



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Ben Brancel, Secretary

DATE: November 15, 2012

TO: The Honorable Fred Risser
President, Wisconsin State Senate
Room 220 South
State Capitol
P.O. Box 7882
Madison, WI 53707-7882

The Honorable Jeff Fitzgerald
Speaker, Wisconsin State Assembly
Room 211, West, State Capitol
PO Box 8952
Madison, WI 53708-895

FROM: Ben Brancel, Secretary
Department of Agriculture, Trade and Consumer Protection

**SUBJECT: Retail Food Establishments, ch. ATCP 75; Final Draft Rule
(Clearinghouse Rule #12-033)**

Introduction

The Department of Agriculture, Trade and Consumer Protection (“DATCP”) is transmitting this rule for legislative committee review, as provided in s. 227.19 (2) and (3), Stats. DATCP will publish notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19 (2), Stats.

This rule updates the Wisconsin Food Code (in the Appendix to Ch. ATCP 75) to be consistent with the 2009 edition of the Model Food Code issued by the United States Food and Drug Administration (FDA). The rule changes the numbering and adds the new prioritization system found in the 2009 edition, and also makes other updates and minor changes to the current rules.

The Department of Health Services (“DHS”) currently is proposing an identical version of DATCP’s food code in an appendix to their administrative rule relating to restaurants (DHS 196) so that the same rules will also apply to the restaurants. ***DATCP and DHS request that both ATCP 75 and DHS 196 be submitted to the same respective legislative committees for review.***

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Background

The FDA Model Food Code provides practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness. While the FDA Model Food Code is not federal law, it serves as a model for state and local regulation of retail food establishments. Forty-nine states base their retail food regulations on a version of the FDA Model Food Code. Since it was first issued in 1993, the FDA Model Food Code has been revised every two or four years. The most recent revisions were issued in 2001, 2005, and 2009. The Wisconsin Food Code presently being used is based on the 2005 FDA Model Food Code

DATCP licenses and inspects 3,472 retail food establishments, under s. 97.30, Stats. These retail food establishments include grocery stores, bakeries, and convenience stores. In addition, under s. 97.41, Stats., cities and counties may choose to contract with DATCP as local agents and inspect retail food establishments in their jurisdiction. Presently, 42 local agents contract with DATCP to inspect 6,647 retail food establishments.

Rule Content

This rule updates DATCP's Wisconsin Food Code, which was last updated in 2006. Although the substance of most of the provisions of the Wisconsin Food Code has not changed, this proposed rule has been amended to be consistent with the internal formatting and prioritization system changes in the 2009 FDA Model Food Code. These changes include (1) the removal of the entire numbering system for definitions, (2) the use of new terms reflecting the internal prioritization system within the food code, and (3) the use of different superscript letters (reflecting the changed terms) throughout the Wisconsin Food Code.

In addition to changes in prioritization and formatting, the rule does the following:

Definitions

- The term “potentially hazardous food” has been replaced with “potentially hazardous food (time/temperature control for safety food)” to be consistent with the FDA Model Food Code and to clarify that “potentially hazardous food” is food that requires time and/or temperature control to promote food safety.
- “Potentially hazardous foods (time-temperature control for safety foods)” now include "cut leafy greens" and “cut tomatoes”.

Food Establishment Management and Personnel

- “Food allergy awareness” has been added as part of the food safety training required to be provided to employees by the “person in charge”.

- Food establishment managers are required to inform food employees of their responsibility to report certain symptoms of illness, as they relate to diseases transmittable through food. As a result of certain symptoms or diseases, activities of food employees temporarily may be limited.
- Food employees' bare-hand contact with ready-to-eat foods is restricted to certain limited conditions, using the detailed guidelines in the model food code. Special training requirements by management must be implemented.

Food Safety and Labeling

- Frozen, commercially processed, and packaged raw animal foods (*e.g.*, meat) are exempted from the requirement that they be separated from ready-to eat foods (raw or cooked) during frozen storage.
- Serving hamburgers and other ground meats in an undercooked form upon a consumer's request is no longer an option for items ordered from a children's menu.
- Certain requirements related to methods for processing of foods stored in reduced-oxygen packaging, such as "cook-chill" and "sous vide," are described.
- Criteria are provided for using a non-continuous process for cooking of raw animal foods (meat in particular).

