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): 3717-1-01; 3717-1-02.2; 3717-1-02.4; 3717-1-03.2; 3717-1-03.3; 3717-1-03.4; 3717-1-03.5; 3717-1-04.2; 3717-1-04.4; 3717-1-04.5; 3717-1-04.7; 3717-1-07.1; and 3717-1-09.

Date: March 25, 2015

Rule Type:

- ☐ New
- X Amended
- X 5-Year Review
- ☐ Rescinded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 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 FDA issued a Supplement to the 2009 Food Code in 2011 and a new

edition of the Food Code in 2013. The changes purposed, which have been recommended by the Retail Food Safety Advisory Council for adoption, consist of the updates from the 2011 Supplement and the 2013 FDA Code. These sections of 3717-1 OAC also underwent a five year review by the Ohio Department of Health Food Program staff.

The following amendments from the 2011 FDA Supplement and the 2013 FDA Code are being proposed:

- 3717-1-01(B)(37) Deleted definition of "Enterohemorrhagic Escherichia coli (EHEC)" since it is included in the revised definition of Shiga toxin-producing Escherichia coli.
- 3717-1-01(B)(75)(a) Deleted the term "securely" in the definition of "Packaged" to avoid undue emphasis on nature of the package.
- 3717-1-01(B)(75)(b) Definition of "Packaged" amended to remove the phrases "carry out box" and "other nondurable container" to clarify when foods packaged at retail need to be labeled.
- 3717-1-01(B)(91)(c)(v) Definition of "Reduced Oxygen Packaging (ROP)" amended to clearly defines the sous vide process.
- 3717-1-01(B)(112) Definition of "Shiga toxin-producing Escherichia coli (STEC)" revised to reflect current nomenclature.
- 3717-1-02.2(C)(8) Amended language to clarify the requirement for washing hands before donning gloves before working with food.
- 3717-1-02.2 (E)(1)(b) Amended language to clarify and align the rule with applicable C.F.R.'s and the FD&C Act with regard to the use of hand antiseptics as a food additive.
- 3717-1-02.4(A)(2) New language added to require one employee that has supervisory and management responsibility be certified in food protection according to rule 3701-21-25 OAC within one year of the effective date of the rule.
- 3717-1-02.4(A)(3) New language added to exempt temporary, mobile, vending and risk level I and risk level II food service operations (FSO) or retail food establishments (RFE) from the requirement to have an employee certified in food protection.
- 3717-1-02.4(C)(6) New language added to require that the person in charge ensure that employees are verifying that foods delivered to an FSO or RFE during non-operating hours are from approved sources and are placed into appropriate storage locations at the required temperatures, protected from contamination, unadulterated, and accurately presented.
- 3717-1-02.4(C)(14) Modified the language to require the person in charge to ensure that food employees and conditional employees are informed **in a verifiable manner** of their responsibility to report to the person in charge information about their health as it relates to diseases that are transmissible in food.
- 3717-1-02.4 (C)(15) New language added to require the person in charge to ensure that all written procedures and plans be maintained and implemented as required.

- 3717-1-02.4(C)(16) New language added to require the person in charge to ensure that FSO's and RFE's have a written procedure for employees to follow when responding to vomiting or diarrheal events.
- 3717-1-03.2(A)(3)(b) Amended language to clarify if a food employee contacts ready-to-eat food with bare hands at the time the ready-to-eat food is added as an ingredient to a food that does not contain a raw animal food and the combined product will be heated to at least 145°F instead of 165°F.
- 3717-1-03.2(C)(3) Removed the language that required non-intact meats be stored separately from whole-muscle intact cuts of meat, because it is already addressed in 03.2(C)(2).
- 3717-1-03.2(G)(3) New language added to establish requirements for devices used on-site to generate chemicals for washing raw, whole fruits and vegetables.
- 3717-1-03.2(J)(3) New language added to clarify that food may contact surfaces of linens and cloth napkins as specified in modified paragraph (L) of this rule.
- 3717-1-03.2(L) Amended language to clarify that "napkin" refers to cloth napkins and is by definition considered linens.
- 3717-1-03.2(P) Amended existing language and added new language to clarify conditions in which the re-use and refilling of returnable take-home containers is permitted.
- 3717-1-03.3(D)(4) Amended language to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under paragraphs (A)(1)-(A)(3) of this rule.
- 3717-1-03.3(E)(2)(b) New language added to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction.
- 3717-1-03.3 (H)(3) Amended language to clarify that commercially processed and packaged time/temperature controlled safety foods (TCS) that are ready-to-eat must be heated for hot holding to at least 135°F.
- 3717-1-03.4(C)(5) Added language to specify that frozen fish packaged using reduced oxygen packaging (ROP) shall be removed from the ROP environment either prior to initiating thawing procedures, or immediately upon completion of thawing.
- 3717-1-03.4(G)(1) Amended the language to match the FDA food code by updating references and to reorder the wording.
- 3717-1-03.4(G)(2) Amended the language to match the FDA Food Code by updating references and rearranging the wording.
- 3717-1-03.4(G)(6) New language added to exempt raw, live in-shell molluscan shellfish from date marking requirements.
- 3717-1-03.4(G)(7)(f) Amended language to clarify that the exemption from date marking for shelf-stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing.

