

WISCONSIN LEGISLATIVE COUNCIL STAFF

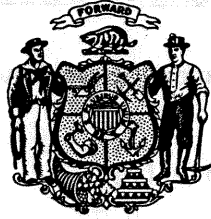
LCRC  
FORM 2

'JUN 28 REC'D

**RULES CLEARINGHOUSE**

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**CLEARINGHOUSE REPORT TO AGENCY**

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[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 99-079**

AN ORDER to repeal HSS 165.02 (4), (12) (b) and (14), 165.03 (1) (title) and (intro.), (a) (intro.) and (b) to (d); 165.14 (2) (a) 11. and (3) (g), 165.20 (2) and 165.23 (1) (g); to renumber HSS 165.03 (1) (a) 1. to 7.; to amend HSS 165.01 (1) and (2), 165.02 (8), (9), (12) (intro.), (13) and (17), 165.03 (1) (intro.) and 165.04 (1) (intro.); to repeal and recreate ch. ATCP 77; and to create HSS 165.03 (intro.), relating to certification of laboratories engaged in public health testing of milk, water and food.

Submitted by **DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION**

05-03-99 RECEIVED BY LEGISLATIVE COUNCIL.

06-01-99 REPORT SENT TO AGENCY.

RS:MM;jal;rv

**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

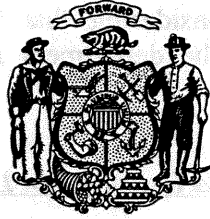
YES NO

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## CLEARINGHOUSE RULE 99-079

### 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

a. Section HSS 165.01 (1) should be further amended to correct the statutory reference to s. 252.22, Stats. This section of the statutes no longer exists. Also, the phrase "department of health and social services" should be replaced by the defined term "department." The name of the department has been changed to the Department of Health and Family Services.

b. Section HSS 165.02 (12) (intro.) and (a) should be consolidated into one subsection, since sub. (12) (b) is repealed.

c. In s. ATCP 77.01 (13), the second sentence should be rewritten to read: "Person' includes a county, a municipality, the state and an agency of the state."

d. In s. ATCP 77.01 (15), the notation "s." should precede the reference to "NR 108.02 (12)."

e. In s. ATCP 77.04 (1) (e) 3., the second occurrence of the notation "ATCP" should be deleted.

f. In s. ATCP 77.14 (3), the notation "s." should be replaced by the notation "ss." Also, in the note following this section, the second occurrence of the notation "s." should be deleted.

g. In the effective date provision, it is not necessary to provide an exception for s. ATCP 77.34 (5). The entire rule may take effect on the first day of the month following publication in the Wisconsin Administrative Register and s. ATCP 77.34 (5) will become applicable, by its own terms, on July 1, 1999. [Considering that Clearinghouse Rule 99-079 cannot be promulgated prior to July 1, 1999, the department may wish to consider altering the date specified in s. ATCP 77.34 (5).]

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

a. In s. ATCP 77.02 (1) (intro.), should "any" be changed to "all"?

b. Should the title to s. ATCP 77.03 refer to the certification of a laboratory operator rather than a laboratory? It appears that the laboratory operator, rather than the laboratory, receives certification under that section. The entire rule should be reviewed for the question of whether it is the operator who, or the laboratory that, is certified.

c. Section ATCP 77.03 (1) refers to public health standards required under federal or state law. However, s. ATCP 77.01 (14) defines the term "public health standard" to include a local "statute, rule or ordinance." Are local regulations intentionally excluded from the provisions contained in s. ATCP 77.03 (1)?

d. In the note following s. ATCP 77.04, the word "from" should be inserted after the word "forms."

e. In s. ATCP 77.04 (1) (e) 3., the third occurrence of the word "proficiency" is misspelled.

f. In s. ATCP 77.16 (3), should "operator" be changed to "person"?

g. In s. ATCP 77.20 (2) (c) 1., how is an operator to determine whether an "authoritative reference manual" exists which applies to the type of food testing for which the laboratory is certified? How are these unnamed manuals to be incorporated by reference under s. 227.21, Stats.? (A reference to incorporation is included in the analysis.)

h. Section ATCP 77.22 (7) should specify the length of time for which an analyst who fails a proficiency evaluation may remain provisionally certified. In addition, the rule should set forth a time limit within which a provisionally certified analyst must perform a proficiency evaluation.

i. The note following s. ATCP 77.24 (3) is unclear. Will the department approve only those evaluators who are approved by the Federal Drug Administration? If so, that should be clearly stated in the text of the rule. If not, the standards which apply for the approval of an evaluator should be set forth in the text of the rule.

j. In s. ATCP 77.24 (4), what are the standards and procedures for department approval of a standard evaluation procedure?

k. In s. ATCP 77.30 (2) (c), it appears that "Standards" should be changed to "Standard."

l. Section ATCP 77.32 should specify the documentation that a laboratory operator must provide as proof that analysts are properly trained to perform tests.

m. In s. ATCP 77.34 (2), the rule requires the evaluator to "rate" the operator's proficiency. The rule should set forth the rating system that is to be used in order to assure consistency in evaluations.

n. In s. ATCP 77.34 (3), "be the evaluator in a" should be changed to "conduct the."

o. In s. ATCP 77.34 (5) (a) 3., should "negative" be changed to "positive"?

p. Section ATCP 77.34 (5) (b) should state when the operator must report the test results to the evaluator. In addition, it appears that the second sentence of that paragraph should require the evaluator to report the test results to the department within 40 days after the operator mails the samples to the evaluator, rather than vice versa.

q. Section ATCP 77.32 (7) (b) should set forth a time limit by which a provisionally certified operator must perform two consecutive proficiency evaluations in order to regain full certification.

r. In s. ATCP 77.34 (7) (c), it appears that the word "the" in the first sentence should be deleted.

**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 ss. HSS 165.02(4), (12)(b) and (14), 165.03(1)(title) and (intro.),  
3 165.03(1)(a)(intro.), 165.03(1)(b) to (d), 165.14(2)(a)11. and (3)(g), 165.20(2), and 165.23(1)(g);  
4 to renumber HSS 165.03(1)(a)1. to 7.; to amend HSS 165.01(1) and (2), 165.02(8), (9),  
5 (12)(intro.), (13) and (17), 165.03(1)(intro.) and 165.04(1)(intro.); to repeal and recreate ch.  
6 ATCP 77; and to create HSS 165.03(intro.) relating to certification of laboratories engaged in  
7 public health testing of milk, water and food.

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

Statutory authority: ss. 93.07(1) and 93.12(3), (5) and (7), Stats.

Statutes interpreted: ss. 93.06(7) and (8), 93.08, 93.12, 93.14, 93.15,  
93.16 and 97.12, Stats.

The 1995-97 biennial budget act, 1995 Wis. Act 27, transferred much of the administration of Wisconsin's laboratory certification program from the Department of Health and Family Services ("DHFS") to the Department of Agriculture, Trade and Consumer Protection ("DATCP").

Under this program, DATCP is now responsible for certifying laboratories that test milk, food and drinking water for compliance with public health standards. (DHFS retains jurisdiction over certain public health laboratories, such as medical laboratories.) Laboratory certification helps ensure that public health lab tests are accurate and reliable.

This rule is the foundation for the lab certification program now located in DATCP. This rule does not make major changes in the current lab certification program. However, this rule streamlines and clarifies current rules so they will be easier to read and understand. This rule repeals former DHFS lab certification rules under ch. HSS 165, Wis. Adm. Code. It also repeals and recreates DATCP's interim lab certification rules under ch. ATCP 77, Wis. Adm. Code.

## Coverage

Under s. 93.12, Stats., and this rule, DATCP must certify laboratories that perform certain tests on milk, water or food, to determine compliance with federal, state or local public health standards. This rule specifies the tests for which a laboratory must be certified. Both private and public laboratories must be certified under this rule. However, certification is not required for any of the following:

- The United States government.
- Milk testing by DATCP.
- An educational institution that operates a laboratory solely for teaching or academic research purposes, and does not test milk, water or food for human consumption .
- A person who operates a laboratory solely to conduct quality control tests on food or water sold by that person, provided that the tests are not required by statute, rule or ordinance.

## Scope of Certification

DATCP must certify a laboratory on an annual basis. An annual certification expires on December 31 of each year. A person who operates 2 or more laboratories must obtain a separate certification for each lab. DATCP must specify, in its certification, the tests which the laboratory is certified to perform.

## Applying for Certification

A laboratory must apply to DATCP for certification, and must pay an annual certification fee of \$216 per test. If DATCP certifies a lab to perform a test for less than a full year, the lab must pay a certification fee of \$18 for each full month of certification.

DATCP must act on a certification application within 40 calendar days after it receives a complete application. A laboratory may apply, at any time, for certification to perform additional tests. A certified laboratory must file an annual renewal application by December 31 of each year.

## Granting and Withdrawing Certification

DATCP must grant or deny a lab certification application within 40 days after it receives that application. DATCP will grant an application if the laboratory meets applicable certification requirements. DATCP must inspect a laboratory before certifying the laboratory to perform any test for the first time. DATCP may not certify an operator to perform any milk or food test unless DATCP has certified all the analysts who perform that test at that laboratory.

is this part of  
\$216?

