

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

1 The Wisconsin department of agriculture, trade and consumer protection hereby proposes the following
2 rule *to re-number* ATCP 77.02 (3) (q), 77.24 (5) (c) 4. and 5.; to *amend* ATCP 77.01 (4m), (7), (11),
3 77.02 (1) (3), 77.04 (1) (b), and 77.04 (1) (e) 3. (Note), 77.06 (1) (a) to (d), and (2) (a) and (b), 77.08 (5),
4 77.10 (2) (b), 77.14 (1) (b) and (c), 77.20 (2) (c) (intro.) and 3., 77.22 (3) (c), 77.23 (3) (a), (b) (intro.),
5 and (c) to (f), 77.24 (5) (a) (1) and 5. (c) (intro.), 77.34 (5) (a) 1. to 3. and (b); to *repeal and recreate*
6 ATCP 77.22 (2) and (7); to *create* ATCP 77.24 (5) (c) 4m. and 5m.; *relating to* milk, food and water
7 testing laboratories.

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

Under Wis. Admin. Code ch. ATCP 77 (Laboratory Certification), the Wisconsin Department of Agriculture, Trade and Consumer Protection (Department) oversees the certification of 81 certified milk or food laboratories and the approval of 96 drug residue screening laboratories under a cooperative agreement with the Federal Food and Drug Administration (FDA) through direction from the National Conference on Interstate Milk Shipments (NCIMS). Also, under this rule the Department accredits 127 safe drinking water testing laboratories under a primacy agreement with the U.S. Environmental Protection Agency (EPA) through the Wisconsin Department of Natural Resources (WDNR).

Statutes Interpreted

Statute Interpreted: Wis. Stat. §§ 93.07 and 93.12.

Statutory Authority

Statutory Authority: Wis. Stat. §§ 93.07 (1) and 93.12 (5) and (7).

Explanation of Statutory Authority

The Department has specific authority under Wis. Stat. § 93.12 (5) to make and enforce regulations to establish uniform minimum standards to be used in the evaluation and certification of laboratory examinations. The Department also has authority under Wis. Stat. § 93.12 (7) to establish a fee schedule to offset the cost of certifying the laboratories and the collection of those fees. Additionally, the Department has general authority, under Wis. Stat. § 93.07 (1), to adopt rules to implement programs under its jurisdiction.

Related Statutes and Rules

- Wis. Admin. Code ch. ATCP 65 (Milk and Milk Products)
- Wis. Admin. Code ch. ATCP 76 (Safety, Maintenance, and Operation of Public Pools and Water Attractions)
- Wis. Admin. Code ch. NR 809 (Safe Drinking Water)
- Wis. Admin. Code ch. NR 812 (Well Construction and Pump Installation).

Plain Language Analysis

In revising Wis. Admin. Code ch. ATCP 77 (Laboratory Certification), the Department is revising the laboratory certification fee structure, updating requirements to reflect modern laboratory practices, and providing flexibility for laboratory operations.

Revised Fee Structure

The fees for laboratory certification were last updated in 2008. The proposed fee increases are 20% and consistent with changes in the consumer price index since 2008. An exception is the prorated monthly fee for the addition of a milk or water test to a laboratory's license mid-year. Those fees were not increased properly in 2008. Monthly fees now correctly reflect 1/12th of the annual fee.

- Annual fee for a laboratory, for each milk or food test the laboratory is certified for, changes from \$410 to \$492.
- Annual fee for a certified analyst changes from \$30 to \$36.
- Annual fee for a laboratory, for each water test the laboratory is certified for, changes from \$340 to \$408.
- The prorated fee for the addition of a test procedure mid-year changes from \$23 to \$35 per month for each water test, and from \$28 to \$42 per month for each milk or food test.
- The fee for a supplemental inspection done at a time other than the mandatory inspection changes from \$150 to \$180.
- Initial fee for licensing of a drug residue screening laboratory changes from \$610 to \$732 for most facilities, and from \$150 to \$180 for very small facilities.
- Drug residue screening laboratory annual fees change from \$60 to \$72 for most facilities, and from \$30 to \$36 for very small facilities.

