



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
Bradley M. Pfaff, Secretary

DATE: March 28, 2019

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Bradley M. Pfaff, Secretary
Steve Ingham, Administrator, Division of Food and Recreational Safety

SUBJECT: Wis. Admin Code ch. ATPC 77, Laboratory Certification

PRESENTED BY: Steve Ingham, Ph.D.

REQUESTED ACTION:

At the March 28, 2019, DATCP Board meeting, the Department will ask the DATCP Board to approve the proposed rule hearing draft of Wis. Admin. Code ch. ATPC 77 relating to Laboratory Certification.

SUMMARY:

This rule revision will update the following: 1) references, standards and test procedures for ensuring the reliability of certified laboratory testing; 2) certification fees to adequately cover costs, as required under Wis. Stat. § 93.12 (7); 3) the structure for prorating partial-year certification fees in accordance with Wis. Stat. § 93.12 (4); and 4) the frequency of on-site certified wastewater-testing laboratory reviews to optimize efficiency without jeopardizing public safety.

Background

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 U.S. Food and Drug Administration (FDA) through direction from the National Conference on Interstate Milk Shipments (NCIMS). The Department also 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).

Rule Content

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. Although those monthly fees should have been increased in proportion to the increased annual fees in 2008, the monthly fees were not increased at all. Monthly fees now correctly reflect 1/12th of the annual fee.

- Annual fee for a laboratory, for each milk test the laboratory is certified for, changes from \$410 to \$492.

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- 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 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 of 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 to attend 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 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 the 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.

Fiscal Impact

No new staff will be required for DATCP to enforce the proposed rule and appendix. These rules replace and update rules that are already in effect. DATCP will train staff in the new requirements, and the new requirements will be enforced as part of the normal evaluations.

Business Impact

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.

Federal and Surrounding State Programs

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 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 sanitary 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 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, in turn, 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 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.

Next Steps

If the DATCP Board authorizes public hearings on this rule, DATCP will refer a copy of the proposed rule to the Legislative Council Rules Clearinghouse for publication of the hearing notice in the Wisconsin Administrative Register. DATCP will hold public hearings on the dates listed in the hearing notice and at

locations specified in the hearing notice. DATCP will also consult with representatives of the local health departments as well as representatives from the Department's staff.

Following the public hearings, the Department will prepare the final draft of the proposed rule for the DATCP Board's consideration. If approved by the DATCP Board, the final draft will be transmitted to the Governor for his written approval. If the Governor approves the final draft of the rule, it will be transmitted to the Legislature for review by the appropriate legislative committees. If the Legislature takes no action to stop the rule, the Secretary will sign the final rulemaking order and transmit it for publication and adoption.

**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
2 following rule *to amend* ATCP 77.01 (4m), (7), (11), 77.02 (3) (e), (g), and (n), 77.04 (1) (b),
3 and (Note), 77.06 (1) (a) to (d), and (2) (a) and (b), 77.08 (5), 77.10 (2) (b), 77.14 (1) (b) and (c),
4 77.20 (2) (c) (3), 77.22 (3) (c), 77.23 (3), 77.24 (5) (a) (1) and (c), 77.34 (5) (a) and (b); *to*
5 *repeal and recreate* ATCP 77.02 (1), 77.22 (2) (a), and (7); *to create* ATCP 77.02 (3) (q), (r),
6 and (s); and *to re-letter* ATCP 77.02 (q) *relating to* milk, food and water testing laboratories.

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

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 food and drug administration (FDA) through direction from the national conference on interstate milk shipments (NCIMS). The Department also 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

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

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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.

DATCP Contact

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Where and When Comments May Be Submitted

Questions and comments related to this rule may be directed to:

Caitlin Jeidy, Program and Policy Analyst – Advanced
Division of Food and Recreational Safety
Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4696
Email: Caitlin.Jeidy@Wisconsin.gov

Comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this hearing draft rule is approved by the board of agriculture, trade and consumer protection.

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

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

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

1 **ATCP 77.01 (7)** “Food and recreational safety administrator” means the administrator of the
2 Department’s division of food and recreational safety.

