

DATE: February 20, 2002
TO: Beata Kalies
Committee on Agriculture
FROM: John Scocos, Assembly Chief Clerk
RE: Clearinghouse Rules Referral

The following Clearinghouse Rule has been referred to your committee.

CLEARINGHOUSE RULE 01-058

AN ORDER to repeal ATCP 80.56 (4); to renumber ATCP 80.56 (intro.) and (1) to (3); and to create ATCP 80.24 (5) and 80.56 (2), relating to pathogen tests on ready-to-eat dairy products.

Submitted by **Department of Agriculture, Trade and Consumer Protection.**

Report received from Agency on **February 15, 2002.**

To committee on **Agriculture.**

Referred on **Wednesday, February 20, 2002.**

Last day for action - **Friday, March 22, 2002.**

Under section 227.19 (4) of the Wisconsin Statutes, your committee has 30 days to take action or get an extension. The day **after** the official referral date is day one of your review period. Therefore, the 30th day should fall four weeks and two days after the referral date. For example, for Clearinghouse Rules referred on a Monday, a Wednesday would be your 30th day. For Clearinghouse Rules referred on a Tuesday, a Thursday would be your 30th day. For Clearinghouse Rules referred on a Wednesday, a Friday would be your 30th day. For Clearinghouse Rules referred on a Thursday or Friday, your 30th day would fall on a weekend. Therefore, your time would expire on the next working day (Monday) as provided for in s. 990.001 of the Wisconsin Statutes. Also, if the 30th day falls on a legal holiday, time would expire on the next working day.

Section 227.19 **requires** you to notify each member of your committee that you have received this Clearinghouse Rule. Although some committee chairs do so, you are not required to send a copy of the text of the rule to each member at this time. Your notice could state that members should contact you if they wish to receive a hard copy of the rule. **(Please note that the text of Clearinghouse Rules beginning with the prefix "01" is now available online in the Clearinghouse Rules infobase in FOLIO.)** Please put a copy of your official notification memo in the rule jacket.

Three copies of the Clearinghouse Rule and its accompanying documents are contained in the jacket. If you wish to have your Legislative Council attorney review the Clearinghouse Rule, send him/her a copy. I only need one copy remaining in the jacket when you report it out of committee at the end of the review period.

The identical process is happening simultaneously in the Senate. Keep track of their action on the rule.

For assistance with the Clearinghouse Rule process, please consult Ken Stigler (6-2406) or your Legislative Council attorney. If you wish to learn more on this subject, read section 227.19 of the Wisconsin Statutes or part 2 of the *Administrative Rules Procedures Manual* written by the Revisor of Statutes Bureau and the Wisconsin Legislative Council staff.



Al Ott

State Representative • 3rd Assembly District

**Assembly Agriculture Committee
MEMO**

TO: Members of the Assembly Agriculture Committee

FROM: Representative Al Ott, Chair

DATE: February 20, 2002

The following Clearinghouse Rules have been referred to the Assembly Agriculture Committee for a 30-day review period.

Clearinghouse Rule 01-057 - Relating to cheese grading.

This rule changes Wisconsin standards for Swiss Cheese eye size, so that it matches the recently changed federal standards.

Clearinghouse Rule 01-058 - Relating to pathogen tests on ready-to-eat dairy products.

This rule changes the current requirements and encourages more pathogen testing.

The deadline for action on these rules is Wednesday, March 20th, 2002. A brief summary is enclosed. If you would like a copy of the rules in their entirety or would like additional information, please contact Beata Kalies in my office - 266-5831. The rules are also available on Folio Clearinghouse Rule Database. Thank you.



State of Wisconsin
Scott McCallum, Governor

Department of Agriculture, Trade and Consumer Protection
James E. Harsdorf, Secretary

PUBLIC NOTICE

FINAL DRAFT RULE TO LEGISLATURE

The Department of Agriculture, Trade and Consumer Protection announces that it is submitting the following rule for legislative committee review, pursuant to s. 227.19, Stats.:

CLEARINGHOUSE RULE #: **01-058**

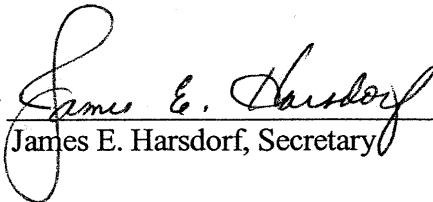
SUBJECT: **Pathogen Tests on Ready-to-Eat Dairy Products**

ADM. CODE REFERENCE: **ATCP 80.56(4)**

DATCP DOCKET #: **01-R-04**

Dated this 4th day of February, 2002.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

