

Under current rules, persons installing C-I-P (cleaned in place) systems must submit plans for DATCP approval. This rule requires the dairy plant operator, not the installer, to submit the plans. DATCP must act on the plans within 20 business days (currently 30 calendar days).

This rule regulates the use of flexible pipelines in dairy plants, to prevent sanitation hazards. Dairy plant operators may use flexible pipelines, subject to conditions specified in this rule, if rigid pipelines are impractical. This rule also modifies current standards for chlorine sanitizers used to sanitize equipment and utensils.

Milk from Dairy Farms

This rule clarifies a dairy plant operator's responsibilities related to the receipt of raw milk from dairy farms. A dairy plant operator may not collect or receive milk from a dairy farm unless all the following apply:

- The dairy farm is properly licensed.
- A licensed milk weigher and sampler collects a sample of the producer's milk (for milk quality testing), and measures and records the temperature and quantity of the producer's milk.
- The operator complies with applicable milk testing and follow-up requirements under ch. ATCP 60 (dairy farms).

Bulk Milk Tanker Deliveries

Current rules prohibit a dairy plant operator from receiving a grade A bulk milk tanker delivery unless the bulk milk tanker operator holds a grade A permit for that tanker. This rule also prohibits a dairy plant operator from receiving any bulk milk tanker delivery unless the tanker operator holds a bulk milk tanker license under s. 97.21(2)(a), Stats., and ch. ATCP 82.

Product Temperature

Current rules require dairy plant operators to keep dairy products above or below specified temperatures, to prevent hazardous bacterial growth. This rule modifies some of these current temperature requirements.

- Under current rules, an operator who receives raw grade B milk or grade B dairy products for processing must keep those dairy products at 50° F. or less until they are pasteurized. Under this rule, the operator must keep those grade B dairy products at 45° or less until they are pasteurized (the same temperature currently required for grade A products). There is an exemption for milk received within 2 hours of milking, provided the milk is pasteurized or cooled to 45° within 4 hours.
- Under current rules, a dairy plant operator may not hold milk or dairy products for more than 4 hours at a temperature that is between 45° F. and 140° F. Certain dairy products are currently exempt. This rule adds some limited exemptions.

- Under current rules, dairy plant operators must keep certain non-dairy foods (including certain dairy product ingredients) at “safe temperatures” to prevent hazardous bacterial growth. This rule establishes new “safe temperature” requirements for these non-dairy foods, as follows:

- For refrigerated foods: 41° F. (currently 40° F.)
- For heated foods: 140° F. (currently 150° F.)
- For frozen foods: 0° F. (same as now)

Reprocessing Returned Products

Current rules prohibit a dairy plant operator from reprocessing *grade A* packaged dairy products returned to a dairy plant. There are certain exemptions. This rule prohibits a dairy plant operator from reprocessing *any* packaged dairy products (not just grade A products) returned to the dairy plant, except that it does not prohibit any of the following:

- The use, as ingredients, of packaged dairy products that are specifically manufactured and packaged for use as ingredients in other dairy products.
- Reprocessing packaged dry milk and dry milk products, if the inner package is intact.
- Reprocessing packaged cheese or butter returned for failure to meet grade or color standards, if the inner package is intact and there is no evidence of product or temperature abuse.
- Reprocessing dairy products collected from a packaging defoamer system, or drained from processing equipment at the end of a run, if the products are handled in a sanitary manner and repasteurized.
- Reprocessing specifically authorized by DATCP in writing, under terms and conditions specified by DATCP.

Bacteria, Coliform, Yeast and Mold

This rule establishes more comprehensive bacteria and coliform standards for pasteurized dairy products. Under this rule, bacteria counts may not exceed 20,000 per ml. for most pasteurized dairy products. This standard does not apply to cultured dairy products (such as yogurt). Bacteria counts for the following products may not exceed the following levels:

- 30,000 per ml. for condensed milk, whey, dried whey and nonfat dry milk.
- 50,000 per gram for frozen desserts, except that the bacteria count for frozen dessert mixes may not exceed 20,000 per gram.

Under this rule, coliform counts in pasteurized dairy products may not exceed 10 per ml., except that coliform counts for pasteurized cheese, cheese products, butter and butter products may not exceed 100 per gram. If pasteurized cheese is manufactured from unpasteurized dairy products, its coliform count may not exceed 1,000 per gram.

Under this rule, the yeast and mold count in pasteurized cottage cheese may not exceed 10 per gram.

Fortified Dairy Products

This rule updates current standards for fortified dairy products. This rule incorporates the latest PMO standards (1999). DATCP will ask the Attorney General and the Revisor of Statutes for permission to incorporate these standards by reference in this rule.

Milk Quality and Milk Component Test Methods

This rule updates current milk quality and milk component test methods. Milk test methods must be those prescribed in "Standard Methods for the Examination of Dairy Products," 16th edition (1992), or in the "Official Methods of Analysis of the Association of Analytical Chemists (AOAC) International, 17th edition (2000). DATCP will ask the Attorney General and the Revisor of Statutes for permission to incorporate the updated AOAC standards by reference in this rule. DATCP may approve other test methods.

Pasteurization Standards

This rule establishes standards for higher-heat shorter-time (HHST) pasteurizers, including minimum temperature and hold times. This rule also updates standards for conventional batch pasteurizers and high-temperature short-time (HTST) pasteurizers. HTST and HHST pasteurizers must meet technical standards published jointly by FDA, the International Association of Food Industry Suppliers and the International Association of Food Protection. DATCP will ask the Attorney General and the Revisor of Statutes for permission to incorporate the updated standards by reference in this rule.

DATCP periodically tests pasteurizers according to procedures specified in the PMO. This rule updates current procedures to meet current PMO standards. DATCP will ask the Attorney General and the Revisor of Statutes for permission to incorporate the updated PMO standards by reference in this rule.

When DATCP determines that a pasteurizer is operating correctly, it seals the pasteurizer to prevent alterations that might allow unpasteurized product to flow through the system. A dairy plant operator must immediately notify DATCP whenever a pasteurizer malfunctions or the operator breaks the seal (to repair a malfunctioning pasteurizer, for example). The dairy plant operator may not resume pasteurizer operations until certain safety requirements are met. This rule expands and clarifies those safety requirements. This rule extends, by 5 days, the current 5-day deadline for resealing the pasteurizer.

Pasteurization Records

This rule expands and updates current pasteurization record keeping requirements. Among other things it expands current record keeping requirements related to HTST and HHST pasteurization. Records must document that pasteurization met minimum standards designed to ensure dairy product safety.

Dairy Plant Records

Under current rules, a dairy plant operator must keep certain records and make those records available for inspection and copying by DATCP. This rule expands and clarifies current record keeping requirements. This rule:

- Authorizes a dairy plant operator to keep cleaning and sanitizing records for C-I-P (“cleaned in place”) systems in electronic form, with or without a hard copy. Electronic records must be accessible by a DATCP inspector.
- Requires a dairy plant operator to keep records related to vitamin fortification of fluid milk products, including inventory records and vitamin assay records.

Grade A Audit Surveys

Under the PMO, current state statutes and current DATCP rules, the Department of Health and Family Services (DHFS) must audit grade A dairy plants and dairy farms for compliance with PMO requirements. DHFS also audits DATCP’s compliance program for compliance with the PMO. This rule updates current audit standards to meet current PMO requirements. DATCP will ask the Attorney General and the Revisor of Statutes for permission to incorporate the updated PMO standards by reference in this rule.

Drafting and Organizational Changes

This rule makes a number of drafting and organizational changes to clarify and update current rules.

ATCP 77 (Emergency Rule and Proposed Rule)

Analysis Prepared by the Department of Agriculture, Trade and Consumer Protection

Statutory authority: ss. 93.07(1) and 93.12(3), (5) and (7), Stats.,
and s. 227.24, Stats. (emergency rule)

Statutes interpreted: ss. 93.12, Stats.

Background

The Department of Agriculture, Trade and Consumer Protection (DATCP) certifies laboratories that test milk, food and drinking water for compliance with public health standards. Laboratory certification helps ensure that public health lab tests are accurate and reliable. DATCP has adopted laboratory certification rules under ch. ATCP 77, Wis. Adm. Code.

Under current rules, DATCP certifies laboratories and approves analysts who conduct confirmatory drug residue tests on milk samples. But DATCP does not currently approve analysts who conduct “visual read” drug residue screening tests. The U. S. Food and Drug Administration (FDA), recently required states to approve laboratory analysts who

conduct "visual read" screening tests. Analysts must be approved by March 1, 2002, or dairy plants may no longer be able to ship milk in interstate commerce.

This emergency rule implements the new FDA mandate. Under this emergency rule, DATCP will immediately begin to evaluate and approve analysts performing "visual read" screening tests, so that approvals will be in place by the March 1, 2002 deadline. DATCP will charge fees to cover the cost of the new program.

The emergency rule will expire after 150 days, unless extended. In order to continue the new program, DATCP also proposes to adopt the emergency rule as a "permanent" rule. This will ensure continued compliance with grade A interstate milk shipment requirements.

Rule Contents

Under this rule, analysts conducting drug residue screening tests on milk must be approved by DATCP. DATCP will evaluate and approve laboratory analysts who conduct "visual read" tests. DATCP will evaluate analysts who work for certified laboratories. Analysts at an approved laboratory will be authorized to conduct "visual read" tests for which the laboratory is also approved. Analysts will be approved to conduct those tests at that laboratory, but will not be approved to conduct the same tests at a different laboratory.

An approved laboratory may not employ unapproved analysts to conduct "visual read" tests. Before DATCP approves an analyst to perform a "visual read" test, DATCP will observe and evaluate the analyst's competency to perform that test. An approval expires on December 31 of each year unless, by that date, the laboratory documents to DATCP that the analyst has completed an annual proficiency test and has correctly identified both positive and negative samples.

Under this rule, a laboratory conducting "visual read" drug residue screening tests must pay the following fees:

- \$500 for initial approval of up to 3 analysts, and \$25 for approval of each additional analyst during the same initial laboratory visit.
 - \$150 for any subsequent visit to approve analysts, regardless of the number of analysts approved on that visit.
 - \$100 for the annual renewal of analyst approvals. A \$100 annual renewal covers all analysts currently approved to perform milk drug residue screening tests at that laboratory. No site visit is required for an annual renewal. An annual renewal does not cover new analysts, nor does it cover analysts performing tests that they have not yet been approved to perform.
-

Fiscal Estimate

ATCP 80 & 69

The proposed rule to modify chs. ATCP and 69, Wis. Adm. Code, will not have a significant fiscal impact on DATCP or local units of government. This rule updates current food safety requirements, and accommodates recent changes in dairy plant operations. It also clarifies the responsibility of dairy plant operators with respect to milk procurement from dairy farms. It does not affect DATCP staffing or funding.

ATCP 77

The emergency rule and proposed rule related to DATCP approval of milk laboratory analysts under ATCP 77, Wis. Adm. Code, will have a fiscal impact on DATCP. Under this rule, DATCP staff must perform additional evaluations of lab analysts, and must process additional approvals and annual renewals. DATCP must conduct evaluations at approximately 30 laboratories throughout the state. DATCP will incur some overtime costs in order to complete initial approvals by March 1, 2002. DATCP anticipates that this program will cost approximately \$15,000 each year.

DATCP's laboratory certification program is entirely fee-funded. DATCP will not be able to absorb the additional costs, and will need to charge additional fees to cover the costs. Under this rule, a laboratory conducting "visual read" drug residue screening tests must pay the following fees:

- \$500 for initial approval of up to 3 analysts, and \$25 for approval of each additional analyst during the same initial laboratory visit.
- \$150 for any subsequent visit to approve analysts, regardless of the number of analysts approved on that visit.
- \$100 for the annual renewal of analyst approvals. A \$100 annual renewal covers all analysts currently approved to perform milk drug residue screening tests at that laboratory. No site visit is required for an annual renewal. An annual renewal does not cover new analysts, nor does it cover analysts performing tests that they have not yet been approved to perform.

DATCP estimates that these fees will generate approximately \$15,000 in new revenues each year. DATCP estimates that these revenues will be approximately commensurate with the additional costs that DATCP will incur to evaluate and approve lab analysts under this rule.

Initial Regulatory Flexibility Analysis

ATCP 80 & 69

This rule applies to dairy plant operators, many of whom are "small businesses." This rule merely updates current rules and will not, in and of itself, have a major impact on small business. Much of this rule codifies federal requirements that Wisconsin processors must meet in order to ship milk and dairy products in interstate commerce. The rule will not add significant new costs, nor will it require dairy plants to retain additional professional services such as accounting or legal services.

ATCP 77

This rule affects milk testing laboratories, some of which are "small businesses." This rule requires DATCP approval of laboratory analysts performing "visual read" screening tests for drug residues in milk. DATCP will charge fees to certified laboratories to cover the cost of evaluating and approving analysts. This will impose some additional costs on laboratories, but will help Wisconsin's dairy industry by facilitating sales of Wisconsin dairy products in interstate commerce.

Under this rule, a laboratory conducting "visual read" drug residue screening tests must pay the following fees:

- \$500 for initial approval of up to 3 analysts, and \$25 for approval of each additional analyst during the same initial laboratory visit.
- \$150 for any subsequent visit to approve analysts, regardless of the number of analysts approved on that visit.
- \$100 for the annual renewal of analyst approvals. A \$100 annual renewal covers all analysts currently approved to perform milk drug residue screening tests at that laboratory. No site visit is required for an annual renewal. An annual renewal does not cover new analysts, nor does it cover analysts performing tests that they have not yet been approved to perform.

