Clearinghouse Rule 96-149

STATE OF WISCONSIN

DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION ss.

Clearinghouse Rule No. 96-149

CERTIFICATION:

I, Alan T. Tracy, Secretary of the State of Wisconsin, Department of Agriculture, Trade and Consumer Protection, and custodian of the department's official records, hereby certify that the attached rulemaking order relating to lab certification, was signed and adopted by the Department on December 12, 1996.

I further certify that I have compared the attached copy to the original on file in the department, and that the attached copy is a complete and accurate copy of the original.

Signed and sealed this 12th day of December, 1996.



STATE OF WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

By Secretary Tracy, Alan T.





2-1-97

Final Draft 12/12/96

ORDER OF THE STATE OF WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION ADOPTING, AMENDING OR REPEALING RULES

1 The state of Wisconsin department of agriculture, trade and 2 consumer protection adopts the following order <u>to repeal</u> HSS 3 165.21 and <u>to create</u> ATCP 77 relating to laboratory certification 4 fees.

Analysis Prepared by the Department Agriculture, trade and Consumer Protection

Statutory authority:

ss. 93.07(1), 93.12(7), and 97.24(3), Stats.

Statutes interpreted:

ss. 93.12(4) and (7) and 97.24, Stats.

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 social services to the department of agriculture, trade and consumer protection ("department"), effective July 1, 1996.

Under this program, the department will be responsible for certifying laboratories that test milk, food or water for compliance with public health standards prescribed by federal, state or local laws. Under 1995 Wis. Act 27, the department's public health lab certification program must be funded by certification fees paid by the certified laboratories. The department must establish these fees by rule.

Current rules governing the public health lab certification program are contained in ch. HSS 165, Wis. Adm. Code. The current rules remain in effect until the department amends or repeals them. This rule repeals portions of HSS 165 related to lab certification and fees, and creates new certification and fee requirements under ch. ATCP 77, Wis. Adm. Code. The department expects to propose the adoption of additional rules related to the lab certification program in 1997. This rule does all of the following:

- Identifies the laboratories which must be certified by the department.
- Establishes a procedure by which a laboratory may obtain and annually renew its certification.
- Establishes certification fees. A certified laboratory must pay an annual certification fee of \$216 for each different type of test performed by the laboratory. If a laboratory applies for certification in mid-year, the certification fee is prorated by the number of months remaining in the calendar year for which the applicant seeks certification.

SECTION 1. Section HSS 165.21 is repealed. 1 SECTION 2. Chapter ATCP 77 is created to read: 2 CHAPTER ATCP 77 3 LABORATORY CERTIFICATION FEES 4 5 ATCP 77.01 <u>DEFINITIONS</u>. In this chapter: (1)"Dairy plant laboratory" means a laboratory, owned and 6 operated by a dairy plant operator, which is solely engaged in 7 testing milk or dairy products. 8 9 (2)"Department" means the state of Wisconsin department of 10 agriculture, trade and consumer protection. "Laboratory" means an entity that performs (3)11 microbiological, biological, physical, chemical, bacteriological 12 13 or microscopic examinations of milk, water or food. (4)"Laboratory operator" means the person who owns or 14 operates a laboratory and who assumes legal responsibility for 15 the laboratory's compliance with this chapter. 16

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1	ATCP 77.02 LABORATORY CERTIFICATION REQUIRED. (1)
2	GENERAL. Except as provided under sub. (2), no laboratory may
3	perform any of the following tests to determine whether milk,
4	water or food complies with health or safety standards prescribed
5	under federal, state or local statutes, rules or ordinances
6	unless that laboratory is currently certified by the department
7	to perform those tests:
8	(a) Milk. Any of the following tests related to milk, milk
9	products or milk containers:
10	1. Standard plate count.
11	2. Plate loop count on raw milk only.
12	3. Spiral plate count on raw milk only.
13	4. Petrifilm aerobic count.
14	5. Bacillus stearothermophilus disc assay test for beta
15	lactam drug residues.
16	6. Charm BsDa.
17	7. Charm I/Cowside II.
18	8. Charm II Competitive.
19	9. Charm II Sequential.
20	10. Charm II Quantitative.
21	11. Charm Farm.
22	12. Charm RlTe.
23	13. Charm Transit.
24	14. Charm I/Cowside Cloxacillin.
25	15. Charm II Cloxacillin.
26	16. Charm II Sulfa.