✓ By 
James E. Harsdorf, Secretary



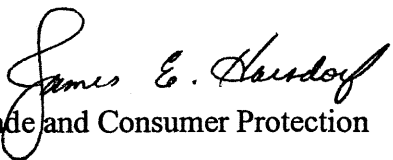
State of Wisconsin
Scott McCallum, Governor

Department of Agriculture, Trade and Consumer Protection
James E. Harsdorf, Secretary

DATE: February 4, 2002

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

The Honorable Scott R. Jensen
Speaker, Wisconsin State Assembly
Room 211 West, State Capitol
P.O. Box 8952
Madison 53708-8952

FROM: James E. Harsdorf, Secretary 
Department of Agriculture, Trade and Consumer Protection

SUBJECT: **Pathogen Tests on Ready-to-Eat Dairy Products;
Final Draft Rule (Clearinghouse Rule #01-058)**

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

Background

DATCP licenses and inspects dairy plants under s. 97.20, Stats. Current DATCP rules under s. ATCP 80.56(4), Wis. Adm. Code, require dairy plant operators to report to DATCP the results of any microbiological test that confirms the presence of a pathogenic organism in a pasteurized or ready-to-eat dairy product. The current reporting requirement discourages pathogen testing, because test reports become public records that may be open to public inspection, even if the affected products are withheld from sale.

The rule repeals this counterproductive reporting requirement, and creates alternative rules that provide better public health protection and encourage more pathogen testing.

Rule Contents

Under current rules, a dairy plant operator must keep records of all pathogen and toxin test results. This requirement will continue. DATCP may inspect and copy test records as necessary.

Under this rule:

- A dairy plant operator may not sell or distribute any ready-to-eat dairy product in which a microbiological test has confirmed the presence of a pathogenic organism or toxin.
- A dairy plant operator must report test results that confirm the presence of pathogens or toxins in ready-to-eat dairy products unless all the following apply:
 - The tested product bears a product code or production lot number and the product is still under the custody or control of the dairy plant operator.
 - The operator withholds, from sale or distribution, all ready-to-eat products that bear that product code or production lot number.

Hearings

The department held two public hearings on this rule. The first was in Appleton on June 14, 2001, and the second was in Dodgeville on June 15, 2001. Representatives of the Wisconsin Dairy Products Association and the Wisconsin Cheesemakers Association registered and spoke in favor of the rule. The hearing record remained open for written comments until June 30, 2001. Alto Dairy, Waupun, and the Wisconsin Center for Dairy Research filed written comments. Both recommended adding the phrase "beyond established tolerance limits" at the end of the sentence that prohibits the sale of a ready-to-eat dairy product when testing has confirmed the presence of a pathogenic organism or toxin.

Changes from the Hearing Draft

The department made a number of minor changes in the final draft rule:

- The final draft clarifies when a dairy plant operator is not required to report to the department the presence of a pathogenic organism or toxin in a ready-to-eat dairy product. The reporting requirement is not applicable if all of the affected product is under the control or custody of the dairy plant operator.
- The department did not accept the recommendation to add the phrase "beyond established tolerance limits" to the requirement prohibiting the sale of a ready-to-eat

dairy product in which the presence of a pathogenic organism or toxin is confirmed. If a positive test result for any product no longer under control of the dairy plant operator is reported, the department, in cooperation with the reporting dairy plant, will determine the scope and extent of any recall that may be necessary.

Response to Rules Clearinghouse Comments

- The department accepted the recommendation of LCRC and reversed the order of treatment Sections 4 and 5, since s. ATCP 80.56(2) numerically precedes s. ATCP 80.56(4).
- The department did not accept the suggestion to define the terms “product code”, “pathogenic organism” or “toxin,” since these terms are well known and understood in the dairy industry. Additionally, government regulatory agencies and the dairy industry routinely use these terms as part of good manufacturing practices.
- The department revised the Analysis to be more specific on the issue of when a dairy plant operator does not have to report the presence of a pathogenic organism or toxin in a ready-to-eat dairy product. In addition to the two already stated conditions, the reporting exemption only applies when the product is still under the custody or control of the dairy plant operator.

Small Business Analysis

This rule modifies and updates ch. ATCP 80 regarding pathogen tests on ready-to-eat dairy products. The rule will encourage dairy plants to conduct more pathogen tests, which will provide better public health protection. Under current rules, a dairy plant operator must keep records of all pathogen and toxin test results. This rule requires no additional recordkeeping or other procedures for dairy plants. Small dairy plants will need no additional professional skills or assistance in order to comply with this rule. The rule will have minimal financial impact on the dairy industry.

