CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3717-1

Rule Number(s): 3717-1-01; 3717-1-02; 3717-1-02.1; 3717-1-02.2; 3717-1-02.3; 3717-1-02.4; 3717-1-03; 3717-1-03.1; 3717-1-03.2; 3717-1-03.3; 3717-1-03.4; 3717-1-03.5; 3717-1-03.6; 3717-1-03.7; 3717-1-04; 3717-1-04.1; 3717-1-04.2; 3717-1-04.3 3717-1-04.4; 3717-1-04.5; 3717-1-04.6; 3717-1-04.7; 3717-1-04.8; 3717-1-05; 3717-1-05.1; 3717-1-05.2; 3717-1-05.3; 3717-1-05.4; 3717-1-06; 3717-1-06.1; 3717-1-06.2; 3717-1-06.3; 3717-1-06.4; 3717-1-07; 3717-1-07.1; 3717-1-07.2; 3717-1-08; 3717-1-08.1; 3717-1-08.2; 3717-1-08.3; 3717-1-08.4; 3717-1-09; and 3717-1-20

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- ☐ Rescinded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 following amendments are being proposed:

- **3717-1-01:** provides the definitions of the terms used within the food code. Changes to this rule include: eliminated hanging sentences; put the definitions in alphabetical order; corrected the definitions (easily movable, packaged, restricted egg, safe material, slacking) to be consistent with FDA's Model Food Code; corrected the definition of general use pesticide and restricted use pesticide to be consistent with the Ohio Department of Agriculture's law; corrected a typo of coli in Shiga toxin-producing Escherichia coli; corrected references in time/temperature controlled for safety food; and clarified who is the regulatory authority in the definition of variance.
- **3717-1-02:** establishes standards for local health departments to determine the primary business of a facility for issuing either a food service operation license or a retail food establishment license. The changes to this rule include: the reordering the language to have food service operation and retail food establishment placed in alphabetical order; and to designate a hanging paragraph as a new section.
- **3717-1-02.1:** establishes standards for a facility to determine when an employee must be restricted or removed from being a food handler. Changes include: (A)(2)(e) removed the term "Enterohemorrhagic"; (A)(2)(k) added "spp." to the end of "Shigella"; (A)(4)(b) removed the term "Enterohemorrhagic", increased the exposure time to past ten days and deleted the reference to Shigella spp; (A)(4)(c) added the Shigella spp exposure time and increased to past four days; (A)(5)(e) exposure time increased to past fifty days; (A)(5)(b) removed the term "Enterohemorrhagic", increased the exposure time to past ten days and deleted the reference to Shigella spp; (A)(5)(c) added the Shigella spp exposure time and increased to past four days; and (A)(5)(e) exposure time increased to past fifty days.
- **3717-1-02.2:** provides the requirements for personal cleanliness for food employees. Changes to this rule were to be consistent with the Food and Drug Administration's Model Food Code by providing the exception in paragraph (B)(1) and changing the word "or" to "and" in the standing paragraph under (C).
- **3717-1-02.3:** provides the requirements for hygienic practices of food employees. Changes to this rule include: amended language to clarify that all food employees must wear hair restraints; and change the word "or" to "and" to be consistent with the FDA Model Food Code.
- **3717-1-02.4:** provides the requirement for the person in charge to demonstrate the knowledge and duties that apply to their facility. Changes included: (A)(2) replaced "One year after the effective date of this rule" with "Each risk level III and risk level IV food service operation and retail food establishment shall have", and removed "shall" between "service" and "obtain"; (B) split out the methods to determine demonstration of knowledge to paragraphs (1) and (2) and deleted the reference to have level two as a way to demonstrate knowledge; (C)(9) added new section "Employees are properly maintaining the temperatures of time/temperature controlled for safety foods during hot and cold holding through daily

oversight of the employees' routine monitoring of food temperatures;"; and (C)(17) replaced "shall have" to "has".

