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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Ronald Sklansky**  
*Clearinghouse Director*

**Richard Sweet**  
*Clearinghouse Assistant Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Laura D. Rose**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### 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**

05-15-01 RECEIVED BY LEGISLATIVE COUNCIL.

06-12-01 REPORT SENT TO AGENCY.

RNS:RW;jal;wu

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached      YES       NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached      YES       NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached      YES       NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

Comment Attached      YES       NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached      YES       NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

Comment Attached      YES       NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached      YES       NO



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### CLEARINGHOUSE RULE 01-058

#### Comments

**[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]**

#### 2. Form, Style and Placement in Administrative Code

SECTIONS 4 and 5 should be reversed since s. ATPC 80.56 (2) numerically precedes s. ATPC 80.56 (4).

#### 5. Clarity, Grammar, Punctuation and Use of Plain Language

a. The department may wish to be more specific about the reasons for the rule. It would appear that the authorization not to report a test disclosing the presence of a pathogenic organism or toxin could result in the department not being aware of significant contaminants within a dairy plant. Is the department confident that "non-reporting" will not shield serious problems within a dairy plant?

b. Is there a need to define "product code"?

c. Is there a need to define the terms "pathogenic organism" or "toxin"?

**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.

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**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.
  - \* 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.

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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(4) is repealed. ~~ATCP 80.56(4)~~

11 SECTION 5. ATCP 80.56(2) is created to read:

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

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

19 1. The ready-to-eat dairy product is identified by a product code or production lot  
20 number.

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

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 \_\_\_\_\_, 2001

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

By \_\_\_\_\_  
James E. Harsdorf  
Secretary



State of Wisconsin  
Scott McCallum, Governor

FEB 27 2001

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

DATE: February 23, 2001

TO: State Legislators

FROM: Ben Brancel, Secretary

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

Pursuant to s. 227.24(3), Stats., the Department of Agriculture, Trade and Consumer Protection (DATCP) is forwarding a copy of an emergency rule related to pathogen tests on ready-to-eat dairy products. DATCP believes that this emergency rule will provide better public health protection and encourage dairy plants to perform more pathogen tests. It will also facilitate sales of Wisconsin dairy products.

### **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.

This emergency 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.
  - \* 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.

**Why an Emergency Rule is Needed**

Many dairy product distributors are currently asking dairy plant operators to perform pathogen tests on dairy products, before the distributors accept those products from the dairy plant operators. Many dairy plant operators are willing to perform these tests, but they are discouraged by current rules that require them to report test results to DATCP – even on products withheld from sale.

This emergency rule will remove the disincentive to test, and will improve public health protection. Under this rule, a dairy plant operator must report pathogen findings to DATCP *unless* the operator withholds the entire affected lot of dairy products from sale. This rule will encourage more routine testing for pathogens.

This rule creates a “win-win” situation for consumers and dairy plant operators. By encouraging more pathogen testing, it will provide immediate public health benefits. It will also eliminate current obstacles to the sale of Wisconsin dairy products. In order to protect the public health, safety and welfare, it is important to implement these rule changes as soon as possible. This emergency rule will implement the changes on an interim basis, pending the adoption of “permanent” rules.

**Fiscal Effect**

This rule will have no fiscal effect on DATCP or local units of government. A fiscal note is attached.

**Next Steps**

This emergency rule will take effect upon publication in the official state newspaper, and will remain in effect for 150 days. The Legislature’s Joint Committee for Review of Administrative Rules may extend the emergency rule for up to 120 more days. DATCP will begin work on “permanent” rules to implement this rule change on a long term basis.



**ORDER OF THE STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION  
ADOPTING EMERGENCY RULES**

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

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**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 emergency 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.
  - \* 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.