DATCP may conditionally certify a laboratory pending action to correct deficiencies which DATCP has identified. DATCP may suspend a lab certification for cause, and may summarily suspend a certification if there is an imminent health or safety threat. DATCP may summarily suspend a conditional certification if the laboratory fails to comply with the conditions specified by DATCP.

### **Laboratory Facilities**

A laboratory must have adequate facilities, equipment and supplies to perform the tests for which DATCP certifies that laboratory. A laboratory must also maintain the facilities, equipment and supplies in proper working condition. This rule establishes some specific facility and maintenance requirements. Under this rule, a laboratory must notify DATCP whenever the laboratory remodels lab facilities or installs new equipment that materially affects the performance of certified tests.

### **Laboratory Procedures**

A certified laboratory must perform tests according to recognized methods. This rule incorporates, by reference, authoritative lab manuals which spell out those recognized methods. As required under s. 227.21, Stats., DATCP has requested permission from the attorney general and the revisor of statutes to incorporate these manuals by reference in this rule.

### **Laboratory Administrator**

A certified laboratory must designate an administrator who personally supervises the operations of the laboratory. The administrator (or a designated agent of the administrator) must be present at the laboratory during daytime business hours, and must do all of the following on behalf of the lab operator:

- Supervise the lab and its compliance with this rule.
- Review and approve the lab's certification applications to DATCP.
- Supervise the procurement and maintenance of lab facilities, equipment and supplies.
- Facilitate DATCP inspections of the lab.
- Notify DATCP of changes in lab facilities or personnel that affect the lab's certification.
- Notify lab customers if DATCP suspends or revokes the lab's certification.
- Report lab test results to the appropriate regulatory agency, if required by law.
- Supervise lab recordkeeping.



### **Inspecting a Laboratory**

DATCP must inspect a laboratory at all of the following times:

- Before certifying the laboratory for the first time.
- At least once every 2 years after it certifies the laboratory.
- Before certifying the laboratory to perform a test for which it was not previously certified.

DATCP may inspect a laboratory whenever any of the following occurs:

- The laboratory materially alters its facilities, or equipment.
- A milk or food laboratory assigns a new analyst to perform a test for which the lab is currently certified.
- DATCP concludes that an inspection is necessary to determine whether the lab complies with this rule.

### **Milk and Food Laboratories; Certified Analysts**

DATCP may not certify a milk or food laboratory to perform any test unless DATCP individually certifies the analysts who perform those tests. DATCP certifies analysts by conducting on-site "competency evaluations." DATCP performs these "competency evaluations" when it conducts its initial, and subsequent biennial, inspections of the laboratory. An analyst's certification remains in effect until one of the following occurs:

- DATCP conducts its next biennial inspection of the laboratory.
- The analyst leaves the laboratory.
- DATCP suspends or revokes the analyst's certification.

A milk or food laboratory must notify DATCP whenever a certified analyst leaves the laboratory, or whenever there is a staffing change that affects the lab's compliance with this rule.

### **Milk and Food Analysts; Annual Proficiency Evaluation**

Milk and food analysts must pass annual "proficiency evaluations." In an annual proficiency evaluation, an analyst must examine samples prepared by an approved evaluator. The evaluator knows the contents of the samples, but the analyst does not. The evaluator rates the analyst's proficiency by comparing the analyst's results to the known sample contents, and reports the rating to DATCP.

DATCP may "conditionally certify" an analyst before the analyst completes an annual proficiency evaluation. But if a "conditionally certified" analyst fails an annual proficiency evaluation, DATCP must summarily suspend the analyst's certification. If a "conditionally certified" analyst passes an annual proficiency evaluation, the analyst is fully certified.

If a fully certified analyst fails an annual proficiency evaluation, the analyst is "provisionally certified." If a "provisionally certified" analyst passes a new proficiency evaluation, the analyst is again fully certified. But if a "provisionally certified" analyst fails another proficiency evaluation, DATCP must summarily suspend the analyst's certification. The analyst may then regain full certification only by completing a training course and passing a new proficiency evaluation.

Analysts need not complete annual proficiency evaluations for a milk or food test until DATCP has established written proficiency evaluation procedures for that test. DATCP has established written procedures for milk tests, and is developing written procedures for food tests. This rule establishes basic standards for proficiency evaluations.

### **Water Laboratory Analysts**

DATCP does not individually certify water analysts, as it does food and milk analysts. However, a water lab operator must annually document, to the department, that analysts are trained and competent to perform water tests for which the lab is certified. Whenever DATCP conducts an initial or biennial inspection of a water laboratory, DATCP must evaluate the competency of an analyst who performs tests for which the water lab is certified.

### **Water Laboratories; Annual Proficiency Evaluation**

Before the department certifies a water laboratory to perform any test, the laboratory must complete a "proficiency evaluation" for that test. The laboratory must also complete an annual proficiency evaluation before the department renews the laboratory's annual certification.

In a proficiency evaluation, an analyst designated by the lab operator must examine samples prepared by an approved evaluator. The contents of the samples are known only to the evaluator. The evaluator must rate the laboratory's proficiency by comparing the lab analyst's results to the known contents of the samples, and must report those results and ratings to DATCP.

DATCP must approve lab evaluation procedures. A laboratory is not required to undergo a proficiency evaluation for any test unless DATCP has established an evaluation procedure for that test. DATCP has established written procedures for most water tests. This rule establishes basic standards for proficiency evaluations.

If a water laboratory fails to pass an annual proficiency evaluation for any test which the lab is certified to perform, DATCP must notify the operator that the lab is "provisionally certified" to perform that test. A "provisionally certified" lab may regain full certification by passing 2 consecutive proficiency evaluations. But if a "provisionally certified" lab fails to pass either of

the next 2 proficiency evaluations, DATCP must summarily suspend the lab's certification. DATCP may restore the lab's certification if (a) the lab operator documents steps taken to correct the performance deficiency, and (b) the lab passes a new proficiency evaluation.

### Laboratory Records

A laboratory must keep complete records related to all of the following:

- The training, experience and proficiency evaluation of analysts.
- Laboratory evaluations.
- Laboratory policies and procedures.
- Laboratory facilities, equipment and supplies, including records related to procurement, calibration, testing and maintenance.
- Quality control procedures and monitoring.
- Tests performed at the laboratory, including the nature of the test, the person for whom the test is performed, the assigned analysts, the test methods used, the date and time of testing, and the test results obtained.
- Test reports filed with the department and other government agencies.

A laboratory must keep these records for at least 5 years, and must make them available for inspection and copying by DATCP upon request. A laboratory may not falsify any records.

### Notice to DNR and Lab of Hygiene

Pursuant to s. 93.12(5), Stats., the department has given notice of this rule to the department of natural resources and the state laboratory of hygiene.

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- 1           **SECTION 1.** HSS 165.01(1) and (2) are amended to read: ?
- 2           HSS 165.01(1) STATUTORY REQUIREMENT. Section 252.22, Laboratories, approval of, *doesn't exist*
- 3           Wis. Stats., requires in part: that laboratories, except physician office laboratories serving not
- 4           more than 2 physicians, performing clinical laboratory tests ~~or examinations of milk, water, and~~ *KS, oil*
- 5           ~~food products~~ for the purpose of protecting the health of the public shall apply to the department *det*
- 6           of health and social services for an evaluation of the examinations and appropriate certification;

1 that the certification normally will be valid for 12 months and subject to revocation, denial, or  
2 suspension for cause; that the department of health and social services shall establish certification  
3 standards; and that laboratories shall not operate without a certificate.

4 (2) OTHER PROGRAM RELATIONSHIPS. In addition to functioning for the attainment of  
5 reliable clinical, ~~water, milk, and food product~~ testing, the certification program endeavors to  
6 assure the development of clinical and disease control laboratory services to meet the needs and  
7 requirements of a number of federal and state health related programs and to achieve better  
8 laboratory morbidity reporting systems for disease detection and management. The health related  
9 laws or programs receiving input from the laboratory evaluation and certification program  
10 include the infant metabolic disorder testing law, alcohol analyses for implied consent and  
11 coroner motor vehicle and snowmobile death laws, codes for controlling enteric disease cases  
12 and carriers, the Wisconsin Hospital Approval Act, federal Medicare, Medicaid certification, and  
13 interstate laboratory licensure law, ~~and appropriate municipal, state, and federal laws controlling~~  
14 ~~the quality of laboratory testing services for water, milk, and food products.~~

15 SECTION 2. HSS 165.02(4) is repealed.

16 SECTION 3. HSS 165.02(8), (9) and (12)(intro.) are amended to read:

17 HSS 165.02(8) "Facility" means a clinical laboratory, or a blood bank laboratory, ~~or a~~  
18 ~~laboratory engaged in the testing of milk, water, or food products.~~

19 (9) "Laboratory" or "clinical laboratory" means a facility where microbiological,  
20 biological, physical, serological, chemical, hematological, immunological, cytological, or  
21 microscopic examinations of specimens taken from the human body, ~~milk, water, food products,~~  
22 or other matter, are performed for screening, diagnostic, and treatment purposes.