- **3717-1-03:** states that food in a food service operation and retail food establishment shall be safe, unadulterated and honestly presented. No changes are proposed.
- **3717-1-03.1:** provides the requirements for sources of food used in a food service operation or for sale in a retail food establishment. Changes included: added in paragraph (A)(4) "if they are"; changed paragraph (O)(1)(b) to reference the exception that was a hanging paragraph but is paragraph (O)(4); and paragraph (S)(1) replaced "and either" with "or".
- **3717-1-03.2:** provides the requirement for protecting food from contamination after it is received. Changes included: adding "Nail Brushes" to new paragraph (A)(4)(f)(ii); converted standalone paragraph to paragraph (C)(1); updated the sections to the paragraphs under the new (C)(1); correction the reference in paragraph (C)(1)(a); replaced "; and" with a period; section (D) put the exception at the beginning of the paragraph; section (F)(2)(b) put the exception at the beginning of the paragraph; section (K)(1) added new reference since a new (K)(2) was added; Added new section (K)(2) "In any manner within a food ingredient, provided the entire ingredient batch undergoes further cooking as specified in rule 3717-1-03.3 of the Administrative Code, and the utensil is cleaned and sanitized at a frequency specified under paragraphs (A) and (B) of rule 3717-1-04.5 of the Administrative Code and paragraph (B) of rule 3717-1-04.6 of the Administrative Code;" (N)(4) added new section: "The use of latex gloves is prohibited in food service operations and retail food establishments. Types of non-latex gloves that are permitted for use in food service operations and retail food establishments include but are not limited to nitrile, polyethylene, and vinyl"; converted the floating paragraph to new section (Q)(1); and converted the second floating paragraph to the new section (Q)(2).
- **3717-1-03.3:** provides the temperature requirements for destroying organisms of public health concern. Changes made to this rule included correcting the internal reference in paragraph (F)(2).
- **3717-1-03.4:** provides the requirements for limiting the growth of organisms of public health concern with time/temperature control. Changes include: in paragraph (D)(3) added an "a" between "rule" and "time/temperature"; and added new section (L)(2) "A description of the training program that ensures individuals responsible for implementing the HACCP plan understand the:" with subsections (a)-(d).
- **3717-1-03.5:** provides for the requirement for identifying, presenting and labeling of food in a food service operation or retail food establishment. Changes included: (C)(2)(c) added "net" before "quantity"; (C)(4) removed "such as bakery products and unpackaged foods"; and (C)(4)(b) removed "or" between "establishment" and "at" and added a comma after "establishment" in two places.
- **3717-1-03.6:** provides the requirements for when food shall be discarded. No changes are proposed.
- **3717-1-03.7:** provides for special requirements for food used for the highly susceptible populations in a food service operation or retail food establishment. Changes included (D)(2)(c)(iv) added "as specified in paragraph (L) of rule 3717-1-03.4 of the Administrative Code,".

- **3717-1-04:** provides the requirements for materials for construction and repair of equipment and utensils to be used in a food service operation or retail food establishment. Changes included: (G)(1) reworded the floating paragraph and made it (G)(1); (G)(2) removed "that" between "wood" and "may"; (G)(2)(a) removed "and" at the end of the paragraph; (G)(2)(b) added "; and" at the end of the paragraph; (G)(2)(c) added new section "Wood fermentation tanks, wood maturation barrels, and other wood used in the alcoholic beverage making process"; (G)(3) removed "Wood shipping containers in which"; added "may be kept in the wood shipping containers in which they were"; removed "are" before "received"; added ",until" after "received"; removed "if" in front of the fruits; and removed "kept in them until"; (G)(4) removed "Untreated wood containers or wood containers treated with a preservative that meets the requirements specified in 21 C.F.R. 178.3800, and"; added "If the nature of" to the beginning of the paragraph; removed "that is stored in them is whole, uncut, raw food that"; added ", the whole, uncut, raw food may be kept in:" at the end of the paragraph; and deleted the period at the end of the paragraph; (G)(4)(a) added new section "Untreated wood containers; or"; and (G)(4)(b) added new section "Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 C.F. R. 178.3800."
- **3717-1-04.1:** provides the requirements for the design and construction of equipment, utensils and linens used in a food service operation or retail food establishment. Changes included: (R) corrected the spelling for "cannot"; (Y)(4) moved "Food temperature measuring devices and" to the beginning of the paragraph; (LL)(1) corrected the spelling for "temperature"; and (LL)(1)(b) corrected the internal reference to (LL)(1)(a).
- **3717-1-04.2:** provides the requirements for the numbers and capacities of equipment, utensils and linens needed in a food service operation or retail food establishment. Changes included: (E) separated the floating paragraph into two new sections (E)(1) and (E)(2); (G)(2) corrected the spelling of "fillets"; (H) removed the period in between (H) and (1); and (J) added new section dealing with cleaning agents and sanitizers, availability.
- **3717-1-04.3:** provides the requirement for the location and installation permitted for equipment, utensils and linens. No changes are proposed.
- **3717-1-04.4:** provides the requirements for maintaining and operating equipment in a food service operation or retail food establishment. Changes included: (L) converted the floating paragraphs into section (L)(1). Subsections (a) – (b), and (L)(2); and (N) replaced the "and" with a "or" between "instructions" and "shall".
- **3717-1-04.5:** provides the requirement for cleaning of equipment and utensils. Changes included: (C)(1) corrected the reference; (F)(1) corrected the spelling of "scraped"; (G) combined the floating paragraph with the title; (I) combined the floating paragraph with the title; (I)(2) corrected the spelling of "scraped"; and (J) combined the floating paragraph with the title.
- **3717-1-04.6:** provides the requirement for sanitizing of equipment and utensils. No changes are proposed.
- **3717-1-04.7:** provides the requirements for the laundering of linens in a food service operation or retail food establishment. Changes included: (B)(5) replaced the "or" with an "and"; (C) replaced the "or" with an "and"; (D) split the floating paragraph into two new