An approval expires on December 31 of each year unless, by that date, the approved laboratory documents to DATCP that the analyst has completed an annual proficiency test and has correctly identified both positive and negative samples. This may require some laboratories to conduct and report proficiency tests that they are not now conducting. Laboratories currently have sufficient expertise to administer these proficiency tests to their analysts. No new equipment is required. This rule will not require laboratories to retain additional professional services, such as legal or accounting services.

Dated this 30th day of October, 2001

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By Leslie F. Harsdorf
James E. Harsdorf, Secretary



State of Wisconsin
Scott McCallum, Governor

Department of Agriculture, Trade and Consumer Protection
James E. Harsdorf, Secretary

PUBLIC NOTICE

FINAL DRAFT RULE TO LEGISLATURE

The Department of Agriculture, Trade and Consumer Protection announces that it is submitting the following rule for legislative committee review, pursuant to s. 227.19, Stats.:

CLEARINGHOUSE RULES #: **01-124**
SUBJECT: **Dairy Plants and Dairy Laboratories;
Final Draft Rule**
ADM. CODE REFERENCE: **ATCP 80**
DATCP DOCKET #: **98-R-3**

Dated this 29 day of July, 2002.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE
AND CONSUMER PROTECTION

By James E. Harsdorf
James E. Harsdorf
Secretary



State of Wisconsin
Scott McCallum, Governor

Department of Agriculture, Trade and Consumer Protection
James E. Harsdorf, Secretary

DATE: July 17, 2002

TO: The Honorable Fred Risser
President, Wisconsin State Senate
Room 220 South, State Capitol
P. O. Box 7882
Madison, WI 53707-7882

The Honorable Scott R. Jensen
Speaker, Wisconsin State Assembly
Room 211 West, State Capitol
P. O. Box 8952
Madison, WI 53708-8952

FROM: James E. Harsdorf, Secretary *James E. Harsdorf*
Department of Agriculture, Trade and Consumer Protection

SUBJECT: **Dairy Plants and Dairy Laboratories; Final Draft Rule**
(Clearinghouse Rule # 01-124)

The Department of Agriculture, Trade and Consumer Protection is transmitting this rule for legislative committee review, as provided in s. 227.19(2) and (3), Stats. The department will publish a notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19(2), Stats.

Background

Dairy Plants

The Wisconsin Department of Agriculture, Trade and Consumer Protection ("DATCP") regulates dairy plants to protect consumers and facilitate interstate shipment of Wisconsin dairy products. DATCP currently licenses dairy plants under s. 97.20, Stats., and ch. ATCP 80, Wis. Adm. Code. DATCP licenses individual cheesemakers under s. 97.17, Stats., and ch. ATCP 69, Wis. Adm. Code. Dairy plants processing grade A fluid milk products must hold a grade A permit from DATCP. Dairy plants must also comply with safe milk procurement standards under ch. ATCP 60, Wis. Adm. Code (Dairy Farms).

All dairy products must be produced under sanitary conditions. Dairy plants producing grade A fluid milk products must also comply with the Interstate Pasteurized Milk Ordinance (PMO). Failure to comply with PMO requirements may jeopardize the interstate shipment of Wisconsin dairy products. Current DATCP rules establish standards for all dairy plants, including grade A dairy plants. DATCP rules incorporate PMO standards.



Current DATCP rules spell out requirements related to:

- Dairy plant licensing and fees.
- Dairy plant facilities and operations.
- Dairy product quality standards and testing.
- Pasteurization of dairy products.
- Dairy plant records and reports.
- Inspection and enforcement.
- Cheesemaker license qualifications.

This rule updates existing food safety requirements, and accommodates recent changes in dairy plant operations. This rule applies to grade A and grade B dairy plants. This rule incorporates current grade A dairy plant standards under the Interstate Pasteurized Milk Ordinance (PMO).

Dairy Laboratories

DATCP currently certifies laboratories that test milk, food and drinking water for compliance with public health standards. Laboratory certification helps ensure that public health lab tests are accurate and reliable. DATCP has adopted laboratory certification rules under ch. ATCP 77, Wis. Adm. Code.

Under current rules, DATCP certifies laboratories and approves analysts who conduct *confirmatory* drug residue tests on milk. But until recently, DATCP did not approve analysts who conduct preliminary drug residue *screening* tests. FDA recently required states to evaluate and approve those analysts. FDA required *on-site* competency evaluations of analysts who conduct "visual read" screening tests. FDA required the states to evaluate and approve the analysts by March 1, 2002, and to continue evaluations and approvals on an annual basis.

DATCP adopted a temporary emergency rule, effective November 15, 2001, to implement this new FDA mandate. DATCP evaluated and approved analysts by the March 1, 2002 deadline, so that Wisconsin could continue shipping milk in interstate commerce. DATCP must now adopt a "permanent" rule, so that it can continue to comply with the FDA requirements.

Under the emergency rule and this "permanent" rule, DATCP will conduct on-site competency evaluations, renew annual approvals based on continuing evidence of proficiency, and charge fees to cover program costs. This "permanent" rule reduces some of the fees charged under the emergency rule.

Rule Contents

Dairy Plants

This rule updates current dairy plant rules under chs. ATCP 69 and 80, Wis. Adm. Code. Among other things, this rule:

- Establishes alternative training options for persons who wish to be licensed as cheesemakers.
- Updates current standards for dairy plant facilities.
- Authorizes a dairy plant operator to use reclaimed water for dairy plant operations, subject to specified conditions.
- Clarifies a dairy plant operator's responsibilities related to the receipt of raw milk from dairy farms.
- Modifies current dairy product temperature standards.
- Modifies current standards for bacteria and coliform in pasteurized dairy products.
- Updates current pasteurization standards, and establishes standards for higher-heat shorter-time (HHST) pasteurizers.
- Updates current pasteurization record keeping requirements. Among other things, this rule clarifies record keeping requirements related to high-temperature short-term (HTST) and higher-heat shorter-time (HHST) pasteurization.
- Establishes standards for "aseptic processing systems" used to process and package milk or milk products.
- Updates current standards related to dairy product fortification, dairy product test methods, and grade A audit surveys.
- Makes other drafting and organizational changes to update and clarify current rules.

Dairy Laboratories

Under this rule, DATCP must approve laboratories to conduct drug residue screening tests on milk samples. An approved laboratory must employ DATCP-approved analysts to conduct the tests. DATCP must perform an on-site evaluation of every laboratory and analyst that conducts "visual read" screening tests. The laboratory must pay specified fees to help cover DATCP costs.

An individual's approval to conduct drug residue screening tests expires on December 31 of each year unless, by that date, the laboratory documents to DATCP that the analyst has passed an annual proficiency evaluation. This rule spells out standards and procedures for the annual proficiency evaluation. DATCP may authorize the laboratory operator to conduct annual proficiency evaluations, except that an independent evaluator must evaluate analysts performing "visual read" screening tests.

Under this rule, a laboratory conducting drug residue screening tests must pay the following fees:

- \$500 for initial approval of a laboratory seeking approval to perform "visual read" screening tests. Certain small laboratories that meet specified conditions and seek "visual read" approval are exempt from the higher fee. The fee for initial approval of a qualifying small laboratory is \$150. Fees for initial approval of laboratories performing "visual read" tests include on-site evaluation of up to 3 "visual read" analysts. There is a supplementary fee of \$25 for each additional "visual read" analyst evaluated during the initial laboratory visit. The fee for initial approval of a screening laboratory that does not perform "visual read" tests is \$50, irrespective of the number of analysts at the laboratory
- A \$50 annual renewal fee for laboratories that perform either "visual read" or "mechanical read" drug residue screening tests (\$25 for certain small laboratories). This fee covers the annual laboratory renewal, including the renewal of analysts performing drug residue screening tests at the laboratory. No site visit is required for an annual renewal.
- \$150 for any subsequent visit to evaluate "visual read" analysts, regardless of the number of analysts approved on that visit. An analyst may not perform "visual read" tests until the department approves the analyst based on an on-site evaluation.

Hearings

The department held four public hearings on this rule. Hearing notices announced that the hearings would address draft changes to ATCP 69 and 80, as well as the emergency rule provisions added under ATCP 77. DATCP held the hearings on November 29, 2001 in Eau Claire; December 4, 2001 in Appleton; December 5, 2001 in Monroe; and December 6, 2001 in Madison. The hearing in Madison also had video-conferencing sites at Wisconsin Rapids, LaCrosse and Green Bay.

The following persons appeared at the hearings and spoke in general support of the proposed rules:

- John Umhoeffer, representing the Wis. Cheesemakers Association (Appleton hearing).
- Dean Sommers, representing Alto Dairy (Appleton hearing).
- John Manske, representing the Wisconsin Federation of Cooperatives (Madison hearing).
- Brad Legreid, representing the Wisconsin Dairy Products Association (Madison hearing).

- William Wendorff, Food Science Department, University of Wisconsin – Madison (Madison hearing).

The hearing record remained open until December 15, 2001 for receipt of additional written comments. The following persons submitted written comments suggesting some changes to the draft rule:

- John Umhoeffer, representing the Wisconsin Cheesemakers Association.
- Dean Sommers, representing Alto Dairy.
- John Manske, representing the Wisconsin Federation of Cooperatives.
- William Wendorff, Food Science Department, University of Wisconsin – Madison.

Changes from Hearing Draft

Dairy Plants

- The final draft clarifies requirements for use of reclaimed water:
 - Reclaimed water must have less than one coliform bacterium per 100 ml. of water.
 - Whenever a dairy plant operator installs a new reclamation system, the operator must test the water for 10 working days. Whenever the operator repairs or alters an existing system, the operator must test the water for 5 working days.
 - Reclaimed water may be used for certain purposes only on the day it is reclaimed, except that reclaimed water may be stored for later use if it is automatically maintained at a temperature of not less than 145°F. (63 °C.) or is chemically treated to suppress bacterial growth.
- The final draft modifies provisions related to the use of flexible hoses to transport dairy products at a dairy plant. The final draft eliminates specific hose length restrictions, but provides that hoses should be only as long as necessary for the transport operation. Under the final draft, the dairy plant operator must clean and sanitize the hose when the transport operation is completed, or at least once every 24 hours.
- The final draft retains, with some modifications, current prohibitions against the reprocessing of fluid dairy products that are returned to a dairy plant. The final draft eliminates language that would have extended this prohibition to some non-fluid products.
- The final draft eliminates a proposed pasteurization standard for cheese starter.
- The final draft exempts whey products, while being crystallized, from certain holding temperature requirements.

- The final draft authorizes the use of a digital probe thermometer, as an alternative to a mercury column product thermometer, in a batch pasteurizer.
- The final draft establishes standards for “aseptic processing and packaging systems” used to process and package milk or milk products.
- The final draft allows a dairy plant operator to use facsimile (FAX) transmission to notify the department when a regulatory seal on pasteurization equipment is broken (current rules require telephone notification). The final draft eliminates a hearing draft provision that would also have allowed the operator to give notice by e-mail.

Dairy Laboratories

- The final draft reduces initial fees, and annual renewal fees, for laboratories performing drug residue screening tests:
 - The emergency rule set an initial fee of \$500 for all approved laboratories (\$150 for certain small laboratories). This rule offers a lower fee of \$150 for laboratories that do not perform “visual read” screening tests (as well as for the smaller laboratories that paid the lower \$150 fee under the emergency rule).
 - The emergency rule set an annual renewal fee of \$100 (or \$25 per analyst for certain small laboratories). This rule offers a lower annual renewal fee of \$50 (\$25 for certain small laboratories, and for laboratories that perform no “visual read” screening tests). The laboratory pays this single renewal fee of \$50 or \$25, regardless of the number of analysts employed.
- The final draft makes minor editorial and drafting changes, including terminology changes to distinguish laboratory *certification* (to perform *confirmatory* tests) from laboratory *approval* (to perform drug residue *screening* tests).

Response to Rules Clearinghouse Comments

The department accepted most of the recommendations of LCRC. The suggested changes were non-substantive and related to form, style and placement in the administrative code. Other changes related to clarity, grammar, punctuation and use of plain language.

The department did not accept a recommendation to provide specific information regarding test procedures or acceptable test results when the rules require a dairy plant operator to conduct various tests. Test methods required under ch. ATCP 80 are found in the current rule under s. ATCP 80.32. This section cross-references “Standard Methods for the Examination of Dairy Products,” “Official Methods of Analysis of the Association of Official Analytical Chemists” and acceptable results for required tests.

The department did not accept the recommendation to make any further distinction between a "bulk transport container" and a "bulk milk tanker." The rules currently distinguish the former as a unit into which a milk producer transfers milk as cows are milked on the dairy farm and in which milk is both stored on the farm and transported to a dairy plant. The latter is a unit used by a bulk milk hauler to collect and transport to a dairy plant the milk picked up from several milk producers.

The department also did not accept the LCRC recommendation to provide contact information for a dairy plant operator to notify the department of a broken pasteurization seal. A dairy plant operator has numerous sources for that information, such as license documents, inspection forms, technical service bulletins and records. The requirement has been in existence for many years and dairy plant operators have not indicated they were unable to contact the department because the information was not in the rule.