Fiscal Estimate and Economic Impact Analysis

This rule's fiscal estimate has not changed from the original submitted. Revisions to the Wisconsin Food Code (Appendix to ch. ATCP 75, Wis. Adm. Code) will have no ongoing fiscal effect on state or local government. Proposed revisions will not significantly alter state or local retail food enforcement activities. Costs to local government agencies will be limited to staff time to attend training.

The economic impact analysis, which includes discussion on approaches to food regulation used in neighboring states, has been updated to include the fact that Michigan recently amended its state food code to reflect the 2009 edition of the FDA Model Food Code.

Business Impact Analysis and Effect on Small Business

This rule is not expected to have a significant impact on business, including small business, because the food sanitation requirements contained in this rule are similar to those that currently apply. This rule will require some additional training of retail food establishment personnel. However, it should not be necessary for retail food establishments to hire additional professional services to comply with this rule.

The FDA develops and publishes the FDA Model Food Code based on the best available science and information related to food safety. The FDA Model Food Code encourages consistent state and local regulation of food establishments.

Because the FDA Model Food Code establishes minimum requirements for safe food handling, DATCP is unable to lessen or exempt food establishments from those requirements. However, the department may grant a variance in cases where it is impractical for a food establishment to achieve strict adherence to the Wisconsin Food Code if the variance does not jeopardize the public's health, safety or welfare. DATCP will provide training, fact sheets, and handouts to Wisconsin retail food establishments, including small businesses, to help explain and implement the modified requirements contained in this rule.

Small Business Regulatory Review Report

The Small Business Regulatory Review Board did not issue a report on this rule.

Public Hearings

DATCP and DHS jointly held three public hearings on this rule and written comments were accepted until October 25, 2012. The dates and locations of the hearings were:

October 9, 2012	Madison
October 11, 2012	Waupaca
October 12, 2012	Green Bay

A total of six persons either appeared at a hearing or submitted written comments. Of those six, four who appeared at a hearing registered in support of the proposed rule. The fifth testified that he supported the rule but did find some of the new naming conventions confusing. The sixth (written comments only) indicated support for revisions in chapter two of the rule and then had several questions. The department received two written comments generally in support of the rule.

Two individuals who work as regulators indicated the proposed language in the Wisconsin Food Code is less user-friendly. However, because the new terminology comes from the latest FDA Model Food Code, the terminology is being kept to ensure uniformity nationally. The Wisconsin Restaurant Association expressed their support of the rule and suggested efforts to adopt future revisions of the FDA Model Food Code be started within six months of publication and be completed within one year thereafter. DATCP agrees that this is a good idea and encourages cooperation and productive use of resources in future rule drafting efforts.

Changes from the Hearing Draft

The Legislative Council Rules Clearinghouse made a number of comments on the proposed rule. In particular, the Clearinghouse pointed out various inconsistencies between DATCP's and DHS's rules, and other inconsistencies between the proposed and existing Wisconsin Food Code. The two departments responded by comparing every page of their rule draft versions side by side. DATCP and DHS reconciled the two versions of the rule, which resulted in one rule draft document of the Wisconsin Food Code. DATCP and DHS also compared every page of that rule draft document to the current Wisconsin Food Code. Both departments are now using a single, reconciled draft of the food code going forward in the rulemaking process.

DATCP did not make certain suggested changes, as described more fully below:

- Comment 2.a.(3). The suggestion that numbers generally should be expressed using Arabic numerals was not followed because this rule is modeled on the 2009 FDA Model Food Code, which expresses numbers that occur in sentences using words. DATCP seeks to keep language and certain format conventions consistent with the FDA Model Food Code.
- Comment 2.b. The suggestion that DATCP's rule analysis should include the same detailed listing of changes to the Wisconsin Food Code as provided by DHS was not added, but DATCP will offer a copy of DHS's listing as a general resource if that information is requested.
- Comment 2.c. The question was asked whether there should be a corresponding provision to s. DHS 196.12, Wis. Adm. Code, which generally states that an amended version of the federal model food code has been adopted in the application and enforcement of food safety requirements. DATCP did not make any additions to its ch. ATCP 75, Wis. Adm. Code, because it already has two provisions, ss. ATCP 75.02(3) and 75.05, Wis. Adm. Code, which provide that retail food establishments must meet food safety standards in the food code appended to ch. ATCP 75. DATCP did review definitions that were removed from the food code, as suggested.
- Comment 2.i. The question was asked why the department is proposing to remove the numbering system in the definitions section of the Wisconsin Food Code. The reason DATCP removed the numbering system in the proposed rule is that the numbering system was removed in the 2009 FDA Model Food Code, and DATCP is simply updating its food code to reflect that change. After consultation with Clearinghouse staff, it was understood that the Clearinghouse no longer questioned the reasoning behind the proposed removal of the numbering system in the definitions.
- Comment 2.j. The suggestion was made to move the definition of "CIP" before the definition of "CFR" to maintain alphabetical order of the terms themselves. DATCP did not make this change because it was inconsistent with the 2009 Federal Model Food Code, which appears

