

# Clearinghouse Rule 98-142

STATE OF WISCONSIN

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DEPARTMENT OF AGRICULTURE,  
TRADE & CONSUMER PROTECTION

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Clearinghouse Rule  
No. 98-142  
Docket No. 97-R-5

## CERTIFICATION:

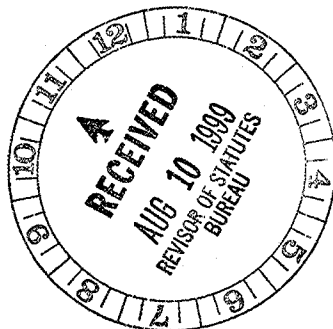
I, Ben Brancel, Secretary of the State of Wisconsin, Department of Agriculture, Trade and Consumer Protection, and custodian of the department's official records, hereby certify that the attached rulemaking order relating to certification of laboratories engaged in public health testing of milk, water, and food was signed and adopted by the department on August 9, 1999.

I further certify that I have compared the attached copy to the original on file in the department, and that the attached copy is a complete and accurate copy of the original.

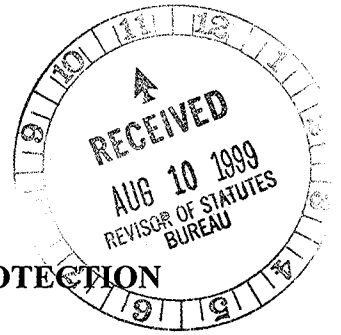
Signed and sealed this 9th day of August, 1999.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By *Ben Brancel*  
Ben Brancel, Secretary



10-1-99



**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 adopts 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.

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,  
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~~  
5 ~~food products~~ for the purpose of protecting the health of the public shall apply to the department  
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:

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:



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 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.

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 and submit  
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.

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 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.

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.

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 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.

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  
6 shall have all of the following:

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

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.

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, 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. If the department determines under sub. (3) that an  
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 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  
17 approves that evaluator for the same purpose.

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. 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).

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. 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  
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.

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 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 9 day of August, 1999.

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

By Ben Brancel  
Ben Brancel, Secretary