



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

DATE: May 26, 2009

TO: The Honorable Fred Risser
President, Wisconsin State Senate
Room 220, South, State Capitol
PO Box 7882
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The Honorable Michael Sheridan
Speaker, Wisconsin State Assembly
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FROM: Rodney J. Nilsestuen, Secretary
Department of Agriculture, Trade and Consumer Protection

SUBJECT: **Food Processing Plants; Final Draft Rule** (*Clearinghouse Rule #09-009*)

The Department of Agriculture, Trade and Consumer Protection ("DATCP") is transmitting this final draft 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.

Background

The Department of Agriculture, Trade and Consumer Protection ("DATCP") administers Wisconsin food safety programs. Among other things, DATCP licenses and inspects wholesale food processing plants. DATCP has adopted food processing plant rules under ch. ATCP 70, Wis. Adm. Code.

This rule updates current food processing plant rules. This rule applies to wholesale food processing plants *other than* dairy plants and meat processing plants. This rule does *not* apply to food warehouses (except those included in food processing plants) or retail food establishments.

Food processing is constantly changing, and it is important to keep rules up-to-date with current food technology and food safety concerns. Modern regulation emphasizes hazard analysis and critical control point (HACCP) systems to identify and control food safety hazards. Disease outbreaks in other states have also underlined the importance of food identification, tracking, recordkeeping and recall plans. DATCP also strives to keep its rules reasonably consistent with federal rules, to ensure a seamless national system of regulation.

Agriculture generates \$51.5 billion for Wisconsin

Rule Contents

This rule updates current DATCP rules and harmonizes them with current federal rules. This rule does all of the following:

- ***Definitions.*** This rule harmonizes current definitions with federal rules and Wisconsin retail food rules under ch. ATCP 75 (Model Food Code).
- ***Handwashing facilities.*** This rule updates current standards related to handwashing facilities serving toilet rooms and food processing areas. New requirements apply only to facilities installed after the effective date of this rule, to food processing plants initially licensed after the effective date of this rule, or to food processing plants licensed to a new operator after the effective date of this rule.
- ***Hand contact with ready-to-eat food.*** This rule prohibits bare hand contact with ready-to-eat food, unless bare hand contact is reasonably necessary and does not contaminate food. If a food processing plant operator allows bare-hand contact with ready-to-eat food, the operator must establish written policies and procedures, and an employee training program, to prevent food contamination from bare-hand contact. Requirements are consistent with current retail food rules under ATCP 75 (Model Food Code).
- ***Cleaning and sanitizing procedures.*** This rule updates and clarifies current requirements for cleaning and sanitizing food processing equipment and utensils, and it creates procedures by which DATCP may authorize alternative procedures and sanitizing materials.
- ***Reclaimed water.*** This rule updates and clarifies current standards related to use of reclaimed water in food processing plants.
- ***Re-circulated water systems.*** This rule regulates the use of re-circulated water in coolers and heat exchangers (if there is any possibility that the re-circulated water may come in contact with any food product or food contact surface).
- ***Water and potable liquids transported in bulk.*** This rule regulates the transportation and handling of water and other potable liquids transported to or from a food processing plant. Transported water must be obtained from a potable source that complies with DNR rules. Bulk tankers must be constructed, maintained, cleaned and sanitized for sanitary operation, and bulk liquids must be loaded and unloaded in a sanitary manner.
- ***Labeling packaged food.*** This rule incorporates, by reference, current federal and state food packaging and labeling requirements. Among other things, this rule incorporates current federal rules related to disclosure of major food allergens.

- ***Recall plan.*** Consistent with current federal rules, this rule requires a food processing plant operator to have a written plan for identifying and recalling food produced at the plant, should a food recall become necessary. This rule establishes general content standards, but allows operators to determine plan specifics. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- ***Low-acid food packaged in hermetically sealed containers.*** This rule clarifies that low-acid food packaged in hermetically sealed containers (including aseptically processed food as well as thermally processed food) must be processed according to federal rules under 21 CFR 113.
- ***Fish processing; general.*** This rule repeals and recreates current rules related to fish processing, in order to make the rules consistent with federal rules under 21 CFR 123.
 - Under federal rules and this rule, fish processors must have a HACCP plan to identify and control food safety hazards associated with fish processing. Plans must meet federal standards.
 - This rule repeals current required procedures related to smoked-fish processing, in favor of the more flexible HACCP plan approach. However, this rule encourages smoked fish processors to incorporate and adapt the repealed procedures, as appropriate, in their HACCP plans (this rule includes the repealed procedures in an appendix, which processors may consult for guidance).
 - This rule updates and clarifies current rules related to the labeling and sale of smoked fish. Among other things, this rule repeals the current 21-day shelf-life limit on sales of smoked fish (this rule requires a stated shelf-life expiration date, but shelf-life will be based on the HACCP plan per federal rules).
 - This rule updates and clarifies current rules related to processing, labeling and sale of fish eggs (roe). This rule applies to all fish roe, not just “caviar.” This rule clarifies current labeling requirements related to processed fish roe. A fish roe product, other than a sturgeon roe product, may not be labeled as “caviar” unless the name of the fish species is also disclosed (e.g., “whitefish caviar”).
- ***Bottling establishments.*** This rule updates and clarifies current rules related to bottling establishments.
 - Bottling establishments producing bottled water must comply with federal rules under 21 CFR 129.
 - Bottling establishments engaged in juice processing must comply with federal rules under 21 CFR 120.