sections (D)(1) and (D)(2); and (E) split the floating paragraph into two new sections (E)(1) and (E)(2).

- **3717-1-04.8:** provides the requirements for protecting clean items in a food service operation or retail food establishment. No changes are proposed.
- **3717-1-05:** provides the requirement for safe water in a food service operation or retail food establishment. No changes are proposed.
- **3717-1-05.1:** provides the requirement for the plumbing system in a food service operation or retail food establishment. Changes included: replacing all references to the building code with plumbing code; and in paragraph (E) added the word construction between for and installation.
- **3717-1-05.2:** provides the requirements for a water tank in a mobile food service operation or mobile retail food establishment. No changes are proposed.
- **3717-1-05.3:** provides the requirements for how sewage, liquid waste and rainwater are handled in a food service operation or retail food establishment. Changes included: (C) converted the floating paragraph and section (C)(1) and (C)(2) into new section (C)(1), and converted the bottom floating paragraph into new section (2).
- **3717-1-05.4:** provides the requirements for how waste, recyclables and returnables are handled in a food service operation or retail food establishment. Changes included: (Q)(1) removed "the" between "and" and "waste"; and (Q)(2) replaced "or" with "and" between "recyclables" and "returnables".
- **3717-1-06:** provides the requirements for the indoor and outdoor areas in a food service operation or retail food establishment. No changes are proposed.
- **3717-1-06.1:** provides the requirements for the design, construction and installation of the floors, walls and ceilings in a food service operation or retail food establishment. Changes included: (F)(2) the exception was placed at the beginning of the paragraph; (H) the exception was placed at the beginning of the paragraph; (K)(2)(b) replaced the "or" with "and" in three locations; (L) replaced the "or" with "and" between "establishment" and "does"; (M)(1) replaced "(M)(2) and (M)(3)" with "(M)(3) and (M)(4)"; (M)(2) converted the floating paragraph that was at the bottom of (M)(1)(c) to this new section; (M)(4) added "Except as specified in paragraphs (M)(2) and (M)(5) if" to the beginning of the paragraph; and (M)(5) converted the floating paragraph that was at the bottom of (M)(4) to this new section.
- **3717-1-06.2:** provides the requirements for the number and capacities of the physical facilities located in a food service operation or retail food establishment. Changes included: (I)(2)(c) added a "," after "rooms"; removed the "and" after "rooms"; added "and" between "warewashing" and "equipment"; and replaced "storage, or" with "and".
- **3717-1-06.3:** provides the requirements for the location and placement of handwashing sinks, toilet rooms, designated area for staff, location for distressed merchandise, and waste handling. No changes are proposed.
- **3717-1-06.4:** provides the requirement for the physical facilities of a food service operation and retail food establishment to be maintained and operated. Changes included: (H) removed "and maintenance" in the title, and "and maintained" at the end of the paragraph.