- 3717-1-03.4(G)(7)(g) Amended language to clarify that the exemption from date marking for shelf stable salt-cured products such as prosciutto and parma (ham) produced in USDA-regulated facilities is not dependent on the product being labeled “Keep refrigerated”.
- 3717-1-03.4(J)(4) Amended language to clarify when a variance is required for packaging foods using ROP.
- 3717-1-03.4(J)(10) Removed the requirement for a variance when harvesting seed or bean sprouts.
- 3717-1-03.4(K)(1) Removed the references to sections (K)(3) – (K)(5).
- 3717-1-03.4(K)(2) Added the reference to the new section 3717-1-03.4(K)(6), which exempts certain facilities from developing a Hazard Analysis Critical Control Point (HACCP) plan; Added the reference to the new section 3717-1-03.4(L), which provides the information required in a HACCP plan.
- 3717-1-03.4(K)(2)(b) Modified the language to include the reference from (K)(3) to (K)(5); Corrected the spelling of “degrees”.
- 3717-1-03.4(K)(2)(c)(ii) Replaced “fourteen” days with “thirty” days.
- 3717-1-03.4(K)(2)(d) Replaced “fourteen” days with “thirty” days.
- 3717-1-03.4(K)(2)(e)(i) Added “ready-to-eat” to prohibit bare hand contact.
- 3717-1-03.4 (K)(2)(g) Added new language to specify that a HACCP plan shall be provided to the regulatory authority prior to its implementation for ROP.
- 3717-1-03.4(K)(4) Added the reference to the new language in (K)(6); Added the term “Time/Temperature controlled for safety food” to clarify that this section only applies to TCS food.
- 3717-1-03.4(K)(4)(a) Amended language to clarify that a facility must notify the regulatory authority prior to implementing and executing a HACCP plan for Cook-Chill or Sous Vide.
- 3717-1-03.4(K)(4)(b) Added “Ensure the” to the beginning of the sentence.
- 3717-1-03.4(K)(4)(b)(i) Added the language “or prepared and consumed off the premises but within the same business entity”; Replaced “bagged” with “packaged”; Replaced “location” with “entity”.
- 3717-1-03.4(K)(4)(b)(ii) Amended language to specify only certain cooking parameters apply to ROP.
- 3717-1-03.4(K)(4)(b)(v) Removed “subsequently”.
- 3717-1-03.4(K)(4)(b)(v)(a) Replaced “preparation” with “packaging”.
- 3717-1-03.4(K)(4)(b)(v)(b) Amended language to allow ROP food to be held at 41°F or less for no more than seven days.
- 3717-1-03.4(K)(4)(b)(v)(c) Language removed due to new language in 03.4(K)(4)(b)(v)(b).
- 3717-1-03.4(K)(4)(c) Amended language to clarify record keeping requirements.
- 3717-1-03.4(K)(4)(c)(i) Modified language for clarity.
- 3717-1-03.4(K)(4)(c)(ii) Modified language for clarity.
- 3717-1-03.4(K)(4)(d) Modified language for clarity.

- 3717-1-03.4(K)(5) Amended language to clarify when a HACCP plan is not required for reduced oxygen packaging of cheese.
- 3717-1-03.4(K)(5)(b) Reference to 3717-1-03.4(L) added.
- 3717-1-03.4(K)(6) New language added to specify when a FSO or RFE does not need a HACCP plan when using ROP.
- 3717-1-03.4(L) New language added to specify the contents of a HACCP plan.
- 3717-1-03.5(C)(2)(b) Language modified to clarify labeling requirements.
- 3717-1-03.5(C)(2)(g) Added "or astaxanthin" to clarify requirements for labeling of salmonid fish.
- 3717-1-03.5(C)(3)(b) Amended a reference to clarify requirements for labeling of bulk food containers.
- 3717-1-4.2(H) Added "and mechanical" to the title.
- 3717-1-4.2(H)(1) Amended to re-designate the existing language into this section.
- 3717-1-4.2(H)(2) New language added to require an irreversible registering temperature indicator be provided for hot water mechanical warewashing operations.
- 3717-1-04.4(N) Removed "using" from the title.
- 3717-1-04.4 (N)(6) New language added to allow for the use of a chemical sanitizer generated by a device located on-site.
- 3717-1-04.5(B)(1)(a) Added reference to the new paragraph in (B)(2).
- 3717-1-04.5(B)(2) New language added to clarify cleaning frequency requirements of equipment used for different types of raw animal foods.
- 3717-1-04.5(B)(3) New language that references the exception in paragraph (B)(4).
- 3717-1-04.5(B)(4) Modified language for clarity.
- 3717-1-04.5(K) Incorporated this section into 3717-1-03.2(P).
- 3717-1-04.7(B)(3) Amended to clarify requirements for laundering linens and cloth napkins.
- 3717-1-07.1(E) Added new language to include criteria for chemical sanitizing solutions generated on site; moved the C.F.R. reference in a new section.
- 3717-1-07.1(E)(1) The C.F.R. reference in (E) moved to this section.
- 3717-1-07.1(E)(2) Added new C.F.R. reference.
- 3717-1-07.1(F) Added to the title "treatment, storage and processing".
- 3717-1-07.1(F)(1) New language added to include requirements for chemicals generated on-site for the washing or peeling of raw, whole fruits and vegetables.
- 3717-1-07.1 (F)(2) New language added to include requirements for using ozone as an antimicrobial agent in the treatment, storage, and processing of fruits and vegetables.
- 3717-1-09(A)(3) Added new language to clarify what must be included in a facility site plan submitted to the licensor.

