CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

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

Rule Number(s): 01; 02; 02.1; 02.2; 02.4; 03.1; 03.2; 03.3; 03.4; 03.5; 03.7; 04; 04.1; 04.2; 04.4; 04.5; 04.6; 04.8; 05; 05.2; 06.2; 06.4; 07.1; 08; 08.3; 09.

Date: 2/21/2012

Rule Type:

- ☐ New
- X 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- ☐ Rescinded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. The code is based on the

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Federal Food and Drug Administration (FDA) Model Food Code, which was updated in November 2009 and September 2011. The changes purposed, which have been recommended by the Retail Food Safety Advisory Council for adoption, consist of the updates from the FDA Code, corrections to typos/punctuations, and the addition of new language for "micro-markets". The addition of the "micro markets" language was to accommodate a request from the vending industry in Ohio.

The changes being adopted from the 2009 FDA Code include: add the definition of "cut leafy greens", and defines "cut leafy greens" as a time/temperature controlled for safety food (TCS food) which would require "cut leafy greens" to be held at the required temperature; modified the definition of "injected" to eliminate the public health statement and the process where no liquid is introduced into the meat; added the definition of "mechanically tenderized" to cover when meat is manipulated without the use of a process that does not use a liquid solution; added the definition of "non-continuous cooking" and the procedure that allows a facility to cook a raw animal food, stop the process before it is totally cooked, and then cool the food down to finish the cooking process at a later time; added to the person in charge duties that they train food employees to be aware of food allergens; added language to exempt frozen, commercially processed and packaged raw foods from separate storage or display from frozen ready-to-eat foods; added language to require meats that have been mechanically tenderized to be cooked to heat all parts of the food to 155 degrees F. for 15 seconds; added language to exempt fish eggs, which have been removed from the skein and rinsed, from the requirement for freezing for parasite destruction; added to the rule that clarifies that all reduced oxygen packaging methods require controls for growth and/or toxin formation of *Clostridium botulinum*, as well as controls for *Listeria monocytogenes*; added the requirement that a variance be obtained for an operation that displays shellfish for human consumption in a life support system display tank; added new language to allow the application of a post-sanitizing rinse to certain commercial warewashing machines using an EPA approved sanitizer; and added language to allow the use of a high velocity blade of non-heated, pressurized air for hand drying.

Changes being adopted from the 2011 Supplement of the FDA Code include; added the requirement to the person-in-charge duties to inform the food employee and conditional employee in a verifiable manner of their responsibility to report information about their health, as it relates to diseases that are transmissible through food; added language to clarify that when a ready-to-eat food is added as an ingredient to a food that is to be cooked to required temperatures, it may be handled with bare hands; and added language to allow the storage of intact meats packaged in a manner that precludes cross-contamination over whole muscle intact cuts of meat.

The changes below are not from the FDA Code, but are needed to accommodate a new type of retail food establishment being defined in these changes as a "Micro-market". "Micro-market" is defined as a retail food establishment that offers prepackaged non-TCS foods and/or prepackaged refrigerated or frozen TCS foods that are stored in equipment that complies with the code in a display of not more than two hundred and fifty linear feet. The rules also require that the "micro-market" use refrigerated equipment approved by a testing agency, as well as require self-closing doors with an automatic shutoff on the unit, which will lock the doors to prevent food being sold when the temperature exceeds 41 degrees F. The proposed rule also exempts these types of operations from having a person-in-charge at the facility during times of operation, because they are designed to be operated in a closed location without personnel available.

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

   Chapter 3717.05 of the Ohio Revised Code gives the Director of Agriculture and the Public Health Council the authority to adopt rules establishing standards for safe food handling and sanitation in retail food establishments and food service operations. This code also requires the adoption of the most current United States FDA Model Food Code.

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 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 and presented food supply. The changes proposed, except for the requirements for "micro-markets", are based on the most current FDA Model Food Code. The addition of the information on "micro-markets" is to accommodate the vending industry's request to allow a facility to sell prepackaged TCS foods at a location without a person-in-charge.

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 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.

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 worked on the rules jointly with the Ohio Department of Agriculture Division of Food Safety. Once the rules were developed, they were presented to the Retail Food Safety Advisory Council for acceptance to proceed to rule adoption. The Retail Food Safety Advisory Council consists of representatives from the food service and retail food establishment industry, the general public, academia and the local health districts.