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

4 **(11)** “Milk” means the lacteal secretion of cows, sheep, ~~or~~ goats, water buffalo, or camelids and
5 includes dairy products made from milk.

6 **SECTION 4.** ATCP 77.02 (1) is repealed and recreated to read:

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

8 (a) Standard plate count

9 (b) Plate loop count (raw milk only)

10 (c) Spiral Plate Count (raw milk only)

11 (d) Petrifilm Aerobic Count

12 (e) Petrifilm Rapid Aerobic Count

13 (f) TEMPO Aerobic Count

14 (g) Peel Plate Aerobic Count

15 (h) BactoScan FC

16 (i) BactoCount IBC

17 (j) BacSomatic Bacteria Count

18 (k) Charm BSDA

19 (l) Charm II Competitive

20 (m) Charm II Sequential

21 (n) Charm II Quantitative

22 (o) Charm II Sulfa

23 (p) Charm II Chloramphenicol

- 1 (q) Charm II Tetracycline
- 2 (r) Charm SL (Safe Level)
- 3 (s) Charm 3 SL-3
- 4 (t) Charm FLUSLBL
- 5 (u) Charm ROSA SULF
- 6 (v) Charm ROSA Tetracycline SL
- 7 (w) Charm ROSA TRIO
- 8 (x) Delvotest P
- 9 (y) Delvotest P 5 Pack
- 10 (z) New SNAP Beta Lactam
- 11 (za) SNAP Tetracycline
- 12 (zb) BetaStar Advanced Test for Beta Lactams
- 13 (zc) BetaStar Advanced Test for Tetracyclines
- 14 (zd) Direct Microscopic Somatic Cell Count
- 15 (ze) Electronic Somatic Cell Count
- 16 (zf) Petrifilm Coliform Count/High Sensitivity Coliform Count
- 17 (zg) Coliform Plate Count
- 18 (zh) TEMPO Coliform Count
- 19 (zi) Peel Plate Coliform Count
- 20 (zj) Pasteurized Milk Containers
- 21 (zk) Disintegration Test
- 22 (zl) Flat Lid or Pour Contact Tests
- 23 (zm) Phosphatase Test-Fluorophos

1 (zn) Phosphatase Test-Charm PasLite

2 (zo) Phosphatase Test – Charm FAP

3 (zp) Accupoint Advanced Alkaline Phosphatase

4 (zq) Tests performed to comply with ch. ATCP 65, other than milk component tests which are
5 not related to public health.

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

7 (e) ~~Readycult or Fluorocult LMX~~

8 **SECTION 6.** ATCP 77.02 (3) (g) is amended to read:

9 (g) Modified Colitag

10 **SECTION 7.** ATCP 77.02 (3) (n) is amended to read:

11 (n) PCA HPC or R2A

12 **SECTION 8.** ATCP 77.02 (3) (q) through (s) are created to read:

13 (q) Pseudalert

14 (r) Enterolert

15 (s) Cryptosporidium and Giardia

16 **SECTION 9.** ATCP 77.02 (3) (q) is amended to read:

17 (qt) Other tests under ch. NR 809 or 812 to detect microbiological contamination in drinking
18 water.

19 **SECTION 10.** ATCP 77.04 (1) (b) is amended to read:

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

21 **SECTION 11.** ATCP 77.04 (Note) is amended to read:

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

1 Wisconsin department of agriculture, trade and consumer protection

2 Division of food and recreational safety, bureau of food Safety and recreational businesses ~~and~~

3 ~~Inspection~~

4 Laboratory Certification Program

5 P.O. Box 8911

6 Madison, WI 53708-8911

7 (608) 224-4712

8 **SECTION 12.** ATCP 77.06 (1) (a) through (d) are amended to read:

9 (a) Milk or food tests. An annual certification fee of ~~\$492410~~ for each test under s. ATCP
10 77.02 (1) or (2) at each laboratory for which the operator is certified. This fee does not apply to a
11 laboratory that is approved under s. ATCP 77.23 only to conduct drug residue screening tests on
12 milk samples.