1 (12)(intro.) "Laboratory specialty" or "specialty" means a science discipline used for the  
2 examination of materials derived from the human body or other matter, for the purpose of disease  
3 prevention, laboratory screening, diagnosis or treatment of patients, ~~or the examination of milk,~~  
4 ~~water or food products for the purpose of determining purity, potability or freedom from harmful~~  
5 ~~substances.~~ For purposes of this chapter, laboratory specialties include but are not limited to the  
6 following:

*remember (a)*

7 **SECTION 4.** HSS 165.02(12)(b) is repealed.

8 **SECTION 5.** HSS 165.02(13) is amended to read:

9 HSS 165.02(13) "Local public health agency laboratory" means a laboratory operated by  
10 a single city or county health department, a multiple county health department, or a city-county  
11 health department which performs clinical, ~~milk, water, or food~~ tests for the prevention,  
12 detection, diagnosis, and control of disease.

13 **SECTION 6.** HSS 165.02(14) is repealed.

14 **SECTION 7.** HSS 165.02(17) is amended to read:

15 HSS 165.02(17) "Proficiency testing program" means those activities which are required  
16 by the department to define, monitor, and measure the accuracy of testing by a laboratory and  
17 which meet the applicable requirements of federal agencies for licensure or certification of  
18 clinical ~~and milk, water and food~~ laboratories.

19 **SECTION 8.** HSS 165.03 (intro.) is created to read:

20 HSS 165.03(intro.) The department designates the following examinations of body  
21 fluids, tissues, discharges, respiratory and environmental air as necessary for the health of the  
22 public:

*repeal & recreate*  
*see current 165-03 intro*  
*remember*

*a.k.  
reverse  
8d9*



1 (4) "Department" means the state of Wisconsin department of agriculture, trade and  
2 consumer protection.

3 (5) "FDA" means the United States department of health and human services, public health  
4 service, food and drug administration.

5 (6) "Food" has the meaning given in s. 97.01(6), Stats.

6 (7) "Food safety administrator" means the administrator of the department's division of  
7 food safety.

8 (8) "Individual" means a natural person.

9 (9) "Laboratory" means a facility at which an operator performs tests.

10 (10) "Laboratory administrator" means an individual who supervises a laboratory under s.  
11 ATCP 77.12.

12 (11) "Milk" means the lacteal secretion of cows, sheep or goats, and includes dairy  
13 products made from milk.

14 (12) "Operator" means a person who owns or controls a laboratory.

15 (13) "Person" means an individual, corporation, partnership, cooperative association,  
16 limited liability company, trust, or other organization or entity. "Person" includes counties,  
17 municipalities, the state of Wisconsin and agencies of the state.

18 (14) "Public health standard" means a federal, state or local statute, rule or ordinance which  
19 specifies a standard for the safety or wholesomeness of milk, water or food for human  
20 consumption.

21 (15) "Public water system laboratory" means a laboratory that tests water for a public water  
22 system as defined in <sup>s.</sup> NR 108.02(12).

1 (16) "Test" means a laboratory examination of milk, water or food.

2 **ATCP 77.02 Laboratory tests to protect public health.** For purposes of s. 93.12,  
3 Stats., the department declares that the following milk, water or food tests are necessary to  
4 protect public health:

5 (1) MILK. Any of the following tests related to milk and dairy products:

6 (a) Standard plate count.

7 (b) Plate loop count.

8 (c) Petrifilm aerobic count.

9 (d) Coliform plate count.

10 (e) Petrifilm coliform count.

11 (f) Charm BsDa.

12 (g) Charm I/ Cowside II.

13 (h) Charm II competitive.

14 (i) Charm II sequential.

15 (j) Charm II cloxacillin.

16 (k) Charm II sulfa.

17 (l) Charm II tetracycline.

18 (m) Delvotest P.

19 (n) Delvotest P 5 pack.

20 (o) LacTek B/L.

21 (p) LacTek ceftiofur.

22 (q) Penzyme milk.



- 1 (r) Penzyme III.
- 2 (s) SNAP B/L.
- 3 (t) Direct microscopic somatic cell count.
- 4 (u) Optical somatic cell count.
- 5 (v) Pasteurized milk containers.
- 6 (w) Phosphatase test; Scharer rapid method.
- 7 (x) Phosphatase test; fluorophos.
- 8 (y) Phosphatase test; Charm II.
- 9 (z) Tests performed to comply with ch. ATCP 60 or 80, other than milk component tests
- 10 which are not related to public health.

11 (2) FOOD. Any of the following tests related to food:

- 12 (a) Standard plate count.
- 13 (b) Plate loop count.
- 14 (c) Petrifilm aerobic count.
- 15 (d) Coliform plate count.
- 16 (e) Petrifilm coliform count.
- 17 (f) Other tests under ch. ATCP 75 to detect pathogens in food.

18 (3) WATER. Any of the following tests related to water:

- 19 (a) Multiple tube fermentation procedure (MTF).
- 20 (b) Membrane filter technique (MF).
- 21 (c) Enzymatic substrate (MMO-MUG).
- 22 (d) Clark's Presence/Absence (P/A).

1 (e) Heterotrophic plate count (HPC).

2 (f) Other tests under ch. NR 809 or 812 to detect microbiological contaminants in drinking  
3 water.

4 **ATCP 77.03 Laboratory certification; general.** (1) ANNUAL CERTIFICATION

5 REQUIRED. No person may perform, at any laboratory, a test listed under s. ATCP 77.02 to  
6 determine whether milk, food or water complies with public health standards required under  
7 federal or state law unless the department annually certifies the laboratory operator to perform  
8 that test at that laboratory. An annual certification expires on December 31 of each year.

*def. term  
mean to  
exclude  
local?*

9 (2) SCOPE OF CERTIFICATION. (a) A person who operates 2 or more laboratories shall  
10 obtain a separate certification under sub. (1) for each laboratory. A certification may not be  
11 transferred between operators or laboratories.

12 (c) The department shall identify, in each certification under sub. (1), the tests which the  
13 operator is certified to perform at that laboratory.

14 (3) CERTIFICATE DISPLAYED. An operator shall display, at a prominent location in each  
15 certified laboratory, the current certification issued for that laboratory under sub. (1).

16 (4) EXEMPTIONS. Subsection (1) does not apply to any of the following:

17 (a) The United States government.

18 (b) Milk testing by the department.

19 (c) An educational institution that operates a laboratory solely for teaching or academic  
20 research purposes, and does not test milk, water or food for human consumption.

21 (d) A person who operates a laboratory solely to conduct quality control tests on food or  
22 water sold by that person, provided that the tests are not required by statute, rule or ordinance.

1 **ATCP 77.04 Applying for certification.** (1) INITIAL APPLICATION. An operator shall

2 apply for initial certification under s. ATCP 77.03 on a form provided by the department. The  
3 operator shall submit a separate application for each laboratory. An application shall include all  
4 of the following:

5 (a) The operator's correct legal name and address, and any trade names used by the  
6 operator. The application shall indicate whether the operator is an individual, corporation,  
7 partnership, cooperative association, limited liability company, trust, or other organization or  
8 entity.

9 (b) The name, address and telephone number of the laboratory.

10 (c) The name of the laboratory administrator under s. ATCP 77.12.

11 (d) The tests under s. ATCP 77.02 for which the operator seeks certification.

12 (e) Documentation that the laboratory is qualified to perform each test which the  
13 operator identifies under par. (d). Documentation shall include all of the following:

- 14 1. Proof that the laboratory has all of the equipment needed to perform each test.
- 15 2. Written test procedures used for each test, or an identification of the standard test  
16 methods used for each test.
- 17 3. Proof of analytical proficiency in each test. Proof may consist of quality assurance  
18 test results from comparison studies, split samples or proficiency tests which meet the  
19 proficiency evaluation requirements under s. ATCP 77.24 or ~~ATCP~~ 77.34. The operator of a  
20 water laboratory shall also provide documentation required under s. ATCP 77.32.

21 **NOTE:** An operator may obtain application forms <sup>from</sup> and submit <sup>5)</sup>  
22 applications to the department at the following address:

23 Wisconsin Department of Agriculture, Trade and Consumer Protection  
24 Division of Food Safety, Bureau of Food Safety and Inspection

1 Laboratory Certification Program  
2 P.O. Box 8911  
3 Madison, WI. 53708-8911  
4 (608) 224-4719

5 (2) ANNUAL RENEWAL. To renew an annual certification, the operator of a certified  
6 laboratory shall file a renewal application with the department by December 31 of each year.  
7 The operator shall file the renewal application on a form provided by the department. The  
8 renewal application shall include all of the following:

9 (a) The information required under sub. (1) (a) to (d). The application shall identify any  
10 changes since the last annual renewal.

11 (b) The information required under sub. (1)(e) if the operator requests certification to  
12 perform a test which the department has not yet certified the operator to perform. *Do while the operator is not currently certified job* 5)

13 (c) The certification fees required under s. ATCP 77.06.

14 **NOTE:** The department will send renewal application forms to certified  
15 laboratories approximately 6 weeks before their current annual  
16 certifications expire.

