



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Agriculture

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Food Safety – Chapter 5

Rule Number(s): 901:3-5-01 to 901:3-5-05

Date of Submission for CSI Review: December 22, 2021

Public Comment Period End Date: January 17, 2022

Rule Type/Number of Rules:

New/___ rules

No Change/ 5 rules (FYR? 5)

Amended/ ___ rules (FYR? ___)

Rescinded/ ___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- Requires specific expenditures or the report of information as a condition of compliance.**
- Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

- 2. 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 located in Chapter 901:3-5 regulate the processing of acidified foods in heretically sealed containers. Examples of hermetically sealed containers are cans, glass jars, or aseptic juice boxes. The rules contained in this rule package mirror federal regulations in order to allow Ohio's manufacturing industry to be able to ship all across the country.

Rule 901:3-5-01 outlines the criteria and definitions as used in the chapter.

Rule 901:3-5-02 sets forth training requirements for processing and packaging operators.

Rule 901:3-5-03 sets forth the processing requirements for all acidified canning operations. The rule outlines acceptable pH levels as well as coding requirements for product tracking.

Rule 901:3-5-04 sets forth the requirements relating to the scheduled processes for the operation. The rule outlines the procedures for when a deviation from the scheduled process occurs.

Rule 901:3-5-05 sets forth the record keeping requirements of the chapter.

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- 3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Ohio Revised Code 913.04

- 4. 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 regulations do not implement a federal requirement. The rules contained in this package allows the Department of participate in the Federal Drug Administration's (FDA) Manufactured Foods Regulatory Program Standards (MFRPS). This allows the Department's manufactured food inspection program to be considered equivalent to the FDA's inspection program.

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

Not Applicable.

- 6. 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 Department is tasked with ensuring that all food products manufactured in the state of Ohio are produced and stored in a safe, sanitary establishment. The Department is also required to adopt standards which meet federal standards by section 3715.021 of the Revised Code. These regulations reduce the risk of contaminated products and therefore protecting public health.

- 7. 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, there is no increase in the number of complaints, and there are minimal health related outbreaks attributed to food products.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

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9. 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.

The following stakeholders were contacted via email on September 3, 2021 for a public comment period open until September 17, 2021:

Capitol Advocates – Rob Eshenbaugh

Maple Producers – Dan Brown

Ohio Association of Food Banks – Lisa Hamler-Fugit

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 Ecological Food and Farm Association – Amalie Lipstreu

Ohio Farm Bureau – Adam Sharp, Jack Irvin, Leah Curtis, Roger High, and Tony Seegers

Ohio Farmers Union – Joe Logan

Ohio Lawn Care Association – Mark Bennett

Ohio Manufacturer’s Association – Ryan Augsberger

Ohio Pork Producer’s Council – Bryan Humphreys

Ohio Poultry Association – Jim Chakeres

Ohio Produce Growers Association – Lisa Schacht

Ohio State University – Peggy Hall, Adam Ward, Christie Welch, and Gwen Wolford

Snack Food Association (Arlington, VA) – David Walsh

Wholesale Beer and Wine Association – Timothy Bechtold

Great Lakes Community Action Partnership – Robin Richter

PACA Inc. – David P. Corey

Wood County Committee on Aging – Angie Bradford

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

During the public comment period, no stakeholder comments were received.

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11. 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 this rule package mirror the standards set for the by the FDA. The rules were developed over years of scientific research. The rules present the best scientific, proactive approach to protect public safety.

12. 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 did not consider any other regulatory alternatives because the current regulatory mechanism allows Ohio manufacturers to ship their products interstate and internationally.

13. 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 rule package are performance-based regulations. The manufacturing processes must be followed to protect against pathogenic organisms; however, the rules allow for flexibility to accomplish the requirements.

14. 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.

15. 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.

The rules are already implemented within the industry and the Department works with all manufacturers to educate and inform them on the requirements and regulations.

Adverse Impact to Business

16. 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; and

All facilities canning acidified foods in the state of Ohio.

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

A canning license is required under section 913.02 of the Revised Code to produce acidified canned foods. There are no fines associated with this regulation. There are

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additional requirements that would involve employer time which include keeping equipment in working order, calibration of equipment, and record keeping.

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 price for a license to produce acidified canned foods is \$200.

The adverse impact for these regulations is difficult to quantify. The regulations dictate some equipment specifications; however, equipment manufacturers specifically tailor their machinery to meet the regulations. Additionally, there are record keeping requirements which require employer time; however, most of the machinery used in the industry automatically records the information.

17. 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

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

As the primary purpose of the regulations is public safety, exemptions for small businesses would not be applicable.

19. 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 before legal remedy is sought.

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

The staff of the Division of Food Safety ensures that all manufacturers in Ohio are treated in a fair and consistent manner. The Department has online resources and field staff available to provide assistance.

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