- This rule updates and clarifies current product testing requirements, including test frequencies, and harmonizes current requirements with applicable federal rules. Operators who obtain ingredient water from municipal sources are exempt from some, but not all, testing requirements.
- This rule regulates the transportation and handling of water and other potable liquids transported to or from a bottling establishment (see above). If ingredient water is transported to a bottling establishment in bulk, the operator must test the ingredient water at least weekly for coliform bacteria and heterotrophic plate count. An operator must keep records of bulk shipments.
- Labeling of bottled products must comply with general food labeling standards (see above). Bottled water labeling must also comply with specific federal requirements under 21 CFR 165.110. A juice label may not misrepresent that juice has been pasteurized. A juice label may not represent as “fresh” any juice that has been treated with ultra-violet light.
- ***Lab test methods.*** This rule updates required laboratory methods for food safety tests, based on the latest methods published by AOAC International and the American Public Health Association.
- ***Organizational and technical drafting changes.*** This rule makes other organizational, technical and drafting changes to update and clarify current rules.

Public Hearings

DATCP held 3 public hearings on this rule (hearings were extensively publicized). DATCP held the hearings on March 3, 2009 in Eau Claire, on March 12, 2009 in Appleton, and on March 13, 2009, in Madison. Twenty-five persons attended the hearings (3 in Eau Claire, 12 in Appleton and 10 in Madison).

- Seventeen persons registered no position, and did not comment on the proposal.
- Three persons registered in support, but did not comment.
- Three persons registered general concerns about provisions related to reclaimed and re-circulated water, but did not provide any specific comments.
- One person registered in opposition, but did not comment.
- Only one person registered to speak. Nick George, representing the Midwest Food Processors Association, expressed concerns about proposed rule provisions related to reclaimed and re-circulated water.

DATCP received subsequent written comments from Nick George on behalf of the Midwest Food Processors Association (comments were directed mainly at rule provisions related to reclaimed and re-circulated water). DATCP staff also met with Mark Collins from McCain Foods USA, Inc., to discuss proposed rule provisions related to reclaimed and re-circulated water. A more complete hearing summary is attached as *Appendix A*.

Changes from the Hearing Draft

- In response to comments from McCain Foods and the Midwest Food Processors Association, DATCP modified provisions related to reclaimed and re-circulated water. The modifications clarify DATCP intent, and meet the needs of food processing plants that routinely and safely use reclaimed and re-circulated water in their processing operations.
- DATCP made several editorial and structural changes suggested by the Legislative Council Rules Clearinghouse.
- DATCP made a substantive change to the section on caviar and fish eggs in response to a question posed by the Rules Clearinghouse.
- DATCP added a provision referencing the current food processing plant license fee surcharge under s. 97.29(3)(d), Stats., for plant operators found operating without a license. This is a purely technical change. It does not add a new surcharge, or change the amount of the existing statutory surcharge, but merely references the statutory surcharge that already exists (so that readers of the rule will be aware of that surcharge).

Response to Rules Clearinghouse Comments

DATCP modified the final draft rule to address all of the Rules Clearinghouse Comments except the following:

- *Comment 2.k:* Comment applies to future rules.
- *Comment 5.a:* Adopted some but not all of the grammatical suggestions. Explained the “HACCP” acronym earlier in the rule preface.
- *Comment 5.c:* We assume that the Rules Clearinghouse question refers to s. ATCP 70.06(7)(c), not (6)(c). Tanks should be inspected more often if necessary for food safety. There are many potential circumstances that might warrant more frequent inspection (not all can be listed).

Fiscal Impact

This rule will have no significant fiscal impact on Wisconsin state government and no fiscal impact on local units of government. DATCP will incur some costs to provide information and education to affected businesses. However, DATCP expects to absorb those costs. A complete *fiscal estimate* is attached.

Business Impact

This rule will help Wisconsin food processors to produce safe food products. Food safety regulation is important not only for consumers, but also for the food processors themselves. Food safety problems can harm individual businesses and the overall food industry.

- For the most part, this rule merely updates and clarifies current rules, and it makes the rules consistent with other federal and state rules. These changes will eliminate inconsistent and duplicative regulation, and that will make it easier for food processors to comply. For the most part, this rule gives affected food processors more flexibility to design effective food safety systems tailored to their operations. But in some instances, this rule provides definite compliance standards that are not provided by federal rules.
- This rule requires fish processors and juice processors to implement hazard analysis and critical control point (HACCP) plans. But there will be no added cost to affected businesses because those plans are already required by federal rules. DATCP will help train affected businesses on the implementation of HACCP plans and other food safety measures. The University of Wisconsin-Extension may offer seminars and training sessions at modest cost.
- Consistent with current federal rules, this rule requires food processors to have written recall plans. However, this rule gives processors considerable flexibility to design recall plans that are tailored to their operations. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- This rule incorporates current state and federal labeling requirements for processed food, including current federal requirements related to disclosure of major allergens. This rule may prompt food processors to review their labels for compliance with current law, but it does not add any major new labeling requirements.
- This rule requires food processors to keep certain records related to food processing operations, to help ensure food safety. Since the recordkeeping requirements are consistent with normal business practices, they will not impose significant new burdens or costs. There are no new professional skills required.
- This rule may require some changes in some food processing facilities and operations. But for most food processors, the changes (if any) will not be large or costly. Most food

processors are already complying with most of the requirements. New requirements related to hand-washing facilities will apply prospectively to newly installed facilities or newly licensed operations.