17 (3) FALSE INFORMATION. No person may misrepresent or falsify any information  
18 contained in a certification application under this section.

19 **ATCP 77.06<sup>Operator</sup> Certification fees.** (1) FEE AMOUNTS. Except as provided under sub. (2)  
20 or (3), an operator shall pay an ~~annual certification fee of \$216 for each test at each laboratory~~  
21 ~~for which the operator is certified.~~ 2 ?

22 (2) PARTIAL FEES. If the department certifies an operator to perform a test for less than a  
23 full calendar year, the operator shall pay a fee of \$18 for each full month of certification for that  
24 test.

1 (3) FEE EXEMPTIONS. A county or municipality that contracts with the department to  
2 license and inspect retail food establishments as the department's agent under s. 97.41, Stats., is  
3 not required to pay any certification fee. *for the tests it performs under 97.41? (5)*

4 (4) PAYING CERTIFICATION FEES. (a) If the department has not previously certified an  
5 operator to perform any of the tests listed under s. ATCP 77.02 at the laboratory for which the  
6 operator is seeking certification, the department shall bill the operator under sub. (1) or (2) after  
7 the department inspects *and approves (5)* the laboratory under s. ATCP 77.14(1)(a). The department may not  
8 certify the operator to perform any test until the operator pays the required certification fee for  
9 that test.

10 (b) If the operator of a certified laboratory applies for certification to perform additional  
11 tests under sub. (5), or files a renewal application under s. ATCP 77.04(2), the operator shall  
12 include with that application the fees required under sub. (1) or (2).

13 (5) ADDITIONAL TESTS. The operator of a certified laboratory may, at any time, apply for  
14 certification to perform additional tests which the department has not yet certified the operator to  
15 perform at that laboratory. The operator shall apply on a form provided by the department. The  
16 application shall include all of the following:

- 17 (a) The additional tests for which the operator seeks certification.
- 18 (b) Documentation, under s. ATCP 77.04(1)(e), that the operator is qualified to perform  
19 each additional test under par. (a).
- 20 (c) The fees required under sub. (1) or (2).

21 **NOTE:** An operator may apply under sub. (5) at any time during a license  
22 year, and need not wait until the annual license renewal.

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1 **ATCP 77.08 Granting and withdrawing certification.** (1) GRANTING CERTIFICATION.

2 The department shall certify an operator under s. ATCP 77.03 if the operator and laboratory  
3 comply with this chapter. The department may conditionally certify an operator pending action  
4 by the operator to correct deficiencies which the department has identified. The department may  
5 summarily suspend a conditional certification, without prior hearing, if the operator fails to  
6 correct the deficiencies within the time specified by the department.

7 (2) DEADLINE FOR ACTION ON CERTIFICATION REQUEST. Within 40 calendar days after the  
8 department receives a complete application under s. ATCP 77.04, the department shall do all the  
9 following:

10 (a) Inspect the laboratory if an inspection is required under s. ATCP 77.14(1).

11 (b) Grant the application, grant the application subject to conditions, or deny the  
12 application.

13 (3) MILK AND FOOD LABORATORIES; CERTIFIED ANALYSTS. (a) The department may not  
14 certify an operator to perform any test under s. ATCP 77.02(1) or (2) unless the department has  
15 certified all of the analysts who perform that test at that laboratory.

16 (4) SUSPENDING OR REVOKING CERTIFICATION. The department may suspend or revoke  
17 an operator's certification for cause, including a violation of this chapter or failure to file  
18 required laboratory reports with other government agencies. The department shall comply with  
19 applicable requirements under ch. 227, Stats., and ch. ATCP 1.

20 **NOTE:** See ss. 93.06(7) and 93.12, Stats.

21 (5) SUMMARY SUSPENSION. The food safety administrator may issue a written notice,  
22 summarily suspending all or part of an operator's certification, if the food safety administrator  
23 finds in the suspension notice that the operator has not complied with this chapter, that the

1 noncompliance poses an imminent threat to the health or safety of the public or laboratory  
2 workers, and that the noncompliance is likely to continue unless the food safety administrator  
3 summarily suspends the operator's certification. The operator may contest the summary  
4 suspension according to s. ATCP 1.03(3).

5 **ATCP 77.10 Laboratory facilities.** (1) ADEQUATE FACILITIES. ~~A certified laboratory~~ *laborant actually*  
6 shall have all of the following: *operator*

7 (a) Adequate facilities, equipment and supplies to perform the tests which the operator is  
8 certified to perform at that laboratory.

9 (b) At least 5 linear feet of level bench top working space per analyst.

10 (c) At least 50 foot candles of light on each bench top.

11 (d) Effective climate controls to maintain proper temperature and humidity for testing.

12 (2) QUALITY CONTROL AND MAINTENANCE. The operator of a certified laboratory shall  
13 do all of the following:

14 (a) Maintain laboratory facilities, equipment and supplies in proper working condition.

15 (b) Maintain temperature-controlled equipment, including incubators, water baths,  
16 refrigerators and freezers, so that the equipment functions effectively. The operator shall  
17 measure and record equipment temperatures at least daily when the equipment is in use.

18 (c) Maintain autoclaves to ensure proper temperature and pressure throughout the entire  
19 sterilization cycle, and keep a record of autoclave maintenance.

20 (d) Calibrate each electronic test instrument as recommended by the instrument  
21 manufacturer, and record the results.

22 (e) Ensure that each reagent and solution is clearly labeled to show its identity, its titer  
23 or concentration, its expiration or preparation date, instructions for proper storage, and other

1 pertinent information. An operator shall store reagents and solutions according to the  
2 manufacturer's specifications.

3 (f) Ensure that glassware is free of chips, excessive scratches or cloudiness. Glassware  
4 used for measurement, including pipettes, graduated cylinders and volumetric flasks, shall have  
5 clear graduations.

6 (3) NOTICE OF MATERIAL CHANGES. An operator shall notify the department whenever  
7 the operator remodels laboratory facilities or installs new equipment if the remodeling or  
8 installation materially affects the performance of tests under s. ATCP 77.02 which the operator  
9 is certified to perform at that laboratory.

10 **ATCP 77.12 Laboratory administrator.** The laboratory administrator or a designated  
11 agent of the administrator shall be present at every certified laboratory during daytime business  
12 hours. The laboratory administrator shall do all of the following on behalf of the laboratory  
13 operator:

14 (1) Supervise the laboratory and its compliance with this chapter.

15 (2) Review and approve, for submission to the department, every certification application  
16 which the operator submits for that laboratory under s. ATCP 77.04.

17 (3) Supervise the procurement and maintenance of laboratory facilities, equipment and  
18 supplies, and notify the department of material changes under s. ATCP 77.10(3).

19 (4) Facilitate department inspections of the laboratory. At the request of the department,  
20 the administrator shall grant the department access to laboratory facilities, equipment and  
21 records, and shall arrange for analysts to demonstrate their testing proficiency.

22 (5) Notify the department of changes in laboratory analysts under s. ATCP 77.22(10).



1 (6) Notify all laboratory customers if the department suspends or revokes all or part of  
2 the laboratory's certification.

3 (7) Report test results to the appropriate regulatory agency, if required by law.

4 (8) Supervise laboratory recordkeeping under s. ATCP 77.16.

5 **ATCP 77.14 Inspecting a laboratory.** (1) MANDATORY INSPECTIONS. The department  
6 shall inspect a laboratory at all of the following times:

7 (a) Before certifying the operator under s. ATCP 77.03, for the first time, to perform tests  
8 at that laboratory.

9 (b) At least once every 2 years after the department first certifies the operator under s.  
10 ATCP 77.03 to perform tests at that laboratory.

11 (c) Before the department certifies the operator to perform a test under s. ATCP 77.02  
12 which the department has not previously certified that operator to perform at that laboratory.

13 (2) DISCRETIONARY INSPECTIONS. The department may inspect a certified laboratory  
14 whenever any of the following occurs:

15 (a) The operator materially alters laboratory facilities or equipment.

16 (b) The operator assigns a new analyst to perform a test for which the operator is  
17 currently certified.

18 (c) The department concludes that an inspection is necessary to determine whether the  
19 operator, or the operator's laboratory, complies with this chapter.

20 (3) INSPECTION AUTHORITY. The department may exercise its authority under <sup>ss-</sup> s. 93.08,  
21 93.14, 93.15, 93.16 and 97.12, Stats., in support of an inspection under this chapter. The  
22 department may suspend or revoke the certification of any operator who obstructs or fails to  
23 permit an inspection under this section.

1           **NOTE:** The department conducts its inspections during laboratory  
2           business hours. The department ordinarily pre-arranges inspection  
3           dates and times that are acceptable to laboratory operators, but is  
4           not required to do so. A person who obstructs or interferes with an  
5           inspection may also be subject to penalties under s. 93.21(2) or (4)  
6           or ~~s.~~ 97.12(4), Stats. ✓

7           **ATCP 77.16 Laboratory records.** (1) **RECORDS REQUIRED.** An operator shall make  
8           complete records related to all of the following:

9           (a) The training, experience and proficiency testing of every analyst who performs tests  
10          for which the laboratory is certified.