- **3717-1-07:** provides for the labeling and identification of poisonous or toxic materials found in a food service operation or retail food establishment. No changes are proposed.
- **3717-1-07.1:** provides the requirements for storing and use of poisonous or toxic materials within the food service operation and retail food establishment. Changes included: (B) removed "the" between "for" and "cleaning"; removed "of" between "sanitizing" and "equipment"; added "," removed "and the control of" and added "licensed application for controlling" between "utensils" and "insects"; and added "or for using as an incidental use pesticide as defined in paragraph (C)(3) of this rule," between "rodents," and "shall"; (C)(3) removed "after July 1, 2004" and added "," between "use" and "or"; (L)(1) added "Except as specified in (L)(2) of this rule, a" to the beginning of the paragraph; (L)(2) added "If used, a" to the beginning of the paragraph; added "and" between "linens" and "single-service"; and replaced "articles, or" with "and".
- **3717-1-07.2:** provides for the proper storage and display of poisonous or toxic materials for retail sale. No changes are proposed.
- **3717-1-08:** provides for the requirement when packaging fresh juice in a food service operation or retail food establishment. Changes include in (A)(2)(a) converted the first floating paragraph into this new section; (A)(2)(b) converted the second floating paragraph into this new section; and (B) replaced "The" with "A".
- **3717-1-08.1:** provides for the requirements for using a heat treatment dispensing freezer is a food service operation or retail food establishment. No changes are proposed.
- **3717-1-08.2:** provides for the requirements for custom processing of game animals, migratory waterfowl or game birds in a food service operation or retail food establishment. Changes included: in (A) replaced "may" with "shall" between "establishment" and "be"; (C) added comma after "owner"; (E) added comma after processing; and (F) replaced "must" with "shall" between "number" and "remain".
- **3717-1-08.3:** provides for the requirements for using a bulk water machine in a food service operation or retail food establishment. No changes are proposed.
- **3717-1-08.4:** provides the requirement for acidifying whit rice as a non TCS food. Changes included: (B)(4) replaced "must" with "shall" between "rice" and "have"; added comma and replaced "and an equilibrium" with "not to exceed a" between "4.1" and "pH"; and replaced "4.6 or less" with "4.3"; (B)(5) replaced "must" with "shall" between "solution" and "be"; (C)(1) added comma and replaced "and an equilibrium" with "not to exceed a" between "4.1" and "pH"; replaced "4.6 or less" with "4.3" at the end of the paragraph; (C)(2) moved "Blending the slurry for approximately twenty seconds to create a thorough mix." from the end of the paragraph to new section (C)(3); (C)(4) added "to ensure a pH of 4.3 or less is achieved." behind "slurry"; and removed "Repeated measurements with a new slurry from the same batch of rice must be taken to assure the equilibrium pH of 4.6 or less is achieved" and (E) replaced "Describes" with "A description of".
- **3717-1-09:** provides the requirement for reviewing facility layout and equipment specifications in a new or renovated food service operation or retail food establishment. Changes included: (A)(1) added "food service" in front of "operation" and "retail food" in front of "establishment" and (A)(7) replaced "the" with "all".

- **3717-1-20:** provides the requirements for dealing with existing facilities and equipment when they no longer comply with the code. Changes included: Combined paragraphs (A) and (B) into new floating paragraph; (A) to read "They no longer comply with the following:"; (A)(3) Replaced "and" with "or"; (B) to read "Criteria upon which they were originally approved" and (C) to read "The food service operation or retail food establishment changes ownership."

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 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 amendments to the rules in Chapter 3717-1 were presented to the Retail Food Safety Advisory Council (Council) at meetings on October 18, 2017, April 25, 2018 and June 5, 2018. The Council is authorized to make recommendations to the Directors of Health and Agriculture for the Ohio Uniform Food Safety Code. In addition to the council, stakeholders (listed below council members) were invited to participate in the discussion on the rule on October 18, 2017, April 25, 2018 and June 5, 2018. The proposed rules were provided to the council and stakeholders prior to all three council meetings. The membership of this council is listed below.

Individuals representing the local health departments:
Christina Ritchey Wilson, Columbus City Public 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
R Joseph Ebel, MS, R.S., MBA Health Commissioner

Individual representing the general public:
Michael Agosta

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

Abigail Snyder, Assistant Professor, Ohio State University Food Science

Individuals representing retail food establishments:
Kristin Mullins, Ohio Grocers Association
Terry Levee, Director Food Safety Compliance, Giant Eagle
Lora Miller, Director Gov't Relations, Ohio Council of Retail Merchants

Individuals representing food service operations:
Darryl Jacobs, Director Regulatory Operations, Wendy's International
Joe Rosato, Director of Government Affairs, Ohio Restaurant Association
Amy Kotterman, Director, Hospitality Services, United Church Homes

The following stakeholders attended RFSAC meetings:

Name	Agency/Organization/ Company	Meetings Attended
Becky Hardy	General Consumer	4/25/2018; 6/5/2018
Mike Tedrick	Food Safety Consultant	10/18/17; 4/25/2018
Mike Diskin	Giant Eagle	10/18/17; 4/25/2018; 6/5/2018
Maria Villareal	Head Start	4/25/2018
Linda Eichenberger	School Nutrition Association	4/25/2018
Rachel Tilford	School Nutrition Association	4/25/2018, 6/5/2018
Susan Whitaker	School Nutrition Association	4/25/2018