13 (b) Certified analysts; milk or food tests. An annual certification fee of ~~\$3630~~ for each analyst
14 who performs one or more tests under s. ATCP 77.02 (1) or (2). This fee does not apply to an
15 individual approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk
16 samples.

17 (c) Discretionary inspection or additional analyst certification; milk or food tests. A
18 supplemental fee of ~~\$180450~~ for each discretionary inspection or requested certification of one or
19 more analysts to conduct any test under s. ATCP 77.02 (1) or (2), if the certification occurs at any
20 time other than during a mandatory inspection under s. ATCP 77.14 (1). This fee does not apply
21 to an individual approved under s. ATCP 77.23 only to conduct drug residue screening tests on
22 milk samples.

1 (d) Water tests. An annual certification fee of ~~\$408340~~ for each test under s. ATCP 77.02
2 (3) for which the operator is certified.

3 **SECTION 13.** ATCP 77.06 (2) (a) and (b) are amended to read:

4 (a) If the department certifies an operator of a milk or food laboratory to perform a test for
5 less than a full calendar year, the operator shall pay a fee of ~~\$4228~~ for each full month of
6 certification for that test. This fee does not apply to a laboratory that is authorized under s. ATCP
7 77.23 only to conduct drug residue screening tests on milk samples.

8 (b) If the department certifies an operator of a water laboratory to perform a test for less than
9 a full calendar year, the operator shall pay a fee of ~~\$3523~~ for each full month of certification for
10 that test.

11 **SECTION 14.** ATCP 77.08 (5) is amended to read:

12 (5) SUMMARY SUSPENSION. The food and recreational safety administrator may issue a
13 written notice, summarily suspending all or part of an operator's certification, if the food and
14 recreational safety administrator finds in the suspension notice that the operator has not complied
15 with this chapter, that the noncompliance poses an imminent threat to the health or safety of the
16 public or laboratory workers, and that the noncompliance is likely to continue unless the food
17 and recreational safety administrator summarily suspends the operator's certification. The
18 operator may contest the summary suspension according to s. ATCP 1.03 (3).

19 **SECTION 15.** ATCP 77.10 (2) (b) is amended to read:

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

1 **SECTION 16.** ATCP 77.14 (1) (b) and (c) are amended to read:

2 (b) At least once every 2 years after the department first certifies the operator under s. ATCP
3 77.03 to perform tests under s. ATCP 77.02 (1) at that laboratory and at least once every 3 years
4 after the department first certifies the operator under 77.03 to perform any tests under s. ATCP
5 77.02 (2) or (3).

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

10 **SECTION 17.** ATCP 77.20 (2) (c) (3) is amended to read:

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

13 **SECTION 18.** ATCP 77.22 (2) (a) is repealed and recreated to read:

14 (a) The laboratory administrator or designated agent requests the analyst's certification to be
15 withdrawn or the certified laboratory does not pay the annual license fee for the analyst.

16 **SECTION 19.** ATCP 77.22 (3) (c) is amended to read:

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

22 **SECTION 20.** ATCP 77.22 (7) is repealed and recreated to read:

1 (7) PROVISIONAL CERTIFICATION. An analyst shall be placed in provisional
2 certification if one of the following occurs:

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

6 (b) If the department conducts the next biennial inspection of the laboratory under s. ATCP
7 77.14 (1) and the analyst is not present to demonstrate competence to perform the test(s) they are
8 certified for, the department shall issue a laboratory report stating that the analyst is provisionally
9 certified to perform that test.

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

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

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

21 **SECTION 21.** ATCP 77.23 (3) is amended to read:

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

1 (a) An initial fee of ~~\$732610~~, except as provided in par. (b) or (c).

2 (b) An initial fee of ~~\$180150~~ if the laboratory tests milk for only one dairy plant operator and
3 all the following apply:

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

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

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

7 (c) An initial fee of ~~\$7260~~ if the laboratory does not apply for approval to perform any visual
8 read test.

9 (d) A fee of ~~\$3630~~ for each individual, in excess of 3 individuals, that the department evaluates
10 under sub. (4) at the time of the initial laboratory inspection under sub. (1) (c).