11          (b) Laboratory evaluations required under this chapter.

12          (c) Laboratory policies and procedures.

13          (d) Laboratory facilities, equipment and supplies, including records related to  
14          procurement, calibration, testing and maintenance.

15          (e) Quality control procedures and monitoring.

16          (f) Tests performed at the laboratory, including records related to the nature of the test,  
17          the person for whom the test is performed, the assigned analysts, the test methods used, the date  
18          and time of testing, and the test results obtained.

19          (g) Test reports filed with the department and other government agencies.

20          **NOTE:** For example, see reporting requirements under chs. ATCP 60, 70  
21          and 80, and chs. NR 809 and 812.

22          (2) **RECORD RETENTION; AVAILABILITY.** (a) The operator of a milk or food laboratory  
23          shall retain all records under sub. (1) for at least 2 years. The operator of a water laboratory shall  
24          retain all records under sub. (1) for at least 5 years.  
25          retain all records under sub. (1) for at least 5 years.

26          (b) An operator shall make records under sub. (1) available to the department for  
27          inspection and copying upon request.

1 (c) An operator may keep records under sub. (1) in hard copy or electronic form, or both,  
2 provided that the department can obtain ready access to the records.

3 (d) An operator shall take reasonable security measures to prevent record loss, damage or  
4 tampering.

5 (3) FALSIFYING RECORDS. No operator may falsify any laboratory records.

6 SUBCHAPTER II

7 MILK AND FOOD LABORATORIES

8 **ATCP 77.20 Milk and food laboratories; procedures.** (1) TEST METHODS. An

9 operator who performs any test listed under s. ATCP 77.02(1) and (2) shall perform that test  
10 according to methods specified in applicable reference materials under sub. (2), or according to  
11 methods which the department approves in writing.

12 (2) REFERENCE MATERIALS. (a) *General.* An operator who performs any test listed  
13 under s. ATCP 77.02(1) or (2) shall keep, at the certified laboratory, the manufacturer's complete  
14 operating and maintenance instructions for equipment used to perform that test.

15 (b) *Milk tests.* An operator who performs any test listed under s. ATCP 77.02(1) shall  
16 keep the following reference materials at the certified laboratory:

- 17 1. The FDA 2400 series laboratory evaluation forms for that test.  
18 2. The "Standard Methods for the Examination of Dairy Products," 16th edition,  
19 published by the American Public Health Association, Inc.

20 (c) *Food tests.* An operator who performs any test listed under s. ATCP 77.02(2) shall  
21 keep all of the following reference materials at the certified laboratory:

- 22 1. The authoritative reference manual, if any, that applies to each type of food testing for  
23 which the laboratory is certified.

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1 2. The "Compendium of Methods for Microbiological Examination of Foods," 3rd  
2 edition, published by the American Public Health Association, Inc.

3 3. The FDA "Bacteriological Annual Manual," 8th edition, if the operator performs a  
4 microbiological test on food. *Culture is specified? (2)*

5 **NOTE:** Copies of reference manuals cited under sub. (2) are on file with  
6 the department, the secretary of state and the revisor of statutes.  
7 To find out how to order these manuals from the publishers, you  
8 may contact the department at the following address:

9 Wisconsin Department of Agriculture, Trade and Consumer Protection  
10 Division of Food Safety, Bureau of Food Safety and Inspection  
11 Laboratory Certification Program  
12 P.O. Box 8911  
13 Madison, WI. 53708-8911  
14 (608) 224-4719

15 (3) CULTURE MEDIA. Culture media used for any test listed under s. ATCP 77.02(1) or  
16 (2) shall be effectively sterilized before they are used. Culture media shall be autoclaved for the  
17 total cycle time and sterilization time specified by the media manufacturer or by the applicable  
18 test method under this section.

19 **ATCP 77.22 Milk and food laboratories; certified analysts.** (1) CERTIFICATION  
20 REQUIRED. No analyst may perform a test listed under s. ATCP 77.02(1) or (2) unless the  
21 department certifies that analyst to perform that test. The department shall certify the analysts  
22 employed at a laboratory when it conducts a mandatory inspection of that laboratory under s.  
23 ATCP 77.14(1). The department may certify new analysts, or certify analysts to perform  
24 additional tests, at other times.

25 (2) TERM OF CERTIFICATION. An analyst's certification to perform a test remains in effect  
26 until one of the following occurs:

1 (a) The department conducts the next biennial inspection of the laboratory under s.  
2 ATCP 77.14(1).

3 (b) The analyst is no longer employed at the laboratory where the analyst was employed  
4 when the department last granted or renewed the analyst's certification.

5 (c) The department suspends or revokes the analyst's certification.

6 (3) COMPETENCY EVALUATION. (a) Before the department certifies an analyst to perform  
7 any test listed under s. ATCP 77.02(1) or (2), the department shall observe and evaluate that  
8 analyst's competency to perform that test.

9 (b) Whenever the department performs a mandatory inspection of a laboratory under s.  
10 ATCP 77.14(1), the department shall perform a competency evaluation under par. (a) of every  
11 analyst who performs a test listed under s. ATCP 77.02(1) or (2).

12 (c) The department shall use an appropriate FDA 2400 series form or, if no FDA 2400  
13 series form applies, another standard form to evaluate an analyst's competency under par. (a). If  
14 an analyst performs plate loop counts or electronic somatic cell counts, the department shall  
15 check the analyst's ability to perform the statistical comparisons required by those tests.

16 (4) ANNUAL PROFICIENCY EVALUATION. An analyst who performs a test listed under s.  
17 ATCP 77.02(1) or (2) shall complete an annual proficiency evaluation for that test if an annual  
18 proficiency evaluation is required under s. ATCP 77.24.

19 (5) CONDITIONAL CERTIFICATION. *for how long is conditional if failed?*  
20 analyst is competent to perform a test, but the analyst has not yet completed a proficiency  
21 evaluation under s. ATCP 77.24 for that test, the department shall conditionally certify the  
22 analyst. If a conditionally certified analyst fails a proficiency evaluation under s. ATCP 77.24,  
23 the department shall summarily suspend the analyst's certification to perform that test.

1 (6) FULL CERTIFICATION. If the department determines under sub. (3) that an analyst is  
2 competent to perform a test, and the analyst also passes a proficiency evaluation under s. ATCP  
3 77.24 for that test, the department shall fully certify that analyst to perform that test.

4 (7) PROVISIONAL CERTIFICATION. If a fully certified analyst fails a proficiency evaluation  
5 under s. ATCP 77.24 for any test, the department shall issue a notice stating that the analyst is  
6 provisionally certified <sup>for 1 year only</sup> to perform that test. If a provisionally certified analyst passes a  
7 proficiency evaluation under s. ATCP 77.24 on a new set of proficiency samples, the department  
8 shall restore the analyst to full certification. If a provisionally certified analyst fails a proficiency  
9 evaluation on a new set of proficiency samples, the department shall summarily suspend the  
10 analyst's certification to perform that test.

11 (8) RESTORING CERTIFICATION. The department may restore the certification of any  
12 analyst whose certification is summarily suspended under sub. (5) or (7) if the analyst completes  
13 a training program approved by the department and passes a proficiency evaluation under s.  
14 ATCP 77.24 on a new set of proficiency samples. The department shall restore the analyst to full  
15 certification, even if the analyst was conditionally certified when certification was suspended.

16 (9) LIST OF CERTIFIED ANALYSTS. The department shall maintain, for each certified  
17 laboratory, a list of analysts currently certified to perform tests listed under s. ATCP 77.02(1) and  
18 (2). The list shall identify the tests which each analyst is certified to perform.

19 (10) NOTICE OF CHANGES. (a) An operator shall notify the department within 30 days  
20 after any of the following occurs:

- 21 1. An analyst certified under this section is no longer employed by the laboratory.
- 22 2. There is a change in the name of any analyst certified under this section.

1 (b) An operator shall notify the department of a staffing change within 7 days after that  
2 change occurs if, as a result of that change, the operator no longer meets applicable certification  
3 requirements under s. ATCP 77.08(3).

4 **ATCP 77.24 Milk and food analysts; proficiency evaluation.** (1) ANNUAL  
5 PROFICIENCY EVALUATION REQUIRED. Except as provided in sub. (4), the department may not  
6 renew an analyst's certification to perform any test listed under s. ATCP 77.02(1) or (2) unless,  
7 within the year immediately preceding that renewal, the analyst passes a proficiency evaluation  
8 for that test. The proficiency evaluation shall comply with this section.

9 (2) FORM OF EVALUATION. In a proficiency evaluation under sub. (1), an analyst shall  
10 examine samples prepared by an approved evaluator under sub. (3). The contents of the samples  
11 shall be known only to the evaluator. The evaluator shall rate the analyst's proficiency by  
12 comparing the analyst's results to the known contents of the samples, and shall report those  
13 results and ratings to the department.

14 (3) APPROVED EVALUATOR. The department, or another evaluator approved by the  
15 department in writing, shall serve as a proficiency evaluator under sub. (2).