Discretionary Inspection fees

Wis. Admin. Code ch. ATCP 77 previously referred to discretionary inspections, but the fees for this type of inspection were not clearly defined. The rule now specifies that the fee for a discretionary inspection is the same as the supplemental survey fee of \$180.

Documentation of temperature for temperature-controlled equipment

The current rule requires all laboratories to measure and record equipment temperatures at least daily. Many laboratories are thereby required to staff Sundays and holidays in order to read and record equipment

temperatures. Both the FDA and the EPA exempt laboratories from recording equipment temperatures on days when the laboratory is not normally staffed. This modification to Wis. Admin. Code ch. ATCP 77 aligns the rule with the FDA and EPA. Further, the modification will eliminate a staffing burden for laboratories and result in a cost savings to these businesses.

Inspections Every 3 years

Laboratories operating pursuant to the FDA cooperative agreement must be inspected once every two (2) years. Laboratories operating pursuant to the EPA primacy agreement must be evaluated once every three (3) years.

The Department's revised position is that those laboratories solely performing water testing will only be required to be evaluated once every three (3) years. This revision, pertaining to the frequency of water laboratory evaluation, will also create more flexibility for the Department and laboratories in scheduling laboratory surveys.

Similar Methodology

The proposed rule includes language that enables laboratories certified for one specific test method to add or switch to an alternative test method, which uses the same or very similar test methodology, without the mandate of requiring the laboratory to undergo a lab re-inspection by the Department. This modification to the proposed rule will speed up the certification process for laboratories interested in implementing a new test procedure. This will also result in cost savings because laboratories will no longer be required to pay for an additional supplemental survey fee.

Analyst term of certification and provisional status

As currently written in Wis. Admin. Code ch. ATCP 77, analysts lose their certification if they fail to be present for their laboratory's mandatory inspection. The language will be altered to state that an analyst faces termination of certification only if the laboratory administrator requests withdrawal of the analyst's certification or the laboratory does not pay the analyst's annual renewal fee. Thus, should an analyst miss the laboratory's mandatory inspection, the analyst's certification will be placed in provisional status, absent the laboratory administrator's request for withdrawal of the analyst's certification or failure to pay the analyst's annual renewal fee.

An analyst in provisional status, due to the analyst's failure in attending the mandatory inspection, will remain in provisional status until the analyst demonstrates competence during an inspection of the laboratory. However, the analyst would lose certification in the event the analyst fails proficiency testing or fails to be present for the laboratory's next mandatory inspection.

This change will align the rule with FDA requirements and will create less of a hardship for analysts who fail to attend an on-site evaluation due to a family emergency or illness.

Fecal coliform to E. coli

The WDNR change in water testing, which targets bacteria from fecal coliform to *Escherichia coli* for drinking water testing, required the Department to change the directions for preparation of the water proficiency samples to also contain the target organism of *Escherichia coli*.

Other Revisions

The rule contains other revisions to match updated terminology and technology, adds newly approved test procedures, and removes test procedures that are no longer approved or commercially available. Some revisions align the rule with recent changes in state and federal law. Among these revisions are the following:

- The Division's name has changed from the Division of Food Safety to the Division of Food and Recreational Safety. This change has been made throughout the document.
- The rule expands the definition of milk to include the other species of animals (water buffalo and camelids) that are recognized by the FDA.
- The rule aligns the list of approved test procedures with the lists of currently approved procedures from the FDA and EPA, and corrects some of the technical names.
- The rule adds the requirement that the operator of a laboratory provide not just name and address, but also the e-mail address of the laboratory.
- The rule indicates current revisions of reference materials.
- As required, the new test procedures have been added to the proficiency evaluation standards specifying the number of samples that shall be run each year and how "acceptable" and "unacceptable" test results will be determined.

The Department held three public hearings on this rule on June 25, 2019 at Moraine Park Technical College in Fond du Lac, WI; June 26, 2019 at CESA 10 - Teleconference Center in Chippewa Falls, WI; and June 27, 2019 at the Department of Agriculture, Trade and Consumer Protection - Board Room 106 in Madison, WI.

