

JUN 15 REC'D

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTIONNOTICE OF SUBMISSION OF PROPOSED RULES TO
PRESIDING OFFICERS OF EACH HOUSE OF THE LEGISLATURE

NOTICE IS HEREBY GIVEN, pursuant to s. 227.19 (2), Stats., that the State of Wisconsin Department of Agriculture, Trade and Consumer Protection is submitting a final draft of proposed Clearinghouse Rule Number 98-142 to the presiding officer of each house for standing committee review. The proposed rule repeals ss. HSS 165.02(4), (12)(b) and (14), 165.03(1)(title) and (intro.), 165.03(1)(a)(intro.), 165.03(1)(b) to (d), 165.14(2)(a)11. and (3)(g), 165.20(2), and 165.23(1)(g); renumbers HSS 165.03(1)(a)1. to 7.; amends HSS 165.01(1) and (2), 165.02(8), (9), (12)(intro.), (13) and (17), 165.03(1)(intro.) and 165.04(1)(intro.); repeals and recreates ch. ATCP 77; and creates HSS 165.03(intro.) relating to certification of laboratories engaged in public health testing of milk, water and food.

Dated this 12 day of June, 1999.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Ben Brancel
Ben Brancel, Secretary



State of Wisconsin
Tommy G. Thompson, Governor

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary



DATE: June 3, 1999

TO: The Honorable Fred Risser
President, Wisconsin State Senate
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PO Box 7882
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The Honorable Scott Jensen
Speaker, Wisconsin State Assembly
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FROM: Ben Brancel, Secretary *Ben Brancel*
Department of Agriculture, Trade and Consumer Protection

SUBJECT: **Proposed Rule Relating to Certification of Laboratories Engaged in Public Health Testing of Milk, Water and Food (Clearinghouse Rule No. 98-142)**

In accordance with ss. 227.19 (2) and (3), Stats., the Department of Agriculture, Trade and Consumer Protection hereby transmits the above rule for legislative committee review. We are enclosing 3 copies of the final draft rule, together with the following report. In accordance with s. 227.19 (2), Stats., the department will publish a notice of this referral in the Wisconsin Administrative Register.

1. BACKGROUND AND EXPLANATION OF NEED FOR RULE

The 1995-97 biennial budget act, 1995 Wis. Act 27, transferred much of the administration of Wisconsin's laboratory certification program from the Department of Health and Family Services ("DHFS") to the Department of Agriculture, Trade and Consumer Protection ("DATCP").

Under this program, DATCP is now responsible for certifying laboratories that test milk, food and drinking water for compliance with public health standards. (DHFS retains jurisdiction over certain public health laboratories, such as medical laboratories.) Laboratory certification helps ensure that public health lab tests are accurate and reliable.

This rule is the foundation for the lab certification program now located in DATCP. This rule does not make major changes in the current lab certification program. However, this rule streamlines and clarifies current rules so they will be easier to read and understand. This rule replaces relevant portions of DHFS lab certification rules under ch. HSS 165, Wis. Adm. Code. It also repeals and recreates DATCP's interim lab certification rules under ch. ATCP 77, Wis. Adm. Code.

2. SUMMARY OF RULE PROVISIONS; LABORATORY CERTIFICATION PROGRAM

Who Must be Certified

Under s. 93.12, Stats., and this rule, DATCP must certify laboratories that test milk, water or food for compliance with federal, state or local public health standards. This rule specifies the tests for which a laboratory must be certified. Both private and public laboratories must be certified under this rule. However, certification is not required for any of the following:

- The United States government.
- Milk testing by DATCP.
- An educational institution that operates a laboratory solely for teaching or academic research purposes, and does not test milk, water or food for human consumption .
- A person who operates a laboratory solely to conduct quality control tests on food or water sold by that person, provided that the tests are not required by statute, rule or ordinance.

Scope of Certification

DATCP must certify a laboratory on an annual basis. An annual certification expires on December 31 of each year. A person who operates 2 or more laboratories must obtain a separate certification for each lab. DATCP must specify, in its certification, the tests which the laboratory is certified to perform.

Applying for Certification

A laboratory must apply to DATCP for certification, and must pay an annual certification fee of \$216 per test. If DATCP certifies a lab to perform a test for less than a full year, the lab must pay a certification fee of \$18 for each full month of certification.

DATCP must act on a certification application within 40 calendar days after it receives a complete application. A laboratory may apply, at any time, for certification to perform

additional tests. A certified laboratory must file an annual renewal application by December 31 of each year.

