CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: 3717-1 Ohio Uniform Food Safety Code

Rule Number(s): 3717-1-02.3; 3717-1-03; 3717-1-03.6; 3717-1-04.3; 3717-1-5.1; 3717-1-05.3; 3717-1-05.4; 3717-1-06; 3717-1-06.1; 3717-1-06.3; 3717-1-07; 3717-1-07.2; 3717-1-08.1; 3717-1-08.2; 3717-1-08.4; and 3717-1-20

Date: August 18, 2014

Rule Type:

New	X 5-Year Review
Amended	Rescinded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.

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 Ohio Uniform Food Safety Code provides the standards for safe food handling and sanitation in retail food establishments and food service operations. 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. These rules are being filed as no change.

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

   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.

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.***

   This regulation does not implement a federal requirement.

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)?**

   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.

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

   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 Departments of Agriculture and 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 Ohio Revised Code, and by monitoring the number of foodborne illnesses reported.

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 Ohio Department of Health Food Safety Program, jointly with the Ohio Department of Agriculture Division of Food Safety, work together to assure that the Food Code is current with the FDA Model Code. As required in 3717.02 of the Revised Code, a council was created to: make recommendations for the uniform 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 Retail Food Safety Advisory Council (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:

Alan Pierce, M.P.H., R.S., Supervisor, Public Health Dayton & Montgomery County
Frank Kellogg, R.S., M.P.H., Health Commissioner, Lake County Health District
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

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

Linnette Goard, M.S., Ohio State University Extension Family & Consumer Sciences

Individuals representing retail food establishments:

Nate Filler, President/CEO, Ohio Grocers Association
Gale Prince, Your Food Safety Coach
Donald Barrett, R.S., Safety/Food Safety Specialist, Giant Eagle Inc.

Individuals representing food service operations:

Dennis A. Hecker, Senior V.P. Quality Assurance, Wendy's International
Richard Mason, Director of Government Affairs, Ohio Restaurant Association
Amy Kotterman, Corporate Dietitian, United Church Homes

As part of our regular contact with the council, the notice of meeting was emailed to the members on November 12, 2013. Attached to the email was the agenda that noted as new business that these rules are being proposed for five year review. The Ohio Department of Agriculture also posts the meeting announcements on their public website. At the meeting on November 19, 2013, copies of the rules in Chapter 3717-1 of the Administrative Code that

were being proposed as no change were distributed and discussed. The council had no objection to filing the rules with no changes.

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

On November 19, 2013 at the Retail Food Safety Advisory Council meeting, the members discussed the rules in Chapter 3717-1 of the Administrative Code that were being proposed as no change. During the meeting, any member may provide input on the draft regulations. At this meeting, no input was provided on the proposed rules. At the end of each council meeting, the audience is permitted to address any issues or proposed rules. No audience comments were provided at this meeting.

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 Ohio Food Code is based on the most current version of the FDA Model Food Code, which states in the Preface on page iii 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 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 FDA Model Food Code issues a new edition every four years. During the four years between issues, FDA may issue supplements to the existing edition. Ohio Revised Code Section 3717.05 (B)(1) requires the Ohio Uniform Food Safety Code to be based on the most current version of the FDA's Model Food Code. When FDA adopts, modifies, or rescinds a provision in the model food code, not later than twelve months after the administration's action, the Directors of Agriculture and Health shall adopt, amend, or rescind provisions in the Ohio Uniform Food Safety Code to ensure that it continues to conform to the FDA Model Food Code. Section 3717.05 (B)(2) Revised Code does state that the Ohio Uniform Food Safety Code may omit provisions that do not correspond to the FDA model food code if the Directors of Agriculture and Health concur.

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.

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?

There are currently no alternative regulations on food safety that the Ohio Departments of Agriculture and Health could consider. The FDA Model Food Code was developed in 1993 to eliminate duplication of regulations that can be adopted by state agencies that 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.

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.***

The Ohio Uniform Food Safety Code, which is based on the FDA Model Food Code that we are required to adopt, is a performance-based regulation. For example, the code requires the food industry to maintain cold temperatures at 41 degrees or below, but does not tell the industry how this should be done. To assure that the industry is in compliance with the cold holding temperature, the local health departments inspect them based on a frequency set by rule. The Departments of Agriculture and Health verify that the local health departments are inspecting the facilities by conducting a survey of their food safety programs every three years.