Public hearing notices were posted at the State Legislature's Active Rules Clearinghouse website and in the Administrative Register. Notices were mailed out to all Department licensed facilities as well as affected industry groups. A total of five persons/organizations attended the hearings and/or submitted comments. Attendees included representatives from Sartori Company, Plymouth; Marshfield Utilities, and Matrix Sciences/Northland Laboratories. Comments were also received from industry groups including the Midwest Food Products Association and the Wisconsin Cheese Makers Association.

Feedback received from industry groups and organization representatives was generally in support of the proposed rule change. A commenter concurred with the Department's change to inspection frequency, equipment temperature documentation only when the laboratory is staffed, and the change to the status of a certified analyst. Both industry groups advocated for the proposed fee increase and encouraged the Department to be more diligent in adjusting program costs to reflect the actual requirements to staff and equip the program. The Department has already begun tracking costs, as suggested. The Department also heeded suggested editorial changes to improve sentence structure and increase readability within the proposed rule.

The Department received a written proposal from a licensed laboratory concerning ATCP 77.20 (2) (c) (3) and the NCIMS program's prohibition against the use of microwave ovens to prepare media. The Department is obligated to follow the requirement outlined within the FDA and NCIMS standard, which does not allow the use of microwave ovens. For any test type this requirement does not apply to, the laboratory is able to use microwave ovens for media preparation.

The Department also received a proposed edit to eliminate the sentence in ATCP 77.22 (7) (e) “or is not present to demonstrate their competence during a biennial inspection of the laboratory.” This change cannot be made because the FDA requires the decertification of a provisionally certified analyst that has a “second miss” of either split samples or on-site evaluation.

Summary of, and Comparison with, Existing or Proposed Federal Statutes and Regulations

State milk and drug residue screening laboratories operate under a cooperative agreement with the FDA through the NCIMS. The laboratory certification program was established to be in accordance with the FDA program documents, as well as the grade “A” Pasteurized Milk Ordinance (PMO) and the Evaluation of Milk Laboratories (EML), which are amended biennially. The latest revisions of these documents are dated 2017. The PMO is incorporated by reference in federal specifications for the procurement of milk and milk products and is used as the model regulation for milk and milk products.

State water laboratories operate under a primacy agreement between the EPA and WDNR. The Department has a memorandum of understanding with the WDNR for the certification of these laboratories. The accreditation of water laboratories was established to be in accordance with the EPA’s manual for the certification of laboratories analyzing water and wastewater. The Safe Drinking Water Act and the Revised Total Coliform Rule give the EPA the responsibility for ensuring the safety of drinking water in this country.

Comparison with Rules in Adjacent States

Participation in the NCIMS requires a state milk regulatory program to meet the requirements laid out in the PMO and EML for approval of milk and milk products analysis laboratories. The water laboratory certification rules in Illinois are more proscriptive than Wisconsin. For example, the Illinois rule sets minimum requirements for use of specific pieces of equipment. The Wisconsin rule does not spell out this requirement, allowing greater flexibility to incorporate new technologies.

The Minnesota rule is more open in that it allows for mobile laboratories, but stricter in requiring laboratories to respond to any deficiencies found within 30 days. ATCP 77 does not prescribe a time frame, which enables each program to determine its own corrective action time frames. The Minnesota rule also requires laboratories to have a written set of standard operating procedures, whereas ATCP 77 only requires reference materials to be kept on-site.

Summary of Factual Data and Analytical Methodologies

Input and analysis were provided by Department experts. The Department reviewed and studied statutory provisions and federal regulations. Over the last several years, the Department gathered information from stakeholders. A copy of the draft of the proposed rule was presented at meetings to representatives of each type of laboratory affected by the proposed change, including: The WDNR, the Wisconsin association of local health departments and boards, and the Wisconsin laboratory association.

Analysis and Supporting Documents used to Determine Effect on Small Business

The Department consulted with representatives from each type of laboratory (large milk, small milk, drug residue, large water, and small water) as well as other interested parties such as the WDNR.

