

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Shellfish Processing

Rule Number(s): 901:3-8-(01-07)

Date: October 2, 2018

Rule Type:

5-Year Review

Amended

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.

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 handling, processing, and transportation of shellfish products in the state of Ohio. As indicated in paragraph (A) of OAC 901:3-8-01, all food processing establishments that handled shellstock for interstate distribution shall meet the requirements of this Chapter to assure the sale or distribution of shellfish from safe sources and to assure shellfish has not been adulterated during cultivating, harvesting, processing, shipping, or handling.

Without proper safeguards, errors in the food production process can result in the growth of highly dangerous pathogens such as Clostridium botulinum, *E. coli* 0157:H7, Salmonella, and Listeria monocytogenes. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting, and in some cases can result in the death of the infected individual. Due to this high level of risk there is significant regulation to monitor the food production industry which is designed to prevent illness and protect consumers.

These rules contained in this package mirror nationally approved standards in order to allow Ohio's producers of shellfish and shellstock products 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 with the following changes:

901:3-8-01 sets forth the food processing establishments that are subject to the rules of this chapter. Additionally, this rule sets out the terms that have been defined in the chapter. The rule has been amended to update a code reference from 901:3-1 to 901:3-17.

901:3-8-02 outlines the transportation and shipping requirements for moving shellfish. Specifically, the rule outlines when shipments must be rejected and other equipment specifications. No changes have been made to this rule.

901:3-8-03 sets forth the requirement that each processor shall have a written hazard analysis to determine at what steps in their food production are food hazards likely to occur and ways that processors can apply controls to these hazards to limit their likelihood. All shellfish and shellstock product processors subject to the rules of this chapter shall develop a written Hazard Analysis and Critical Control Point plan, otherwise known as a HACCP plan. This is required whenever the hazard analysis reveals one or more food hazards are likely to occur during production. Additionally, the HACCP plan outlines how processors will monitor these critical control points and requires the development and implementation of corrective action plans should a deviation from the critical limits occur.

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The rule also requires processors to verify and validate that their HACCP plan is being implemented according to its design. A processor verifies and validates their HACCP plan by reviewing any consumer complaints, calibrating instruments, and recording any deviation that may occur. This validation must take place at least once every twelve months.

Finally, the rule requires that all processors maintain records which document the processor's HACCP plan. The processor must maintain records documenting that the processor continues to monitor the critical control points and their critical limits.

The rule has been amended to update a code reference from 901:3-1 to 901:3-17.

901:3-8-04 outlines the requirements for shucking and packing of shellstock. The rule outlines critical control points that must be accounted for in addition to sanitation requirements for the facility and personnel. To comply with the incorporation by reference rules, a date was added to the CFR section. No other changes were made to this rule.

901:3-8-05 outlines the requirements for the repacking of shucked shellfish. The rule outlines critical control points that must be accounted for in addition to sanitation requirements for the facility and personnel. To comply with the incorporation by reference rules, a date was added to the CFR section. No other changes were made to this rule.

901:3-8-06 outlines the requirements for the shipping of shellfish. The rule outlines critical control points that must be accounted for in addition to sanitation requirements for the facility and personnel. No changes have been made to this rule.

901:3-8-07 outlines the requirements for the re-shipping of shellfish. The rule outlines critical control points that must be accounted for in addition to sanitation requirements for the facility and personnel. No changes have been made to this rule.

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)?

Food safety regulations are essential in protecting consumers from food borne illnesses. Without these regulations, the quality and safety of food products would be dramatically decreased, likely resulting in the illness and death of consumers. When ideal conditions for bacterial growth exist, vegetative cells multiply rapidly within the product and may produce a deadly toxin within 3 to 4 days. When not properly treated, these bacteria can cause numerous health problems including but not limited to, death of the infected individual. 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 shellfish and shellstock 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 shellfish and shellstock 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 13, 2018, the rules were submitted to the following stakeholders:

Capitol Advocates	Rob Eshenbaugh
Environmental Law & Policy Center	Madeline Fleisher
Maple Producers	Dan Brown
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

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Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio Farm Bureau	Adam Sharp
Ohio Farm Bureau	Jack Irvin
Ohio Farm Bureau	Leah Curtis
Ohio Farm Bureau	Roger High
Ohio Farm Bureau	Tony Seegers
Ohio Farm Bureau	Yvonne Lesicko
Ohio Farmers Union	Joe Logan
Ohio Farmers Union	Linda Borton
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
The Ohio State University	Peggy Hall
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 stakeholders had no comments to these rules. As these rules mirror the nationally accepted standards, the industry believes that this is the best regulatory structure at this time.

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 that are nationally accepted. 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?

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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 structure 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 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. These processes are 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 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 shellfish and shellstock product manufacturers operating within the state of Ohio.

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

Each shellfish and shellstock product manufacturers must register as a food processing establishment under Ohio Administrative Code 901:3-21-01.

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.

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 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 cost of a food processing establishment registration depends on the size of the establishment. The smallest facilities, those smaller than 5000 square feet, must pay a \$50 registration fee annually. The largest facilities, over 100,000 square feet, must pay \$300 annually to register as a food processing establishment.

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.

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

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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 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.