Small Business Analysis

This rule affects dairy plant operators, some of whom are small businesses. For the most part, this rule will help small businesses by modernizing current regulations to accommodate changing industry practices.

This rule establishes new requirements for dairy laboratories that perform drug residue screening tests. Dairy plant operators operate most of these laboratories, and some of the operators are "small businesses." DATCP must approve laboratories and analysts to conduct screening tests, and must charge fees to recover a portion of its costs. Laboratories must conduct and report annual proficiency tests of their analysts.

This rule will impose some additional costs on dairy laboratories, but will help Wisconsin's dairy industry by facilitating sales of Wisconsin dairy products in interstate commerce. This rule is needed to comply with federal requirements. Laboratories can comply with this rule without acquiring new equipment or professional services. This rule reduces laboratory fees previously established by emergency rule. A small business analysis ("final regulatory flexibility analysis") is attached.

Fiscal Estimate

The proposed dairy plant rules under chs. ATCP 69 and 80 will have no fiscal impact on the department or local units of government. However, the proposed dairy *laboratory* rules under ATCP 77 will have a significant fiscal impact on DATCP. DATCP projects ongoing costs of approximately \$8400 per year to administer the new laboratory approval requirements contained in this rule. DATCP expects to recover approximately 50% of these costs from the fees proposed in this rule. For the time being, DATCP will absorb the remaining costs by spending down current reserves derived from lab certification fees already paid. A fiscal estimate is attached.

**PROPOSED 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 consumer protection proposes the
2 following order to repeal ATCP 80.22(5)(d) and 80.28(1)(b)2.(note); to renumber ATCP
3 77.03(2)(c) and 80.40; to renumber and amend ATCP 80.40(2)(a); to amend ATCP 77.06(1)(a)
4 to (c), 80.01(10), (11) and (34), 80.08(8)(d)4., 80.12(1)(a)(note) and (7)(b)(intro.), 80.14(3)(a)
5 and (c), 80.18(1)(c) and (3)(note), 80.22(8)(note), 80.24(4) and (note), 80.26(2)(a), 80.28(1)(c),
6 80.32(1)(b), (1)(c)(note), (2)(a) and (6), 80.34(2)(c)3. and (note), (5)(d) and (note), (6)(c) and
7 (note), (7)(c) and (note), and (8) and (note), 80.36(3), 80.44(1) and (2)(Table 2), 80.46, 80.48
8 and (note), 80.52(2) and (note), (6)(a), (b)2., 3. and 4., and (c)(intro.), 80.54(1)(g), and
9 80.62(1)(b); to repeal and recreate ATCP 69.02(title) and (1), 77.06(2), 77.22(1), 80.08(7) and
10 (8)(f), 80.10(1)(d), 80.20(1) and (3), 80.22(2)(d) and (5)(a), 80.24(3)(a) and (b), 80.50; and to
11 create ATCP 69.02(4)(title) and (5), 77.01(4m) and (17), 77.03(2)(c), 77.06(1)(e), 77.23,
12 80.01(1g), 80.08(8m), 80.12(1)(g), 80.20(1)(note), 80.24(3)(d), 80.40, 80.44(2m), 80.49, and
13 80.54(1)(L) and (m); relating to dairy plants and drug residue screening laboratories.

**Analysis Prepared by the Department of Agriculture,
Trade and Consumer Protection**

Statutory authority: ss. 93.07(1), 93.12(3), (5) and (7), 97.09(4), 97.20(4), 97.22(8),
97.24(3) and 97.52, Stats.

Statutes interpreted: ss. 93.06(7) and (8), 93.12, 97.02, 97.03, 97.12, 97.17, 97.20,
97.22 to 97.24, 97.50 and 97.52, Stats.

Overview

The Wisconsin Department of Agriculture, Trade and Consumer Protection ("DATCP") regulates dairy plants and dairy laboratories to protect consumers, and to facilitate interstate shipment of Wisconsin dairy products. This rule updates current rules related to dairy plants and dairy laboratories. Among other things, this rule:

- Updates current standards for dairy plant facilities and operations.
- Updates dairy product safety standards.
- Establishes federally-mandated regulations related to laboratories that perform drug residue screening tests on milk. DATCP must approve laboratories to conduct screening tests, and must evaluate and approve individual analysts.
- Establishes alternative training options for persons who wish to be licensed as cheesemakers.

Background

Dairy Plants

DATCP currently licenses and inspects dairy plants under s. 97.20, Stats., and ch. ATCP 80, Wis. Adm. Code. DATCP licenses individual cheesemakers under s. 97.17, Stats., and ch. ATCP 69, Wis. Adm. Code. Dairy plants processing grade A fluid milk products must hold a grade A permit from DATCP. Dairy plants procuring milk from farms must comply with dairy farm rules under ch. ATCP 60, Wis. Adm. Code.

All dairy products must be produced under sanitary conditions. Dairy plants producing grade A fluid milk products must also comply with the Interstate Pasteurized Milk Ordinance (PMO). Failure to comply with PMO requirements may jeopardize the interstate shipment of Wisconsin dairy products. Current DATCP rules establish standards for all dairy plants, including grade A dairy plants. DATCP rules incorporate PMO standards.

Current DATCP rules spell out requirements related to:

- Dairy plant licensing and fees.
- Dairy plant facilities and operations.
- Dairy product quality standards and testing.
- Pasteurization of dairy products.
- Dairy plant records and reports.
- Inspection and enforcement.
- Cheesemaker license qualifications.

This rule updates existing food safety requirements, and accommodates recent changes in dairy plant operations. This rule applies to grade A and grade B dairy plants. This rule incorporates current grade A dairy plant standards under the Interstate Pasteurized Milk Ordinance (PMO).

Dairy Laboratories

DATCP currently certifies laboratories that test milk, food and drinking water for compliance with public health standards. Laboratory certification helps ensure that public health lab tests are accurate and reliable. DATCP has adopted laboratory certification rules under ch. ATCP 77, Wis. Adm. Code.

Under current rules, DATCP certifies laboratories and approves analysts who conduct *confirmatory* drug residue tests on milk. But until recently, DATCP did not approve analysts who conduct preliminary drug residue *screening* tests. FDA recently required states to evaluate and approve those analysts. FDA further required *on-site* competency evaluations of analysts who conduct "visual read" screening tests. FDA required the states to evaluate and approve the analysts by March 1, 2002, and to continue evaluations and approvals on an annual basis.

DATCP adopted a temporary emergency rule, effective November 15, 2001, to implement this new FDA mandate. DATCP evaluated and approved analysts by the March 1, 2002 deadline, so that Wisconsin could continue shipping milk in interstate commerce. DATCP must now adopt a "permanent" rule, so that it can continue to comply with the FDA requirements.

Under the emergency rule and this "permanent" rule, DATCP will conduct on-site competency evaluations, renew annual approvals based on continuing evidence of proficiency, and charge fees to cover program costs. This "permanent" rule reduces some of the fees charged under the emergency rule.

Rule Contents

Cheesemaker License Qualifications

Under current rules, individuals must meet certain training and experience requirements in order to be licensed as cheesemakers. An individual may be licensed if the individual does any of the following:

- Completes an 18-month apprenticeship under a licensed cheesemaker.
- Completes a 12-month apprenticeship, and either completes a university short course in cheesemaking or obtains a dairy-related associate degree at a vocational school.
- Completes a 6-month apprenticeship and obtains a 4-year dairy-related college degree.

This rule creates an additional option for license applicants. Under this rule, an individual may be licensed as a cheesemaker if the individual completes a 240-hour apprenticeship, and completes DATCP-approved courses in all the following:

- Cheesemaking.
- Production of safe dairy foods
- Hazard analysis critical control point (HAACP) process control.
- Milk pasteurization.
- Dairy sanitation.

DATCP may license the individual on a conditional basis, and may summarily suspend the license if the license holder fails to meet continuing education and performance standards.

Laboratory Approved to Conduct Drug Residue Screening Tests

Under this rule, DATCP must approve laboratories to conduct drug residue screening tests on milk samples. An approved laboratory must employ DATCP-approved analysts to conduct the tests. DATCP must also perform an on-site evaluation of every laboratory and analyst that conducts "visual read" screening tests. The laboratory must pay fees to cover DATCP costs.

No individual may conduct a drug residue screening test required under current DATCP rules unless all the following apply:

- The individual conducts that test at a laboratory authorized by DATCP to conduct that test.
- DATCP has approved that individual to conduct that test. Before DATCP approves an individual to conduct a "visual read" screening test, DATCP must perform an on-site evaluation of that individual's competency to perform that test.

An individual's approval to conduct a drug residue screening test expires on December 31 of each year unless, by that date, the laboratory documents to DATCP that the analyst has passed an annual proficiency evaluation. This rule spells out standards and procedures for the annual proficiency evaluation. DATCP may authorize a laboratory operator to conduct annual proficiency evaluations, except that an independent evaluator must evaluate analysts performing "visual read" screening tests.

Under this rule, a laboratory conducting drug residue screening tests must pay the following fees:

- \$500 for initial approval if the laboratory performs "visual read" screening tests (\$150 for certain small laboratories). This fee includes on-site evaluation of up to 3 "visual read" analysts. There is a supplementary fee of \$25 for each additional "visual read" analyst evaluated during the initial laboratory visit.
- \$50 for initial approval if the laboratory performs no "visual read" screening tests.
- \$150 for any subsequent visit to evaluate new "visual read" analysts, regardless of the number of analysts approved on that visit. An analyst may not perform "visual read" tests until the department approves the analyst based on an on-site evaluation.
- A \$50 annual renewal fee (\$25 for certain small laboratories). This fee covers the annual renewal of the laboratory and its individual analysts. No site visit is required for an annual renewal.

Fluid Milk Products

Fluid milk products must be produced by grade A dairy plants, according to grade A standards. This rule updates the current "fluid milk product" definitions to conform to the interstate Pasteurized Milk Ordinance (PMO).

Dairy Plant Rooms

This rule clarifies, but does not substantially alter, current rules related to room separation in dairy plants. Certain activities must be separated from other activities to prevent contamination of dairy products.

Re-circulated Water; Testing

Under current rules, re-circulated water used in a dairy plant cooler or heat exchanger must be tested semi-annually by the department. This rule requires the dairy plant operator, not the department, to test semi-annually.

Reclaimed Water

This rule clarifies spells out standards for a dairy plant's use of water reclaimed from the condensation of milk or dairy products. The standards are designed to prevent dairy product contamination that may result from the improper use of reclaimed water. Under this rule:

- A dairy plant operator may use water reclaimed by means of evaporation, reverse osmosis or ultrafiltration. The water must meet different standards, depending on how it is used.
- Reclaimed water may not be used for any purpose requiring *potable* water unless all the following apply:
 - DATCP pre-inspects and pre-approves the reclamation system.
 - The reclaimed water is free of coliform bacteria.
 - The standard plate count of the reclaimed water does not exceed 500 per ml. and meets DNR bacteriological standards.
 - The organic content of the reclaimed water is less than 12 mg. per liter.
 - The reclaimed water has no off-odors, off-flavors or slime formations. The dairy plant operator must check these things weekly.
 - DATCP pre-approves any chemicals used to suppress bacterial growth, tastes or odors in the reclaimed water. Automatic proportioning devices must be used to add chemicals to the water. The dairy plant operator must test at least daily for chemical content. Chemicals may not contain substances that may contaminate dairy products.
 - The reclaimed water is stored in properly constructed tanks.
 - The dairy plant operator tests the reclaimed water for bacteriological and organic content at least semi-annually, and more often after the reclamation system is initially installed or repaired.

- There is no cross-connection between reclaimed water lines and any public or private water system.
- Reclaimed water may be used for the limited purposes of producing culinary steam, pre-rinsing food contact surfaces of equipment or utensils, or preparing cleaning solutions if all the following apply:
 - The reclaimed water meets all potable water standards, other than bacteriological standards.
 - The reclaimed water is used only on the day that it is reclaimed.
 - The reclaimed water is automatically maintained at a temperature of not less than 145° F., or is chemically treated to suppress bacterial propagation. Chemical treatments must comply with standards for potable water.
 - Distribution lines and hose stations used to distribute the reclaimed water are clearly identified as “**limited-use reclaimed water.**”
 - The dairy plant operator posts clear instructions for the use of the reclaimed water. The instructions must limit the purposes for which the reclaimed water may be used.
 - Water lines distributing the reclaimed water are not permanently connected to dairy product vessels. Temporary connections must be protected to avoid product contamination.
- Reclaimed water that does not qualify for any of the above uses may only be used as boiler feed water.

Dairy Plant Personnel; Sanitation

Under current rules, persons with discharging or infected lesions on their hands or arms may not handle unpackaged dairy products. This rule prohibits them from handling unpackaged dairy products unless they have appropriate sanitary protection (including bandages and gloves) specified in this rule.

Equipment and Utensils

Current rules spell out sanitary design and construction requirements for dairy plant equipment and utensils. The current rules incorporate, by reference, “3-A” technical standards published by FDA and the International Association for Food Protection.

Under current rules, persons installing C-I-P (cleaned in place) systems must submit plans for DATCP approval. This rule requires the dairy plant operator, not the installer, to submit the plans. DATCP must act on the plans within 20 business days (currently 30 calendar days).