11 (e) An annual renewal fee of ~~\$7260~~ for each annual renewal of the laboratory approval, except
12 that the renewal fee is ~~\$3630~~ if the laboratory qualifies under par. (b).

13 (f) A fee of ~~\$180150~~ for each laboratory visit, other than the initial inspection under sub. (1)
14 (c), that the department makes for the purpose of evaluating individuals under sub. (4). This
15 single fee of ~~\$180150~~ covers all of the individual evaluations performed during the department's
16 visit, regardless of the number of individuals evaluated.

17 **SECTION 22.** ATCP 77.24 (5) (a) (1) is amended to read:

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

20 **SECTION 23.** ATCP 77.24 (5) (c) is amended to read:

21 (c) In a proficiency evaluation for any of the following tests, a sample result is unacceptable
22 if it falls outside the statistical limits established in FDA's "Evaluation of Milk Laboratories,"
23 20171995 edition.

- 1 1. Standard plate count.
- 2 2. Petrifilm aerobic count.
- 3 3. Plate loop count.
- 4 4. Petrifilm Rapid Aerobic Count
- 5 5. Peel Plate Aerobic Count
- 6 ~~4~~6. Direct microscopic somatic cell count.
- 7 ~~5~~7. Electronic somatic cell count.

8 **SECTION 24.** ATCP 77.34 (5) (a) is amended to read:

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

- 13 1. One to 4 samples of an aerogenic strain of Escherichia coli which, if properly tested
14 according to methods under s. ATCP 77.30 (1), will test positive for total and ~~fecal coliform~~ E.
15 coli.
- 16 2. One to 4 samples of Enterobacter sp. or other microorganisms which, if properly tested
17 according to methods under s. ATCP 77.30 (1), will test positive for total coliform and negative
18 for ~~fecal coliform~~ E. coli.
- 19 3. One to 4 samples of Pseudomonas sp. or other microorganisms which, if properly tested
20 according to methods under s. ATCP 77.30 (1), will test negative for total coliform and ~~fecal~~
21 ~~coliform~~ E.coli.
- 22 4. One to 4 blank samples.

23 **SECTION 25.** ATCP 77.34 (5) (b) is amended to read:

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

6 **EFFECTIVE DATE.** This rule takes effect on the first day of the month following publication
7 in the 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 _____
Bradley M. Pfaff, Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Regulatory Flexibility Analysis

Rule Subject: Laboratory Certification

Adm. Code Reference: ATCP 77

Rules Clearinghouse #: Not assigned

DATCP Docket #: _____ 18 – R - 04

Rule Summary

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 food and drug administration (FDA) through direction from the national conference on interstate milk shipments (NCIMS). The Department also 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).

This rule revision will update the following: 1) references, standards and test procedures for ensuring the reliability of certified laboratory testing; 2) certification fees to adequately cover costs, as required under Wis. Stat. § 93.12 (7); 3) the structure for prorating partial-year certification fees in accordance with Wis. Stat. § 93.12 (4); and 4) the frequency of on-site certified wastewater-testing laboratory reviews that optimize efficiency without jeopardizing public safety.

Small Businesses Affected

The Department believes the changes proposed will have minimal effect on small businesses. While fees are increasing, cost saving will be realized through the proposed rule’s elimination of the necessity of conducting a supplemental survey if the lab switches to a similar test method or if an analyst misses a mandatory inspection. 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.

Reporting, Bookkeeping and other Procedures

The proposed rule will not require any additional reporting, bookkeeping, or other procedures beyond what is already required of certified laboratories in the current version of Wis. Admin. Code ch. ATCP 77.

Professional Skills Required

The proposed rule does not require any new professional skills from small businesses.

Accommodation for Small Business

The requirements for certified laboratories are not size-dependent. There is very little, if any, differentiation of standards to accommodate the size of a given laboratory in FDA and EPA regulations.

Conclusion

Adjustments to Wis. Admin. Code ch. ATCP 77 will allow laboratories to enjoy greater flexibility in their day-to-day practices as well as ease staffing requirements. For example, analysts will no longer lose their certification if they are not present for a laboratory's mandatory inspection. The analyst would instead be placed in provisional status until a competency demonstration can be conducted, or the analyst loses certification due to a failure in proficiency testing or failure to be present for the laboratory's next mandatory inspection. This modification will more closely align with FDA requirements and will create less hardship for analysts who are unable to be present for a given on-site evaluation due to a family emergency or illness.

