



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: May 11, 2017

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Administrator, Division of Food and Recreational Safety *Steve Ingham*

SUBJECT: **ATCP 77-Laboratory Certification; Rulemaking Scope Statement**

PRESENTED BY: Steve Ingham, Division of Food and Recreational Safety

REQUESTED ACTION:

At the May 25, 2017, Board meeting, the Department of Agriculture, Trade and Consumer Protection ("Department") will ask the Agriculture, Trade and Consumer Protection Board ("Board") to approve a scope statement (copy attached) for potential changes to Wis. Admin. ch. ATCP 77 relating to standards and procedures for certifying Wisconsin's milk, water, and food laboratories.

Chapter ATCP 77 outlines standards and procedures for certification of Wisconsin's milk, water, and food laboratories. The Department plans to comprehensively review Wis. Admin. ch. ATCP 77 and revise it as necessary to modernize Wisconsin's laboratory certification standards. The last comprehensive review of Wis. Admin. ch. ATCP 77 was in 1998. Wis. Stat. § 93.12 requires the Department to certify any laboratory that performs examinations of milk, water, and food products and to designate which laboratory examinations it deems necessary for the protection of the health of the public. The laboratory certification program was transferred from the Department of Health Services to the Department in 1997. Wisconsin has 196 laboratories that are currently certified by the Department, with approximately another 100 labs that are certified by the Department only to do screening tests for the presence of drug residues in milk.

This rule revision will update, to the extent needed, 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 optimizes efficiency without jeopardizing public safety. The Department may make other revisions, as needed, to update the rule and ensure the program continues to effectively and efficiently ensure the quality of Wisconsin's laboratories responsible for examining milk, water, and food products. The Department does not anticipate that this rule revision will have a significant economic impact on Wisconsin's certified laboratories.

A scope statement spells out the general purpose and scope of a proposed rule. The Department may not begin drafting a proposed rule (including a proposal to amend or repeal an existing rule) until the Governor approves a scope statement for that rule as required under Wis. Stat. § 227.135(2). This scope statement was approved by the Governor on April 13, 2017. Wisconsin statutes also require the Board to approve a scope statement before the

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Department may begin to draft a proposed rule. The Department is required to publish a draft scope statement in the Wisconsin Administrative Register and file a copy with the Department of Administration (“DOA”) at least 10 days before the Board approves the scope statement. The Department has filed the attached scope statement with the Legislative Reference Bureau for publication and with DOA as required.

If the Board approves the scope statement, the Department will begin work to draft the permanent rule. Approval of a scope statement is just the first step in a process for enacting permanent rules. The Board will have at least two further opportunities to review the proposed rule. The Board must approve a hearing draft rule before the Department may hold public hearings on the rule proposal. The Board must also approve the final draft rule before the Department may adopt the rule. The permanent rule will be effective when the final draft has been approved by the Board, approved by the Governor, completed the legislative review process, and adopted by the Secretary.

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Ch. ATCP 77, Wis. Adm. Code (Existing)

Relating to: Laboratory Certification (Permanent)

1. Description of the objective of the rule:

Chapter ATCP 77 outlines standards and procedures for certification of Wisconsin's milk, water, and food laboratories. The Department of Agriculture, Trade and Consumer Protection ("Department") plans to comprehensively review ch. ATCP 77 and revise it as necessary to modernize Wisconsin's laboratory certification standards. The last comprehensive review of ATCP 77 was in 1998.

Specifically, this rule revision will update, to the extent needed, 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 s. 93.12 (7), Stats., 3) the structure for prorating partial-year certification fees in accordance with s. 93.12 (4), Stats., and 4) the frequency of on-site certified wastewater-testing laboratory reviews that optimizes efficiency without jeopardizing public safety, as required pursuant to s. 93.12(5), Stats. The Department may make other revisions, as needed, to update the rule and ensure the program continues to effectively and efficiently ensure the quality of Wisconsin's laboratories responsible for examining milk, water, and food products.

2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:

Background

Section 93.12, Stats., requires the Department to certify any laboratory that performs examinations of milk, water, and food products and to designate which laboratory examinations it deems necessary for the protection of the health of the public. The laboratory certification program was transferred from the Department of Health Services to the Department in 1997. Wisconsin has 196 laboratories that are currently certified by the Department, with approximately another 100 labs that are approved by the Department only to do screening tests for the presence of drug residues in milk. The following are among the requirements of ch. ATCP 77:

- Certification requirements, fees, and standards, including a requirement that a certified laboratory be evaluated by the Department before initial certification and at least once every two years afterward. The Department may also evaluate a laboratory whenever the lab alters its facilities or equipment, assigns a new laboratory analyst to perform a test, or whenever it concludes an evaluation is necessary.
- A requirement that the laboratory has a designated administrator who personally supervises the operations of a laboratory

- Requirements that laboratories perform designated tests according to recognized methods. Chapter ATCP 77 identifies the laboratory tests needed to protect public health and standards and incorporates, by reference, laboratory manuals that define the methods to be used.
- Requirements that laboratories have adequate facilities, equipment, and supplies to perform the tests and have established quality control procedures that comply with current standards.
- A requirement that the Department certifies individual analysts in milk or food laboratories to perform tests after passing an annual proficiency examination. The Department does not certify individual water analysts. However, a water lab operator must annually document to the Department that analysts are trained and competent.

References and Standards

One goal of the rule revision will be to review and revise, to the extent necessary, laboratory examination references and standards to ensure they are current. Section ATCP 77.02 identifies a list of milk, food, water, wastewater, and recreational water laboratory tests the Department has declared as necessary to protect public health. The rule also incorporates certain standards by reference that identify appropriate methods for performing the identified tests.