16 **NOTE:** The department will approve an evaluator under sub. (3) if FDA *also*  
17 approves that evaluator for the same purpose. *sub. 6*

18 (4) EVALUATION PROCEDURE; GENERAL. A proficiency evaluation under sub. (1) shall be  
19 conducted according to a standard evaluation procedure which the department approves in  
20 writing. *procedure by approval* An analyst is not required to complete a proficiency evaluation for any test unless the  
21 department has approved a standard evaluation procedure for that test. A standard evaluation  
22 procedure shall comply with applicable requirements under sub. (5), and shall include standards  
23 for all of the following:

- 1 (a) The evaluator's preparation of proficiency evaluation samples.
- 2 (b) The analyst's examination of proficiency evaluation samples.
- 3 (c) Deadlines for examining proficiency evaluation samples and reporting test results.
- 4 (d) The evaluator's review and rating of the analyst's proficiency.

5 (5) MILK TESTS; EVALUATION STANDARDS. (a) Proficiency evaluations for the following  
6 tests under s. ATCP 77.02(1) shall test include at least the following number of samples:

- 7 1. At least six but not more than 20 samples for standard plate count, petrifilm aerobic  
8 count, plate loop count, or phosphatase tests.
- 9 2. At least eight but not more than 20 samples for direct microscopic somatic cell counts,  
10 electronic somatic cell counts, drug residue tests, or coliform tests

11 (b) To pass a proficiency evaluation under par. (a) which involves 6 to 10 samples, an  
12 analyst shall obtain no more than one unacceptable sample result. To pass a proficiency  
13 evaluation under par. (a) which involves 11 to 20 samples, an analyst shall obtain no more than 2  
14 unacceptable sample results.

15 (c) In a proficiency evaluation for any of the following tests, a sample result is  
16 unacceptable if it falls outside the statistical limits established in FDA's "Evaluation of Milk  
17 Laboratories," 1995 edition.

- 18 1. Standard plate count.
- 19 2. Petirfilm aerobic count.
- 20 3. Plate loop count.
- 21 4. Direct microscopic somatic cell count.
- 22 5. Electronic somatic cell count.



1 (d) In a proficiency evaluation for a test, such as a drug residue or phosphatase test, in  
2 which sample test results are reportable as positive or negative, a sample result is unacceptable if  
3 the analyst fails to report the correct positive or negative result.

4 (e) In a proficiency evaluation for a coliform test, a sample result is unacceptable if the  
5 analyst fails to detect coliform in a sample that contains at least five coliform organisms per  
6 milliliter or per gram of product.

### 7 SUBCHAPTER III

### 8 WATER LABORATORIES

9 **ATCP 77.30 Water laboratories; procedures.** (1) **TEST METHODS.** An operator who  
10 performs any test listed under s. ATCP 77.02(3) shall perform that test according to methods  
11 specified in applicable reference materials under sub. (2), or according to methods which the  
12 department approves in writing.

13 (2) **REFERENCE MATERIALS.** An operator who performs any test listed under s. ATCP  
14 77.02(3) shall keep all of the following reference materials at the certified laboratory:

15 (a) The manufacturer's complete operating and maintenance instructions for equipment  
16 used to perform that test.

17 (b) The U.S. environmental protection agency "Manual for the Certification of  
18 Laboratories Analyzing Drinking Water," 4th edition.

19 (c) "Standards Methods for the Examination of Water and Wastewater," 18th or 19th  
20 edition, published by the American Public Health Association, the American Water Works  
21 Association and the Water Environment Federation.

22 (3) **CULTURE MEDIA.** Culture media for any test listed under s. ATCP 77.02(3) shall be  
23 effectively sterilized before they are used. Culture media shall be autoclaved for the total cycle

1 time and sterilization time specified by the media manufacturer or by the applicable test method  
2 under this section.

3 **ATCP 77.32 Water laboratory analysts.** (1) OPERATOR TO DOCUMENT COMPETENCY.

4 In every initial or renewal application for water laboratory certification, a laboratory operator  
5 shall document that the analysts who perform each test under s. ATCP 77.02(3) for which the  
6 laboratory seeks certification are properly trained to perform that test, and can accurately test  
7 positive and negative blind samples. Analysts are not required to be certified by the department.

8 (2) DEPARTMENT TO AUDIT COMPETENCY. Whenever the department performs a  
9 mandatory inspection of a water laboratory under s. ATCP 77.14(1), the department shall  
10 observe and evaluate the competency of at least one analyst who performs tests under s. ATCP  
11 77.02(3) for which the department is certifying the water laboratory. The department shall use  
12 the United States environmental protection agency "Manual for the Certification of Laboratories  
13 Analyzing Drinking Water," 4th edition, to evaluate the analyst's competency.

14 **ATCP 77.34 Water laboratories; proficiency evaluation.** (1) EVALUATION REQUIRED.

15 Except as provided in sub. (4), the department may not issue or renew an operator's certification  
16 to perform any test listed under s. ATCP 77.02(3) unless, within the year immediately preceding  
17 that certification or renewal, the laboratory passes a proficiency evaluation for that test.

18 (2) FORM OF EVALUATION. In a laboratory proficiency evaluation under sub. (1), an  
19 operator shall assign an analyst to examine samples prepared by an approved evaluator under  
20 sub. (3). The contents of the samples shall be known only to the evaluator. The analyst who  
21 examines the samples shall be an analyst who normally performs that test at the certified  
22 laboratory. The evaluator shall rate the operator's proficiency by comparing the analyst's results  
23 to the known contents of the samples, and shall report those results and ratings to the department.

1 (3) APPROVED EVALUATOR. The state of Wisconsin laboratory of hygiene, or another  
2 evaluator approved by the department in writing, shall be the evaluator in a proficiency  
3 evaluation under sub. (1). (5)

4 (4) EVALUATION PROCEDURE; GENERAL. A proficiency evaluation under sub. (1) shall be  
5 conducted according to a standard evaluation procedure which the department approves in  
6 writing. An operator is not required to complete a proficiency evaluation for any test unless the  
7 department has approved a standard evaluation procedure for that test. A standard evaluation  
8 procedure shall include standards for all the following:

- 9 (a) The evaluator's preparation of proficiency evaluation samples.
- 10 (b) The operator's examination of proficiency evaluation samples.
- 11 (c) Deadlines for examining proficiency evaluation samples and reporting test results.
- 12 (d) The evaluator's review and rating of the operator's proficiency.

13 (5) DRINKING WATER TESTS; EVALUATION PROCEDURES. Beginning on July 1, 1999,  
14 standard evaluation procedures for tests under s. ATCP 77.02(3) shall include the following  
15 requirements:

16 (a) An operator who is evaluated for proficiency in testing for total coliform and fecal  
17 coliform or E. coli shall examine at least 10 samples of at least 100 ml. each annually. The  
18 evaluator shall provide full volume samples, or the concentrate and diluents needed to  
19 reconstitute the concentrates to full volume. Each sample set shall include all of the following:

- 20 1. One to 4 samples of an aerogenic strain of Escherichia coli which, if properly tested  
21 according to methods under s. ATCP 77.30(1), will test positive for total and fecal coliform.

1 2. One to 4 samples of Enterobacter sp. or other microorganisms which, if properly  
2 tested according to methods under s. ATCP 77.30(1), will test positive for total coliform and  
3 negative for fecal coliform.

4 3. One to 4 samples of Pseudomonas sp. or other microorganisms which, if properly  
5 tested according to methods under s. ATCP 77.30(1), will test negative for total coliform and  
6 fecal coliform.

7 4. One to 4 blank samples.

8 (b) An operator testing proficiency evaluation samples under par. (a) shall report the test  
9 results to the evaluator. *when?* The evaluator shall report the test results to the department within 40  
10 calendar days after the evaluator mails or delivers the samples under par. (a) to the operator. For *5)*  
11 each sample tested, the evaluator shall report the operator's test result for total coliform and fecal  
12 coliform or E. coli, and shall indicate whether that test result is correct or incorrect.

13 (c) To pass a proficiency evaluation under par. (a), an operator shall report the correct  
14 result on 90 percent of the samples tested, with no false negatives.

15 (6) FULL CERTIFICATION. The department may fully certify an operator to perform a  
16 test if, in a proficiency evaluation under this section, the operator meets applicable performance  
17 standards under subs. (4) and (5).

18 (7) PROVISIONAL CERTIFICATION; SUSPENSION. (a) If, in any proficiency  
19 evaluation under this section, an operator fails to meet applicable performance standards under  
20 subs. (4) and (5), the department shall issue a notice stating that the operator's certification to  
21 perform that test is provisional. *how about initial cert?*

22 (b) A provisionally certified operator may regain full certification by meeting applicable  
23 standards under subs. (4) and (5) on the next 2 consecutive proficiency evaluations.

- 1 (c) If a provisionally certified operator fails to meet applicable performance standards  
2 under subs. (4) and (5) on the either of the next 2 proficiency evaluations, the department shall  
3 summarily suspend the operator's certification to perform that test. The department may fully  
4 restore the operator's certification if the operator does both of the following:  
5 1. Documents the steps which the operator has taken to correct the performance  
6 deficiency.  
7 2. Meets applicable performance standards under subs. (4) and (5) on a new proficiency  
8 evaluation.