The elimination of the requirement of off-day reading and recording of equipment temperatures aligns Wis. Admin. Code ch. ATCP 77 with the FDA and EPA and will also eliminate a staffing burden for laboratories. The Department's change in position on the frequency of water laboratory evaluation to every 3 years will create more flexibility for the Department and laboratories in scheduling laboratory surveys. Laboratories desirous of adding or changing to an alternative test method will be able to do so with greater ease because the proposed rule no longer automatically requires an additional inspection. Thus, the proposed rule change will speed up the certification process for laboratories and result in a cost savings since laboratories will no longer pay a supplemental survey fee.

This rule will have little if any effect on "small business" and is not subject to the delayed "small business" effective date provided in Wis. Stat. § 227.22(2)(e).

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this 8th day of March, 2019.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Steven C. Ingham
Steven C. Ingham, Ph.D., Administrator,
Division of Food and Recreational Safety

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Repeal Modification

2. Administrative Rule Chapter, Title and Number

Wis. Admin. Code ch. ATPC 77, Laboratory Certification

3. Date Rule promulgated and/or revised; Date of most recent Evaluation

2008

4. Plain Language Analysis of the Rule, its Impact on the Policy Problem that Justified its Creation and Changes in Technology, Economic Conditions or Other Factors Since Promulgation that alter the need for or effectiveness of the Rule.

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 food and drug administration (FDA) through the national conference on interstate milk shipments (NCIMS). 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).

Revised Fee Structure

The fees for laboratory certification were last updated in 2008. The proposed fee increases are 20% and consistent with the change in the consumer price index since 2008. The exception is the prorated monthly fee for the addition of a milk or water test to a laboratory's license mid-year. Although those monthly fees should have been increased in proportion to the increased annual fees in 2008, the monthly fees were not increased at all. Monthly fees now correctly reflect 1/12th of the annual fee.

- Annual fee for a laboratory, for each milk test they are 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 they are 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 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

ATPC 77 always 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.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

Documentation of temperature of temperature-controlled equipment

The rule required all laboratories to measure and record equipment temperatures at least daily. Many laboratories were thus required to bring in staff on a Sunday or holiday just to read and record equipment temperatures. Both the FDA and the EPA have allowed laboratories to not record the temperatures of equipment on days when the laboratory is not normally staffed. This change aligns ATCP 77 with the FDA and EPA and eliminates a staffing burden for laboratories.

Inspections every 3 years

Laboratories operating under the FDA cooperative agreement must be inspected once every 2 years. Laboratories operating under the EPA primacy agreement are only required to be evaluated once every three years. The Department's revised position is that those laboratories only doing water testing are only required to be evaluated once every three years. This change will allow laboratories and the department's program more flexibility in scheduling laboratory surveys.

Similar Methodology

The Department added language that states if a laboratory is certified for a specific test method and they want to add or switch to another test method that uses the same or very similar test methodology, the Department will not be required to inspect the lab. This change will speed up the certification process for laboratories looking to use a new test procedure. This will also save the laboratories money since they will not have to pay a supplemental survey fee.

Analyst term of certification and provisional status

As it is currently written in ATCP 77, analysts lose their certification if not present for a laboratory's mandatory inspection. The language will be changed to read that an analyst's certification is terminated when the laboratory administrator requests that the analyst's certification be withdrawn or the laboratory does not pay the analyst's annual renewal fee. Thus, if an analyst misses a laboratory's mandatory inspection, but the laboratory administrator does not request the withdrawal of that analyst, the analyst will be placed in provisional status.

Analysts in provisional status due to missing a mandatory inspection will remain in provisional status until they demonstrate their competence during an inspection of the laboratory, or they lose their certification because of a failure of proficiency testing or failure to be present for the laboratory's next mandatory inspection.

This change will put the rule in closer alignment with the FDA requirements and will create less of a hardship for analysts who miss an on-site evaluation due to family emergency or illness.

Fecal coliform to E. coli

The WDNR change in water testing, which targets bacteria from fecal coliform to E. 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 E. coli.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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 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.

5. Describe the Rule's Enforcement Provisions and Mechanisms

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 to regulate 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.

Division laboratory evaluation officers (LEO) visit laboratories to ensure they have the proper equipment and are capable of performing the proper procedures to produce accurate test results for the products being tested. These visits are conducted before the laboratory does any official testing and once every 2 years thereafter. If an LEO discovers a major violation during a routine visit that will compromise the laboratory's ability to produce accurate test results, the LEO can perform a chargeable re-survey.

Laboratories and analysts are also required to run proficiency samples. If a laboratory or analyst fails these proficiency samples, the laboratory or analyst will be placed in provisional status. If the laboratory or analyst fails a second time within a prescribed time frame, the laboratory or analyst license will be suspended for that specific test procedure.

6. Repealing or Modifying the Rule Will Impact the Following (Check All That Apply)

- | | |
|---|---|
| <input type="checkbox"/> State's Economy | <input checked="" type="checkbox"/> Specific Businesses/Sectors |
| <input type="checkbox"/> Local Government Units | <input type="checkbox"/> Public Utility Rate Payers |
| | <input checked="" type="checkbox"/> Small Businesses |

7. Summary of the Impacts, including Compliance Costs, identifying any Unnecessary Burdens the Rule places on the ability of Small Business to conduct their Affairs.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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. The overall cost of the fee increase over the entire program (both large and small businesses) is a total of approximately \$35,864.

8. List of Small Businesses, Organizations and Members of the Public that commented on the Rule and its Enforcement and a Summary of their Comments.

Input and analysis was provided by Department experts, and the Department has reviewed statutory provisions and federal regulations. Further, the Department has gathered information over the last several years from stakeholders. The Department solicited information from industry about the potential economic impact of the rule, but no comments were submitted. A copy of the draft 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.

9. Did the Agency consider any of the following Rule Modifications to reduce the Impact of the Rule on Small Businesses in lieu of repeal?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

10. Fund Sources Affected

- GPR FED PRO PRS SEG SEG-S

11. Chapter 20, Stats. Appropriations Affected
20.115 (1) (gb)

12. Fiscal Effect of Repealing or Modifying the Rule

- No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

13. Summary of Costs and Benefits of Repealing or Modifying the Rule
Modernizing Requirements

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EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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- The rule adds the requirement that the operator of a laboratory provide not just name and address, but also 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.

14. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

Yes No

15. Long Range Implications of Repealing or Modifying the Rule

Adjusting ATCP 77 grants laboratories greater flexibility in day-to-day practices as well as an ease in staffing requirements. To begin with, analysts will no longer lose their certification if not present for a laboratory's mandatory inspection. Analysts will instead be put in provisional status until a competency demonstration is conducted, or they lose their certification because of a failure of proficiency testing, or failure to be present for the laboratory's next mandatory inspection. This change will put the rule in closer alignment with the FDA requirements and will create less of a hardship for analysts who miss an on-site evaluation due to family emergency or illness. The elimination of the requirement of off-day reading and recording of equipment temperatures aligns ATCP 77 with the FDA and EPA and will also eliminate a staffing burden for laboratories. The Department's change in position on the frequency of water laboratory evaluation to every 3 years will allow laboratories and the Department's program more flexibility in scheduling laboratory surveys. Laboratories looking to add or switch another test method will find ease in doing so with the addition of language that states that this no longer prompts an inspection. This change will speed up the certification process for laboratories looking to use a new test procedure. This will also save the laboratories money since they will not have to pay a supplemental survey fee.

16. Compare With Approaches Being Used by Federal Government

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 documents, as well as

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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 sanitary 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.

17. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
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, in turn, 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 proscribe a time frame which enables each program to determine its own 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.

18. Contact Name Caitlin Jeidy, Division of Food and Recreational Safety, Program and Policy Analyst - Advanced	19. Contact Phone Number (608) 224-4696
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