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

Section 3717.05 of the Ohio Revised Code states that the Directors of Agriculture and Health shall adopt rules, with each other's concurrence, that establish standards for safe food handling and sanitation in retail food establishments and food service operations. In addition, section 3717.04 of the Revised Code states that no other agency has the authority to adopt regulations pertaining to retail food establishments and food service operations. The Departments of Agriculture and Health work closely together to prevent duplication of

regulations, as well as verify through surveys of the local health district that they have not adopted local regulations affecting the food industry.

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.

At any time when a change occurs to the Ohio Uniform Food Code by the Directors of Agriculture and Health jointly, an effective date will be scheduled to allow time to notify the local health departments and industry of the changes. Regional trainings for the local health departments and the food industry before the effective date would be offered.

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;

The impacted business community would be the licensed food service operations and retail food establishment in the state.

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

For facilities already licensed and operating, these rules will not impose any new adverse impacts. For new facilities, the rules that may impact these facilities are:

3717-1-02.3 - The cost associated with this rule is the staff time for compliance and the need for hair restraints. It is difficult to estimate the amount of staff time needed to assure compliance with proper personal hygiene. The cost of hair restraints will vary from the type of hair restraint the facility uses. The cost for one hair net is as low as ten cents to $4.99 for a chef cap to $9.99 for a chef visor. Hair restraints are to be worn by individuals in the facilities who work with unpackaged food, food equipment or utensils or food-contact surfaces.

3717-1-03.6 - The cost associated with this rule would be the loss of the unsafe and adulterated or contaminated food, providing a storage area to hold food products that are to be returned to the distributor and the staff time to check all food products and then if unsafe, the time spent to discard. Unable to determine actual cost since the cost will vary depending on the situation.

3717-1-05.1 - The cost associated with this rule is the cost to install and maintain their plumbing system according to the Ohio building code. Cost of installing and

maintaining their plumbing system will vary depending on the type of system being installed and the contractor doing the work. Also if the facility is required to obtain a plumbing permit it will vary by jurisdiction. If the facility is in an area where the Ohio Department of Commerce has jurisdiction, the charge for a plumbing permit is $200 plus $20 per fixture.

3717-1-05.3 - The cost associated with this rule is the cost for a facility to install and maintain their plumbing system according to the Ohio building code, and the cost of a wastewater disposal system, which is under the jurisdiction of the Ohio Environmental Protection Agency (OEPA). The cost of installing and maintaining their plumbing system will vary depending on the type of system being installed and the contractor performing the work. The cost of purchasing and installing a backflow prevention device will vary depending on the type of device and the contractor who is installing it. The cost of purchasing and installing a grease trap would also vary depending on the size of the trap and the contractor who installs the grease trap. The price of a grease trap ranges between $140 and $5600. The disposal of waste water is required to be in an approved sewage treatment system. If the facility does not have access to a public sewage treatment plant, they would be required to install a system that is approved by the OEPA. The cost for approving a waste water system under the jurisdiction of the OEPA will vary and is based on the cost of the construction.

3717-1-06 - The cost associated with this rule is the cost for a facility to properly install and maintain the surface areas of their floors, wall and ceilings to assure that they are nonabsorbent, smooth, durable and easily cleanable. Costs for this will vary depending on the type of materials used as well as the contractor that installs. This rule also requires outdoor surface areas to be maintained. Costs associated with this will vary depending on the type of surface and the contractor.

3717-1-06.1 - The cost associated with this rule is the cost for a facility to maintain the physical condition of the facility. The cost will vary depending on the condition of the facility.

3717-1-06.3 - The cost associated with this rule for a facility is the cost to designate space for the storage of waste, distressed merchandise, plus areas for employees to eat/drink and use tobacco.

3717-1-07 – The cost associated with this rule for a facility is staff time to ensure that toxic or poisonous materials are properly labeled and identified.

3717-1-20 – The cost associated with this rule for the facility would be to replace any existing facility and equipment when it no longer meets the requirements of Chapter 3717-1 of the Administrative Code.

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 of any of these rules since the cost will vary depending on the situation. For example, the costs of construction materials, surfaces, etc. will vary by location, contractor, 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.

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

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

<u>Regulatory Flexibility</u>

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

The current regulation allows the industry to apply for a variance from either the Ohio Department of Health or the Ohio Department of Agriculture to certain provisions of the code.

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?**

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

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

The technical staffs at the Ohio Department of Health Food Safety Program, the Ohio Department of Agriculture Division of Food Safety, and the local health departments, are available to assist any business or government agency with compliance of the Ohio Uniform Food Safety Code.