The summary of changes from the 2009 FDA Food Code was introduced to the Retail food Safety Advisory Council at their meeting on January 18, 2011. The Retail Food Safety Advisory Council discussed and recommended the rules they would like to see move forward for adoption. Those changes were drafted and sent to the Retail Food Safety Advisory Council in an email on March 29, 2011. At their meeting on April 12, 2011, the Retail Food Safety Advisory Council discussed and voted to recommend moving forward with the draft changes. When the 2011 Supplement to the FDA Food Code was released, the additional changes were sent to the Retail Food Safety Advisory Council via email on November 9, 2011. The changes were discussed and voted on by the Retail Food Safety Advisory Council at their November 15, 2011 meeting.

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

At the Retail Food Safety Advisory Council meetings, the proposed changes are forwarded to the members to allow time for Council members to share the proposal with constituents. In addition, at the meetings the members of the Retail Food Safety Advisory Council discuss and vote for acceptance of the rules. At any time, non-members of the Retail Food Safety Advisory Council, including industry representatives and the general public, are given opportunities to comment on any of these issues. In regards to the draft changes to include "micro-market", representatives of the vending industry spoke at the Retail Food Safety Advisory Council meeting on November 15, 2001 to answer questions and encourage acceptance of the draft rules.

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 rules are based on the most current FDA Model Food Code, which is based on scientific data. 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.

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 Ohio Department of Health and the Ohio Department of Agriculture did not consider alternative rules, since the changes are based on the United States 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 Department of Health and the Ohio Department of Agriculture did not consider a performance-based regulation, since the changes are based on the United States FDA Model Code.

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 in part that the Director of Agriculture and the Public Health Council shall adopt rules establishing standards for safe food handling and sanitation in retail food establishments and food service operations, with each other's concurrence. Pursuant to Section 3717.04 of the Revised Code, no other agency has the authority to adopt regulations pertaining to retail food establishments and food service operations.

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.**

    Once the rules are adopted by Public Health Council, an effective date will be scheduled to allow time to train the local health departments and industry on the changes.

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 businesses would be the licensed food service operations and retail food establishments in Ohio.

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

An adverse impact was not identified for every rule in Chapter 3717-1. In general, these rules do not represent costs that are independent of those already obligated to food service operations and retail food establishments.

Within the rules, a "micro market" is a new retail food establishment that is identified and would be permitted to operate with certain requirements. The proposed language would allow these types of facilities to operate without a person in charge at each location, as long as the facilities comply with the remainder of the proposed language.

The new language requires equipment that maintains refrigerated/frozen TCS foods in a "micro market" to be equipped with an automatic shutoff, which would lock the doors of the units when there is a loss of power, or when the temperature of the units rises above 41 degrees Fahrenheit.

The requirement to refrigerate cut leafy greens should not have an adverse impact to most licensable facilities, since they already have refrigeration equipment in place.

The rule for non-continuous cooking of raw animal foods was written to allow a specific type of operation to process large quantities of animal foods. These operations who wish to engage in this practice would be required to have adequate facilities to properly cool the animal foods. The FDA adopted this rule change to the 2009 Model Food Code at the request of the food service industry.

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.

The cost of adding an automatic shutoff to a refrigerator/freezer would cost on average $200.00 per unit. Currently there are 70 locations that would be required to install the shutoffs on their equipment. This cost would be offset by the money that each company would save by not being required to hire a person in charge for each facility. This information was obtained from Advantage Food & Beverage Co. from Columbus, Ohio.

For a facility that wishes to use the non-continuous cooking process (food service operations are not required by code to use this process) and does not have adequate equipment, it may cost approximately $4,000 to $12,000 per facility to meet the requirement. This information was provided by Yum Brands, Inc.

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

Installing an automatic shutoff on refrigerated/frozen units would allow the "micro markets" to operate each facility without a person in charge. This would save each company approximately $30,000 a year per employee. This new equipment would also lead to improved food safety and reduce the risk of foodborne illness, since it would prevent the sale of food that has been temperature abused. This proposal has the support of several vending companies in Ohio.

The justification for the requirements to refrigerate cut leafy greens and the non-continuous cooking process is to prevent foodborne illness. The costs associated with a foodborne illness would exceed the cost of meeting these requirements.

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 previsions 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 purposed 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 staff at the Ohio Department of Health Food Safety Program and the Ohio Department of Agriculture Division of Food Safety is available to assist any business or government agency with compliance of the Ohio Uniform Food Safety Code.

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