

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 _____ day of _____, 2019.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
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