

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Division of Food Safety – Processing Acidified Foods

Rule Number(s): 901:3-5-01, 02, 03, 04, and 05.

Date: December 5, 2014

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☐ Rescinded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 regulate the processing of acidified foods in hermetically sealed containers. Examples of hermetically sealed containers are cans, glass jars, or aseptic juice boxes. Canning food is a method of preserving foods for a period of time. Errors in the canning process can result in the growth of a highly dangerous bacterium known as *Clostridium botulinum*. This bacterium is extremely poisonous and often times results in the death of the infected individual. Due to this high level of risk there is significant regulation to monitor the canning industry which is designed to prevent the growth of this bacterium.

These rules contained in this package mirror federal regulations in order to allow Ohio's manufacturing industry to be able to ship all across the country. The rules are being amended as follows:

Rule 901:3-5-01 outline the criteria and definitions as used in the chapter. The rule is being amended to correct a spelling error.

Rule 901:3-5-02 sets forth training requirements for processing and packaging operators. The rule is being amended to make grammatical and stylistic changes.

Rule 901:3-5-03 sets forth the processing requirements for all acidified canning operations. The rules outline acceptable pH levels as well as coding requirements for product tracking. The rule is being amended to correct a spelling error.

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. Additionally, the rule is being amended to add requirements of manufacturers to notify the Ohio Department of Agriculture (Department) when there is a potential significant health risk. Additionally, the rules require the manufactures to prepare and maintain procedures for handling product recalls.

Rule 901:3-5-05 sets forth the record keeping requirements of the chapter. It is being amended to correct a grammatical error.

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

ORC 913.04

- 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)?**

Canning of acidified foods is a high risk activity which may cause fatalities. Errors in the canning process dramatically increase the likelihood that the bacterium *Clostridium botulinum* will form in the food. It is one of the most poisonous naturally occurring substances known. It can cause death by preventing breathing.

This bacterium exists either as spores or as vegetative cells. The spores, which are comparable to plant seeds, can survive harmlessly in soil and water for many years. When ideal conditions exist for growth, the spores produce vegetative cells which multiply rapidly and may produce a deadly toxin within 3 to 4 days. Through these regulations, the risk for contamination and subsequently human death is dramatically decreased.

- 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 the canning industry. 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 outbreaks of *Clostridium botulinum*.

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.

The Department reached out to the Ohio Manufacturers' Association (OMA) and the Ohio Grocery Manufacturers' Association (OGMA) for review of these rules. OMA is an organization dedicated to the promotion and growth of manufacturing in Ohio. They represent many canning manufacturers and have distributed these rules to their constituents. OGMA is an organization which represents approximately 400 grocers, wholesalers, brokers and associate members. Both organizations and their constituents were involved in the initial development of these rules in 2003.

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

The rules have remained relatively unchanged since their inception in 2003. Both the Ohio Manufacturers' Association and the Grocery Manufacturers' Association Members were supportive of the amendments made to this rule.

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. The process authority will determine the critical control points based on the size of the food, the ingredients in the finished product and the process time. The critical control points along with the requirements of the regulation must be followed to protect against the bacterium *Clostridium botulinum*.

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 through a 24 hour helpline 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 facilities canning acidified foods must comply with this regulation.

b. Identify the nature of the adverse impact (e.g., license 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 many factors to determining the cost of complying with this regulation. The equipment must be in working order and calibrated correctly and then records must be maintained to demonstrate that the filed process is being followed to produce a safe food. Records must then be reviewed before product is allowed to go into commerce.

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 of these regulations is difficult to quantify as it is hard to separate production practices from regulation. 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 time for employer compliance however; for the most part the machinery used in this industry automatically records this information.

The new portions of this rule add time for employer compliance by requiring all manufacturers to develop and maintain procedures for handling product recalls. Many food manufacturers already have these plans in place so the adverse impact should be minimal.

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

The prevention of the bacterium *Clostridium botulinum*, which is one of the most poisonous naturally occurring substances on earth, 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 these rules is public safety, exemptions for small businesses would not be applicable.

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 a 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 through a 24 hour helpline to provide assistance. Training and seminars are also available.