This rule regulates the use of flexible pipelines in dairy plants, to prevent sanitation hazards. Dairy plant operators may use flexible pipelines, subject to conditions specified in this rule, if rigid pipelines are impractical. This rule also modifies current standards for chlorine sanitizers used to sanitize equipment and utensils.

Milk from Dairy Farms

This rule clarifies a dairy plant operator's responsibility related to the receipt of raw milk from dairy farms. A dairy plant operator may not collect or receive milk from a dairy farm unless all the following apply:

- The dairy farm is properly licensed.
- A licensed milk weigher and sampler collects a sample of the producer's milk (for milk quality testing), and measures and records the temperature and quantity of the producer's milk.
- The operator complies with applicable milk testing and follow-up requirements under ch. ATCP 60 (dairy farms).

Bulk Milk Tanker Deliveries

Current rules prohibit a dairy plant operator from receiving a grade A bulk milk tanker delivery unless the bulk milk tanker operator holds a grade A permit for that tanker. This rule also prohibits a dairy plant operator from receiving any bulk milk tanker delivery unless the tanker operator holds a bulk milk tanker license under s. 97.21(2)(a), Stats., and ch. ATCP 82.

Product Temperature

Current rules require dairy plant operators to keep dairy products above or below specified temperatures, to prevent hazardous bacterial growth. This rule modifies some of these current temperature requirements.

- Under current rules, an operator who receives raw grade B milk or grade B dairy products for processing must keep those dairy products at 50° F. or less until they are pasteurized. Under this rule, the operator must keep those grade B dairy products at 45° or less until they are pasteurized (the same temperature currently required for grade A products). There is an exemption for milk received within 2 hours of milking, provided the milk is pasteurized or cooled to 45° within 4 hours.
- Under current rules, a dairy plant operator may not hold milk or dairy products for more than 4 hours at a temperature that is between 45° F. and 140° F. Certain dairy products are currently exempt. This rule adds some limited exemptions.
- Under current rules, dairy plant operators must keep certain non-dairy foods (including certain dairy product ingredients) at "safe temperatures" to prevent hazardous bacterial growth. This rule establishes new "safe temperature" requirements for these non-dairy foods, as follows:
 - For refrigerated foods: 41° F. (currently 40° F.)
 - For heated foods: 140° F. (currently 150° F.)
 - For frozen foods: 0° F. (same as now)

Reprocessing Returned Products

Current rules prohibit a dairy plant operator from reprocessing *grade A* packaged dairy products returned to a dairy plant. There are certain exemptions.

- The use, as ingredients, of packaged dairy products that are specifically manufactured and packaged for use as ingredients in other dairy products.
- Reprocessing packaged dry milk and dry milk products, if the inner package is intact.
- Reprocessing dairy products collected from a packaging defoamer system, or drained from processing equipment at the end of a run, if the products are handled in a sanitary manner and repasteurized.
- Reprocessing specifically authorized by DATCP in writing, under terms and conditions specified by DATCP.

Bacteria, Coliform, Yeast and Mold

This rule establishes more comprehensive bacteria and coliform standards for pasteurized dairy products. Under this rule, bacteria counts may not exceed 20,000 per ml. for most pasteurized dairy products. This standard does not apply to cultured dairy products (such as yogurt). Bacteria counts for the following products may not exceed the following levels:

- 30,000 per ml. for condensed milk, whey, dried whey and nonfat dry milk.
- 50,000 per gram for frozen desserts, except that the bacteria count for frozen dessert mixes may not exceed 20,000 per gram.

Under this rule:

- Coliform counts in pasteurized dairy products may not exceed 10 per ml.
- The yeast and mold count in pasteurized cottage cheese may not exceed 10 per gram.

Fortified Dairy Products

This rule updates current standards for fortified dairy products. This rule incorporates the latest PMO standards (1999). DATCP has asked the Attorney General and the Revisor of Statutes for permission to incorporate these standards by reference in this rule.

Milk Quality and Milk Component Test Methods

This rule updates current milk quality and milk component test methods. Milk test methods must be those prescribed in "Standard Methods for the Examination of Dairy Products," 16th edition (1992), or in the "Official Methods of Analysis of the Association of Analytical Chemists (AOAC) International, 17th edition (2000). DATCP has asked the Attorney General and the

Revisor of Statutes for permission to incorporate the updated AOAC standards by reference in this rule. DATCP may approve other test methods.

Pasteurization Standards

This rule establishes standards for higher-heat shorter-time (HHST) pasteurizers, including minimum temperature and hold times. This rule also updates standards for conventional batch pasteurizers and high-temperature short-time (HTST) pasteurizers. HTST and HHST pasteurizers must meet technical standards published jointly by FDA, the International Association of Food Industry Suppliers and the International Association of Food Protection. DATCP has asked the Attorney General and the Revisor of Statutes for permission to incorporate the updated standards by reference in this rule.

DATCP periodically tests pasteurizers according to procedures specified in the PMO. This rule updates current procedures to meet current PMO standards. DATCP has asked the Attorney General and the Revisor of Statutes for permission to incorporate the updated PMO standards by reference in this rule.

When DATCP determines that a pasteurizer is operating correctly, it seals the pasteurizer to prevent alterations that might allow unpasteurized product to flow through the system. A dairy plant operator must immediately notify DATCP whenever a pasteurizer malfunctions or the operator breaks the seal (to repair a malfunctioning pasteurizer, for example). The dairy plant operator may not resume pasteurizer operations until certain safety requirements are met. This rule expands and clarifies those safety requirements. This rule extends, by 5 days, the current 5-day deadline for resealing the pasteurizer.

Pasteurization Records

This rule expands and updates current pasteurization record keeping requirements. Among other things it expands current record keeping requirements related to HTST and HHST pasteurization. Records must document that pasteurization met minimum standards designed to ensure dairy product safety.

Dairy Plant Records

Under current rules, a dairy plant operator must keep certain records and make those records available for inspection and copying by DATCP. This rule expands and clarifies current record keeping requirements. This rule:

- Authorizes a dairy plant operator to keep cleaning and sanitizing records for C-I-P ("cleaned in place") systems in electronic form, with or without a hard copy. Electronic records must be accessible by a DATCP inspector.
- Requires a dairy plant operator to keep records related to vitamin fortification of fluid milk products, including inventory records and vitamin assay records.

Grade A Audit Surveys

Under the PMO, current state statutes and current DATCP rules, the Department of Health and Family Services (DHFS) must audit grade A dairy plants and dairy farms for compliance with PMO requirements. DHFS also audits DATCP's compliance program for compliance with the PMO. This rule updates current audit standards to meet current PMO requirements. DATCP has asked the Attorney General and the Revisor of Statutes for permission to incorporate the updated PMO standards by reference in this rule.

Drafting and Organizational Changes

This rule makes a number of drafting and organizational changes to clarify and update current rules.

1 **SECTION 1.** ATCP 69.02(title) and (1) are repealed and recreated to read:

2 **ATCP 69.02(title) Cheesemaker license; qualifications.** (1) **EXPERIENCE.** An
3 applicant for a cheesemaker's license under s. 97.17., Stats., shall submit proof that the applicant
4 has done at least one of the following:

5 (a) Completed an 18-month cheesemaking apprenticeship under a licensed cheesemaker,
6 including at least one month's experience in the complete process of cheesemaking.

7 (b) Completed a 12-month cheesemaking apprenticeship under a licensed cheesemaker,
8 including at least one month's experience in the complete process of cheesemaking, and
9 completed at least one of the following:

10 1. A cheesemaking short course at the college of agriculture and life sciences, university
11 of Wisconsin or an equivalent course from another accredited college or university.

12 2. A dairy-related associate degree at an accredited school of vocational, technical and
13 adult education.

14 (c) Completed a 6-month cheesemaking apprenticeship under a licensed cheesemaker,
15 including at least one month's experience in the complete process of cheesemaking, and
16 completed a 4-year dairy-related degree program at an accredited college or university.

1 (d) Completed an apprenticeship under a licensed cheesemaker, including at least 240
2 hours experience in the complete process of cheesemaking, and completed department-approved
3 courses in all the following subjects:

- 4 1. Cheesemaking.
- 5 2. Production of safe dairy foods.
- 6 3. Hazard analysis critical control point (HACCP) process control.
- 7 4. Principles of milk pasteurization.
- 8 5. Dairy sanitation.

9 **SECTION 2.** ATCP 69.02(4)(title) is created to read:

10 ATCP 69.02(4)(title) ACTION ON LICENSE APPLICATION.

11 **SECTION 3.** ATCP 69.02(5) is created to read:

12 ATCP 69.02(5) **CONDITIONAL LICENSE.** The department may issue a license under s.
13 97.17, Stats., on a conditional basis. If the department issues a license to an applicant who
14 qualifies under sub. (1)(d), the license shall be a conditional license for at least 2 years. The
15 department may summarily suspend the license at any time during the conditional license term if
16 the license holder fails to do any of the following:

17 (a) Successfully complete a performance evaluation conducted by qualified department
18 staff. The department may conduct an evaluation at any time, at its discretion.

19 (b) Complete 40 hours of department-approved continuing education related to
20 cheesemaking. Continuing education programs may include any of the following:

21 1. Seminars on cheese safety, quality and grading, provided by a trade association or
22 other continuing education provider.

1 2. Short courses on cheesemaking and grading provided by an accredited university or
2 university-extension service.

3 3. Other programs approved by the department.

4 **SECTION 4.** ATCP 77.01(1m), (4m) and (17) are created to read:

5 (4m) "Drug residue screening test" means any test under s. ATCP 77.02(1)(f) to (1)(s) or
6 (1)(z), other than a confirmatory test, that a person uses to comply with drug residue testing
7 requirements under s. ATCP 60.19.

8 (17) "Visual read test" means a drug residue screening test performed by an individual
9 who interprets the result without the aid of a mechanical reader.

10 **SECTION 5.** ATCP 77.03(2)(c) is renumbered (b).

11 **SECTION 6.** ATCP 77.03(2)(c) is created to read:

12 ATCP 77.03(2)(c). If the department authorizes a laboratory to perform a drug residue
13 test on milk, the department shall specify whether the laboratory is approved to perform that test
14 as a screening test or certified to perform that test as a confirmatory test, or both. A laboratory
15 approved to perform a test as a screening test may not perform that test as a confirmatory test
16 unless the laboratory is also certified to perform the confirmatory test.

17 **SECTION 7.** ATCP 77.06(1)(a) to (c) are amended to read:

18 ATCP 77.06(1)(a) *Milk or food tests.* An annual certification fee of \$336 for each test
19 under s. ATCP 77.02(1) or (2) at each laboratory for which the operator is certified. This fee
20 does not apply to a laboratory that is approved under s. ATCP 77.23 only to conduct drug residue
21 screening tests on milk samples.

22 (b) *Certified analysts; milk or food tests.* An annual certification fee of \$25 for each
23 analyst who performs one or more tests under s. ATCP 77.02(1) or (2). This fee does not apply

1 to an individual approved under s. ATCP 77.23 only to conduct drug residue screening tests on
2 milk samples.

3 (c) *Additional analyst certification; milk or food tests.* A supplemental fee of \$150 for
4 each requested certification of one or more analysts to conduct any test under s. ATCP 77.02(1)
5 or (2), if the certification occurs at any time other than during a mandatory inspection under s.
6 ATCP 77.14(1). This fee does not apply to an individual approved under s. ATCP 77.23 only to
7 conduct drug residue screening tests on milk samples.

8 **SECTION 8.** ATCP 77.06(1)(e) is created to read:

9 ATCP 77.06(1)(e) *Drug residues in milk; screening tests.* The fees provided in s. ATCP
10 77.23(3) if the laboratory performs drug residue screening tests on milk samples.

11 **SECTION 9.** ATCP 77.06(2) is repealed and recreated to read:

12 ATCP 77.06(2) PARTIAL FEES. (a) If the department certifies an operator of a milk or
13 food laboratory to perform a test for less than a full calendar year, the operator shall pay a fee of
14 \$28 for each full month of certification for that test. This fee does not apply to a laboratory that is
15 authorized under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

16 (b) If the department certifies an operator of a water laboratory to perform a test for less
17 than a full calendar year, the operator shall pay a fee of \$23 for each full month of certification
18 for that test.

19 **SECTION 10.** ATCP 77.22(1) is repealed and recreated to read:

20 ATCP 77.22(1) CERTIFICATION REQUIRED. (a) Except as provided in par. (b), no analyst
21 may perform a test listed under s. ATCP 77.02(1) or (2) unless the department certifies that
22 analyst under this section to perform that test.

1 (b) Paragraph (a) does not apply to an individual who is solely engaged in performing a
2 drug residue screening test, provided that the department has approved that individual under s.
3 ATPC 77.23(2) to perform that test.

4 (c) The department shall certify the analysts employed at a laboratory when it conducts a
5 mandatory inspection of that laboratory under s. ATPC 77.14(1). The department may certify
6 new analysts, or certify analysts to perform other tests, at other times.

7 **SECTION 11.** ATPC 77.23 is created to read:

8 **ATPC 77.23 Drug residues in milk; screening tests. (1) LABORATORY APPROVED.**

9 (a) No person may perform a drug residue screening test except at a laboratory that the
10 department approves under s. ATPC 77.03 to perform that test.

11 (b) The department may not approve a laboratory to perform a drug residue screening
12 test unless the department has approved at least one individual under sub. (2) to perform that test
13 at that laboratory.