Fiscal Estimate

This rule will have no fiscal impact on the department. Dairy plants are currently required to report the results of any microbiological test or laboratory analysis, which indicates that a ready-to-eat dairy product contains pathogenic organisms or toxins. This rule simply clarifies when a dairy plant operator must report results of pathogen testing to the department.

**PROPOSED ORDER OF THE STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION
ADOPTING, AMENDING OR REPEALING RULES**

1 The state of Wisconsin department of agriculture, trade and consumer protection proposes the
2 following order to repeal ATCP 80.56(4); to renumber ATCP 80.56(intro.) and (1) to (3); and to
3 create ATCP 80.24(5) and 80.56(2); relating to pathogen tests on ready-to-eat dairy products.

**Analysis Prepared by the Department of Agriculture,
Trade and Consumer Protection**

Statutory authority: ss. 93.07(1), 97.09(4) and 97.20(4), Stats.
Statute interpreted: ss. 97.09(4) and 97.20(4), Stats.

The Department of Agriculture, Trade and Consumer Protection (DATCP) licenses and inspects dairy plants under s. 97.20, Stats. Current DATCP rules under s. ATCP 80.56(4), Wis. Adm. Code, require dairy plant operators to report to DATCP the results of any microbiological test that confirms the presence of a pathogenic organism in a pasteurized or ready-to-eat dairy product. The current reporting requirement discourages pathogen testing, because test reports become public records that may be open to public inspection even if the affected products are withheld from sale.

This proposed rule repeals this counterproductive reporting requirement, and creates alternative rules that will provide better public health protection and encourage more pathogen testing. Under this rule:

- A dairy plant operator may not sell or distribute any ready-to-eat dairy product in which a microbiological test has confirmed the presence of a pathogenic organism or toxin.
- A dairy plant operator must report test results that confirm the presence of pathogens or toxins in ready-to-eat dairy products unless all the following apply:
 - * The tested product bears a product code or production lot number and remains under the control or custody of the dairy plant operator.
 - * The operator withholds, from sale or distribution, all ready-to-eat products that bear that product code or production lot number.

Under current rules, a dairy plant operator must keep records of all pathogen and toxin test results. This requirement will continue. DATCP may inspect and copy test records as necessary.

1 **SECTION 1.** ATCP 80.24(title) is amended to read:

2 ATCP 80.24(1)(title) **Milk and dairy products; quality standards**

3 **SECTION 2.** ATCP 80.24(5) is created to read:

4 ATCP 80.24(5) **PATHOGEN CONFIRMED IN READY-TO-EAT DAIRY PRODUCT; SALE**
5 **PROHIBITED.** A dairy plant operator may not sell or distribute any ready-to-eat dairy product in
6 which a microbiological test or laboratory analysis has confirmed the presence of a pathogenic
7 organism or toxin.

8 **SECTION 3.** ATCP 80.56(intro.) and (1) to (3) are renumbered ATCP 80.56(1)(intro.)
9 and (a) to (c).

10 **SECTION 4.** ATCP 80.56(2) is created to read:

11 ATCP 80.56(2)(a) Except as provided in par. (b), a dairy plant operator shall report to
12 the department the result of any microbiological test or laboratory analysis that confirms the
13 presence of a pathogenic organism or toxin in a ready-to-eat dairy product produced by the
14 operator. The operator shall report to the department within 24 hours after the operator obtains
15 the test result. The operator may report orally, electronically or in writing.

16 (b) A dairy plant operator is not required to report a test result under par. (a) if all the
17 following apply:

18 1. The ready-to-eat dairy product is identified by a product code or production lot
19 number and remains under the control or custody of the dairy plant operator.

20 2. The operator does not sell or distribute any ready-to-eat dairy product that bears the
21 product code or production lot number under subd. 1.

22 **SECTION 5.** ATCP 80.56(4) is repealed.

1 **EFFECTIVE DATE.** The rules contained in this order shall take effect on the first day of
2 the month following publication in the Wisconsin administrative register, as provided under s.
3 227.22(2)(intro.), Stats.

Dated this ____ of _____, 2002

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By _____
James E. Harsdorf
Secretary

Final Regulatory Flexibility Analysis

Proposed ATCP 80, Wis. Adm. Code

PATHOGEN TESTING ON READY-TO-EAT DAIRY PRODUCTS

The Department of Agriculture, Trade and Consumer Protection (DATCP) licenses and inspects dairy plants under s. 97.20, Stats. Current DATCP rules under s. ATCP 80.56(4), Wis. Adm. Code, require dairy plant operators to report to DATCP the results of any microbiological test that confirms the presence of a pathogenic organism in a pasteurized or ready-to-eat dairy product. The current reporting requirement discourages pathogen testing, because test reports become public records that may be open to public inspection even if the affected products are withheld from sale.

