STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☐ Original ☒ Updated ☐ Corrected

2. Date
9-5-2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
ATCP 77, Laboratory Certification

4. Subject
Certification of laboratories and analysts testing milk, food, and water

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☒ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$35,864

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
Updating: 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) structure for prorating partial-year certification fessin accordance with Wis. Stat 93.12 (4), and 4) frequency of on-site certified watewater-testing laboratory reviews to optimize efficiency without jeopardizing public safety.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
DATCP personnel calculated changes in fees for each certified laboratory and analyst using existing in-house records. The operator of each certified laboratory was invited in writing to attend rule hearings or submit comments. 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 in making timely adjustments to program fees to reflect the actual requirements to staff and equip the program. The Department has

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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.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.

None. N/A

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

The fees for laboratory certification were last updated. 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 $1/12^{th}$ of the annual fee. While fees are increasing by an estimated $35,864 across the 81 certified milk or food laboratories, 96 drug residue screening laboratories, and 127 safe drinking water testing laboratories, the rule eliminates the requirement to conduct a supplemental survey if the lab switches to a similar test method, or an analyst misses a mandatory inspection. This change will decrease the overall economic impact.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

Implementing the rule provides clearer, up-to-date, and more flexible requirements for laboratory operators. The alternative, not implementing the rule would create confusion about recent changes in federal requirements, e.g. fecal coliform analyte in water being changed to Escherichia coli, and continues less flexible requirements. Failure to implement fee increases would necessitate program costs being borne by other DATCP funding sources.

16. Long Range Implications of Implementing 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.

17. 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 the grade "A" Pasteurized Milk Ordinance (PMO) and the Evaluation of Milk Laboratories (EML), which are amended

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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 Wisconsin Department of Natural Resources. 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.

18. 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.

19. Contact Name	20. Contact Phone Number
Caitlin Jeidy, Division of Food and Recreational Safety, Program and Policy Analyst - Advanced	(608) 224-4696

This document can be made available in alternate formats to individuals with disabilities upon request.

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

DATCP has no way of determining whether certified laboratories are small businesses. Please see summary above.

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

Please see item 12 above.

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ 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:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

None.

5. Describe the Rule's Enforcement Provisions

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 proscribed time frame, the laboratory or analyst license will be suspended for that specific test procedure.

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

☐ Yes ☒ No