



Common Sense Initiative

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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Chapter 3717-1

Rule Number(s): 3717-1-01, -02.4, -03.2, -03.4, 03.6, -04.1, 04.3, -04.7, 06, -06.3, 07, -07.2, and 08.1.

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/ 0 rules

No Change/ 0 rules (FYR? N)

Amended/ 13 rules (FYR? N)

Rescinded/ 0 rules (FYR? N)

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

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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):

- 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 Ohio Uniform Food Safety Code provides the standards for safe food handling and sanitation in retail food establishments (RFE) and food service operations (FSO) in the state. The purpose of the food code is to prevent and reduce foodborne illnesses. As required by 3717.05 Revised Code, the Ohio Uniform Food Safety Code is based on the most current version of the Federal Food and Drug Administration (FDA) Model Food Code.

The following amendments are being proposed:

- 3717-1-01:
 - (B)(7) Add a comma after activity and removed “and is indicated by the symbol a_w”
 - (B)(90)(a)(ii) Replace “under” with “in”.
 - (B)(90)(a)(iii) Replace “under” with “in”.
 - (B)(90)(b)(iv) Replace “in” with “under”.
- 3717-1-02.4(A)(2): Replace “obtain the level two” with “that has obtained manager.”

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- 3717-1-02.4(B)(2): Replace “sanitarian’s” with “environmental health specialist’s”.
- 3717-1-3.2:
 (K)(3): Remove "flour".
 (K)(6): Remove “an”.
 (K)(7): Change reference to “(B)(4)(g) of 04.5”.
- 3717-1-03.4(G)(2): correct spelling of “specified”
- 3717-1-04.1
 (KK)(1): Add reference to (KK)(3).
 (KK)(3): Add language stating rule (KK) does not apply to low risk mobile food service operations and low risk retail food establishments.
- 3717-1-4.7(D): Correct misspellings of “laundering” and “specified”
- 3717-1-06.3(C)(2): Correct misspelling of can not to cannot.
- 3717-1-07.2: Correct misspelling of can not to cannot.
- 3717-1-03, -03.6, -04.3, -06, -07, and -08.1: propose as "amended" rules to add reference to ORC 3717.04 on RSFA forms.

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.

Chapter 3717.05 of the Ohio Revised Code gives the Directors of Agriculture and Health the sole authority to adopt rules establishing standards for safe food handling and sanitation in retail food establishments and food service operations.

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 regulation does not implement a federal requirement or enable the state to obtain or maintain approval to administer and enforce a federal law.

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

N/A

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 purpose of this code is to protect the public by preventing foodborne illnesses. The Ohio Uniform Food Safety Code, which is based on the FDA Model Food Code, is needed to assist the regulatory authority in providing the retail food industry scientific and technical information to operate their facility, and to ensure a safe and properly protected food supply.

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

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The success of this regulation will be measured by the prevention and reduction of foodborne illnesses/outbreaks in relation to food prepared and/or served at food service operations and retail food establishments in Ohio. In addition, regular inspections by local health districts will ensure continuous food safety. The Ohio Department of Health will measure the reduction of foodborne illnesses/outbreaks by conducting a survey of each local health department's food program, as required in 3717.11 of the Revised Code, and by monitoring the number of foodborne illnesses reported.

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.

None of these rules are being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

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 proposed rules were presented to the Retail Food Safety Advisory Council (council) at their meetings on September 18, 2019. As required in 3717.02 Revised Code, the council was created to make recommendations for the Administrative code; examine specific food safety issues that have been raised by the directors; and review all comments and requests for interpretation of the uniform food code. The council consists of the directors of Agriculture and Health, who serve as co-chairs, and twelve members. The current members of the council are:

Individuals representing the local health departments:

Christina Ritchey-Wilson, R.S., Section Chief, Columbus Public Health
Joe Ebel, MS, RS, MBA, Health Commissioner, Licking County Health Department
Peter Schade, M.P.H., R.S., Health Commissioner, Erie County Health Department
Paul DePasquale, M.P.A., R.S., Environmental Health Director, Stark County Health Department

Individual representing the general public:

Michael Agosta

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Individual representing the academic community who is knowledgeable in food science or food technology:

Dr. Barbara Kowalcyk, Assistant Professor, Department of Food Science and Technology,
The Ohio State University

Individuals representing retail food establishments:

Kristin Mullins, President/CEO, Ohio Grocers Association
Terry Levee, Director of Food Safety, Giant Eagle
Lora Miller, Director, Government Affairs and Public Relations, Ohio Council of Retail Merchants

Individuals representing food service operations:

Daryl Jacobs, Director of Regulatory Compliance, Wendy's International
Laura Morrison, Director of Food Safety, Ohio Restaurant Association
Jeff Otterbacher, Figure the Odds, Inc.