The proposed rule repeals this counterproductive reporting requirement, and creates alternative rules that will provide better public health protection and encourage more pathogen testing. The proposed changes are already in effect under an emergency rule which the department adopted. This rule will make the temporary rule changes permanent. Under this rule:

- A dairy plant operator may not sell or distribute any ready-to-eat dairy product in which a microbiological test has confirmed the presence of a pathogenic organism or toxin.
- A dairy plant operator must report test results that confirm the presence of pathogens or toxins in ready-to-eat dairy products unless all the following apply:
 - * The tested product bears a product code or production lot number.
 - * The operator withholds, from sale or distribution, all ready-to-eat products that bear that product code or production lot number.

Under current rules, a dairy plant operator must keep records of all pathogen and toxin test results. This rule requires no additional recordkeeping or other procedures for dairy plants. Small dairy plants will need no additional professional skills or assistance in order to comply with this rule.

This permanent rule will have minimal financial impact on the dairy industry.

Signed this 5th day of ^{February 2} ~~July~~, 2004

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By Steven B. Steinhoff
Steven B. Steinhoff, Administrator
Division of Food Safety

Fiscal Estimate — 2001 Session

- Original Updated
 Corrected Supplemental

LRB Number	Amendment Number if Applicable
Bill Number	Administrative Rule Number

Subject

Permanent rule to repeal ATCP 80.56(4) and to create ATCP 80.24(4) and 80.56(2); relating to pathogen test on ready-to-eat dairy products.

Fiscal Effect

State: No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

- Increase Existing Appropriation Increase Existing Revenues
 Decrease Existing Appropriation Decrease Existing Revenues
 Create New Appropriation

- Increase Costs — May be possible to absorb within agency's budget.
 Yes No
 Decrease Costs

Local: No Local Government Costs

1. Increase Costs
 Permissive Mandatory
2. Decrease Costs
 Permissive Mandatory
3. Increase Revenues
 Permissive Mandatory
4. Decrease Revenues
 Permissive Mandatory

5. Types of Local Governmental Units Affected:
 Towns Villages Cities
 Counties Others
 School Districts WTCS Districts

Fund Sources Affected

- GPR FED PRO PRS SEG SEG-S

Affected Chapter 20 Appropriations

Assumptions Used in Arriving at Fiscal Estimate

The Department of Agriculture, Trade and Consumer Protection ("department") licenses and inspects dairy plants under Wis. Stats. ss 97.20. Under s. 80.56(4), Wis. Admin. Code, the department requires the dairy plant operator to report to the department results of any microbiological test conducted on a pasteurized or ready-to-eat dairy product that confirms the presence of pathogenic organisms in that product. The current reporting requirement discourages pathogen testing, because test reports become public records that may be open to public inspection even if the affected products are withheld from sale.

This permanent rule repeals this counterproductive reporting requirement, and creates alternative rules that will provide better public health protection and encourage more pathogen testing.

The proposed permanent rule has no anticipated fiscal impact on the department.

Long-Range Fiscal Implications

None anticipated

Prepared By: C. Thomas Leitzke	Telephone No. (608) 224-4711	Agency DATCP
Authorized Signature <i>Barbara Knapp</i>	Telephone No. 224-4746	Date (mm/dd/ccyy) 4-24-01



The Flavor and Performance Specialists

From:

Rep. Kestell

3-19-02

March 18, 2002

Steve Kestell, State Representative
27th Assembly District
Post Office Box 8952
Madison, Wisconsin 53708-8952

Dear Steve:

I am writing this letter to provide comments on the Final Draft Rule amendment to the state administrative code ATCP 80 (~~known as Clearing house Rule #01-058~~).

It is important we take into account the ability for technology to advance and to lower the limits of detection of toxins and pathogens. Scientific testing is becoming more and more precise which may allow detection of low level environmental pathogens and toxins which are well within established tolerance limits. If we allow the rule to read simply "if a pathogen or toxin is detected", we may be possibly setting the stage for the unnecessary holding or recalling product, which may not be hazardous or toxic if consumed.

Consider the following scenario:

A hostile animal rights group decides to cause bad publicity for the dairy industry. They know that today PCBs are detected in our environment everywhere. The group sends a sample of Wisconsin cheese to an environmental lab for testing and PCBs are detected but they are present in levels that are below the tolerance level for this food. The group could push for a recall of dairy products under this rule since PCBs are toxic and have been declared as present.

