State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection

DATE: December 16, 2019

TO: The Honorable Roger Roth
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The Honorable Robin Vos
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FROM: Randy J. Romanski, Interim Secretary
Department of Agriculture, Trade and Consumer Protection

SUBJECT: **Ch. ATCP 77– Laboratory Certification; Final Rule Draft**

Introduction

The Department of Agriculture, Trade and Consumer Protection (Department) is transmitting this rule for legislative committee review, as provided in Wis. Stat. ss. 227.19 (2) and (3). The Department will publish notice of this referral in the Wisconsin Administrative Register, as provided in Wis. Stat. s. 227.19 (2). 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. s. 93.12 (7); 3) the structure for prorating partial-year certification fees in accordance with Wis. Stat. s. 93.12 (4); and 4) the frequency of on-site certified wastewater-testing laboratory reviews that optimize efficiency without jeopardizing public safety.

Background

Under Wis. Admin. Code ch. ATCP 77 (Laboratory Certification), the 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). 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).

Rule Content

Revised Fee Structure

The fees for laboratory certification were last updated in 2008. The proposed fee increases are approximately 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. 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 test they are certified for, changes from $410 to $500.
- Annual fee for a certified analyst changes from $30 to $40.
- Annual fee for a laboratory, for each water test they are certified for, changes from $340 to $420.
- 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 $750 for most facilities, and from $150 to $180 for very small facilities.
- Drug residue screening laboratory annual fees change from $60 to $70 for most facilities, and from $30 to $35 for very small facilities.

Discretionary Inspection fees

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 rule requires all laboratories to measure and record equipment temperatures at least daily. Many laboratories are 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. The proposed change aligns ATCP 77 with the FDA and EPA and eliminates a staffing burden for laboratories.

Every 3 year inspections

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 proposed 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 proposed 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, an analyst loses their certification if not present for a laboratory's mandatory inspection. The new proposed 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.

An analyst in provisional status because they missed 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 proposed change will put the rule in 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 target 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 proposed rule contains other revisions to match updated terminology and technology, add newly approved test procedures, and remove test procedures that are no longer approved or commercially available. Some revisions are made to 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 proposed rule expands the definition of milk to include the other species of animals (water buffalo and camelids) that are recognized by the FDA.

- The proposed 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 proposed 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 proposed 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.

Public Hearings

The Department held three public hearings on this rule: 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 on the State Legislature's Active Rules Clearinghouse website and in the Administrative Register. Pre-hearing 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 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.

Response to Clearinghouse Comments

The Department incorporated all of the corrections suggested by the Legislative Council Rules Clearinghouse.

Small Business Regulatory Review Board Report

The Small Business Regulatory Review Board did not issue a report on this rule.

Fiscal and Economic Impact and Effect on Small Business

The Department believes the changes proposed will have 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 approximately $42,250.

Environmental Impact

This rule has no environmental impact.

Federal and Surrounding State Laws

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.

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 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.