Effect on Small Business

The Department believes the changes proposed will have a minimal effect on small businesses. While fees are increasing, eliminating the need to conduct a supplemental survey if the lab switches to a similar test method, or an analyst misses a mandatory inspection, should help offset some of those costs. For a substantial program of this size, the overall cost of the fee increase over the entire program (both large and small businesses) will be approximately \$35,864.

Changes from the Hearing Draft

The Department incorporated all technical corrections suggested by the Legislative Council Rules Clearinghouse. Changes based on the public hearings and comments sent to the Department are discussed above in the "Plain Language Analysis."

Next Steps

If the Board approves this final draft rule, the Department will submit the final draft rule to the Governor for written approval. If the Governor approves the final rule, the Department will then submit the rule to the Legislature for legislative committee review. If the Legislature has no objection to the rule, the Department Secretary will sign the final rulemaking order and transmit it for publication. The rule will take effect on the first day of the month following publication.

8 **SECTION 1.** ATCP 77.01 (4m) is amended to read:

9 **ATCP 77.01 (4m)** "Drug residue screening test" means any test under s. ATCP 77.02 (1) (~~fk~~) to (1)
10 (~~tzc~~) or (1) (~~zqel~~), other than a confirmatory test, that a person uses to comply with drug residue testing
11 requirements under s. ATCP 65.72.

12 **SECTION 2.** ATCP 77.01 (7) is amended to read:

13 **ATCP 77.01 (7)** "Food and recreational safety administrator" means the administrator of the
14 Department's division of food and recreational safety.

15 **SECTION 3.** ATCP 77.01 (11) is amended to read:

16 **(11)** "Milk" means the lacteal secretion of cows, sheep, ~~or~~ goats, water buffalo, or camelids and includes
17 dairy products made from milk.

18 **SECTION 4.** ATCP 77.02 (1) is amended to read:

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

20 (a) Standard plate count.

- 1 (b) Plate loop count (raw milk only).
- 2 (c) Spiral Plate Count (raw milk only).
- 3 (d) Petrifilm Aerobic Count.
- 4 (e) ~~BactoScan FC~~ Petrifilm Rapid Aerobic Count.
- 5 (f) ~~Charm BSDA~~ TEMPO Aerobic Count.
- 6 (g) ~~Charm II Competitive~~ Peel Plate Aerobic Count.
- 7 (h) ~~Charm II Sequential~~ BactoScan FC.
- 8 (i) ~~Charm II Quantitative~~ BactoCount IBC.
- 9 (j) ~~Charm II Cloxacillin~~ BacSomatic Bacteria Count.
- 10 (k) ~~Charm II Sulfa~~ Charm BSDA.
- 11 (L) Charm II ~~Chloramphenicol~~ Competitive.
- 12 (m) Charm II ~~Tetracycline~~ Sequential.
- 13 (n) Charm II ~~SL (Safe Level)~~ Quantitative.
- 14 (o) Charm II ~~SLG~~ Sulfa.
- 15 (p) ~~Delvotest P~~ Charm II Chloramphenicol.
- 16 (q) ~~Delvotest P 5 Pack~~ Charm II Tetracycline.
- 17 (r) ~~Penzyme Milk~~ Charm SL (Safe Level).
- 18 (s) ~~Penzyme III~~ Charm 3 SL-3.
- 19 (t) ~~Snap BL~~ Charm FLUSLBL.
- 20 (u) ~~Direct Microscopic Somatic Cell Count~~ Charm ROSA SULF.
- 21 (v) ~~Electric Somatic Cell Count~~ Charm ROSA Tetracycline SL.
- 22 (w) ~~Petrifilm Coliform Count/High Sensitivity Coliform Count~~ Charm ROSA TRIO.
- 23 (x) ~~Coliform Plate Count~~ Delvotest P.
- 24 (y) ~~Pasteurized Milk Containers~~ Delvotest P 5 Pack.
- 25 (z) ~~Disintegration Test~~ New SNAP Beta Lactam.
- 26 (za) ~~Flat Lid or Pour Contact Tests~~ SNAP Tetracycline.