- Many of the food processing plants affected by this rule are “small businesses.” This rule will not have a significant adverse effect on small businesses, and it will help many small businesses by making food safety regulations clearer and more consistent. This rule does not exempt small businesses, because food safety risks affect small as well as large businesses. DATCP will provide training and assistance to affected small businesses. The University of Wisconsin-Extension may offer seminars and training sessions at modest cost.
- This rule will promote food safety, for the benefit of consumers *and* food processors. This rule will clarify current regulations, and make them more consistent. That will facilitate compliance by food processors. This rule will not have a significant adverse impact on small businesses (or other businesses), and it is not subject to the delayed small business effective date under s. 227.22(2)(e), Stats.

Federal and Surrounding State Regulation

Federal Regulation

At the federal level, the United States Food and Drug Administration (FDA) is primarily responsible for regulating food processing plants. Wholesale food processors must register with FDA, but FDA does not license those food processors. FDA has established basic food safety standards and requirements for food processing plants, but those standards do not preempt consistent or more rigorous state standards. Most food processing plant inspections are conducted by the states (FDA does few inspections).

States generally coordinate their regulatory programs with FDA, and state regulations are based to a considerable degree of federal regulations. This rule incorporates, by reference, certain FDA regulations related to food labeling, canning operations, juice processing, fish processing and bottled water.

Surrounding State Regulation

Michigan, Minnesota, Illinois and Iowa all regulate and inspect food processing plants. Rules in those states are broadly consistent with this rule and federal rules, although there are a number of specific variations between the states.

Environmental Impact

This rule will not have a significant impact on the environment.

Appendix A

Summary of Hearing Testimony

DATCP held 3 public hearings on this rule (hearings were extensively publicized). DATCP held the hearings on March 3, 2009 in Eau Claire, on March 12, 2009 in Appleton, and on March 13, 2009, in Madison. Twenty-five persons attended the hearings (3 in Eau Claire, 12 in Appleton and 10 in Madison).

- Seventeen persons registered no position, and did not comment on the proposal:
 1. Vern Winker, Blue Mounds (DairyFood USA, Inc.).
 2. Marvin Studzinski, Madison (Arctic Glacier, Inc.).
 3. Kelly Stidhum, Menomonie Falls (Arctic Glacier, Inc.).
 4. Dave Aggen, Manitowoc (Lakeside Foods, Inc.).
 5. Ben Scherwitz, Janesville? (Seneca Foods).
 6. Jim Farah, Green Bay (Meat Processors, Inc.).
 7. Chris Weichman, New Berlin (Wisconsin Glacier Springs).
 8. Bob Lace, Neenah (Collen's Tough Times)
 9. Samantha Clark, Fond du Lac
 10. Don Hartwig, Shawano (Twig's Beverage, Inc.).
 11. Michael Thurber, Lakewood (Thurber Distr., Inc.).
 12. Larry Osegard, Neillsville.
 13. Brad Legreid, Middleton (WI Dairy Products Assn.)
 14. Paul France, Two Rivers (Riverside Foods, Inc.).
 15. Guy Wisniewski, Antigo (DATCP).
 16. Herby Radmann, Menomonie (Bullfrog's Eat My Fish Farm).
 17. Jennifer Hall, Madison (Porchlight Products).

- Three persons registered in support, but did not comment:
 1. Michelle Roberts, Appleton (City of Appleton Health Department).
 2. Tim Mirkes, Appleton (City of Appleton Health Department).
 3. Tom Keel, Reedsburg (DATCP).

- Three persons registered general concerns about provisions related to reclaimed and re-circulated water, but did not provide any specific comments.
 1. Dave Vogl, Rochelle, IL (Del Monte, Midwest Food Processors Association).
 2. Steve Schuh, Darien (Birds Eye Foods).
 3. Sandra Welles, Darien (Birds Eye Foods).

- One person registered in opposition, but did not comment:
 1. Michael Yauser, Two Rivers (Riverside Foods, Inc.).
- Only one person registered to speak. Nick George, representing the Midwest Food Processors Association, expressed concerns about proposed rule provisions related to reclaimed and re-circulated water.

DATCP received subsequent written comments from Nick George on behalf of the Midwest Food Processors Association (comments were directed mainly at rule provisions related to reclaimed and re-circulated water). DATCP staff also met with Mark Collins from McCain Foods USA, Inc., to discuss proposed rule provisions related to reclaimed and re-circulated water.