



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 4

Rule Number(s): 901:3-4-01 to 901:3-4-18

Date of Submission for CSI Review: July 1, 2021

Public Comment Period End Date: July 23, 2021

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/_18_ rules (FYR? _18_)

Rescinded/___ rules (FYR?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.

Rule 901:3-4-01 outlines the definitions as used in the chapter. This rule is being amended to update a subsection of IRS code and stylistic amendments.

Rule 901:3-4-02 outlines the process for obtaining and renewing a license to operate a retail food establishment. This rule is being amended to add new paragraphs and stylistic amendments.

Rule 901:3-4-03 outlines the license fees as established in sections 3717.01 and 3717.25 of the Revised Code. This rule is being amended to remove and add paragraphs.

Rule 901:3-4-04 outlines the cost analysis conducted on an annual basis by each of the 113 local health districts. This rule is being amended to remove text no longer necessary and stylistic amendments.

Rule 901:3-4-05 establishes the classifications of retail food establishments by risk levels. This rule is being amended to re-structure the paragraphs of the rule and to add requirements necessary for risk level IV establishments and mobile retail food establishments.

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Rule 901:3-4-06 regulates the frequency at which retail food establishments are inspected. The frequency of inspections depends on the risk level of the establishment. This rule is being amended to clarify the inspections for Risk Level I and New retail food establishments.

Rule 901:3-4-07 sets forth that all retail food establishments must have the layout and equipment specifications approved by the licensor prior to construction, installation, or alteration of a retail food establishment. This rule is being amended to correct an LSC stylistic change.

Rule 901:3-4-08 sets forth the process for the appeal of a proposed denial, suspension, or revocation of a retail food establishment. This rule is being amended to correct LSC stylistic changes.

Rule 901:3-4-09 outlines how and when a licensor shall investigate complaints made regarding a retail food establishment. This rule is being amended to list obligations of the licensor and clarify information included in a written policy of the licensor.

Rule 901:3-4-10 states that a licensor or licensee may request mediation in an attempt to resolve a dispute between the retail food establishment and the licensor. This rule is being amended to correct an LSC stylistic requirement.

Rule 901:3-4-11 outlines when a board of health may request enforcement support from the department of agriculture. This rule is being amended to correct LSC stylistic changes.

Rule 901:3-4-12 sets forth the procedures for removing an article from a retail food establishment when that article presents a public health hazard. This rule is being amended to include food service operations and contains LSC stylistic changes.

Rule 901:3-4-13 outlines the process for which a license holder may request records. This rule is being amended to include a citation for a definition.

Rule 901:3-4-14 sets forth the rules for the collection of food samples for the purposes of identifying if a food product has been adulterated or misbranded. This rule is being amended to correct LSC stylistic changes.

Rule 901:3-4-15 regulates the embargo of food that may be adulterated, misbranded, or expired. This rule sets forth the process for the embargo and the petitioning to remove the embargo. This rule is being amended to include the C.F.R. publication date and an LSC stylistic change.

Rule 901:3-4-16 outlines the process for becoming certified in food protection. The rule also grants the authority to licensors to require training to all retail food establishments. This rule is being amended to correct an OAC cross-reference and amend the certification necessary in food protection.

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Rule 901:3-4-17 sets forth the process for the department of agriculture to evaluate the program every three years. This rule is being amended to correct LSC stylistic changes.

Rule 901:3-4-18 sets forth the process for the department to reinstate a licenser. This rule is being amended to correct LSC stylistic changes.

- 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 sections 3717.04, 3717.07, and 3717.33.

- 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.

- 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)?**

Under Chapter 3717 of the Revised Code, the Department is required to adopt rules which create a uniform set of food safety standards. Currently, there are 113 local health districts in Ohio who license and inspect retail food establishments ensuring that the public is protected from food-borne illnesses. These rules provide uniformity to the industry while protecting the public at large.