- 1 ~~(zb) Phosphatase Test-Fluorophos~~ BetaStar Advanced Test for Beta Lactams.
- 2 ~~(zc) Phosphatase Test-Charm~~ BetaStar Advanced Test for Tetracyclines.
- 3 ~~(zd) Tests performed to comply with ch. ATCP 65, other than milk component tests which are not related~~
- 4 ~~to public health~~ Direct Microscopic Somatic Cell Count.
- 5 (ze) Electronic Somatic Cell Count.
- 6 (zf) Petrifilm Coliform Count/High Sensitivity Coliform Count.
- 7 (zg) Coliform Plate Count.
- 8 (zh) TEMPO Coliform Count.
- 9 (zi) Peel Plate Coliform Count.
- 10 (zj) Pasteurized Milk Containers.
- 11 (zk) Disintegration Test.
- 12 (zl) Flat Lid or Pour Contact Tests.
- 13 (zm) Phosphatase Test-Fluorophos.
- 14 (zn) Phosphatase Test-Charm PasLite.
- 15 (zo) Phosphatase Test – Charm FAP.
- 16 (zp) Accupoint Advanced Alkaline Phosphatase.
- 17 (zq) Tests performed to comply with ch. ATCP 65, other than milk component tests which are not related
- 18 to public health.

19 **SECTION 5.** ATCP 77.02 (3) is amended to read:

- 20 (a) LTB or P-A broth, followed by BGLB and either EC or EC-MUG.
- 21 (b) A-1 broth (fecal coliform, SWTR only).
- 22 (c) Colilert or Colilert 18.
- 23 (d) Colisure.
- 24 (e) Readycult ~~or Fluorocult LMX.~~
- 25 (f) E*Colite.
- 26 (g) Modified Colitag.

- 1 (h) M-Endo or LES Endo, followed by BGLB and either EC, EC-MUG, or NA-MUG.
- 2 (i) MI Medium.
- 3 (j) Coliscan.
- 4 (k) m-ColiBlue24.
- 5 (L) Chromocult.
- 6 (m) mFC agar (fecal coliform, SWTR only).
- 7 (n) ~~PCA~~ HPC or R2A.
- 8 (o) SimPlate.
- 9 (p) m-TEC (fecal coliform).
- 10 (q) ~~Other tests under ch. NR 809 or 812 to detect microbiological contamination in drinking water.~~

11 Pseudalert.

- 12 (r) Enterolert.
- 13 (s) Cryptosporidium and Giardia.

14 **SECTION 6.** ATCP 77.02 (3) (q) is renumbered ATCP 77.02 (3) (t).

15 **SECTION 7.** ATCP 77.04 (1) (b) is amended to read:

16 (b) The name, address, ~~and~~ telephone number, and e-mail address of the laboratory.

17 **SECTION 8.** ATCP 77.04 (1) (e) 3. (Note) is amended to read:

18 Note: An operator may obtain application forms and submit applications to the department at the
 19 following address:

20 Wisconsin department of agriculture, trade and consumer protection
 21 Division of food and recreational safety, bureau of food ~~Safety~~ and recreational businesses and
 22 ~~Inspection~~

23 Laboratory Certification Program

24 P.O. Box 8911

25 Madison, WI 53708-8911

26 (608) 224-4712

1 **SECTION 9.** ATCP 77.06 (1) (a) through (d) are amended to read:

2 (a) Milk or food tests. An annual certification fee of ~~\$410~~492 for each test under s. ATCP 77.02 (1)
3 or (2) at each laboratory for which the operator is certified. This fee does not apply to a laboratory that is
4 approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

5 (b) Certified analysts; milk or food tests. An annual certification fee of ~~\$30~~36 for each analyst who
6 performs one or more tests under s. ATCP 77.02 (1) or (2). This fee does not apply to an individual
7 approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

8 (c) Discretionary inspection or additional analyst certification; milk or food tests. A supplemental fee
9 of ~~\$150~~180 for each discretionary inspection or requested certification of one or more analysts to conduct
10 any test under s. ATCP 77.02 (1) or (2), if the certification occurs at any time other than during a mandatory
11 inspection under s. ATCP 77.14 (1). This fee does not apply to an individual approved under s. ATCP
12 77.23 only to conduct drug residue screening tests on milk samples.