to use the letters of acronyms, rather than the terms themselves, to determine alphabetical order in the definitions section.

- Comment 2.m. The question was asked whether certain portions of the proposed Wisconsin Food Code should contain unusual partial capitalization. DATCP is following the formatting convention of the 2009 FDA Model Food Code, which uses “small caps” for any defined words or portions of defined words, including other forms of a defined word.
- Comment 2.o. A suggestion was made to capitalize or underscore specific heading terms in the margin. DATCP agrees that there is some inconsistency in the way the font styles and underscoring in the margin are used in the 2009 FDA Model Food Code, but left the terms as they are because DATCP seeks to stay consistent with the FDA Model Food Code to reduce confusion when updating the rule in the future.
- Comment 2.q. The suggestion was made that when referencing the title of a certain CFR section and the CFR section itself, there should be some method of separation, such as use of a comma or parentheses (e.g., “21 CFR 131 Milk and cream” could be “21 CFR 131, Milk and cream” or “21 CFR 131 (Milk and cream).” DATCP agrees that this convention of the FDA Model Food Code is unusual but did not make a change to remain consistent with the national standard.
- Comment 4.b. The question was asked why some terms in the rule cite to a CFR definition when there is a corresponding statutory definition in ch. 97, Stats. The Clearinghouse suggested that defined terms in the rule should be reviewed for corresponding statutory definitions. DATCP did review the rule and determined that the CFR definitions were best suited for the terms used in the food code.
- Comment 5.b. The question was whether the department intended to change the term “person” to “individual” throughout the rule. In some instances, the term “person” is correctly used in the 2009 FDA Model Food Code, but in some instances the department takes issue with its use. “Person” is defined in the proposed rule to mean “an individual, partnership, association, firm, company, corporation, organization, municipality, county, town, or state agency.” DATCP only changed the term “person” to “individual” in parts of the rule in which it would not make sense to enforce against any legal entity other than a human individual, e.g., “*SERVICE ANIMALS that are controlled by the disabled EMPLOYEE or PERSON individual.*”
- Comment 5.f. The suggestion made was to capitalize the term “salmonellae.” DATCP did not make this change in order to stay consistent with the 2009 FDA Model Food Code and to reduce confusion when updating the rule in the future.
- Comment 5.i. The suggestion made was to change the heading title from “Handling Prohibition” to “Service Animal Handling.” DATCP did not make this change in order to

stay consistent with the 2009 FDA Model Food Code and to reduce confusion when updating the rule in the future.

Summary of Data and Analytical Methodologies

This rule is based on the *Food Code 2009*, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, College Park, MD 20740. In developing the rule, DATCP and DHS sought input from an advisory group that included local health agencies, the Wisconsin Grocers Association, the Wisconsin Restaurant Association, the Tavern League of Wisconsin, Wisconsin Technical Colleges, the Wisconsin Department of Public Instruction, and the UW-Madison Department of Food Science. Surrounding states were contacted to determine the extent to which they have adopted the 2009 FDA Model Food Code.

Standards Incorporated by Reference

This rule incorporates, by reference, the following documents:

- *Grade "A" Pasteurized Milk Ordinance*, Public Health Service, Food and Drug Administration, U.S. Department of Health and Human Services, 2011 Revision.
- *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services, 2009 Revision.

The department has obtained consent from the Attorney General to incorporate these standards by reference. Copies of these documents will be kept on file with DATCP, DHS, and the Legislative Reference Bureau.

An electronic version of the 2011 version of the *Grade "A" Pasteurized Milk Ordinance* may also be found at: <http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSModelDocuments/UCM291757.pdf>.

An electronic version of the 2009 version of the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish* may be found at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm>