

**Wisconsin Department
of Agriculture, Trade and Consumer Protection**

Final Regulatory Flexibility Analysis

***Rule Subject:* Milk and Milk Products**
***Adm. Code Reference:* ATCP 65**
***Rules Clearinghouse #:* 14-073**
***DATCP Docket #:* 13-R-06 and 13-R-13**

Rule Summary

The Department proposes a comprehensive revision to food safety rules chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants.) The objectives of this proposed rule are to 1) modernize current dairy farm and dairy plant inspection rules to ensure compliance with the federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), 2) accommodate advances in dairying and manufacturing dairy products, 3) indicate which provisions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by dairy plant operators, and 4) continue ensuring the safety and quality of Wisconsin milk and milk products.

Consolidation of dairy farm and dairy plant rules into one rule

This rule revision consolidates chs. ATCP 60 and 80 into a newly created ch. ATCP 65 (Milk and Milk Products) in recognition of the growing integration between Wisconsin dairy farms and dairy plants, where dairy plants are sometimes located directly on a dairy farm. The consolidated rule eliminates duplication between the two previous rule chapters and creates a more user-friendly "one-stop" rule for the dairy industry.

Details of the revision

Wording was changed throughout to provide greater clarity and modernize terms. For example, references to "milk haulers" were changed to "bulk milk weigher and samplers" to reflect the actual name of the license held by people who collect, sample, and transport milk. References to "inspectors" were changed to "division representatives" to reflect the broader range of staff, e.g. sanitarians, food scientists, regulatory specialists, who may conduct inspections. Subchapter, section, and subsection chapter titles were also revised and re-ordered where necessary to more clearly reflect the content of the rule and provide a logical sequence. The following is a summary of other notable changes made to the rule. A complete list of changes may be found as part of the plain language analysis in the hearing draft.

ATCP 65.01, Definitions.

In revising the rule, the Department:

- Added definitions for “abnormal milk,” “aseptic processing and packaging system,” “bulk tank unit,” “facility,” “grade A producer permit,” and “qualified facility.”
- Repealed and replaced definitions for “C-I-P equipment,” “C-I-P milking equipment,” and “C-I-P milk pipelines” with a definition of “C-I-P” which was numbered as 65.01 (9).
- Updated the definition for “dairy product” to be consistent with current statute.
- Replaced the term for “food safety division” with “division.”
- Expanded the definition for “grade B milk” to clarify that grade B milk is not processed into fluid milk for consumption; it is only used in the production of non-grade “A” dairy products.
- Broadened the definition for “equipment” to cover equipment used on dairy farms and in dairy plants.
- Repealed the definition from ATCP 65.01 (6) for “dairy plant” and replaced it with the definition from ATCP 80.01 (5) for “dairy plant.”
- Revised the definition of “milk” to be consistent with the PMO definition by including the phrases “practically free of colostrum, obtained by the complete milking of one or more healthy milking animals.”
- Expanded the definition “procure milk” to indicate that procured milk must be acquired directly from a licensed milk producer.
- Clarified that “sanitizers” shall be in compliance with 21 CFR part 178.1010 or otherwise approved by the division.
- Repealed the definitions “single-service utensil” and “single-service package” and replaced them with a definition for the term “single-service articles.”

ATCP 65.02, Milk producer license and permits; and fees.

ATCP 65.02 includes revised provisions that require a license for each milk producer, for each species of milk animal milked by a single milk producer, and each dairy farm operated by a milk producer at which milk is produced to be offered for sale. Previously, not all of these parameters were mentioned. The rule was also revised to clarify that a representative of the dairy plant may submit an application on behalf of a milk producer and that the dairy plant representative shall certify that both the dairy farm and milking operations comply with applicable requirements under the law. The rule now indicates that a licensed milk contractor (or the contractor’s representative), who procures milk but does not operate a dairy plant, may submit the milk producer license application and certify compliance. The rule allows no more than one milk producer to have a Grade “A”

permit at a single dairy farm unless all of the milk shipped from that dairy farm is assigned to one bulk tank unit and each milk producer is licensed. The rule also describes conditions under which more than one Grade “A” milk producer permit may be held on one dairy farm. Finally, the rule adds the due date of April 30 for paying the annual license fee and indicates that milk producer license fees are non-refundable.

ATCP 65.04, Dairy plant licenses and permits; fees.

The rule clarifies that no dairy plant license is required for a farm manufacturing dairy products solely for the owner/operator, members of the farm household, or nonpaying farm guests or employees. It exempts licensed restaurants from a dairy plant license if they prepare or process commercially pasteurized dairy products. However, licensed restaurants are not allowed to package Grade “A” dairy products without holding a dairy plant license. The rule exempts retail food establishments licensed under s. 97.30, Stats., from the requirement to hold a dairy plant license if they process non-Grade “A” dairy products made from commercially pasteurized and packaged dairy products solely for retail sale. The rule does not modify dairy plant fees. It indicates that dairy plant license fees are non-refundable.

ATCP 65.08, Milkhouse.

ATCP 65.08 (2) prohibits locating milkhouse access driveways and doors such that animal waste could be tracked into the milkhouse.

ATCP 65.10, Dairy farm water supply.

ATCP 65.10 (3) was updated to require wells to comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Water Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.) ATCP 65.10 (5) (a) clarifies that if a milk producer has more than one well, water from each well shall be tested at least once every two years. This change brings the provision into conformance with the PMO.

ATCP 65.14, Milking and milk handling systems.

ATCP 65.14 (5) recognizes the increasing adoption of modernized milking systems by incorporating PMO requirements for automatic milking installations, or robotic milking systems.

ATCP 65.22, Farm premises.

ATCP 65.22 (5) (c) prohibits mixing or storage of human waste or septage with animal manure. This provision was added to prevent recurrence of observed situations in which transmission of human fecal pathogens via dairy farm facilities was clearly possible.

ATCP 65.23, Federal requirements.

ATCP 65.23 indicates which requirements of the FDA Preventive Controls – Human Food rule implementing FSMA must be met by Wisconsin-licensed dairy plants.

ATCP 65.24, Construction and maintenance.

ATCP 65.24 (1) (b) states that a written variance from a construction standard may only be issued for dairy plants that do not hold a Grade A permit, i.e., Grade “B” plants. The PMO does not allow construction variances for Grade “A” dairy plants. ATCP 65.24 (1) (c) also prohibits dairy plants from being directly connected to a milking barn, milking parlor or animal housing area. This latter provision is intended to minimize transmission of pathogenic microorganisms into the dairy plant.

ATCP 65.24 (4) (a) revises a current exemption of overhead doors and electronic sliding doors in delivery areas from the requirement to be kept closed when not in use. The revised requirement excludes Grade “A” dairy plants from the exemption, while continuing to allow receiving stations and Grade “B” dairy plants to keep overhead and electronic sliding doors open when not in use. This change brings Wisconsin’s regulations in compliance with the PMO.

ATCP 65.24 (8), Dairy plant water supply.

ATCP 65.24 (8) contains a modified requirement that water used in dairy products must comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.)

ATCP 65.24 (8) (b) requires that water from a privately owned water system supplying a dairy plant shall be tested to ensure it meets safe drinking requirements under ch. NR 809 (Safe Drinking Water), after a repair or alteration. Finally, ATCP 65.24 (8) (h) was created to require Grade “A” dairy plants using water to flush pasteurized milk or milk products from their milk processing systems to use water that is of equivalent microbiological quality to pasteurized milk.

ATCP 65.28, Equipment and utensils.

ATCP 65.28 (7) (e) 5. was created to exempt dairy plants from having to clean certain reverse osmosis equipment after each day’s use. ATCP 65.28 (7) (f) contains a modified requirement for a dairy plant operator to consult with FDA before seeking division approval of a proposal for alternative cleaning and sanitizing schedule for continuously-operated equipment that comes in contact with Grade “A” products. This provision now conforms with the PMO.