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1 **FINDING OF EMERGENCY**

2 The Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) finds that  
3 an emergency exists and that the following emergency rule is necessary to protect public health,  
4 safety and welfare. The facts constituting the emergency are as follows:

5 (1) DATCP licenses and inspects dairy plants under s. 97.20, Stats. Current DATCP  
6 rules, under s. ATCP 80.56(4), Wis. Adm. Code, require dairy plant operators to report to  
7 DATCP the results of any microbiological test that confirms the presence of a pathogenic  
8 organism in a pasteurized or ready-to-eat dairy product.

9 (2) There has been a nationwide increase in food borne disease outbreaks associated with  
10 food and dairy products. Such outbreaks can occur when ready-to-eat foods enter food  
11 distribution channels without being tested for pathogenic bacteria.

12 (3) There is no national or state law requiring dairy plant operators to test ready-to-eat  
13 dairy products for pathogens prior to sale or distribution. Dairy plant operators have a natural  
14 incentive to test, in order to avoid liability and meet their customers' product safety demands.  
15 But the current test reporting requirement under ATCP 80.56(4) discourages pathogen testing,  
16 because test reports become public records that may be open to public inspection even if the  
17 affected products are withheld from distribution.

18 (4) There is an urgent need to repeal this counterproductive reporting requirement, and  
19 to create alternative rules that will encourage pathogen testing and provide stronger public health  
20 protection. This emergency rule will encourage more pathogen testing, and provide stronger  
21 public health protection, pending the adoption of "permanent" rule changes.

1 **EMERGENCY RULE**

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

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

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

5 ATCP 80.24(5) **PATHOGEN CONFIRMED IN READY-TO-EAT DAIRY PRODUCT; SALE**

6 **PROHIBITED.** A dairy plant operator may not sell or distribute any ready-to-eat dairy product in  
7 which a microbiological test or laboratory analysis has confirmed the presence of a pathogenic  
8 organism or toxin.

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

11 **SECTION 4.** ATCP 80.56(4) is repealed.

12 **SECTION 5.** ATCP 80.56(2) is created to read:

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

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

20 1. The ready-to-eat dairy product is identified by a product code or production lot  
21 number.

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

1           **EFFECTIVE DATE.** The emergency rule contained in this order shall take effect on March  
2 1, 2001, and shall remain in effect for 150 days, as provided under s. 227.24(1)(c), Stats. The  
3 department may seek to extend this emergency rule as provided in s. 227.24(2), Stats.

Dated this 26<sup>th</sup> of February, 2001

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

By 

Ben Brancel, Secretary

### Fiscal Estimate — 1999 Session

- Original       Updated  
 Corrected       Supplemental

LRB Number	Amendment Number if Applicable
Bill Number	Administrative Rule Number Ch. ATCP 80

**Subject**

Emergency rule to repeal ATCP 80.56(4) and to create ATCP 80.24(4) and 80.56(2); relating to pathogen tests 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. <input type="checkbox"/> Increase Costs<br><input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | 3. <input type="checkbox"/> Increase Revenues<br><input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory |
| 2. <input type="checkbox"/> Decrease Costs<br><input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | 4. <input type="checkbox"/> Decrease Revenues<br><input type="checkbox"/> Permissive <input type="checkbox"/> 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  
 20.115(1)(gb)

**Assumptions Used in Arriving at Fiscal Estimate**

The Department of Agriculture, Trade and Consumer Protection ("department") licenses and inspects dairy plants under Wis. Stats. § 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 emergency rule repeals this counterproductive reporting requirement, and creates alternative rules that will provide better public health protection and encourage more pathogen testing.

The proposed emergency 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. <sup>224-</sup> <del>224-4711</del> 4746	Date (mm/dd/ccyy) 2-23-01

MAY 15 2001

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

NOTICE OF HEARING

Rules Relating To Pathogen Tests On Ready-To-Eat Dairy Products

The State of Wisconsin Department of Agriculture, Trade and Consumer Protection announces that it will hold public hearings, at the times and places indicated below, on its emergency rule and a proposed permanent rule to amend Chapter ATCP 80, Wisconsin Administrative Code, relating to pathogen tests on ready-to-eat dairy products. The public is invited to attend the hearings and make comments on the the emergency rule and proposed permanent rule. Following the public hearings, the hearing record will remain open until June 29, 2001, for additional written comments.