Granting and Withdrawing Certification

Within 40 days after DATCP receives a laboratory certification request, DATCP must inspect the laboratory and act on the request. DATCP will grant a certification request if the laboratory meets applicable certification requirements. DATCP may conditionally certify a laboratory pending action to correct deficiencies which DATCP has identified. DATCP may summarily suspend a conditional certification if the laboratory fails to correct the deficiencies within the time specified by DATCP.

Laboratory Facilities

A laboratory must have adequate facilities, equipment and supplies to perform the tests for which DATCP certifies that laboratory. A laboratory must also maintain the facilities, equipment and supplies in proper working condition. This rule establishes some specific facility and maintenance requirements. Under this rule, a laboratory must notify DATCP whenever it remodels lab facilities or installs new equipment that materially affects certified testing.

Laboratory Procedures

A certified laboratory must perform tests according to recognized methods. This rule incorporates, by reference, authoritative lab manuals which spell out those recognized methods. As required under s. 227.21, Stats., DATCP has requested permission from the attorney general and the revisor of statutes to incorporate these manuals by reference in this rule. Consent was granted on March 26, 1999.

Laboratory Administrator

A certified laboratory must designate an administrator who personally supervises the operations of the laboratory. The administrator or a designated agent of the administrator must be present at the laboratory during daytime business hours, and must do all of the following on behalf of the lab operator:

- Supervise the lab and its compliance with this rule.
- Review and approve the lab's certification applications to DATCP.
- Supervise the procurement and maintenance of lab facilities, equipment and supplies.
- Facilitate DATCP inspections of the lab.

- Notify DATCP of changes in lab facilities or personnel that affect the lab's certification.
- Notify lab customers if DATCP suspends or revokes the lab's certification.
- Report lab test results to the appropriate regulatory agency, if required by law.
- Supervise lab recordkeeping.

Inspecting a Laboratory

DATCP must inspect a laboratory at all of the following times:

- Before certifying the laboratory for the first time.
- At least once every 2 years after it certifies the laboratory.
- Before certifying the laboratory to perform a test for which it was not previously certified.

DATCP may inspect a laboratory whenever any of the following occurs:

- The laboratory materially alters its facilities, equipment or procedures.
- The laboratory assigns a new analyst to perform a test for which the lab is currently certified.
- DATCP concludes that an inspection is necessary to determine whether the lab complies with this rule.

Milk and Food Laboratories; Certified Analysts

DATCP may not certify a milk or food laboratory to perform any test unless DATCP individually certifies the analysts who perform those tests. DATCP certifies analysts by conducting on-site "competency evaluations." DATCP performs these "competency evaluations" when it conducts its initial, and subsequent biennial, inspections of the laboratory. An analyst's certification remains in effect until one of the following occurs:

- DATCP conducts its next biennial inspection of the laboratory.
- The analyst leaves the laboratory.
- DATCP suspends or revokes the analyst's certification.

A milk or food laboratory must notify DATCP whenever a certified analyst leaves the laboratory, or whenever there is a staffing change that affects the lab's compliance with this rule.

Milk and Food Analysts; Annual Proficiency Evaluation

Milk and food analysts must pass annual "proficiency evaluations." In an annual proficiency evaluation, an analyst must examine samples prepared by an approved evaluator. The evaluator knows the contents of the samples, but the analyst does not. The evaluator rates the analyst's proficiency by comparing the analyst's results to the known sample contents, and reports the rating to DATCP.

DATCP may "conditionally certify" an analyst before the analyst completes an annual proficiency evaluation. But if a "conditionally certified" analyst fails an annual proficiency evaluation, DATCP must summarily suspend the analyst's certification. If a "conditionally certified" analyst passes an annual proficiency evaluation, the analyst is fully certified.

If a fully certified analyst fails an annual proficiency evaluation, the analyst is "provisionally certified." If a "provisionally certified" analyst passes a new proficiency evaluation, the analyst is again fully certified. But if a "provisionally certified" analyst fails another proficiency evaluation, DATCP must summarily suspend the analyst's certification. The analyst may then regain full certification only by completing a training course and passing a new proficiency evaluation.

Analysts need not complete annual proficiency evaluations for a milk or food test until DATCP has established written proficiency evaluation procedures for that test. DATCP has established written procedures for milk tests, and is developing written procedures for food tests. This rule establishes basic standards for proficiency evaluations.

Water Laboratory Analysts

DATCP does not individually certify water analysts, as it does food and milk analysts. However, a water lab operator must annually document, to the department, that analysts are trained and competent to perform water tests for which the lab is certified. Whenever DATCP conducts an initial or biennial inspection of a water laboratory, DATCP must evaluate the competency of an analyst who performs tests for which the water lab is certified.

Water Laboratories; Annual Proficiency Evaluation

Before the department certifies a water laboratory to perform any test, the laboratory must complete a "proficiency evaluation" for that test. The laboratory must also complete an annual proficiency evaluation before the department renews the laboratory's annual certification.