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

The success of these rules can be measured by the reduction in food borne illnesses/outbreaks associated with retail food establishments. It also provides for consistent uniform administration of retail food establishment programs throughout the state. There are currently 113 local health districts in Ohio; the rules provide structure for them to administer their retail food establishment programs.

- 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.

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Development of the Regulation

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 May 27, 2021 for an open comment period ending on June 10, 2021:

Ohio Greater Showmen Association
Ohio Retail Merchants
Ohio Grocers Association
Ohio Restaurant Association
Ohio Farmers Market Network
Ohio Farm Bureau
Capitol Advocates – Rob Eshenbaugh
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 Ecological Food and Farm Association – Amalie Lipstreu
Ohio Farmers Union – Joe Logan
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 – Lisa Schacht
Ohio State University
Snack Food Association – Arlington, VA – David Walsh

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Wholesale Beer and Wine Association – Timothy Bechtold

Great Lakes Community Action Partnership – Robin Richter

PACA Inc. – David 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 stakeholder outreach comment period, the Department received a single comment suggesting further defining a mobile retail food establishment and prescheduled inspections. The commenter also suggested in rule 901:3-4-05 to amend the term “raw agricultural product” to “fresh unprocessed fruits and vegetables”. The Department has coordinated the language change with Ohio Department of Health for rule 901:3-4-05 and this change is reflected in the rules proposed at this time.

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 are not based on scientific data. However, the rules provide administrative guidance to the local health districts on how to apply chapter 3717 of the Administrative Code. This chapter is based on the most current FDA Model Food Code, which is based on scientific data. The FDA Model Food Code is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

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?

No alternative regulations were considered at this time. The Department has not received any public comments which would indicate a need for alternative regulations.

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.*

Uniformity across all 113 local health districts and all retail food establishments is necessary to operate in an efficient manner is protective of public health and safety. As such, it is inappropriate to consider performance-based regulations for these rules.

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14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Ohio Department of Agriculture and the Ohio Department of Health share regulatory authority over these matters in section 3717.04 of the Revised Code. The Department of Agriculture has sole authority to adopt rules regarding retail food establishments which are contained in this rule package.

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 and are well communicated to the 113 health districts across the state. The department has oversight over these districts and maintains a good line of communication between them. Additional education and outreach will be performed when needed. Licensors have educational materials made available to them and Department staff members are available to assist with any issues that arise.

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

These rules impact the administration of the 113 local health districts as well as all retail food establishments such as grocery and convenient stores. There are approximately 17,000 retail food establishments throughout the state.

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

Every retail food establishment must obtain a license to operate in compliance with these rules. These licenses are for a one-year period and must be renewed annually. The fees associated with this license are calculated using the process outlined in rule 901:3-4-03 of the Administrative Code. Retail food establishments are subject to inspection at least once in a fifteen-month period based on the risk level of the establishment. Establishments must also gain approval from the licensor prior to construction, installation, or alteration of the establishment. This requires that the owner of the establishment dedicate time to compliance.

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.

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The cost of each retail food establishment license varies depending on the district in which the establishment is located. However, an estimated statewide average of the cost of a license for smaller than 25,000 square feet will be from \$150 to \$600. For establishments greater than 25,000 square feet the average cost will be \$180 to \$1,120. Mobile establishments cost on average between \$85 to \$225 annually. Owners of retail food establishments currently pay this fee on an annual basis. Further, minimal time for compliance is necessary to apply for a license. Retail food establishments are subject to minimal record keeping requirements.

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

The regulatory intent of the rules is to ensure public safety and the health of Ohioans by regulating how the 113 local health districts and all retail food establishments operate. The rules achieve this protection by requiring standards that permit all retail food establishments to still operate cost-effectively.

Regulatory Flexibility

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

As these rules apply to all 113 health districts across the state, the need for a uniform application is necessary. No exemptions were created for small businesses.

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?

The Department is primarily concerned with protecting public safety and the health of the citizens with these rules. Whenever possible, the Department will treat administrative violations as opportunities for improvement through warning notices and solicitation of corrective actions.

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

The Department has online resources and has staff available to answer inquiries.