

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): 3717-1-03.1; 3717-1-03.4

Date: 10/23/15

Rule Type:

☐ New

☒ Amended

☒ 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☐ Rescinded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.

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The following amendments are being proposed:

- 3717-1-03.1(S): Amended the rule to allow unpasteurized pre-packaged juice to be obtained from a food processing establishment defined in rule 901:3-23-01 (B) of the Administrative Code.
- 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) Replaced “bagged” with “packaged”.
- 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.

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

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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 Agriculture (ODA) reached out to the Ohio Manufacturers' Association (OMA) for review of rule 3717-1-03.1. OMA is an organization dedicated to the promotion and growth of manufacturing in Ohio. They represent many juice manufacturers and have distributed the rule to their constituents.

In addition, ODA worked with raw juice companies to modify the language for this rule. In particular, a Columbus based raw juice company, Zest Juice Company, worked closely with ODA to amend this rule.

The amendment to rule 3717-1-03.4 was presented to the Retail Food Safety Advisory Council (RFSAC) at their meeting on May 27, 2014. In addition, on February 10, 2015, a conference call/webinar was held with additional stakeholders to discuss the proposed rule and answer questions. Several organizations that represent stakeholders that may be affected by the rules were invited to participate in the call/webinar. A copy of the proposed rule was 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 rule.

The amendment to rule 3717-1-03.1 was presented to RFSAC on August 25, 2015. The Retail Food Safety Advisory Council consists of:

Individuals representing the local health departments:

Brad Sherrick, R.S., Food Safety Program Supervisor, Toledo-Lucas 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

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Individual representing the general public:

Michael Agosta

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

Vacant

Individuals representing retail food establishments:

Nate Filler, President/CEO, Ohio Grocers Association
Gale Prince, Sage Food Safety Consultants

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 main duty of this council is to make recommendations for the Ohio Uniform Food Safety Code. At this meeting the council received a copy of the proposed change to the rule. The council voted unanimously to recommend approval of the change to these rules.

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

The Zest Juice Company worked with ODA to draft the language for rule 3717-1-03.1. Zest Juice and other manufacturers of packaged juice are in support of the proposed amendment. The Ohio Manufacturer's Association did not have any negative comments to the proposed change.

On May 27, 2014 at the Retail Food Safety Advisory Council meeting, the members discussed rule 3717-1-03.4 of the Administrative Code that was being proposed. During the meeting, any member may provide input on the draft regulations. At this meeting, some input was provided on the proposed rule. 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.

Rule 3717-1-03.4 was withdrawn from the five year rule review package as a result of comments received after the public comment period ended. The previously proposed language in rule 3717-1-03.4 potentially conflicted with Ohio Department of Agriculture rules and as a result, ODH amended the proposed language to return to current language.

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

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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?

When ODA modified rule 3717-1-03.1 referenced in the proposed language, they researched how other states were regulating the raw juice industry and found that many states were already allowing production of unpasteurized juice by a food processing establishment. Rule 3717-1-03.4 is included in this package as part of the required five-year review. The changes made to the rule for this period of public comment revert the rule to its existing language to allow for the continuation of existing requirements that ensure the health and safety of food products and related services in Ohio and reflect the national standards 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 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.

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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 the industry of the changes to these rules.

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 impact to the food service operations and retail food establishment would include person in charge and food employee time for compliance. There is no license fee or fines associated with this rule.

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.

In general, this rule does not represent costs that are independent of those already obligated to the food service operation or retail food establishment by virtue of their participation in the industry. Those costs include, but are not limited to, the costs

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associated with the purchasing of approved sources of food used and sold in their facilities. There is also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assessment and performance improvement. 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 service and the services will, more likely than not, already meet or exceed the state requirements.

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.

Regulatory Flexibility

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

As the primary purpose of this rule is to ensure the food used by a food service operation or retail food establishment is safe, exemptions for small businesses would not be applicable.

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?

This rule does 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. Contact information is provided via the ODH website at:

<http://www.odh.ohio.gov/odhprograms/eh/foods/food2.aspx>