A copy of the emergency and proposed permanent rule may be obtained, free of charge, from the Wisconsin Department of Agriculture, Trade and Consumer Protection, Division of Food Safety, 2811 Agriculture Drive, PO Box 8911, Madison, WI 53708-8911, or by calling 608-224-4700. Copies will also be available at the public hearings.

An interpreter for the hearing impaired will be available on request for these hearings. Please make reservations for a hearing interpreter by June 7, 2001 either by writing to Debbie Mazanec, Wisconsin Department of Agriculture, Trade and Consumer Protection, Division of Food Safety, 2811 Agriculture Drive, PO Box 8911, Madison, WI 53708-8911, (608-224-4712), or by contacting the message relay system (TTY) at 608-224-5058. Handicap access is available at the hearing locations.

Hearing Dates, Times And Locations

Date and Time: Thursday, June 14, 2001  
10:00 a.m. - 12:00 noon

Location: Appleton Public Library  
Lower Level Mtg. Room  
925 S. Oneida Street  
Appleton, WI 54911  
Handicapped accessible

Date and Time: Friday, June 15, 2001  
10:00 a.m. - 12:00 noon

Location: Iowa County Courthouse  
County Board Room, 2<sup>nd</sup> Floor  
222 N. Iowa Street  
Dodgeville, WI 53533  
Handicapped accessible

**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 emergency and proposed permanent 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.
  - \* 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.

**Finding Of Emergency**

The Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) finds that an emergency exists and that the following emergency rule is necessary to protect public health, safety and welfare. The facts constituting the emergency are as follows:

(1) 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.

(2) There has been a nationwide increase in food borne disease outbreaks associated with food and dairy products. Such outbreaks can occur when ready-to-eat foods enter food distribution channels without being tested for pathogenic bacteria.

(3) There is no national or state law requiring dairy plant operators to test ready-to-eat dairy products for pathogens prior to sale or distribution. Dairy plant operators have a natural incentive to test, in order to avoid liability and meet their customers' product safety demands. But the current test reporting requirement under ATCP 80.56(4) discourages pathogen testing, because test reports become public records that may be open to public inspection even if the affected products are withheld from distribution.

(4) There is an urgent need to repeal this counterproductive reporting requirement, and to create alternative rules that will encourage pathogen testing and provide stronger public health protection. This emergency rule will encourage more pathogen testing, and provide stronger public health protection, pending the adoption of "permanent" rule changes.

#### 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.

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

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

#### Initial Regulatory Flexibility Analysis

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:



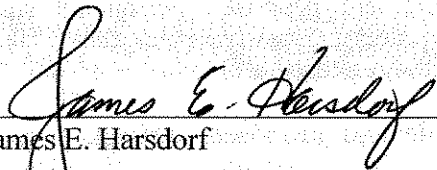
- A dairy plant operator may not sell or distribute any ready-to-eat dairy product in which a microbiological test has confirmed the presence of a pathogenic organism or toxin.
- A dairy plant operator must report test results that confirm the presence of pathogens or toxins in ready-to-eat dairy products 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.

Dated this 14 of May, 2001

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

## PUBLIC NOTICE

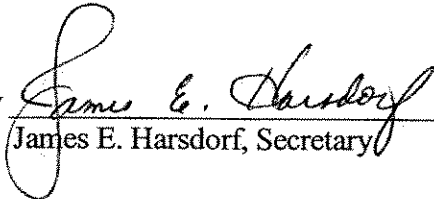
### FINAL DRAFT RULE TO LEGISLATURE

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 4<sup>th</sup> 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 *James E. Harsdorf*  
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); 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.

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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 5<sup>th</sup> day of ~~July~~, <sup>February 2</sup> 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

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Authorized Signature <i>Barbara Knapp</i>	Telephone No. 224-4746	Date (mm/dd/ccyy) 4-24-01