13 (d) Water tests. An annual certification fee of ~~\$340~~408 for each test under s. ATCP 77.02 (3) for
14 which the operator is certified.

15 **SECTION 10.** ATCP 77.06 (2) (a) and (b) are amended to read:

16 (a) If the department certifies an operator of a milk or food laboratory to perform a test for less than a
17 full calendar year, the operator shall pay a fee of ~~\$28~~42 for each full month of certification for that test.
18 This fee does not apply to a laboratory that is authorized under s. ATCP 77.23 only to conduct drug residue
19 screening tests on milk samples.

20 (b) If the department certifies an operator of a water laboratory to perform a test for less than a full
21 calendar year, the operator shall pay a fee of ~~\$23~~35 for each full month of certification for that test.

22 **SECTION 11.** ATCP 77.08 (5) is amended to read:

23 (5) **SUMMARY SUSPENSION.** The food and recreational safety administrator may issue a written
24 notice, summarily suspending all or part of an operator's certification, if the food and recreational safety
25 administrator finds in the suspension notice that the operator has not complied with this chapter, that the
26 noncompliance poses an imminent threat to the health or safety of the public or laboratory workers, and

1 that the noncompliance is likely to continue unless the food and recreational safety administrator
2 summarily suspends the operator's certification. The operator may contest the summary suspension
3 according to s. ATCP 1.03 (3).

4 **SECTION 12.** ATCP 77.10 (2) (b) is amended to read:

5 (b) Maintain temperature-controlled equipment, including incubators, water baths, refrigerators and
6 freezers, so that the equipment functions effectively. The operator shall measure and record equipment
7 temperatures at least daily when the equipment is in use and the laboratory is staffed with trained
8 personnel.

9 **SECTION 13.** ATCP 77.14 (1) (b) and (c) are amended to read:

10 (b) At least once every 2 years after the department first certifies the operator under s. ATCP 77.03 to
11 perform tests under s. ATCP 77.02 (1) at that laboratory and at least once every 3 years after the department
12 first certifies the operator under s. ATCP 77.03 to perform any tests under s. ATCP 77.02 (2) or (3).

13 (c) Before the department certifies the operator to perform a test under s. ATCP 77.02 which the
14 department has not previously certified that operator to perform at that laboratory unless the laboratory is
15 currently certified for a test that utilizes the same or very similar methodology.

16 **SECTION 14.** ATCP 77.20 (2) (c) (intro.) and 3. are amended to read:

17 (c) *Food tests.* An operator who performs any test listed under s. ATCP 77.02 (2) shall keep
18 or have online access to all of the following reference materials at the certified laboratory:

19 3. The FDA "Bacteriological Analytical Manual," ~~8th edition, Revision A~~ current on-line edition, if
20 the operator performs a microbiological test on food.

21 **SECTION 15.** ATCP 77.22 (2) is repealed and recreated to read:

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

24 (a) The laboratory administrator or designated agent requests the analyst's certification to be
25 withdrawn.

26 (b) The certified laboratory does not pay the annual license fee for the analyst.

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

2 **SECTION 16.** ATCP 77.22 (3) (c) is amended to read:

3 (c) The department shall use an appropriate FDA 2400 series form or if no FDA 2400 series form
4 applies, another standard form to evaluate an analyst's competency under par. (a). If an analyst performs
5 plate loop counts, electronic bacteria counts, or electronic somatic cell counts, the department shall check
6 the analyst's ~~ability to perform~~ accuracy based on any statistical comparisons required by those tests.

7 **SECTION 17.** ATCP 77.22 (7) is repealed and recreated to read:

8 (7) PROVISIONAL CERTIFICATION AND RESTORATION OF FULL CERTIFICATION. An
9 analyst shall be placed in provisional certification if one of the following occurs:

10 (a) If a fully certified analyst fails a proficiency evaluation under s. ATCP 77.24 for any test, the
11 department shall issue a notice stating that the analyst is provisionally certified to perform that test.