14 (c) The department shall inspect a drug residue screening laboratory at all the following
15 times:

16 1. Before approving the operator to perform a visual read test, if the department has not
17 previously approved that operator to perform that test at that laboratory.

18 2. Before approving a new individual under sub. (2) to perform a visual read test at that
19 laboratory.

20 (2) **ANALYSTS APPROVED.** (a) No individual may perform a drug residue screening test
21 unless the department approves that individual to perform that test at a laboratory approved
22 under sub. (1).

1 (b) Before the department approves an individual under par. (a) to perform a visual read
2 test, the department shall perform an on-site competency evaluation under sub. (4).

3 (c) The department's approval under par. (a) expires on December 31 of each year
4 unless, by that date, the laboratory operator attests to the department that the individual has
5 successfully completed an annual proficiency evaluation under sub. (5).

6 (d) The department may suspend or revoke an approval under par. (a) for cause.

7 (3) APPROVAL FEES. A laboratory operator shall pay the following fees to acquire and
8 maintain a laboratory approval under sub. (1):

9 (a) An initial fee of \$500, except as provided in par. (b) or (c).

10 (b) An initial fee of \$150 if the laboratory tests milk for only one dairy plant operator
11 and all the following apply:

12 1. The dairy plant operator receives only grade B milk.

13 2. The dairy plant operator receives milk from not more than 5 producers.

14 3. The dairy plant operator receives not more than 10,000 lbs. of raw milk per week.

15 (c) An initial fee of \$50 if the laboratory does not apply for approval to perform any
16 visual read test.

17 (d) A fee of \$25 for each individual, in excess of 3 individuals, that the department
18 evaluates under sub. (4) at the time of the initial laboratory inspection under sub. (1)(c)1.

19 (e) An annual renewal fee of \$50 for each annual renewal of the laboratory approval,
20 except that the renewal fee is \$25 if the laboratory qualifies under par. (b).

21 (f) A fee of \$150 for each laboratory visit, other than the initial inspection under sub.
22 (1)(c)1., that the department makes for the purpose of evaluating individuals under sub. (4). This

1 single fee of \$150 covers all of the individual evaluations performed during the department's
2 visit, regardless of the number of individuals evaluated.

3 (4) COMPETENCY EVALUATION. Before the department approves an individual to
4 perform a visual read test, the department shall observe and evaluate that individual's
5 competency to perform that test. The department shall use an appropriate FDA 2400 series form
6 to conduct the evaluation.

7 **NOTE:** FDA 2400 series forms are on file with the department, the secretary of state and
8 the revisor of statutes.

9
10 (5) ANNUAL PROFICIENCY EVALUATION. (a) An individual approved to perform a drug
11 residue screening test shall complete an annual proficiency evaluation. An evaluator approved
12 by the department shall administer the annual proficiency evaluation. The department may
13 approve the laboratory operator to serve as evaluator, except that an independent evaluator shall
14 administer annual proficiency evaluations for analysts performing visual read tests. The
15 evaluator shall report the results of each proficiency evaluation to the department within 7 days
16 after the evaluation is completed.

17 (b) In a proficiency evaluation, the evaluated individual shall examine the number of
18 samples required under either par. (d) or (e) . The evaluator may prepare the samples used in
19 proficiency evaluations, except for samples used in a visual read proficiency test. The contents
20 of the samples shall be known only to the evaluator, and not to the evaluated individual. The
21 evaluator shall evaluate the individual's proficiency by comparing the individual's results to the
22 known contents of the samples, and shall report those results to the department.

23 (c) A proficiency evaluation under par. (a) shall be conducted according to a standard
24 evaluation procedure that the department approves in writing. A standard evaluation procedure
25 shall comply with this subsection and shall include standards for all the following:

- 1 1. The evaluator's preparation of proficiency evaluation samples.
- 2 2. The analyst's examination of proficiency evaluation samples.
- 3 3. Deadlines for examining proficiency evaluation samples and reporting test results.
- 4 4. The evaluator's review and rating of the individual's proficiency.

5 (d) For a drug residue screening test other than a visual read test, a proficiency
6 evaluation under par. (a) shall include 3 samples. To pass the proficiency evaluation, the
7 individual shall interpret all 3 sample results correctly.

8 (e) For a visual read test, a proficiency evaluation under par. (a) shall include at least 6
9 but not more than 20 samples. To pass a proficiency evaluation involving 6 to 10 samples, an
10 individual shall interpret no more than one sample result incorrectly. To pass a proficiency
11 evaluation involving 11 to 20 samples, an individual shall interpret no more than 2 sample results
12 incorrectly.

13 (6) FAILED PROFICIENCY EVALUATION; LOSS OF APPROVAL. (a) If an individual
14 approved to perform a drug residue screening test fails his or her first annual proficiency
15 evaluation related to that test, the individual is no longer approved to perform that test.

16 (b) If an individual approved to perform a drug residue screening test passes his or her
17 first annual proficiency evaluation related to that test, but subsequently fails 2 consecutive annual
18 proficiency evaluations, the individual is no longer approved to perform that test.

19 (c) The department may restore an approval lost under par. (a) or (b) if the individual
20 completes a training program approved by the department and passes an on-site competency
21 evaluation under sub. (4). If the individual subsequently fails his or her first annual proficiency
22 evaluation related to the drug residue screening test, the individual may no longer perform that

1 test. The department may again restore the approval if the individual again meets the restoration
2 requirements under this paragraph.

3 (7) LIST OF APPROVED ANALYSTS. The department shall maintain, for each laboratory
4 approved under sub. (1), a list of individuals currently approved to perform drug residue
5 screening tests at that laboratory. The list shall identify the drug residue screening tests that each
6 individual is approved to perform.

7 (8) NOTICE OF STAFFING CHANGES. (a) A laboratory operator shall notify the department
8 within 30 days after any of the following occurs:

- 9 1. An individual approved under sub. (2) leaves employment with that laboratory.
- 10 2. There is a change in the name of any individual approved under sub. (2).

11 (b) A laboratory operator shall notify the department within 7 days after a staffing
12 change if, as a result of that change, the laboratory has no individuals approved under sub. (2) to
13 perform a drug residue screening test that the laboratory is authorized to perform.

14 **SECTION 12.** ATCP 80.01(1g) is created to read:

15 ATCP 80.01(1g) "Bulk transport container" means a vehicle or container that a milk
16 producer uses to ship bulk milk from a dairy farm to a dairy plant.

17 **SECTION 13.** ATCP 80.01(10), (11) and (34) are amended to read:

18 ATCP 80.01(10) "Fluid milk product" means cream, sour cream, acidified sour cream,
19 half-and-half, sour half-and-half, whipped cream, concentrated milk, concentrated milk
20 products, reduced fat milk, low fat milk, ~~skim milk~~ nonfat milk, flavored milk, buttermilk,
21 cultured buttermilk, cultured milk, yogurt, low fat yogurt, nonfat yogurt, eggnog, holiday nog,
22 nog-flavored milk, vitamin and mineral fortified milk or milk products, and any other fluid milk
23 product made by adding any substance to milk or any of these products.

1 (11) "Frozen dessert" means ice cream, French ice cream, artificially sweetened ice
2 cream, frozen custard, frozen yogurt, frozen concentrates, ice milk, sherbet, water ice,
3 quiescently frozen confection, quiescently frozen dairy confection, manufactured frozen dessert
4 mix and frozen whipped cream confections. "Frozen dessert" includes frozen dessert mix.

5 (34) "Safe temperatures" as applied to potentially hazardous refrigerated foods means
6 temperatures of 40° 45° F. (5° 7° C.) or below. As applied to potentially hazardous heated foods,
7 "safe temperatures" means temperatures of 150° 140° F. (65° 60° C.) or above. As applied to
8 frozen foods, "safe temperatures" means temperatures of 0° F. (-17° C.) or below.

9 **SECTION 14.** ATCP 80.08(7) is repealed and recreated to read:

10 ATCP 80.08(7) ROOMS. (a) Dairy plant rooms shall be large enough so that activities
11 conducted in those rooms can be conducted in a safe and sanitary manner.

12 (b) Within a dairy plant, the following areas shall be located in separate rooms:

13 1. Raw milk unloading areas.

14 2. Areas used to clean and sanitize bulk milk tankers or bulk transport containers. Bulk
15 milk tankers and bulk transport containers may be cleaned and sanitized in the same room where
16 they are unloaded.

17 3. Processing areas.

18 4. Areas used to clean or sanitize dairy product packages or containers.

19 5. Areas used to store or fabricate dairy product packages. Packaging materials required
20 for each day's processing operations may be kept in a processing area on that day.

21 6. Areas used to store dairy product ingredients, other than raw milk. Ingredients
22 required for each day's processing operations may be kept in the processing area on that day.

23 7. Areas used to receive, handle or store returned packaged dairy products.

1 8. Areas used for boiler, heating plant, utility or maintenance equipment.

2 9. Employee toilet areas.

3 10. Employee locker areas, dressing areas, break areas and lunch areas.

4 11. Areas, if any, used as living quarters.

5 (c) In dairy plants constructed after December 1, 1994, raw milk shall be unloaded in a
6 fully enclosed intake room.

7 (d) Notwithstanding par. (b), a dairy plant operator may store, cool, separate and clarify
8 raw milk in an area that the operator uses to unload bulk milk shipments if all the following
9 apply:

10 1. The area is within a fully enclosed room.

11 2. Containers used to store, cool, separate and clarify the raw milk are filtered or vented
12 to a separate room to protect the milk from airborne contamination in the unloading area. If
13 containers are vented to a separate room, that room shall comply with processing area sanitation
14 standards under this chapter.

15 (e) Notwithstanding par. (d), a dairy plant operator may not store, cool, separate or
16 clarify raw milk in a room used to unload bulk milk shipments if any of the following apply:

17 1. The dairy plant was constructed after December 1, 1994.

18 2. The dairy plant is a grade A dairy plant constructed after July 1, 1980.

19 3. The storage, cooling, separating or clarifying operations were initiated after December
20 1, 1994.

21 (f) Rooms are considered separate, for purposes of this subsection, if they are fully
22 separated by permanent floor-to-ceiling partitions and if doorways between the rooms are
23 equipped with solid, tight-fitting, self-closing doors.

1 **SECTION 15.** ATCP 80.08(8)(d)4. is amended to read:

2 ATCP 80.08(7)(d)4. Tested by the ~~department~~ dairy plant operator at least semiannually.

3 **SECTION 16.** ATCP 80.08(8)(f) is repealed and recreated to read:

4 ATCP 80.08(8)(f) A dairy plant operator may use only potable water, or reclaimed water
5 in compliance with sub. (8m)(c), to produce culinary steam. In boilers used to produce culinary
6 steam, boiler water additives shall comply with 21 C.F.R. 173.310.

7 **SECTION 17.** ATCP 80.08(8m) is created to read:

8 ATCP 80.08(8m) **RECLAIMED WATER.** (a) A dairy plant operator may use water
9 reclaimed from the condensation of milk or dairy products if all the following apply:

- 10 1. The water is reclaimed by means of evaporation, reverse osmosis or ultrafiltration.
11 2. The water meets applicable use conditions under this section.

12 (b) Reclaimed water may not be used for any purpose requiring potable water unless all
13 the following apply:

- 14 1. The department pre-inspects and pre-approves the reclamation system.
15 2. The reclaimed water has less than 1 coliform bacterium per 100 ml. of water.
16 3. The standard plate count of the reclaimed water does not exceed 500 per ml. and
17 meets the bacteriological standards under s. NR 809.30.
18 4. The organic content of the reclaimed water is less than 12 mg. per liter as measured by
19 the chemical oxygen demand or permanganate-consumed test, or has a standard turbidity of less
20 than 5 units. The dairy plant operator shall use an automatic fail-safe monitoring device to
21 identify, and automatically divert to a waste water system, any reclaimed water that fails to meet
22 this standard.

1 5. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-
2 flavors or slime formations. The dairy plant operator shall sample and organoleptically test
3 reclaimed water at weekly intervals.

4 6. The department pre-approves any chemicals used to suppress bacterial growth, tastes
5 or odors in the reclaimed water. An automatic proportioning device shall add the chemicals to
6 the water before the water enters the storage tank. The dairy plant operator shall test reclaimed
7 water at least daily for each added chemical. An added chemical may not contain any substance
8 that may contaminate dairy products or limit the use of reclaimed water.

9 7. The reclaimed water is stored in a properly constructed tank. The tank shall be
10 constructed of a material that will not contaminate the water and can be easily cleaned.

11 8. The dairy plant operator tests the reclaimed water for bacteriological and organic
12 content at least semi-annually. The operator shall test the reclaimed water for 10 working days
13 after the department approves the reclamation system under subd. 1., and for at least 5 working
14 days after any repairs or alterations to the system.

15 9. There are no cross-connections between reclaimed water lines and any public or
16 private water system.

17 (c) Reclaimed water may be used for the limited purposes of producing culinary steam,
18 pre-rinsing food contact surfaces of equipment or utensils, or preparing cleaning solutions if all
19 the following apply:

20 1. The reclaimed water meets all conditions under pars. (b)1., 2., 4. to 7. and 9.

21 2. The reclaimed water is used only on the day that it is reclaimed, except that reclaimed
22 water may be stored for later use if it is automatically maintained at a temperature of not less

1 than 145° F. (63° C.), or is chemically treated to suppress bacterial propagation. Chemical
2 treatments shall comply with par. (b)6.

3 3. Distribution lines and hose stations used to distribute the reclaimed water are clearly
4 identified as **“limited-use reclaimed water.”**

5 4. The dairy plant operator posts clear instructions for the use of the reclaimed water.
6 The operator shall post the instructions so that they will be seen and understood by persons using
7 the reclaimed water. The instructions shall disclose the limited purposes for which the reclaimed
8 water may be used.

9 5. Water lines distributing the reclaimed water are not permanently connected to dairy
10 product vessels. If a water line is temporarily connected to a dairy product vessel, there shall be
11 an atmospheric break and automatic controls to prevent the reclaimed water from contacting
12 dairy products.

13 (d) Reclaimed water that does not qualify for use under par. (b) or (c) may only be used
14 as boiler feedwater.

15 **SECTION 18.** ATCP 80.10(1)(d) is repealed and recreated to read:

16 ATCP 80.10(1)(d) A person with a discharging or infected lesion on a hand or arm may
17 not handle or process unpackaged dairy products without appropriate sanitary protection.

18 Appropriate sanitary protection shall include all the following:

- 19 1. An impermeable bandage on the lesion.
20 2. Single-use sanitary gloves or, if the lesion is on the arm, a full sleeved garment with
21 tight fitting cuffs.

22 **SECTION 19.** ATCP 80.12(1)(a)(note) is amended to read:

23 **NOTE:** The “3-A Sanitary Standards” and “3-A Accepted Practices” listed in
24 APPENDIX A are published jointly by the International Association of Milk,

1 ~~Food and Environmental Sanitarians for Food Protection~~, Inc., and the Food and
2 Drug Administration, Public Health Service, United States Department of Health
3 and Human Services. Copies are on file with the department, the secretary of
4 state and the reviser of statutes. Copies may be purchased from the International
5 ~~Association of Milk, Food and Environmental Sanitarians for Food Protection~~,
6 Inc., 6200 Aurora Avenue, Suite 200 W., Des Moines, Ia 50322, Telephone 1-
7 800-369-2863.

8 **SECTION 20.** ATCP 80.12(1)(g) is created to read:

9 ATCP 80.12(1)(g) A dairy plant operator may use sanitary flexible pipelines to transfer
10 partially processed products in the intermediate stages of cheese production, or to load and
11 unload bulk loads of milk from transport vehicles, if all the following apply:

12 1. The use of rigid pipelines for that purpose is impractical.

13 2. The dairy plant operator properly cleans and sanitizes the flexible pipeline after
14 completing the transfer of product, or at least once every 24 hours.

15 3. The operator uses only a length of flexible pipeline necessary to conduct the transfer
16 operation.

17 **SECTION 21.** ATCP 80.12(7)(b)(intro.) is amended to read:

18 ATCP 80.12(7)(b) (intro.) The department may authorize alternative cleaning, sanitizing
19 and processing procedures, including extended run procedures for continuous production runs of
20 more than 24 hours, if all of the following apply:

21 **SECTION 22.** ATCP 80.14(3)(a) and (c) are amended to read:

22 ATCP 80.14(3) CONSTRUCTION PLANS (a) Before installing or modifying any C-I-P
23 system, ~~the person responsible for installing or modifying the system~~ dairy plant operator shall
24 submit to the department a plan for the installation or modification. The plan shall clearly
25 describe each C-I-P circuit in the installed or modified system, including the size and length of
26 piping, fittings, pitch, drain points, access points, relative elevations, locations and specifications
27 of circulating units, and other features of the system.

1 (c) Within 30 20 business days after any person files plans with the department under
2 this subsection, the department shall return its comments or objections, if any, in writing.

3 **SECTION 23.** ATCP 80.18(1)(c) is amended to read:

4 ATCP 80.18(1)(c) Complete and continuous exposure for at least 2 minutes to a
5 sanitizing solution containing at least 100 50 ppm of available chlorine, and having a pH not
6 higher than 8.3, at a temperature not less than 75° F. (24° C.) nor more than 110° F. (44° C.)

7 **SECTION 24.** ATCP 80.18(3)(note) is amended to read:

8 **NOTE:** Sanitizers approved by the ~~Wisconsin department of health and family services~~
9 under ~~subchapter VII of chapter 254, Stats. s. 4-501.114, ch. ATCP 75 Appendix~~
10 (Wisconsin Food Code), are approved by the department.

11 **SECTION 25.** ATCP 80.20(1) is repealed and recreated to read:

12 ATCP 80.20(1) MILK FROM DAIRY FARMS. (a) No dairy plant operator may collect or
13 receive milk from a dairy farm located in this state unless the milk producer holds a current
14 license for that dairy farm under s. 97.22(2), Stats., and s. ATCP 60.03.

15 (b) No dairy plant operator may collect or receive a milk shipment from a dairy farm in
16 this state unless a person licensed under s. 97.17 or 98.146, Stats., does all the following before
17 that milk shipment is commingled with milk from any other dairy farm:

- 18 1. Collects a sample of milk from the shipment, according to s. ATCP 60.17.
- 19 2. Accurately measures and records the temperature and quantity of milk in the
20 shipment. The person shall give the producer a duplicate copy of the recorded information.

21 **NOTE:** A dairy plant operator shall comply with applicable requirements under subch.
22 IV of ch. ATCP 60.

23 **SECTION 26.** ATCP 80.20(1)(note) is created to read:
24

25 **NOTE:** Subchapter IV of ch. ATCP 60 requires dairy plant operators to sample and test
26 producer milk and report test results. Operators must reject milk shipments and
27 take follow-up action in some cases.
28

1 **SECTION 27.** ATCP 80.20(3) is repealed and recreated to read:

2 ATCP 80.20(3) **BULK MILK TANKER DELIVERIES.** (a) No dairy plant operator may
3 receive any fluid milk or dairy products transported in a bulk milk tanker unless the bulk milk
4 tanker operator holds a current license for that bulk milk tanker under s. 97.21(2)(a), Stats., and
5 s. ATCP 82.02(1).

6 (b) No dairy plant operator may receive any grade A milk or grade A fluid milk products
7 transported in a bulk milk tanker unless the bulk milk tanker operator holds, in addition to the
8 license under par. (a), a current grade A permit for that bulk milk tanker under s. 97.21(2)(b),
9 Stats., and s. ATCP 82.02(7).

10 **SECTION 28.** ATCP 80.22(2)(d) is repealed and recreated to read:

11 ATCP 80.22(2)(d) No milk or dairy product may be held at a dairy plant for more than 4
12 hours at a temperature that is between 45° F. (7° C.) and 140° F. (60° C.). This paragraph does
13 not apply to any of the following:

- 14 1. Grade A cultured dairy products while being cultured.
- 15 2. Dried dairy products.
- 16 3. Butter micro-fixing.
- 17 4. Cheese while being cured, ripened or tempered for further processing.
- 18 5. Pasteurized cream while being ripened for churning into butter.
- 19 6. Whey and whey products during the process of crystallation.
- 20 7. Dairy products that are sterilized and packaged in hermetically sealed packages.
- 21 8. Other dairy products for which the department authorizes different holding
22 temperatures in writing.

23 **SECTION 29.** ATCP 80.22(5)(a) is repealed and recreated to read:

1 ATCP 80.22(5)(a) A dairy plant operator may not reprocess, for use in any dairy
2 product, packaged grade A dairy products that have left the custody of the dairy plant or that
3 have originated from another dairy plant. This does not prohibit any of the following:

4 1. The use, as ingredients, of packaged dairy products that are specifically manufactured
5 and packaged for use as ingredients in other dairy products.

6 2. Reprocessing dry milk and dry milk products returned to the dairy plant, provided that
7 the products' inner packaging is intact.

8 3. Reprocessing dairy products collected from a packaging defoamer system or drained
9 from processing equipment at the end of a run, if those dairy products are collected and handled
10 in a sanitary manner, held at a temperature of 45° F. (7° C.) or less, and re-pasteurized.

11 4. Reprocessing specifically authorized in writing by the department, under conditions
12 specified by the department.

13 **SECTION 30.** ATCP 80.22(5)(d) is repealed.

14 **SECTION 31.** ATCP 80.22(8)(note) is amended to read:

15 **NOTE:** The "3-A Sanitary Standards" and "3-A Accepted Practices" listed in
16 APPENDIX A are published jointly by the International Association of Milk,
17 Food and Environmental Sanitarians for Food Protection, Inc., and the Food and
18 Drug Administration, Public Health Service, United States Department of Health
19 and Human Services. Copies are on file with the department, the secretary of
20 state and the revisor of statutes. Copies may be purchased from the International
21 Association of Milk, Food and Environmental Sanitarians for Food Protection,
22 Inc., 6200 Aurora Avenue, Suite 200 W., Des Moines, Ia 50322, telephone 1-800-
23 369-2863.

24 **SECTION 32.** ATCP 80.24(3)(a) and (b) are repealed and recreated to read:

25 ATCP 80.24(3)(a) Bacterial counts in pasteurized dairy products, other than cultured
26 dairy products or frozen desserts containing nuts or other bulky flavors, may not exceed the
27 following levels:

- 1 1. 20,000 per ml., except as provided in subd. 2. or 3.
- 2 2. 30,000 per ml. for condensed milk, whey, whey products, dried whey and nonfat dry
- 3 milk.
- 4 3. Fifty thousand (50,000) per gram for frozen desserts, except that the bacterial count
- 5 for frozen dessert mixes may not exceed 20,000 per gram.

6 (b) Coliform counts in pasteurized dairy products, other than cultured dairy products,

7 may not exceed ten (10) per ml. or per gram.

8 **SECTION 33.** ATCP 80.24(3)(d) is created to read:

9 ATCP 80.24(3)(d) The yeast and mold count of pasteurized cottage cheese may not

10 exceed 10 per gram.

11 **SECTION 34.** ATCP 80.24(4) and (note) are amended to read:

12 ATCP 80.24(4) FORTIFIED DAIRY PRODUCTS. Whenever milk or a fluid milk product is

13 fortified with vitamin A or D, the fortification shall comply with Appendix O to the "Grade A

14 Pasteurized Milk Ordinance – 1993 1999 Recommendations of the United States Public Health

15 Service/Food and Drug Administration."

16 **NOTE:** Copies of Appendix O to the "Grade A Pasteurized Milk Ordinance – 1993 1999

17 Recommendations of the United States Public Health Service/Food and Drug

18 Administration" are on file with the department, the secretary of state and the

19 revisor of statutes. Copies may be obtained from the department at cost.

20 **SECTION 35.** ATCP 80.26(2)(a) is amended to read:

21 ATCP 80.26(2)(a) Bases the price adjustment on either the arithmetic or weighted

22 average of test results obtained for that producer during the pay period to which the price

23 adjustment applies. The dairy plant operator shall use the same method for computing average

24 test results for all producers shipping milk to the dairy plant.

25 **SECTION 36.** ATCP 80.28(1)(b)2.(note) is repealed.

1 **SECTION 37.** ATCP 80.28(1)(c) is amended to read:

2 ATCP 80.28(1)(c) The department may withdraw its approval under par. (a) or (b) for
3 ~~cause, regardless of whether the department of health and family services withdraws its~~
4 ~~certification.~~ Cause may include false or inaccurate test results or reports, or failure to conduct
5 tests according to required procedures.

6 **SECTION 38.** ATCP 80.32(1)(b) is amended to read:

7 ATCP 80.32(1)(b) A method described in the "Official Methods of Analysis of the
8 Association of Analytical Chemists (AOAC) International," 15th 17th Edition (2000).

9 **SECTION 39.** ATCP 80.32(1)(c)(note) is amended to read:

10 **NOTE:** A laboratory performing milk quality tests must be certified under ch. ATCP 77.

11 The American Public Health Association, Inc., "Standard Methods for the
12 Examination of Dairy Products," 16th edition, is on file in the offices of the
13 department, the secretary of state, and the revisor of statutes, and may be obtained
14 from the American Public Health Association, Inc., 1015 Eighteenth Street, N.W.,
15 Washington, D.C. 20036.

16 The "Official Methods of Analysis of the Association of Analytical Chemists
17 (AOAC) International," 15th 17th Edition (2000), is on file in the offices of the
18 department, the secretary of state and the revisor of statutes, and may be obtained
19 from the Association of Official Analytical Chemists, International, 1970 Chain
20 Bridge Road, Dept. 0742, McLean, VA 22109-0742.

21 **SECTION 40.** ATCP 80.32(2)(a) and (6) are amended to read:

22 ATCP 80.32(2)(a) Milkfat tests shall be performed using the Babcock method, the ether
23 extraction method, or another test method approved by the department. Babcock and ether
24 extraction tests shall be conducted according to the "Official Methods of Analysis of the
25 Association of Analytical Chemists (AOAC) International," 15th 17th edition (2000), except as
26 provided under par. (b).

1 (6) TESTING DEADLINES. A milk quality test shall be ~~completed~~ conducted within the
2 time period specified by the test method.

3 **SECTION 41.** ATCP 80.34(2)(c)3. and (note), (5)(d) and (note), (6)(c) and (note), (7)(c)
4 and (note), and (8) and (note) are amended to read:

5 ATCP 80.34(2)(c)3. The standard deviation of test results, calculated for the set of
6 calibration samples according to the formula set forth in the "Official Methods of Analysis of the
7 Association of Analytical Chemists (AOAC International," 15th 17th edition (2000), section
8 969.16, shall not exceed 0.044 percent for milkfat or protein, or 0.084 percent for total solids or
9 solids-not-fat.

10 **NOTE:** The "Official Methods of Analysis of the Association of Analytical Chemists
11 (AOAC International," 15th 17th edition (2000), is on file with the department,
12 the secretary of state, and the revisor of statutes, and may be obtained from the
13 Association of Official Analytical Chemists International, 1970 Chain Bridge
14 Road, Dept. 0742, McLean, VA 22109-0742.

15 (5)(d) To determine the milkfat content of a calibration sample or daily performance
16 check sample, the sample provider shall use either a manual or robotic version of the Modified
17 Majonnier method as described in the "Official Methods of Analysis of the Association of
18 Analytical Chemists (AOAC International," 15th 17th edition (2000), section 989.05.

19 **NOTE:** The "Official Methods of Analysis of the Association of Analytical Chemists
20 (AOAC International," 15th 17th edition (2000), is on file with the department,
21 the secretary of state and the revisor of statutes, and may be obtained from the
22 Association of Official Analytical Chemists International, 1970 Chain Bridge
23 Road, Dept. 0742, McLean, VA 22109-0742.

24 (6)(c) To determine the protein content of a calibration sample or daily performance
25 check sample, the sample provider shall use the traditional or block digester/steam distillation
26 Kjeldahl method as described in the "Official Methods of Analysis of the Association of
27 Analytical Chemists (AOAC International," 15th 17th edition (2000), section 991.20.

1 **NOTE:** The "Official Methods of Analysis of the Association of Analytical Chemists
2 (AOAC) International," 15th 17th edition (2000), is on file with the department,
3 the secretary of state and the revisor of statutes, and may be obtained from the
4 Association of Official Analytical Chemists International, 1970 Chain Bridge
5 Road, Dept. 0742, McLean, Va 22109-0742.

6 (7)(c) To determine the total solids content of a calibration sample or daily performance
7 check sample, the sample provider shall use the direct forced air oven drying method as
8 described in the "Official Methods of Analysis of the Association of Analytical Chemists
9 (AOAC) International," 15th 17th edition (2000), 1st supplement, section 990.20.

10 **NOTE:** The "Official Methods of Analysis of the Association of Analytical Chemists
11 (AOAC) International," 15th 17th edition (2000), is on file with the department,
12 the secretary of state and the revisor of statutes, and may be obtained from the
13 Association of Official Analytical Chemists International, 1970 Chain Bridge
14 Road, Dept. 0742, McLean, VA 22109-0742.

15 (8) CALIBRATION AND DAILY PERFORMANCE CHECK SAMPLES; SOLIDS-NOT-FAT. The
16 provider of a calibration sample under sub. (2) or a daily performance check sample under sub.
17 (3) shall calculate the known percentage content of solids-not-fat in that sample by subtracting
18 the percent fat as determined under sub. (5) from the total solids for that sample as determined
19 under sub. (7). The calculation method shall be that described in the "Official Methods of
20 Analysis of the Association of Analytical Chemists (AOAC) International," 15th 17th edition
21 (2000), 1st supplement, section 990.21.

22 **NOTE:** The "Official Methods of Analysis of the Association of Analytical Chemists
23 (AOAC) International," 15th 17th edition (2000), is on file with the department,
24 the secretary of state and the revisor of statutes, and may be obtained from the
25 Association of Official Analytical Chemists International, 1970 Chain Bridge
26 Road, Dept. 0742, McLean, VA 22109-0742.

27 **SECTION 42.** ATCP 80.36(3) is amended to read:

28 ATCP 80.36(3) RECORDS RETAINED BY DAIRY PLANT OPERATOR. A dairy plant operator
29 shall retain records required under this section ~~for at least one year~~ for the time period specified

1 under s. ATCP 80.54(1), and shall make the records available for inspection and copying by the
2 department upon request.

3 **SECTION 43.** ATCP 80.40 is renumbered ATCP 80.41 and, as renumbered, ATCP
4 80.41(2)(a) is amended to read:

5 ATCP 80.41(2)(a) ~~Raw milk~~ A dairy product shipped in bulk to another dairy plant for
6 use in manufacturing dairy products, provided that the ~~raw milk~~ shipment is accompanied by a
7 bill of lading that identifies the ~~milk~~ dairy product as unpasteurized ~~raw milk~~.

8 **SECTION 44.** ATCP 80.40 is created to read:

9 **ATCP 80.40 Definitions.** As used in this subchapter:

10 (1) "HHST" means "higher heat shorter time" pasteurization of milk, milk products or
11 dairy products at temperatures of 191°F. (89°C.) and above with holding times of 1 second or
12 less.

13 (2) "HTST" means "high temperature short time" pasteurization of milk, milk products
14 or dairy products for 15 seconds at temperatures between 161°F. (72°C.) and 180°F. (83°C.).

15 **SECTION 45.** ATCP 80.44(1) and (2) (TABLE 2) are amended to read:

16 ATCP 80.44(1) If a dairy product is required to be pasteurized under s. ATCP 80.40
17 80.41, the dairy product shall be pasteurized according to this section unless the department
18 authorizes a different but equally effective pasteurization method in writing. Every particle of
19 the dairy product shall be heated to the required temperature and continuously ~~hold the product~~
20 held at or above the required temperature for the required period of time. Pasteurization
21 equipment shall be equipped with accurate measuring, recording and control devices, as required
22 by ss. ATCP 80.46 and 80.48, to ensure that the time and temperature requirements under this
23 section are met.

1 (2) (TABLE 2)

2 **TABLE 2.**
3 **PASTEURIZATION REQUIREMENTS FOR**
4 **SELECTED DAIRY PRODUCTS**

	Product Group	Batch Pasteurization	HTST Pasteurization
(a)	Milk, skim milk, or buttermilk	145°F. (63°C.) for 30 minutes	161°F. (72°C.) for 15 seconds
(b)	Cream and fluid dairy products having more than 9% <u>10%</u> milkfat	150°F. (66°C.) for 30 minutes	166°F. (75°C.) for 15 seconds
(c)	Cream for butter	166 165°F. (74°C.) for 30 minutes	185°F. (85°C.) for 15 seconds
(d)	Condensed dairy products including condensed products in group (a) and blends of those products	155 150°F. (66°C.) for 30 minutes	166°F. (75°C.) for 15 seconds
(e)	High total solids products (>16%)	155°F. (69°C.) for 30 minutes	166°F. (75°C.) for 15 seconds
(f)	Frozen dessert mixes	155°F. (69°C.) for 30 minutes	175°F. (80°C.) for 25 seconds or 180°F. (83°C.) for 15 seconds
(g)	Egg nog	155°F. (69°C.) for 30 minutes	175°F. (80°C.) for 25 seconds or 180°F. (83°C.) for 15 seconds
(h)	Process cheese	150°F. (66°C.) for 30 seconds	—

1 **SECTION 46.** ATCP 80.44(2m) is created to read:

2 ATCP 80.44(2m) A dairy plant operator may use an HHST pasteurizing system as an
3 alternative to an HTST pasteurizer. An HHST pasteurizer shall operate at temperatures of 191° F.
4 (89° C.) and above with holding times of 1 second or less. An HHST pasteurizer shall heat and
5 hold a dairy product at one of the following temperatures for the corresponding length of time:

6 (a) 191° F. (89° C.) for 1.0 sec.

7 (b) 194° F. (90° C.) for 0.5 sec.

8 (c) 201° F. (94° C.) for 0.1 sec.

9 (d) 204° F. (96° C.) for 0.05 sec.

10 (e) 212° F. (100° C.) for 0.01 sec.

11 **SECTION 47.** ATCP 80.46 is amended to read:

12 **ATCP 80.46 Batch pasteurization.** Batch pasteurization equipment shall be of the non-
13 coil type. Batch pasteurization equipment shall be constructed and operated so that
14 pasteurization complies with s. ATCP 80.44. Batch pasteurization equipment shall be equipped
15 with a leak detector valves valve, a recording ~~thermometers~~ thermometer, a mercury column
16 product ~~thermometers~~ thermometer or calibrated digital probe thermometer, and a thermometer
17 to record the temperature of the air space above the product in the pasteurizer. The temperature
18 of the air space above the pasteurized product shall be at least 5° F. (3° C.) higher than the
19 minimum pasteurization temperature of the pasteurized product.

20 **SECTION 48.** ATCP 80.48 and (note) are amended to read:

21 **ATCP 80.48(title) ~~High-temperature short-time (HTST)~~ HTST and HHST**
22 **pasteurization.** Pasteurization by means of ~~high-temperature short-time~~ HTST or higher heat,
23 shorter time HHST pasteurization shall comply with the standards set forth in "3-A Accepted

1 Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature
2 Short-Time and Higher Heat Shorter Time Pasteurizer Systems,” standard 603-06 (December,
3 1992) 603-07 (November, 2000), published jointly by the International Association of Food
4 Industry Suppliers (IAFIS), International Association of Milk, Food and Environmental
5 Sanitarians for Food Protection, Inc., (IAFP), and the Food and Drug Administration, Public
6 Health Service, United States Department of Health and Human Services (USPHS), and the
7 Dairy Industry Committee (DIC).

8 **NOTE:** Copies of the “3-A Accepted Practices for the Sanitary Construction,
9 Installation, Testing, and Operation of High-Temperature Short-Time and Higher
10 Heat Shorter Time Pasteurizer Systems,” standard 603-06 (December 1992) 603-
11 07 (November, 2000) may be obtained from the International Association of
12 Milk, Food and Environmental Sanitarians for Food Protection, Inc., 6200 Aurora
13 Ave., Suite 200 W., Des Moines, IA 50010. Copies are on file with the
14 department, the secretary of state and the revisor of statutes.

15
16 **SECTION 49.** ATPC 80.49 is created to read:

17
18 **ATCP 80.49 Aseptic processing and packaging.** (1) DEFINITION. In this section,
19 “aseptic processing and packaging system” means a system that is intended to fill commercially
20 sterilized cooled milk or milk products into pre-sterilized containers, and then hermetically seal
21 each container with a pre-sterilized closure, in an atmosphere free of microorganisms.

22 (2) REQUIREMENTS. Aseptic processing and packaging systems shall comply with
23 standards specified in items 16p(C), (D) and (E) of the “Grade A Pasteurized Milk Ordinance
24 (PMO) — 1999 Recommendations of the United States Public Health Service/Food and Drug
25 Administration.”

26 **NOTE:** The “Grade A Pasteurized Milk Ordinance (PMO) — 1999 Recommendations of
27 the United States Public Health Service/Food and Drug Administration,” is on file
28 with the department, the secretary of state and the revisor of statutes. Copies may
29 be obtained from the department at cost.

30 **SECTION 50.** ATPC 80.50 is repealed and recreated to read:

1 **ATCP 80.50 Pasteurization records.** (1) **GENERAL.** A dairy plant operator shall keep
2 pasteurization records for all dairy products processed by the operator. Records shall cover all
3 pasteurization operations, including conventional batch operations, HTST operations, and HHST
4 operations. Records shall comply with this section.

5 (2) **BATCH PASTEURIZATION RECORDS.** Except as provided in sub. (3), pasteurization
6 records shall include all the following:

7 (a) Each date on which dairy products are pasteurized.

8 (b) The identification number or location of each pasteurization time and temperature
9 recorder, if more than one is used.

10 (c) A continuous recorder chart temperature record for each batch of pasteurized product.

11 (d) The pasteurization holding time, as shown on the recorder chart, for each batch of
12 pasteurized product. Records shall include filling and emptying times, if applicable.

13 (e) The temperature reading on the airspace thermometer at the start of the pasteurization
14 holding period, and at a specific time identified as a point on the recorder chart.

15 (f) The temperature reading on the indicating thermometer at the start of the
16 pasteurization holding period, and at a specific time identified as a point on the recorder chart.

17 (g) The name and quantity of pasteurized dairy product included in each batch
18 pasteurization shown on the recorder chart.

19 (h) A record of any unusual circumstances that occurred during each batch
20 pasteurization.

21 (i) The name of the dairy plant.

22 (j) The signature or initials of the dairy plant operator, or a responsible employee or
23 agent of the operator.

- 1 (3) HTST AND HHST PASTEURIZATION RECORDS. Pasteurization records for HTST and
2 HHST pasteurization operations shall include all the following:
- 3 (a) Each date on which dairy products are pasteurized.
 - 4 (b) The identification number or location of each pasteurization time and temperature
5 recorder, if more than one is used.
 - 6 (c) A continuous controller chart temperature record for each pasteurization run.
 - 7 (d) The temperature reading on the indicating thermometer at the start of each
8 pasteurization run, and at a specific time identified as a point on the controller chart.
 - 9 (e) Documentation, on the controller chart, of every time period during which the flow-
10 diversion device on the pasteurizer is in the forward-flow position.
 - 11 (f) The cut-in and cut-out product temperatures at the beginning of each HTST
12 pasteurization run. The pasteurizer operator shall record these temperatures daily on the
13 controller chart.
 - 14 (g) The temperature reading on the indicating thermometer whenever the controller chart
15 for the pasteurization system is changed.
 - 16 (h) The name and quantity of pasteurized dairy product included in each pasteurization
17 run shown on the controller chart.
 - 18 (h) A record of any unusual circumstances that occurred during each pasteurization run.
 - 19 (i) The name of the dairy plant.
 - 20 (j) The signature or initials of the dairy plant operator, or a responsible employee or
21 agent of the operator.