Name	Agency/Organization/ Company	Meetings Attended
Brian Davis	Ohio Department of Education	4/25/2018; 6/5/2018
Vivian Hawkins	Dept. of Rehab and Corrections	10/18/17; 4/25/2018; 6/5/2018
Kevin Barlow	Fairfield Department of Health	4/25/2018
Debbie Kilbarger	Fairfield Department of Health	4/25/2018; 6/5/2018
Amanda Smith	Ohio Health Care Association	10/18/17; 4/25/2018; 6/5/2018
Brooke Kemp	Dietetic Intern	4/25/2018
Kirby Moore	Noble Co Health Department	4/25/2018
Jason Soles	Butler Co Health Department	4/25/2018; 6/5/2018
Rich Neuman	Ohio University	10/18/17; 4/25/2018
Greg Chumney	Licking Co Health Department	10/18/17; 4/25/2018
Chad Brown	Licking Co Health Department	10/18/17
Garrett Guillozet	Franklin Co Health Department	10/18/17; 4/25/2018
Joe Harrod	Richland Public Health	4/25/2018
Heather Hayes	Richland Public Health	4/25/2018
Bob Himes	A Catered Event	4/25/2018
Kelly Dennis	Ross Co Health Dept.	4/25/2018; 6/5/2018
Amanda Sines	Gov Advantage Group	10/18/17; 4/25/2018; 6/5/2018
Amee Bertke	Ohio Assisted Living Assoc.	4/25/2018
J Draier	Miami Co Public Health	4/25/2018
Stephanie DeGenaro	Delaware General Health District	10/18/17; 6/5/2018
Chuck Gossett	Delaware General Health District	10/18/17
Tony Brigano	Ohio Environmental Health Association	6/5/2018
Andrea Denny	Ohio Department of Education	6/5/2018
Duane Stansbury	Warren Co Public Health	6/5/2018
Melissa Henry	Union County Health Dept.	6/5/2018
Tom Blackford	Lorain County Public Health	6/5/2018
Sarah Jensen	Green Co Public Health	6/5/2018
Scott Whittaker	Columbus Public Health	6/5/2018
Rob Acquista	Columbus Public Health	10/18/17
Carrie Winhoven	Darke Co Health Dept.	6/5/2018
Jason J. Blake	Calfee, Halter, Griswold, LLP	10/18/17
Adam Schultz	Union Co. Health Dept.	10/18/17
Ryan Alleraing	Marion Public Health	10/18/17
Joann Dunlevey	Heinen's, Inc.	10/18/17
Kate Piche	National Restaurant Assn.	10/18/17
Ashley Eisenbeiser	Food Marketing Institute	10/18/17
Bobbi Depriest	ODNR	10/18/17
Brian Doerschuk	Bob Evans	10/18/17
Jason Dreier	Miami County Public Health	10/18/17
Craig Ward	Erie County Health Dept.	10/18/17
George Moussi	TAP Series	10/18/17

Name	Agency/Organization/ Company	Meetings Attended
Ashley Davis	Ohio Department of Aging	10/18/17
Abdullah Jones	Assn. of Nutrition & Food Prof.	10/18/17

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

   The stakeholders were given time to review the documents and submit written comments. The comments were compiled into a spreadsheet, and at the April 25, 2018 council meeting, Ohio Departments of Agriculture and Health presented the department's responses to each comment. Stakeholders also provided oral comments during the council meetings. The following amendments proposed by stakeholders were incorporated into the rules:

   - 3717-1-02.1: amended incubation periods for illnesses to match the infectious disease manual.
   - 3717-1-02.2: removed proposal to change "hand cleaner" to "cleaning compound".
   - 3717-1-02.4: changed "inspector" to "sanitarian".
   - 3717-1-03.2: added language to prohibit the use of latex gloves and include examples of gloves that may be used.
   - 3717-1-03.4: modified language to clarify HACCP plan training requirements.
   - 3717-1-05.3: amended language to include examples of three compartment sink and culinary sink for indirect connection requirements.
   - 3717-1-20: amended language to address use of equipment in existing facilities.

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 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?**

    The agency did not consider an alternative regulation since Chapter 3717 of the Revised Code requires the Ohio Uniform Food Safety Code be based on the FDA Model 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 rule requires the food industry to obtain foods from an approved source. To assure that the industry is in compliance with the requirement to obtain/sell food from an approved source, 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 the facilities as required 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.**

Notifications will be sent to the local health departments and stakeholders of the changes to these rules. Training sessions will be conducted across the state for the local health departments.

Adverse Impact to Business

14. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    - **Identify the scope of the impacted business community;**
      The impacted business community includes licensed food service operations and retail food establishments in Ohio.
    - **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
      The adverse impact includes employer time for compliance, cost of equipment, approved sources of food and utensils, and the cost of a food license.
    - **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. 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.

15. **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 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

16. **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.

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 these rules.