CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Food Safety – Preventive Controls

Rule Number(s): 901:3-17-(01-04)

Date: July 31, 2017

Rule Type:

- X 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- ☐ Rescinded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.

   The rules in this package adopt the Preventive Control processes as set forth in Title 21 of the Code of Federal Regulations part 117. All food processing establishments shall comply with the rules established in this package to ensure that the food has been manufactured under such conditions that render the food safe, unadulterated, and not misbranded. These rules contained in this package mirror federal regulations in order to allow Ohio's food manufacturers 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:

   901:3-17-01 incorporates by reference all the food safety regulations housed in 21 CFR 117.

   901:3-17-02 amends the code of federal regulations adopted in OAC 901:3-17-01 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.

   901:3-17-03 sets forth the regulations housed in 21 C.F.R. part1 17 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.

   901:3-17-04 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.

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.

   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 manufactured in the state of Ohio is 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 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 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 June 12, 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
Environmental Law & Policy Center	Madeline Fleisher
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio State University (Farmers Markets)	Christie Welch
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 Dairy Producers	Scott Higgins
Ohio State University (Farmers Markets)	Gwen Wolford
Ohio Farm Bureau	Jack Irvin
Ohio Produce Growers Association	Jennifer Kennedy

Ohio Farm Bureau	Tony Seegers
Ohio Grocers Association	Joe Ewig
Ohio Farm Bureau	Yvonne Lesicko
Ohio Restaurant Association	Joe Rosato
Ohio Farmers Union	Joe Logan
Ohio Restaurant Association	John Barker
Ohio Farmers Union	Linda Borton
Ohio Farmers Union	Roger Wise
Ohio Soft Drink Association	Kimberly McConville
Ohio Grocers Association	Kristen Mullins
Ohio Pork Producers Council	Bryan Humphreys
Ohio Poultry Association	Jim Chakeres
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Produce Growers Association	Lisa Schacht
Ohio Bakery Association	Lora Miller
Ohio Lawn Care Association	Mark Bennett
Ohio Manufacturer's Association	Ryan Augsberger
Wholesale Beer and Wine Association	Timothy Bechtold

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

   The Ohio Farm Bureau provided the lone comment to the rules. Specifically, the Farm Bureau was concerned about the adoption of a process for a qualified exemption. It is ODA's intention to allow the FDA to handle the withdrawal of the qualified exemption. The Farm Bureau indicated that they were fine with that approach however, they requested that the process be spelled out in rule. ODA obliged and clarified this process in the 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 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 manufacturers 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. This process is recognized nationally and allows manufacturer to be able to ship their products across the country. 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.**

    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 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 operating within the state of Ohio, except for those specifically exempted in the rules.

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

Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. 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. Many manufacturer's already have a food safety plan in place. Smaller manufacturers may choose to draft the food safety plan themselves and thereby reduce costs – or – hire an outside company to complete the necessary plan.

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.

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?

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.

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.