12 (b) If the department conducts a biennial inspection of a laboratory under s. ATCP 77.14 (1) and a fully
13 certified analyst is not present to demonstrate competence to perform the test(s) they are certified for, the
14 department shall issue a laboratory report stating that the analyst is provisionally certified to perform that
15 test.

16 (c) If an analyst is provisionally certified because of failing a proficiency evaluation under s. ATCP
17 77.24 and that analyst passes a proficiency evaluation under s. ATCP 77.24 on a new set of proficiency
18 samples, the department shall restore the analyst to full certification.

19 (d) If an analyst is provisionally certified because they were not present to demonstrate their
20 competence to perform the tests they are certified for during the biennial inspection of the laboratory, they
21 shall remain in provisional certification status until they again demonstrate their competence during an
22 inspection of the laboratory.

23 (e) If a provisionally certified analyst fails a proficiency evaluation on a new set of proficiency
24 samples, or is not present to demonstrate their competence during a biennial inspection of the laboratory,
25 the department shall summarily suspend the analyst's certification to perform that test.

26 **SECTION 18.** ATCP 77.23 (3) (a), (b) (intro.), and (c) to (f) is amended to read:

1 (3) APPROVAL FEES. A laboratory operator shall pay the following fees to acquire and maintain a
2 laboratory approval under sub. (1):

3 (a) An initial fee of ~~\$610732~~, except as provided in par. (b) or (c).

4 (b) An initial fee of ~~\$150180~~ if the laboratory tests milk for only one dairy plant operator and all the
5 following apply:

6 1. The dairy plant operator receives only grade B milk.

7 2. The dairy plant operator receives milk from not more than 5 producers.

8 3. The dairy plant operator receives not more than 10,000 lbs. of raw milk per week.

9 (c) An initial fee of ~~\$6072~~ if the laboratory does not apply for approval to perform any visual read test.

10 (d) A fee of ~~\$3036~~ for each individual, in excess of 3 individuals, that the department evaluates under
11 sub. (4) at the time of the initial laboratory inspection under sub. (1) (c).

12 (e) An annual renewal fee of ~~\$6072~~ for each annual renewal of the laboratory approval, except that the
13 renewal fee is ~~\$3036~~ if the laboratory qualifies under par. (b).

14 (f) A fee of ~~\$150180~~ for each laboratory visit, other than the initial inspection under sub. (1) (c), that
15 the department makes for the purpose of evaluating individuals under sub. (4). This single fee of ~~\$150180~~
16 covers all of the individual evaluations performed during the department's visit, regardless of the number
17 of individuals evaluated.

18 **SECTION 19.** ATCP 77.24 (5) (a) (1) is amended to read:

19 1. At least six but not more than 20 samples for standard plate count, petrifilm aerobic count, plate
20 loop count, petrifilm rapid aerobic count, peel plate aerobic count, or phosphatase tests.

21 **SECTION 20.** ATCP 77.24 (5) (c) (intro.) is amended to read:

22 (c) In a proficiency evaluation for any of the following tests, a sample result is unacceptable if it falls
23 outside the statistical limits established in FDA's "Evaluation of Milk Laboratories," ~~1995~~2017 edition:

24 **SECTION 21.** ATCP 77.24 (5) (c) 4. and 5. are renumbered to ATCP 77.24 (5) (c) 6. and 7.

25 **SECTION 22.** ATCP 77.24 (5) (c) 4m. and 5m. are created to read:

26 4m. Petrifilm Rapid Aerobic Count

1 5m. Peel Plate Aerobic Count

2 **SECTION 23.** ATCP 77.34 (5) (a) 1. to 3. are amended to read:

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

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

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

10 **SECTION 24.** ATCP 77.34 (5) (b) is amended to read:

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

16 **EFFECTIVE DATE.** This rule takes effect on the first day of the month following publication in the
17 Wisconsin administrative register, as provided under s. 227.22(2) (intro.).

Dated this _____ day of _____, 2019.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Randy J. Romanski, Interim Secretary