9 **SECTION 16. Effective date.** Except as provided under s. ATCP 77.34(5) as created  
10 by this order, the rules contained in this order shall take effect on the first day of the month  
11 following publication in the Wisconsin administrative register, as provided under s. 227.22(2)  
12 (intro.), Stats.

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 1999.

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

By \_\_\_\_\_  
Ben Brancel, Secretary

FISCAL ESTIMATE

DOA-2048 (R 10/94)

- ORIGINAL       UPDATED  
 CORRECTED       SUPPLEMENTAL

1997 Session

LRB or Bill No. / Adm. Rule No.  
ATCP 77

Amendment No. (If Applicable)

Subject

Laboratory Certification

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 Unit Affected:

- Towns       Villages       Cities  
 Counties       Others \_\_\_\_\_  
 School Districts       WTCS Districts

Fund Source Affected

- GPR       FED       PRO       PRS       SEG       SEG-S

Affected Ch. 20 Appropriations

Assumptions Used in Arriving at Fiscal Estimate

The laboratory evaluation and certification program for milk water and food laboratories was transferred from the Department of Health and Family Services to the Department of Agriculture, Trade and Consumer Protection in July, 1996. The current ch. ATCP 77 was adopted at that time to allow DATCP to collect fees to cover the cost of the program. Certification requirements which apply to milk water and foods laboratories are currently in ch. HFS 165.

The proposed repeal and recreation of ch. ATCP 77 will complete the transfer of the certification program for milk water and food laboratories from DHFS to DATCP. The proposed rule does not substantially change the way in which a lab survey is conducted. The proposed rule uses concepts from ch. HSS 165 for certification of clinical laboratories, but changes the language to that which is specific and more appropriate for milk, water, and food laboratories. Therefore, there will be no state fiscal effect from the addition of the substantive provisions in ch. ATCP 77. The fee structure adopted in January, 1997, is not changed in the proposed rule.

There may be a small effect on local government costs. Under ch. HSS 165, water laboratories were not required to run proficiency tests. The proposed rule requires all laboratories that do official testing to participate in some form of proficiency testing. A municipal water plant would pay approximately \$300 per year to obtain the samples plus the cost of testing the samples.

Long - Range Fiscal Implications

Agency/prepared by: (Name & Phone No.)

DATCP  
C. T. Leitzke, 608/224-4711

Authorized Signature/Telephone No.

*Barbara Knapp*  
Barbara Knapp (608) 224-4746

Date

8/25/98

## APPENDIX A

### SUMMARY OF HEARING TESTIMONY

#### REPEAL AND RECREATION OF CHAPTER ATCP 77 AMENDMENTS TO CHAPTER HSS 165

#### CERTIFICATION OF LABORATORIES ENGAGED IN PUBLIC HEALTH TESTING OF MILK, WATER AND FOOD

The Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) held one public hearing on November 12, 1998 simultaneously in four locations in the state by video-conferencing. The hearing locations were: Madison, Milwaukee, Green Bay and Eau Claire. Copies of the rule had been mailed out to all affected parties and were available at each hearing location the day of the hearing.

A total of 20 people attended the public hearing, of which 9 provided oral testimony. Two individuals registered their opinion but did not speak. The primary issues of concern presented during the oral testimony are summarized on the following page.

SPEAKER/ REGISTRANT #	NAME & AFFILIATION	POSITION
1	Jacqueline Papple - Alto Dairy Cooperative	opposed
2	Jeff MacDonald - Milwaukee Metro Sewerage District	other
3	Steve Heraly - Robert E. Lee & Associates (environmental lab)	opposed
4	John Manske - Wisconsin Federation of Cooperatives	neither
5	Barbara Burmeister - State Laboratory of Hygiene	opposed
6	Paul Harris - Davy Laboratories & Wisconsin Environmental Laboratories Association	opposed
7	John Umhoefer - WI Cheese Makers' Association	neither
8	Tom Luoko - Sartori Foods Corporation	support
9	Brad Legreid - WI Dairy Products Association	support
10	Art Lautenbach - Robert E. Lee & Associates (registered, did not speak)	opposed
11	Bruce Liebzeit - AMPI Falls Dairy Division (registered, did not speak)	neither

**APPENDIX A**

**SUMMARY OF HEARING TESTIMONY (CONTINUED)**

SPEAKER #	TOPIC OF TESTIMONY
1,4	Clarify consequences of failing milk proficiency testing, including procedures for regaining certification once it is lost for failing proficiency testing.
1,7	The word proficiency is used in two ways -- To refer to demonstrated competence and to refer to the split samples.
1,4,7	Conditional certification is not defined in the rule
1,6,7	Clarify operator certification vs. Laboratory Certification vs. Individual Analyst Certification
2,3,6	Include laboratory certification for effluents, sludges and biosolids in this rule.
3,6	More clearly separate milk and food lab certification from drinking water certification.
3	Clarify language such that it is evident that drinking water labs are certified, that individual drinking water lab analysts are not certified.
3,5,6	Change passing score for drinking water proficiency test from 100% correct to 90% correct with no false negatives.
3,6	Clarify consequences of failing drinking water proficiency testing, including procedures for regaining certification once it is lost for failing proficiency testing.
7	Clarify that "other tests" under milk tests certified does not include test for milk quality.
7	Clarify analyst certification criteria. Can an analyst that has successfully participated in split samples, but has not had an on-site evaluation do official testing?
8	Create a standard in the state that requires all food labs in the state to be certified.



## APPENDIX A

### SUMMARY OF HEARING TESTIMONY (CONTINUED)

In addition to the oral testimony, 5 written comments were received from businesses which did not present testimony at the hearing sites:

WRITER #	NAME & AFFILIATION
1	Barbara Hedden - Kenosha Water Utility
2	W. Joe Nosek, Jr. - Northern Lake Services (Environmental lab)
3	Dan Elwood - Commonwealth Technology, Inc. (Environmental lab)
4	A. John Scheidenhelm - Marigold Foods, Inc.
5	Stephen Taylor, Brenda Benbrooks - Badger Laboratories & Engineering (Environmental lab)

WRITER #	TOPIC OF TESTIMONY
1	Clarify language such that it is evident that in drinking water labs all analysts are not required to be present for the on-site.
1	Change calibration requirements to read: calibrate equipment as per manufacturer's prescribed frequency.
1	Clarify consequences of failing drinking water proficiency testing, including procedures for regaining certification once it is lost for failing proficiency testing.
1,2,3	Change passing score for drinking water proficiency test from 100% correct to 90% correct with no false negatives.
2	More clearly separate milk and food lab certification requirements from drinking water certification requirements.
3	Provisional and Conditional certifications are not defined in the rule
4	Do not list specific editions of the manuals. Listing specific editions requires the rule to be changed each time a new edition is printed.
5	Clarify language such that it is evident that drinking water labs are certified, that individual drinking water lab analysts are not certified.
5	Change water laboratory record retention requirements from 5 years to 3 years.

## APPENDIX B

**1997 Session**

FISCAL ESTIMATE

DOA-2048 (R 10/94)

ORIGINAL       UPDATED  
 CORRECTED       SUPPLEMENTAL

LRB or Bill No. / Adm. Rule No.  
**ATCP 77**

Amendment No. (If Applicable)

**Subject**

Laboratory Certification

**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 Unit Affected:

Towns       Villages       Cities  
 Counties       Others \_\_\_\_\_  
 School Districts       WTCS Districts

**Fund Source Affected**

GPR       FED       PRO       PRS       SEG       SEG-S

Affected Ch. 20 Appropriations

**Assumptions Used in Arriving at Fiscal Estimate**

The laboratory evaluation and certification program for milk water and food laboratories was transferred from the Department of Health and Family Services to the Department of Agriculture, Trade and Consumer Protection in July, 1996. The current ch. ATCP 77 was adopted at that time to allow DATCP to collect fees to cover the cost of the program. Certification requirements which apply to milk water and foods laboratories are currently in ch. HFS 165.

The proposed repeal and recreation of ch. ATCP 77 will complete the transfer of the certification program for milk water and food laboratories from DHFS to DATCP. The proposed rule does not substantially change the way in which a lab survey is conducted. The proposed rule uses concepts from ch. HSS 165 for certification of clinical laboratories, but changes the language to that which is specific and more appropriate for milk, water, and food laboratories. Therefore, there will be no state fiscal effect from the addition of the substantive provisions in ch. ATCP 77. The fee structure adopted in January, 1997, is not changed in the proposed rule.

There may be a small effect on local government costs. Under ch. HSS 165, water laboratories were not required to run proficiency tests. The proposed rule requires all laboratories that do official testing to participate in some form of proficiency testing. A municipal water plant would pay approximately \$300 per year to obtain the samples plus the cost of testing the samples.

**Long - Range Fiscal Implications**

Agency/prepared by: (Name & Phone No.)

DATCP  
C. T. Leitzke, 608/224-4711

Authorized Signature/Telephone No.

