureau | Tony Seegers |
| Ohio Farm Bureau | Yvonne Lesicko |
| Ohio Farm Bureau | Leah Curtis |
| Ohio Farmers Union | Joe Logan |
| Ohio Farmers Union | Linda Borton |

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| Ohio Grocers Association | Joe Ewig |
| Ohio Grocers Association | Kristen Mullins |
| Ohio Lawn Care Association | Mark Bennett |
| Ohio Manufacturer's Association | Ryan Augsberger |
| Ohio Pork Producers Council | Bryan Humphreys |
| Ohio Poultry Association | Jim Chakeres |
| Ohio Produce Growers Association | Jennifer Kennedy |
| Ohio Produce Growers Association | Lisa Schacht |
| Ohio Restaurant Association | Joe Rosato |
| Ohio Restaurant Association | John Barker |
| Ohio Soft Drink Association | Kimberly McConville |
| Ohio State University | Adam Ward |
| Ohio State University (Farmers Markets) | Christie Welch |
| Ohio State University (Farmers Markets) | Gwen Wolford |
| Snack Food Association – Arlington, VA | David Walsh |
| Wholesale Beer and Wine Association | Timothy Bechtold |

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

The Department did not receive any comments from the stakeholders. The Department believes this is due to the regulated community's understanding of the implementation of current good manufacturing practices..

8. 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, proactive approach as a means to protect public safety.

9. 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 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 manufacturers to ship their products interstate and internationally. For those reasons, no other regulatory alternatives were considered.

10. 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.

The rules contained in this package are performance-based regulations. The good manufacturing processes must be followed to protect against *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, and other pathogenic organisms. However, the rules allow for flexibility to accomplish the requirements.

11. 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.

12. 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 manufacturers to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all manufacturers in Ohio are treated in a fair and consistent manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.

Adverse Impact to Business

13. 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 operating within the state of Ohio.

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

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.

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. .

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

The prevention of food borne illnesses 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

15. 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.

16. 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. 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.

17. 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 fair and consistent manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.