As part of our regular contact with the council, the meeting notice, agenda and proposed rules were emailed to the members prior to the meeting. The Ohio Departments of Health and Agriculture also posts the meeting announcement and agenda on their public websites.

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

At the council meeting on September 18, 2019, a copy of the rules in Chapter 3717-1 of the Administrative Code that are being proposed were distributed and discussed. The council recommended that the Director of Health proceed with filing the rules as proposed.

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?

Chapter 3717-1 of the Administrative Code is based on the FDA Model Food Code, which states in its preface that the federal code is based on scientific data. Within the 2013 FDA Model Food Code Annex 2 – References, documentation is provided that the code is based on scientific data with a list of frequent references to federal statutes contained in the United States Code and the Code of Federal Regulations, along with a compilation of documents that were taken into consideration in developing the Food Code. The FDA Model Food Code

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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. The process for updating provisions of the FDA Model Food Code is to receive concerns and recommendations from any individual or organization. FDA is especially interested in addressing problems identified by those in government and industry that are responsible for implementing the food code. FDA is also responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns. Included are organizations such as the Conference for Food Protection that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates.

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?

There are currently no alternative regulations on food safety that the Ohio Department of Health could consider. The FDA Model Food Code was developed in 1993 to eliminate duplication of regulations that can be adopted by state agencies which regulate the retail food industry. The Ohio Department of Health adopted portions of the 1993 FDA Model Food Code in 1996. In 2001, the Departments of Health and Agriculture developed a uniform food code, which included portions of the 1999 FDA Model Food Code, for regulating the retail food industry. Section 3717.05(B)(1) of the Revised Code requires that the Ohio Uniform Food Safety Code be based on the most current version of the FDA Model Food Code.

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 Ohio Uniform Food Safety Code, which is based on the FDA Model Food Code as required by Revised Code, is a performance-based regulation. For example, the rule requires food service operations and retail food establishments to obtain foods from approved sources. To assure that the industry complies with requirement to obtain/sell food from approved sources, the local health departments inspect these facilities based on a frequency set by rule. The Departments of Agriculture and Health verify that the local health departments are inspecting facilities as required by conducting a survey of their food safety programs every three years, as required by 3717.11 ORC.

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

The Director of Health has sole authority to regulate food service operations, which is contained within 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.

Notifications will be sent to the local health departments and stakeholders once these rules are adopted. Additional education and outreach will be performed when needed, and ODH staff are available to assist with any questions or 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

The impacted business community includes licensed food service operations and retail food establishments in Ohio.

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

The adverse impact includes employee time for compliance and cost of equipment and supplies.

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.

It is difficult to estimate the cost for most of these rules since the cost will vary depending on the situation. For example, the costs of equipment, cleaning supplies, etc. will vary by location, type of equipment, vendors, etc. The staff time to ensure compliance will also vary depending on the size of the operation and the staff needed to comply with these rules. The similar requirements set forth in this rule are unlikely to require a significant amount of time or costs in addition to that which is already expended by the facility.

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

The intent of these rules is to provide a system of prevention and safeguards designed to minimize foodborne illness; ensure industry manager knowledge, safe food, nontoxic and

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cleanable equipment, and acceptable levels of sanitation; and promote fair dealings with the consumer. It is a shared responsibility of the food industry and regulators to ensure that food provided to consumers is safe and does not become a vehicle in a disease outbreak. This shared responsibility extends to ensuring that consumer expectations are met, and that food is unadulterated, prepared in a clean environment, and honestly presented.

Regulatory Flexibility

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

A food service operation may submit a request for a variance for any of these rules to the Department of Health, and a retail food establishment may submit a request for a variance for any of these rules to the Department of Agriculture.

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 rules being proposed do not require the facility to submit any paperwork that would have a fine or penalty fee.

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

The technical staffs at the Ohio Department of Health and Ohio Department of Agriculture food safety programs and the local health departments are available to provide technical assistance to any business or government agency regarding compliance with OAC 3717-1.