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 and 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, the Retail Food Safety Advisory Council (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 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:

Brad Sherrick, R.S., Food Safety Program Supervisor, Toledo-Lucas County Health Department
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, Sage Food Safety Consultants
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
Joe Rosato, Director of Government Affairs, Ohio Restaurant Association
Amy Kotterman, Corporate Dietitian, United Church Homes, Inc.

The notice of the council meeting was emailed to the members on May 21, 2014. Attached to the email was the agenda that noted that these rules are being proposed, along with copies of the proposed rules. The Ohio Department of Agriculture also posts the meeting announcements on their public website. At the council meeting on May 27, 2014, copies of the rules in Chapter 3717-1 of the Administrative Code that were being proposed as amended were distributed and discussed. The council recommended filing the rules as amended.

In addition, on February 10, 2015, a conference call/webinar was held with additional stakeholders to discuss the proposed rules and answer questions. Several organizations that represent stakeholders that may be affected by the rules were invited to participate in the call/webinar. Copies of the proposed rules were also emailed to these organizations. The participants on the call, which included members and staff from the Ohio Restaurant Association, Ohio Department of Education, and the Ohio Environmental Health Association, had no objections to the proposed rules.

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

On May 27, 2014 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. During the meeting, any member may provide input on the draft regulations. At this meeting, some 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.

During the conference call with stakeholders on February 10, 2015, the stakeholders had no comments.

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 that the FDA's purpose is to provide regulators at all levels a scientifically sound technical and legal basis for regulating the retail segment of the food industry. 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 be based on the most current version of the FDA's Model Food Code. When the 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. The 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 as required by Revised Code, is a performance-based regulation. For example, the code requires the food industry to maintain cold temperatures at 41°F 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, as required by 3717.11 ORC.

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 have exclusive power in the state to adopt rules establishing standards for safe food handling and sanitation in retail food establishments and food service operations, and that these rules shall be uniformly applied throughout the state. In addition, section 3717.04 of the Revised Code authorizes only the Directors of Agriculture and Health 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 establishments in the state.

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

The nature of the adverse impact to Food Service Operations and Retail Food Establishments identified for these rules may include:

3717-1-01 – Person in charge and food employee time for compliance.

3717-1-02.2 - Person in charge and food employee time for compliance.

3717-1-02.4 - Person in charge and food employee time for compliance; the cost of a person in charge per facility in Risk Level three and four FSO's/RFE's to complete a certification in food protection course and exam.

3717-1-03.2 - Person in charge and food employee time for compliance.

3717-1-03.3 - Person in charge and food employee time for compliance.

3717-1-03.4 - Person in charge and food employee time for compliance.

3717-1-03.5 - Person in charge and food employee time for compliance; the cost of labeling foods that are packaged in FSO's/RFE's and made available for customer self-service.

3717-1-04.2 – Person in charge and food employee time for compliance; cost of equipment for cold and hot holding, three-compartment sinks, food thermometers, irreversible registering temperature indicators for ware washing machines, and sanitizer solution testing devices.

3717-1-04.4 – Person in charge and food employee time for compliance.

3717-1-04.5 – Person in charge and food employee time for compliance.

3717-1-04.7 – Person in charge and food employee time for compliance.

3717-1-07.1 – Person in charge and food employee time for compliance.

3717-1-09 – Person in charge and food employee time for compliance; cost of submitting facility layout and equipment specifications to the licensor for new or altered FSO's/RFE's.

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 labeling foods, food thermometers, three compartments sinks, 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. An average cost that can be identified is:

- The cost of completing a certification in food protection course and exam ranges from $150-250 per person, based on information provided to ODH by approved course providers.

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.

The FDA states in their 2013 Model Food Code Annex that a study by the Centers for Disease Control and Prevention suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for a food establishment and was a distinguishing factor between facilities that experienced an outbreak and those that had not.

Regulatory Flexibility

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.