Pro-rated Fees for Partial-Year Certifications

Another goal of the rule revision will be to align the partial-year fee policy, found in ATCP 77.06 (2), with statutory requirements for prorating fees. Sections 93.12 (4) and (7), Stats., require the Department to establish fees to cover the cost of certifying laboratories, requires the certifications to be issued on a calendar-year basis, and requires the Department to issue an interim certificate for initial certification of a laboratory. The interim certificate is to be valid for the remainder of the year for which it is issued. The Department is required under s. 93.12 (4), Stats., to prorate fees at one-twelfth of the annual fee for each month remaining in the calendar year remaining for initially certified laboratories or for laboratories that apply to expand an existing certification during the calendar year. The Department may also examine the current fee structure to determine whether fees cover the cost of certifying laboratories, as required under s. 93.12 (7), Stats.

Frequency of Wastewater Laboratory Certification: Coordination with the DNR Lab Certification Program

Section 93.12 (5), Stats., requires the Department to coordinate laboratory certification requirements with the Department of Natural Resources (DNR), who also operates a laboratory certification program under s. 299.11, Stats. The Department is required to consult with the DNR in administering their laboratory certification programs, to avoid duplication. The Department is also required to recognize the certification or registration of a laboratory certified by the DNR under s. 299.11, Stats., and to accept the results of any test conducted by a laboratory certified or registered under that section.

The DNR is currently in the process of revising ch. NR 219; its rule related to analytical test methods and procedures. Chapter NR 219 establishes methods, sample-preservation procedures, requirements for laboratories and procedures applicable to enforcing effluent limitations for discharges from point sources as authorized under ss. 299.11 and 283.55 (1), Stats. As part of the Department's review of ch. ATCP 77, the Department will evaluate any proposed changes to ch. NR 219 and revise ch. ATCP 77, if necessary, to maintain consistency. The Department will also examine provisions related to the frequency of on-site reviews of laboratories that analyze wastewater, to identify possible efficiencies that may be achieved by reducing the frequency of these on-site reviews.

The Department is required to submit any rules establishing standards for the evaluation and certification of laboratories that affect the DNR's laboratory certification program to the DNR and the State Laboratory of Hygiene for review and comment. The rule may not take effect unless it is approved by the DNR within 6 months after submission

Other General Rule Revisions

The Department may make other revisions, as needed, to modernize standards for certified laboratories, ensure a fair fee schedule to meet the requirements of s. 93.12 (7), Stats., and improve the efficiency and effectiveness of Wisconsin's laboratory certification program. This rule revision will be a comprehensive review of the requirements in ch. ATCP 77 done to modernize standards for laboratories.

3. Statutory authority for the rule (including the statutory citation and language):

Sections 93.07 (1) and 93.12 (5) and (7), Stats.

93.07 Department duties. It shall be the duty of the department:

(1) REGULATIONS. To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, which regulations shall have the force of law.

93.12 Laboratories, approval of.

(5) The department shall establish uniform minimum standards to be used in the evaluation and certification of laboratory examinations. The department shall submit any rules proposed under this subsection which affect the laboratory certification program under s. 299.11 to the department of natural resources and to the state laboratory of hygiene for review and comment. These rules may not take effect unless they are approved by the department of natural resources within 6 months after submission.

(7) The department shall promulgate rules establishing a fee schedule to offset the cost of the certification of laboratories and the collection of fees under sub. (4).

4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:

The Department estimates that it will use approximately 0.20 FTE staff to develop this rule, including time required for investigation and analysis, rule drafting, preparing related documents, holding public hearings, and communicating with affected persons and groups. The Department will use existing staff to develop this rule.

5. Description of all entities that may be impacted by the rule:

This rule revision would impact Wisconsin's certified milk, food and water testing laboratories.

6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:

Federal regulations establish standards for milk, water, or food. Laboratory certification ensures that tests conducted to measure these product safety and quality standards are accurate. For example, the Grade "A" Pasteurized Milk Ordinance (PMO) requires several milk tests. The PMO requires milk tests to be

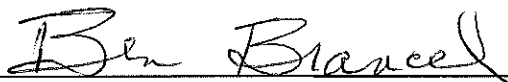
performed in an accredited milk laboratory. These milk laboratories are required to be evaluated and meet requirements included in the "Evaluation of Milk Laboratories", which is a set of standards established by the Public Health Service of the Food and Drug Administration and the National Conference on Interstate Milk Shipments, to ensure the competency of milk laboratories. Although compliance with the PMO is technically a voluntary effort by state regulatory agencies, Wisconsin is periodically evaluated by the FDA for compliance with the PMO. Failure to pass the FDA audit would jeopardize the state's interstate and international dairy industry.

Public water systems serving at least 25 people or having at least 15 service connections must comply with the federal Safe Drinking Water Act (SDWA) and the requirements of the National Primary Drinking Water Regulations (NPDWR) (40 CFR 141). 40 CFR 142.10 requires states to adopt drinking water regulations that are no less stringent than the NPDWR and to maintain procedures for enforcement of those state regulations. The enforcement program under 40 CFR 141.10 (3) (i) requires states to establish and maintain a state laboratory certification program for laboratories conducting analytical measurements of drinking water contaminants. Although DNR has primary enforcement responsibility, or "primacy," under the law, DNR has designated the Department as the certifying agency under the act.

7. Anticipated economic impact

The rule revision may result in minor modifications of the fee structure and the frequency of on-site reviews of laboratories that analyze wastewater may change. However, these changes are not expected to have a significant economic impact on Wisconsin's certified laboratories.

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Ben Brancel
Secretary
Department of Agriculture, Trade and Consumer Protection



Date Submitted