*Barbara Knapp*  
Barbara Knapp (608) 224-4746

Date

8/25/98

## APPENDIX C

### Final Regulatory Flexibility Analysis

The repeal and recreation of ch. ATCP 77, Wis. Adm. Code, Laboratory Certification will have a small fiscal impact on small businesses as defined in s. 227.114 (1)(a), Stats. Approximately 200 laboratories are currently licensed and inspected by the department. The laboratories range from small establishments that are only certified for one test to large dairy cooperatives that have a full service milk testing laboratory at one or more locations.

the laboratory certification rule replaces the existing rule (HSS 165). The standards are based on established federal (FDA and EPA) guidelines and are designed to be consistent with other state and local requirements. The changes from HSS 165 are designed to replace the clinical language with language that is more applicable to milk, water, and food testing laboratories. The fee structure outlined in the current ATCP 77 is unchanged.


Key issues in the proposed rule include:

- modifying all language that refers to clinical laboratory testing and substituting language that is applicable to milk, water, and food laboratories;
- application requirements;
- procedures for suspending or revoking a laboratory's certification;
- basic requirements for laboratory facilities and equipment;
- responsibilities of a laboratory administrator;
- record keeping and reporting requirements, including the reporting of changes in laboratory facilities, equipment and personnel;
- adding the requirement for proficiency testing for water laboratories and identification of acceptable levels of performance;
- certification of individual analysts for performing milk and food tests;

The addition of the required proficiency testing for water laboratories will have a fiscal impact on municipal water plants. These water labs will pay approximately \$300 per year for proficiency samples and the cost of testing those samples. The proposed laboratory certification rules will have a negligible fiscal impact on private water labs and milk and food laboratories. It should not be necessary for any type of certified laboratory to retain additional professional services to comply with this rule.

Dated this 8th day of January, 1999

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

By   
Steven B. Steinhoff, Administrator  
Division of Food Safety

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

NOTICE OF HEARING

RULES RELATED TO CERTIFICATION FEES FOR LABORATORIES ENGAGED IN  
PUBLIC HEALTH TESTING OF MILK, WATER AND FOOD

The State of Wisconsin Department of Agriculture, Trade and Consumer Protection announces that it will hold public hearings on proposed amendments to ch. ATCP 77, Wis. Adm. Code, relating to certification fees for laboratories engaged in public health testing of milk, water and food. The hearings will be held at the times and places shown below. The public is invited to attend the hearings and make comments on the proposed rule. Following the public hearings, the hearing record will remain open until June 30, 1999, for additional written comments.

A copy of this rule may be obtained free of charge, from the Wisconsin Department of Agriculture, Trade and Consumer Protection, Division of Food Safety, 2811 Agriculture Drive, P.O. Box 8911, Madison WI 53708, 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 July 15, 1996 either by writing to Debbie Mazanec, 2800 Agriculture Drive, P.O. Box 8911, Madison, WI 53708, (608- 224-4712 ), or by contacting the message relay system (TTY) at 608-266-4399 to forward your call to the Department at 608-224-5058. Handicap access is available at the hearings.

Three (3) hearings are scheduled. The hearings will be held simultaneously by videoconferencing at the following locations on Friday, June 18, 1999, from 9:00 a.m. - 10:30 a.m.

Wisconsin Department of Agriculture, Trade and Consumer Protection  
Room 472  
2811 Agriculture Drive  
Madison, WI 53704  
Handicapped accessible

State of Wisconsin Office Building  
Room 618  
200 North Jefferson Street  
Green Bay, WI 54301  
Handicapped accessible

State of Wisconsin Office Building  
Room 139  
718 West Clairemont Avenue  
Eau Claire, WI 54701  
Handicapped accessible

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

Statutory authority: ss. 93.07(1) and 93.12(4) and (7), Stats.

Statutes interpreted: ss. 93.12(4) and (7), Stats.

The 1995-97 biennial budget act, 1995 Wis. Act. 27, transferred administration of Wisconsin's laboratory certification program for milk, food and water laboratories from the department of health and family services to the department of agriculture, trade and consumer protection ("department"), effective July 1, 1996.

Under this program, the department is now responsible for certifying laboratories that test milk, food or water for compliance with public health standards prescribed by federal, state or local laws. Under 1995 Wis. Act 27, the department's public health lab certification program must be funded by certification fees paid by the certified laboratories. The department must establish these fees by rule.

The department adopted the current fees in 1996. Under current rules, a laboratory operator must pay an annual certification fee of \$216 for each test at each laboratory for which the operator is certified. If a laboratory operator performs a test for less than a full calendar year, the annual certification fee is prorated at \$18 per month for each full month of certification for that test. Under current rules, milk and food laboratories pay the same fees as water laboratories.

This rule amends the current fee structure to account for cost differences between different types of laboratories. Certification of milk and food laboratories requires more time than certification of water laboratories. In a milk or food laboratory, the department must also certify each individual analyst who performs any milk or food test. In a water laboratory, the department is only required to certify one analyst who performs the water test for which the department is certifying the laboratory.

This rule increases lab certification fees to provide sufficient program revenue to fund the lab certification program. It also creates a variable fee schedule that more closely reflects the time required to conduct on-site certification visits in different types of labs and, when required, determine the competency of individual analysts to conduct specific tests.

Under the proposed rule, a certified laboratory must pay the following applicable fees:

- *Water tests.* An annual certification fee of \$276 for each test which detects microbiological contaminants in drinking water. If the department certifies a water laboratory to perform a test for less than a full calendar year, the lab operator must pay a fee of \$23 for each full month of certification.
- *Milk or food tests.* An annual certification fee of \$336 for each milk or food test. If the department certifies a milk or food laboratory to perform a test for less than a full calendar year, the lab operator must pay a fee of \$28 for each full month of certification.
- *Certified analysts who perform milk or food tests.* An annual certification fee of \$25 for each analyst who performs one or more milk or food tests. An analyst's certification is valid for an entire year, even if the analyst is no longer employed at the laboratory where the analyst was employed when the department last granted or renewed the analyst's certification.

*Additional analyst certification.* A supplemental fee of \$150 for each requested certification of one or more analysts to conduct any milk or food test, if the certification occurs at any time other than during a mandatory inspection.

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### FISCAL ESTIMATE

The proposed rule increases fees for laboratory certification to offset the costs of this program as required in s. 93.12, Wis. Stats.

The Department certifies approximately 180 milk, food and water laboratories in Wisconsin. Currently, the laboratory certification program is underfunded. Portions of this program are mandatory. The Federal Pasteurized Milk Ordinance (PMO) requires laboratories examining milk and water for the grade A dairy industry to be certified. In order for grade A dairy plants to ship fluid milk and milk products out of state, the milk they process and the water they use must be examined at a laboratory certified under this program. About 85% of milk produced in Wisconsin is shipped out of state.

Certain local health departments and local units of government operate certified laboratories. These may be milk and water laboratories or water only laboratories. These are currently certified by the Department. These laboratories currently pay laboratory certification fees unless they are exempted from paying fees by being an agent of the Department for the retail food inspection program.

As stated above, this program is underfunded.

- A. During the current fiscal year the Department collected \$123,000.
- B. The program is authorized 2.5 FTE's requiring \$160,000 annual funding.

C. Proposed fees will likely generate \$182,000 annually, which should support the program for four (4) years without any additional fee increases.

The proposed annual fee schedule is as follows:

- A. Milk or food test - \$336
- B. Water test - \$276
- C. Analyst fee - \$ 25
- D. New analyst fee - \$150

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### **INITIAL REGULATORY FLEXIBILITY NOTICE**

This rule establishes fees for certification of laboratories examining milk, food or water for the protection of public health. The 1995-97 biennial budget act transferred much of the administration of Wisconsin's laboratory certification program from the Department of Health and Family Services (DHFS) to the Department of Agriculture, Trade and Consumer Protection (DATCP). Shortly after that transfer, DATCP proposed rules establishing fees to offset the costs of certification of laboratories as required in s. 93.12, Wis. Stats. These fees are based on recovering 100% of the costs of this program from the industry affected by the program. Those rules also required the DATCP to evaluate laboratory certification fees by FY 2000 and make appropriate adjustments to the fees.

The approximately 180 laboratories currently certified range from small, one person laboratories to large facilities with dozens of analysts. This rule will have a fiscal impact on "small businesses" as defined in s. 227.114(1)(a) Wis. Stats. Annual laboratory fees are increased as compared to the \$216 per test fee currently charged by DATCP. This fee increase is due to the fact that the laboratory certification program is inadequately funded. Inadequate funding occurs because the number of laboratories requiring certification has decreased. Costs of the program have actually been reduced in the past two years by reducing program support activities.

The proposed rule will increase costs for laboratories that test milk, food or water. These laboratories currently pay a fee of \$216 per test. Fees under the proposed rule range from \$336 for one milk or food test to \$3,360 for 10 tests. Fees for water laboratories under the proposed rule range from \$276 for one test to \$1104 for four tests.

The proposed rule will impact local government water laboratories. These laboratories currently pay fees of \$216 per test, based on the number of tests they run. Under the proposed rule, these laboratories would pay a \$276 fee for each test.

The proposed rule has no other impact on small businesses. It would not be necessary for certified laboratories to retain additional professional services such as accounting or legal services to comply with this rule.

Dated this 14 day of May, 1999

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By: Ben Brancel  
Ben Brancel, Secretary