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1		17. Delvotest P.
2		18. Delvo-X-Press.
3		19. Delvotest P 5-Pack.
4		20. LacTek BL.
5		21. LacTek CEF.
6		22. Penzyme Milk.
7		23. Penzyme III.
8		24. Snap BL.
9		25. Direct somatic cell count.
10		26. Optical somatic cell count.
11		27. Petrifilm coliform count.
12		28. Coliform count.
13		29. Pasteurized milk containers.
14		30. Phosphatase test; Scharer rapid.
15		31. Dairy water.
16		32. Disintegration test.
17		33. Flat lid or pour contact tests.
18		34. Phosphatase test; Fluorophos
19		35. Phosphatase test; Charm.
20		36. Other tests performed to comply with ch. ATCP 60 or 80,
21	Wis.	Adm. Code.
22		(b) <u>Water</u> . Water microbiology tests.
23		(c) <u>Food</u> . Any of the following tests related to food:
24		1. Bacteriological or microscopic examinations of food or
25	food	products.
26		2. Microbiology tests.

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3. Chemical tests.

4. Physical tests.

5. Biological tests

4 (2) EXEMPTIONS. Subsection (1) does not apply to any of 5 the following:

6

(a) A laboratory operated by the United States government.

7 (b) A laboratory which is operated exclusively for teaching
8 or research purposes and which does not test water, milk or food
9 for public consumption.

10 (c) A laboratory which is operated exclusively for internal 11 quality control or product quality purposes, and which does not 12 test water, milk or food for compliance with federal, state or 13 local statutes, rules or ordinances.

(3) ANNUAL CERTIFICATION. The department shall annually
 certify laboratories under sub. (1). An annual certification
 expires on December 31 of each year.

17 ATCP 77.03 APPLYING FOR LABORATORY CERTIFICATION. (1) 18 INITIAL APPLICATION. A laboratory operator shall apply for 19 certification under s. ATCP 77.02 on a form provided by the 20 department. The operator shall submit a separate application for 21 each laboratory location. The application shall include all of 22 the following:

(a) The name and address of the laboratory operator.
(b) The name, address and telephone number of the
laboratory.

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(c) The name and address of the laboratory director.

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(d) The tests under s. ATCP 77.02(1) for which the
 laboratory seeks certification.

3 (e) Other relevant information which the department
4 requires in order to certify the laboratory.

An annual certification fee of \$216 for each test under 5 (f) 6 s. ATCP 77.02(1) for which the applicant seeks certification. If an application for certification is filed for less than a full 7 8 calendar year, the applicant shall include a fee of \$18 for each test for which the applicant wishes to be certified, multiplied 9 by the number of full months remaining in the calendar year for 10 11 which the applicant seeks certification. Fees under this paragraph are nonrefundable if the department has made an 12 13 inspection of the laboratory as part of the approval process.

14 (2) ANNUAL RENEWAL APPLICATION. A laboratory operator
15 wishing to renew an annual laboratory certification shall file a
16 renewal application with the department by December 31 of each
17 year. The operator shall file the renewal application on a form
18 provided by the department. The application shall include all of
19 the following:

(a) The information required under sub. (1)(a) to (e). The
application shall identify changes, if any, from the last annual
renewal.

(b) A renewal fee of \$216 for each test under s. ATCP
77.02(1) for which the applicant seeks to renew or add
certification.

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NOTE: The department will send renewal application forms to certified laboratories approximately 6 weeks before their current annual certifications expire.

4 (3) FEE EXEMPTION. A public health laboratory operated by
5 a county or municipality that has contracted with the department
6 to license and inspect retail food establishments as the
7 department's agent under s. 97.41, Stats., is exempt from
8 certification fees under sub. (1)(f), (2)(b) and (4)(d).

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9 (4) SUPPLEMENTARY APPLICATION. The operator of a certified 10 laboratory may, at any time during a certification year, request 11 certification to perform additional tests which are not included 12 in its current annual certification. The operator shall make the 13 request on a form provided by the department. The request shall 14 include all of the following:

(a) The additional tests under s. ATCP 77.02(1)(a) forwhich the laboratory seeks certification.

17 (b) Information showing that the laboratory is qualified to18 perform the additional tests.

19 (c) Other relevant information which the department20 requires in order to evaluate the request.

(d) A fee of \$18 for each test under s. ATCP 77.02(1) for
which the applicant seeks certification, multiplied by the number
of full months remaining in the calendar year for which the
applicant seeks certification.

(5) FALSIFIED APPLICATION. No person may misrepresent or
 falsify any information related to a certification application
 under this section.

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1 ATCP 77.04 <u>REVIEW OF CERTIFICATION FEES</u>. Before June 30, 2 1999, the department shall evaluate the provisions of this 3 chapter related to laboratory certification program costs and 4 revenues and the need for modification of annual and renewal 5 fees.

6 EFFECTIVE DATE. The rules contained in this order shall 7 take effect on the first day of the month following publication 8 in the Wisconsin administrative register, as provided under 9 s. 227.22(2)(intro), Stats.

Dated this Alth day of Meinher 1996.

STATE OF WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

By Alan T. Tracy, Secretary