In a proficiency evaluation, an analyst designated by the lab operator must examine samples prepared by an approved evaluator. The contents of the samples are known only to the evaluator. The evaluator must rate the laboratory's proficiency by comparing the lab analyst's results to the known contents of the samples, and must report those results and ratings to DATCP.

DATCP must approve lab evaluation procedures. A laboratory is not required to undergo a proficiency evaluation for any test unless DATCP has established an evaluation procedure for that test. DATCP has established written procedures for most water tests. This rule establishes basic standards for proficiency evaluations.

If a water laboratory fails to pass an annual proficiency evaluation for any test which the lab is certified to perform, DATCP must notify the operator that the lab is "provisionally certified" to perform that test. A "provisionally certified" lab may regain full certification by passing 2 consecutive proficiency evaluations. But if a "provisionally certified" lab fails to pass either of the next 2 proficiency evaluations, DATCP must summarily suspend the lab's certification. DATCP may restore the lab's certification if (a) the lab operator documents steps taken to correct the performance deficiency, and (b) the lab passes a new proficiency evaluation.

Laboratory Records

A laboratory must keep complete records related to all of the following:

- The training, experience and proficiency evaluation of analysts.
- Laboratory evaluations.
- Laboratory policies and procedures.
- Laboratory facilities, equipment and supplies, including records related to procurement, calibration, testing and maintenance.
- Quality control procedures and monitoring.
- Tests performed at the laboratory, including the nature of the test, the person for whom the test is performed, the assigned analysts, the test methods used, the date and time of testing, and the test results obtained.
- Test reports filed with the department and other government agencies.

A laboratory must keep these records for at least 5 years, and must make them available for inspection and copying by DATCP upon request. A laboratory may not falsify any records.

3. SUMMARY OF PUBLIC HEARING TESTIMONY

The department held one hearing on November 12, 1998, to solicit comments on the draft rule. The hearing was conducted for video-conference participation by all persons in attendance at any of four separate locations. A combined total of 20 people attended in Eau Claire, Green Bay, Milwaukee and Madison, with 9 persons giving oral testimony. Five written comments were also received before the close of the hearing record.

A summary of the hearing testimony with a list of persons attending, testifying or submitting written comments for the hearing record is attached as APPENDIX A.

4. RULE MODIFICATIONS AFTER PUBLIC HEARING

In response to hearing comments, the department made significant changes to the final draft rule. Changes included the following:

- The final draft rule requires individual certification of analysts who perform tests at milk and food laboratories, but does not require individual certification of analysts at water laboratories.
- The final draft clarifies requirements for proficiency evaluations, and clarifies the consequences for labs and analysts that fail proficiency evaluations.
- The final draft clarifies the standards used to determine whether a lab or analyst "passes" or "fails" a proficiency evaluation.
- The final draft clarifies that milk component tests (e.g., butterfat and protein tests) are not covered by this rule, because they are not public health tests.
- The final draft reorganizes portions of the hearing draft to incorporate key changes. It also makes a number of editorial and drafting changes.

The DATCP Board approved the final draft rule on January 21, 1999.

5. RESPONSE TO RULES CLEARINGHOUSE COMMENTS

The department made a number of editorial and drafting changes in response to comments from the Legislative Council Rules Clearinghouse.

The Rules Clearinghouse did not think the hearing draft clearly stated the laboratory examinations the department deemed necessary for the protection of public health. In the final

draft, the department specifies in s. ATCP 77.02 which laboratory tests of milk, water and food it deems necessary for this purpose.

Quality control procedures are specified in s. ATCP 77.10(2). The consequences of a laboratory's failure to follow those standards and practices is the suspension or revocation of a laboratory operator's certification, as provided under s. ATCP 77.08(4).

Revisions in the final draft rule created three certification categories, i.e., full certification, conditional certification and provisional certification. Under the latter category, certification is withdrawn or revoked if an analyst does not meet minimum standards on proficiency samples in two successive evaluations. These changes were made in response to LCRC comment 1.c. and the rule now complies with the statutory requirement of s. 93.12(4), Stats.

6. FISCAL ESTIMATE

This rule does not substantially alter the procedures which DATCP uses to inspect and certify laboratories. Nor does it change current laboratory fees. Therefore, this rule will have no state fiscal effect. A fiscal estimate is attached as APPENDIX B.

7. REGULATORY FLEXIBILITY ANALYSIS

This rule will have a negligible impact on small business, because laboratories are currently meeting these standards. It will not be necessary for certified laboratories to retain additional professional services to comply with this rule. A final regulatory flexibility analysis ("small business analysis") is attached as APPENDIX C.