



Common Sense Initiative

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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 18

Rule Number(s): 901:3-18-01, 901:3-18-02, 901:3-18-03, 901:3-18-04

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/ 4 rules

No Change/ _____ rules (FYR? ____)

Amended/ _____ rules (FYR-2)

Rescinded/ _____ rules (FYR?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.

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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):

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **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 901:18 incorporate by reference 21 C.F.R. Chapter 1, Subchapter B, Part 121.

This rule requires firms to develop a food defenses plan to protect food from intentional adulteration. There are monitoring and record retention requirements that the firm must follow.

Rule 901:3-18-01 is a new rule which incorporates by reference 21 C.F.R. Chapter 1, Subchapter B, Part 121.

Rule 901:3-18-02 is a new rule which amends definitions adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 121. This allows for the crossover of the rule to meet definitions used in Ohio.

Rule 901:3-18-03 is a new rule which deletes certain regulations adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 121. These sections address public disclosure and compliance under FDA authority. These are removed since the department has its own public disclosure and compliance protocols.

Rule 901:3-18-04 is a new rule which modifies regulations adopted in 21 C.F.R. Chapter 1, Subchapter B, Part 121. This inserts the department's definition of a food processing establishment.

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.**

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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.

Yes, these rules are federal requirements for all applicable food processing establishments.

5. **If the regulation implements a federal requirement, but 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)?**

Food safety regulations are essential in protecting consumers by ensuring safe and wholesome food that is labeled correctly. This rule addresses intentional adulteration of food and requires that firms evaluate their operations to determine what mitigation strategies are needed to protect food that is in their control.

How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The rules are judged as being successful when inspections and investigations find few violations.

7. **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

8. **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 February 10, 2023, for a public comment period open until February 24, 2023.

Capitol Advocates – Rob Eshenbaugh

Maple Producers – Dan Brown

Ohio Association of Food Banks – Lisa Hamler-Fugit

Ohio Bakery Association- Lora Miller

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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

9. 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 ODA received two comments. ODA organized a Microsoft Teams meeting between the CSI office, Ohio Farm Bureau and ODA to discuss concerns about this rule. ODA and Farm Bureau discussed methods of outreach to the food safety community which will provide guidance and training with all rules within the Food Safety division. The second comment, ODA Chief Legal Counsel responded by email to the stakeholder to clarify the definition of food and to provide clarification as to why ODA does not duplicate liquor control inspections.

10. 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 research by the FDA utilizing the industry and other public entities. The rules present the best approach to address protecting the food supply from intentional adulteration.

11. 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? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

These rules are federal rules and there are no alternatives to these rules.

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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 in Ohio.

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.

The Department will work with all manufacturers to educate and inform them of the requirements and regulations. The Department has online resources and has field staff available to assist firms. Training and seminars will also be available.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

This covers all qualified food processing establishments in Ohio.

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

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.

There are many factors to determine the cost of complying with this regulation. Each firm must develop a plan that fits their operation. They will need to develop the plan and monitor and record findings.

There are no fines associated with this regulation. However, failure to comply with the requirements may result in adulteration and eventual embargo or destruction of products.

15. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

There are exemptions within the rule for very small businesses and for certain types of food.

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

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Protecting food from intentional adulteration is an extension of rules that require firms to evaluate their operations. The regulatory intent of these rules is considered justified due to the public safety risk.

Regulatory Flexibility

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

Yes, very small businesses- making less than \$10,000,000 a year, during a three-year average, are exempt. It also exempts certain warehousing activities where food is protected from contamination.

18. 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.

19. 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 help. Training and seminars are also available.