I agree with both the Wisconsin Cheese Makers and the Wisconsin Center for Dairy Research that the phrase "~~beyond established tolerance limits~~" ~~should be included in this rule~~. I believe that unless this phrase is included, we may be opening both our state and the dairy industry to possibly bad publicity and embarrassment. I urge you to support the inclusion of this phrase in the rule.

Keep up the good work in Madison!

Sincerely,

James C Sartori
President and CEO

cc. Steven M. Tittel
Director of Quality Assurance
and Risk Management

SARTORI FOOD CORPORATION

107 Pleasant View Road
P.O. Box 258
Plymouth, WI 53073 USA
920.893.6061
800.558.5888
Fax: 920.892.2732
www.sartorifoods.com

Call Datep: Byron Dennison, Food Safety,
224-4715

Talked over at public hearing quite a bit.

rule is ^{for this only} for pathogens:
do ^{have} Not establish tolerance
either have or not have it

history does not indicate
tampering or terrorism in food supply
not know when or if it will happen

for "pathogens" only - Not foreign materials - that's
covered elsewhere
↳ ex. ecoli 157, Salmonella,

"toxins" → broad term for lots of ^{pathogenic} organisms that
if large enough can produce a toxin
specific to that def / substance but ^{does} not include
other toxins in general

WI Center for Dairy Research + Alta Dairy recommends phrase
"baseline establishment tolerance limits."
- From Rule Summary - Dept did not accept this phrase.

If positive test results, Datep will work w/ plant to
determine scope + extent of any recall that may be needed.

Send copy of rule contents + call on this issue. Datep comments to Dave 3/19



STATE REPRESENTATIVE
STEVE KESTELL

27TH ASSEMBLY DISTRICT

March 21, 2002

Representative Al Ott, Chairman
Assembly Committee on Agriculture
Room 318-North, State Capitol

Dear Chairman Ott,

I am writing to express my concerns on Clearinghouse Rule 01-058, related to pathogen tests on ready-to-eat dairy products. I am in agreement with Sartori Foods, Alto Dairy and the Wisconsin Center for Dairy Research on including specific language related to the presence of a pathogenic organism or toxin.

I urge you to add the phrase "beyond established tolerance limits" at the end of the section that prohibits the sale of ready-to-eat dairy products when testing has confirmed the presence of a pathogenic organism or toxin. I support adding this language in order to avoid a situation where a product may be unnecessarily held or recalled when it may not be hazardous or toxic if consumed.

Please feel free to contact me if you have any questions.

Sincerely,


Steve Kestell
State Representative
27th Assembly District

cc: Sartori Food Corporation



Al Ott

State Representative • 3rd Assembly District

April 11, 2002

Representative Steve Kestell
Room 17-West, State Capitol

Dear Representative Kestell,

Thank you for your letter regarding Clearinghouse Rule 01-058, relating to pathogen testing of ready-to-eat dairy products. I understand your office has received communication, which has been shared with my staff, from Satori Foods of Plymouth.

I appreciate your request and that of Satori Foods to include the phrase "beyond established tolerance limits" to identify a pathogen level when products become unsafe and avoiding recall of products that are consumable despite presence of pathogens. Satori Foods suggests that this would minimize a recall due to action by someone tainting products to create bad publicity for the industry.

My staff spoke with Byron Dennison with the Food Safety Department at the Department of Agriculture, Trade, and Consumer Protection. The Department considered but did not accept this phrase when it was presented during a public hearing.

The Department clarified its position by explaining that we do not have established tolerance levels for such pathogens, it's either you have it or you do not have it. This rule is specific to certain pathogens, like salmonella and e-coli. Mere presence of such substances make food unsafe, and not more unsafe if more organisms are detected.

Furthermore, if products are tampered with, other specific rules would be enacted to address the issues. The "toxins" referred to in the rule apply to specific pathogenic organisms, which could create a toxic environment if large enough in number, but not all known toxins are covered by this rule.

If positive test results do occur, the Department will work with the plant and determine the scope and extent of any recall or hold that may be needed. Recalls would not be automatic but a decision based on food safety. The Department would not want to implement unneeded recalls.

Kestell, page 2



Al Ott
Taking this information into consideration, the Department seems to have the issue under control, thus we did not make any changes to Clearinghouse Rule 01-058. I appreciate your concern and thank you for taking the time to share it with me.

Sincerely,

Al Ott
Assembly Committee on Agriculture Chairman

AO:bk