22 **SECTION 51.** ATCP 80.52(2) and (note), (6)(a), (b)2., 3. and 4., and (c)(intro.) are
23 amended to read:

1 ATCP 80.52(2) TEST PROCEDURE. The department shall test grade A and grade B
2 pasteurization systems according to the procedure specified in Appendix I of the "Grade A
3 Pasteurized Milk Ordinance – 1993 1999 Recommendations of the United States Public Health
4 Service/Food and Drug Administration."

5 **NOTE:** Appendix I of the "Grade A Pasteurized Milk Ordinance – 1993 1999
6 Recommendations of the United States Public Health Service/Food and Drug
7 Administration" is on file with the department, the secretary of state and the
8 revisor of statutes. Copies may be obtained from the department at cost.

9 (6)(a) A dairy plant operator shall immediately notify the department by telephone or
10 facsimile (FAX) transmission whenever the dairy plant operator breaks a seal applied by the
11 department under sub. (5), or whenever a pasteurizing system malfunctions to the possible
12 detriment of public health or safety.

13 (b)2. The dairy plant operator determines and documents that pasteurization time and
14 temperature requirements under s. ATCP 80.44 are met, and that the pasteurization system is
15 repaired and functioning properly. Time and temperature records required by s. ATCP 80.50
16 shall be retained for at least 6 months.

17 3. The dairy plant operator ~~confirms, at least once during every 8 hours of operation,~~
18 performs phosphatase tests to confirm that pasteurized milk and dairy products, other than dry
19 milk and dry milk products, contain less than one microgram of phosphatase per ml. as
20 ~~determined by the Sharer rapid method, or less than 500 milliunits of phosphatase per liter as~~
21 ~~determined by the fluorometric procedure.~~ The dairy plant operator shall perform a phosphatase
22 test at least once during every 4 hours of operation when a regulatory seal is broken, using the
23 Sharer rapid method, the Fluorophus ALP method, the Charm II method or other test methods
24 approved by the department. The department shall certify the individual who performs the
25 phosphatase test for the operator.

1 4. A pasteurizer operator qualified under s. ATCP 80.40(3) 80.41(3) is present to operate
2 the pasteurizer, or to supervise its operation.

3 (c)(intro.) A dairy plant operator may not operate a pasteurizer for more than 5 10
4 calendar days after breaking a seal applied by the department under sub. (5) unless one of the
5 following occurs:

6 **SECTION 52.** ATCP 80.54(1)(g) is amended to read

7 ATCP 80.54(1)(g) Cleaning and sanitizing records for all C-I-P systems, as required
8 under s. ATCP 80.14 (2) (b). Records under this paragraph shall be retained for at least 90 days.
9 Records may be stored in electronic form, with or without hard copy printouts, if the electronic
10 records are readily accessible by a department inspector.

11 **SECTION 53.** ATCP 80.54(1)(L) and (m) are created to read:

12 ATCP 80.54(1)(L) Inventory control records for vitamin fortification of fluid milk
13 products, including vitamins used and the quantity of fluid milk products produced. Records
14 under this paragraph shall be retained for at least 2 years.

15 (m) Vitamin assay test results conducted on fortified dairy products under
16 s. ATCP 80.24(4). Records under this paragraph shall be retained for at least 2 years.

17 **SECTION 54.** ATCP 80.62(1)(b) is amended to read:

18 ATCP 80.62(1)(b) *Survey method.* A survey under par. (a) shall include an inspection of
19 the grade A dairy plant, an inspection of a randomly selected statistical sample of dairy farms
20 shipping grade A milk to that dairy plant, and an evaluation of enforcement methods. A survey
21 shall be conducted in compliance with "Methods of Making Sanitation Ratings of Milk
22 Supplies," 1987 1999 revision, published by the Food and Drug Administration, Public Health
23 Service, United States Department of Health and Human Services.

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

Dated this _____ day of _____, 2002

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By _____
James E. Harsdorf,
Secretary

Fiscal Estimate — 2001 Session

Original Updated
 Corrected Supplemental

LRB Number	Amendment Number if Applicable
Bill Number	Administrative Rule Number ATCP 80, 69 & 77

Subject

Proposed rule related to Dairy Plants, Buttermakers and Cheesemakers and Laboratory Certification.

Fiscal Effect

State: No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

Increase Existing Appropriation Increase Existing Revenues
 Decrease Existing Appropriation Decrease Existing Revenues
 Create New Appropriation

Increase Costs — May be possible to absorb within agency's budget.
 Yes No
 Decrease Costs

Local: No Local Government Costs

1. <input type="checkbox"/> Increase Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory 2. <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	3. <input type="checkbox"/> Increase Revenues <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory 4. <input type="checkbox"/> Decrease Revenues <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	5. Types of Local Governmental Units Affected: <input type="checkbox"/> Towns <input type="checkbox"/> Villages <input type="checkbox"/> Cities <input type="checkbox"/> Counties <input type="checkbox"/> Others <input type="checkbox"/> School Districts <input type="checkbox"/> WTCS Districts
--	--	--

Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

Affected Chapter 20 Appropriations
20.115(1)(gb)

Assumptions Used in Arriving at Fiscal Estimate

The proposed dairy plant rules under chs. ATCP 69 and 80 will not have a major fiscal effect on DATCP or local units of government. These rules update existing food safety requirements, and accommodate recent changes in dairy plant operations. The proposed rules related to DATCP approval of milk laboratory analysts under ATCP 77, Wis. Adm. Code, will have a fiscal impact on DATCP. Under this rule, DATCP staff must perform additional evaluations of lab analysts, and must process additional approvals and annual renewals. Under an emergency rule, DATCP conducted on-site evaluations at approximately 30 laboratories throughout the state at a cost of about \$500 each. DATCP incurred some overtime costs in order to complete initial approvals by March 1, 2002. DATCP anticipates that this start-up cost will total approximately \$15,000. In addition, we expect ongoing costs of \$8,400 per year. This reflects the time, travel and support costs to conduct annual workshops, review annual renewal documentation, process certificates, and provide documentation required by the U.S. Food and Drug Administration for all drug residue screening laboratories.

Under this rule, a laboratory conducting drug residue screening tests must pay the following fees:

- * \$500 for initial approval of a laboratory that performs "visual read" screening tests. Certain small laboratories seeking "visual read" approval must pay a \$150 fee for initial approval. Fees for initial approval of laboratories performing "visual read" tests include on-site evaluation of up to 3 "visual read" analysts. There is a supplement fee of \$25 for each additional "visual read" analyst evaluated during the initial laboratory visit.
- * \$50 for initial approval of a drug residue screening laboratory that performs no "visual read" screening tests.
- * \$150 for any subsequent visit to evaluate "visual read" analysts, regardless of the number of analysts approved on that visit. An analyst may not perform "visual read" tests until the department approves the analyst based on an on-site evaluation.
- * A \$50 annual renewal fee (\$25 for certain small laboratories) for drug residue screening laboratories that perform a drug residue screening test. This fee covers the annual laboratory renewal, including the renewal of analysts performing drug residue screening tests at the laboratory. No site visit is required for an annual renewal.

Long-Range Fiscal Implications

DATCP estimates that annual fees will generate approximately \$4200 in new revenues each year. DATCP will only recover about 50% of on-going costs of this new program from annual renewal fees.

Prepared By:	Telephone No.	Agency
C. Thomas Leitzke	608-224-4711	DATCP
Authorized Signature	Telephone No.	Date (mm/dd/ccyy)
<i>Barbara Knapp</i>	224-4746	3/22/02

FISCAL ESTIMATE WORKSHEET

2000 SESSION

Detailed Estimate of Annual Fiscal Effect
DOA-2047 (R10/94)

ORIGINAL UPDATED
 CORRECTED SUPPLEMENTAL

LRB or Bill No/Adm. Rule No.
Ch. ATCP 80, 69 and 77

Amendment No.

SUBJECT

Dairy plants, Cheesemakers & Buttermakers and Laboratory Certification

I. One-time Cost or Impacts for State and/or Local Government (do not include in annualized fiscal effect):
\$15,000.

II. Annualized Cost:		Annualized Fiscal Impact on State funds from:	
A. State Costs by Category	Increased Costs	Decreased Costs	
1. State Operations - Salaries and Fringes <i>[Department staff time to: develop grant application forms, instructions, and reimbursement request forms; conduct grant writing training sessions; assist engineering consultants; review grant application; prepare grant award summary; prepare annual grant contracts and transmittal letters; review reimbursement request forms; issue payments.]</i>	\$8,100	\$ - 0	
2. (FTE Position Changes)	(0.1 FTE)	(-0 FTE)	
3. State Operations - Other Costs <i>[Phone, e-mail, internet access, postage, paper, printer use and toner, copier use and toner, and envelope costs related to staff activities identified above.]</i>	300	- 0	
4. Local Assistance	0	- 0	
5. Aids to Individuals or Organizations	0	- 0	
TOTAL State Costs by Category	\$ 8400	\$ - 0	
B. State Costs by Source of Funds	Increased Costs	Decreased Costs	
1. GPR	\$ 0	\$ - 0	
2. FED	0	- 0	
3. PRO/PRS	8400	- 0	
4. SEG/SEG-S	0	- 0	
III. State Revenues -	Increased Revenue	Decreased Revenue	
<small>Complete this section only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fees)</small>			
• GPR Taxes	\$ 0	\$ - 0	
• GPR Earned	0	- 0	
• FED	0	- 0	
• PRO/PRS	4200	- 0	
• SEG/SEG-S	0	- 0	
TOTAL State Revenues	\$ 4200	\$ - 0	

NET ANNUALIZED FISCAL IMPACT

STATE

LOCAL

NET CHANGE IN COSTS

\$ 8,400

\$ 0

NET CHANGE IN REVENUES

\$ 4,200

\$0

Agency Prepared by: (Name & Phone No.) DATCP C. Thomas Leitzke (608) 224-4711	Authorized Signature/Telephone No. <i>Barbara Knapp</i> Barbara Knapp (608) 224-4746	Date 22 March 21, 2002
---	--	------------------------------

Wisconsin Department of Agriculture, Trade and Consumer Protection

Final Regulatory Flexibility Analysis

Rule Subject: Dairy plants and drug residue screening laboratories
Adm. Code Reference: ATCP 80, ATCP 69 and ATCP 77
Rules Clearinghouse #: 01-124
DATCP Docket #: 98-R-3

Rule Description

This rule updates current dairy plant rules (ATCP 69 and 80, Wis. Adm. Code). The rule incorporates new food safety standards for dairy plants, and accommodates recent changes in dairy plant operations. The rule applies to grade A and grade B dairy plants. It incorporates current grade A dairy plant standards under the Interstate Pasteurized Milk Ordinance (PMO). Revisions in ch. ATCP 69 establish alternative training options for persons who wish to be licensed as cheesemakers.

In July, 2001, the U. S. Food and Drug Administration (FDA) issued a new directive requiring states to approve laboratory analysts who conduct drug residue screening tests. Analysts must be approved or dairy plants may no longer be able to ship milk in interstate commerce. The revisions to ch. ATCP 77, Wis. Adm. Code, require DATCP to approve laboratories to conduct drug residue screening tests on milk samples. An approved laboratory must employ DATCP-approved analysts to conduct the tests. DATCP must perform an on-site evaluation of every laboratory and analyst that conducts "visual read" screening tests without the aid of a mechanical reader. The laboratory must pay specified fees necessary to recover DATCP costs.

Small Businesses Affected by this Rule

This rule affects dairy plants, which are businesses that process or manufacture dairy products from raw milk shipped to the dairy plant by milk producers. This includes approximately 450 dairy plants in this state that are licensed and inspected by the department. The rule also affects approximately 85 drug residue screening laboratories. Many of these businesses are "small businesses" as defined in s. 227.114(1)(a), Stats.

Effects on Small Business

The dairy plant rule changes affect dairy plant operators, some of whom are small businesses. For the most part, these rules will help small businesses by modernizing current regulations to accommodate changing industry practices. This rule merely implements changes in the interstate Pasteurized Milk Ordinance and redrafts existing requirements for dairy plants so they will be easier to read and understand. This rule will not, by itself, have a major impact on small business.

Changes in the laboratory certification rule require DATCP approval of laboratory analysts performing screening tests for drug residues in milk. DATCP will conduct on-site competency evaluations of analysts performing "visual read" tests. DATCP will charge fees to authorized laboratories to cover the cost of the new program. This will impose some additional costs on laboratories, but will help Wisconsin's dairy industry by facilitating sales of Wisconsin dairy products in interstate commerce. This rule update is necessary to ensure compliance with federal requirements. The Department reduced approval fees for certain small laboratories to minimize the fiscal impact on such businesses.

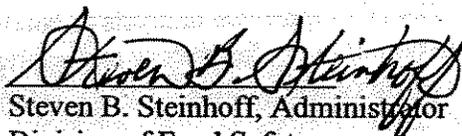
Conclusion

This rule will not, by itself, have a major impact on small business. For the most part, this rule merely implements changes in the interstate Pasteurized Milk Ordinance and a FDA mandate to approve drug residue screening laboratories. A dairy plant operator or laboratory operator will not need additional professional services to comply with this rule.

Dated this 22nd day of March, 2002.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By


Steven B. Steinhoff, Administrator
Division of Food Safety