ATCP 65.36, Receiving milk and dairy products.

ATCP 65.36 (3) indicates that a bulk milk tanker transporting Grade “A” milk may hold a Grade “A” permit issued by another state’s regulatory agency. This change recognizes reciprocity requirements of the PMO and recent changes in ch. ATCP 82 (Bulk Milk Collection, Sampling, and Transportation.)

ATCP 65.40, Storing and handling milk and dairy products.

ATCP 65.40 (2) allows the division to authorize alternative temperature limits for storing milk and milk products.

ATCP 65.40 (2) (d) 7. exempts acid whey with at least a minimum specified percent titratable acidity or no more than a maximum specified pH from storage time and storage temperature requirements applicable to other dairy products. This change is in response to information presented by industry.

ATCP 65.41, Low-acid or acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage.

ATCP 65.41 (1) requires manufacturing of low-acid dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal canning regulations.

ATCP 65.41 (2) requires manufacturing of acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal regulations pertaining to acidified canned foods.

ATCP 65.42, Recall plan.

ATCP 65.42 requires dairy plants manufacturing or processing dairy products to have a written plan for identifying and recalling dairy products should a food recall become necessary, and describes the required contents of such a plan. This new requirement is consistent with the recall plan requirements in ch. ATCP 70 (Food Processing Plants) and ch. ATCP 88 (Eggs). The new requirement does not apply to receiving stations or transfer stations.

ATCP 65.58, Pasteurization time and temperature.

ATCP 65.58 (1) requires that alternative methods of pasteurization of Grade “A” products be recognized by the FDA.

ATCP 65.72, Drug residue testing.

ATCP 65.72 (3) (c) was revised to indicate that a bulk load of milk must be agitated sufficiently to ensure that the sample taken for drug residue testing is representative of the bulk load of milk. Further revision allowed for Department approval of an alternative sampling methods that is not dependent on agitation to obtain a representative sample.

ATCP 65.72 (6) allows dairy plants to recover the cost of an entire bulk load of milk from a milk producer responsible for contaminating that load with milk adulterated with drug residues, or from the milk contractor from whom the milk was procured. The milk contractor may, in turn, recover the cost of the entire load from the milk producer responsible for contaminating that load with milk adulterated with drug residues.

ATCP 65.74, Milk and dairy products; quality standards.

ATCP 65.74 (2) (a) states that bacterial counts for nonfat dry milk shall not exceed 10,000 per gram. This provision is in conformance with the PMO.

ATCP 65.910, Inspection of dairy farms; general.

ATCP 65.910 (2) increases the inspection frequency for Grade “B” dairy farms from once every two years to once a year. This provision is made to ensure maintenance of adequate conditions on the Grade “B” dairy farms.

ATCP 65.912, Performance-based farm inspection.

ATCP 65.912 contains language which was modified to bring Wisconsin’s performance-based farm inspection program in full compliance with Appendix P of the PMO. Specifically, the rule prohibits placing farms in categories requiring inspection once or twice per year under the program if they have been cited during the past year with any violation that presents an imminent health hazard. The rule also prohibits placing farms in a category requiring inspection once or twice per year if they have received a warning under s. ATCP 65.923 (1) during the past year. ATCP 65.923 (1) continues to require the division to issue a warning notice if an inspection finds a noncompliance with a key violation. However, the definition of a key violation was expanded to include instances when a farm receives one or more identical violations during two consecutive inspections, i.e., double debits. Finally, the rule prohibits placing farms in categories requiring inspection once or twice per year if the milk shipped from the farm was found to have had any drug residues during the past year.

ATCP 65.923, Drug residue violations; milk producer sanctions.

ATCP 65.923 requires the Department to issue a warning notice whenever a producer milk sample test result is confirmed positive for drug residue. Once a milk producer receives a warning notice for drug residues, the milk producer must implement a drug residue prevention program within 21 days of the effective date of the notice or the producer’s Grade A permit will be suspended. If the drug residue prevention program isn’t completed within 45 days, the milk producer’s license will be suspended. The rule already included this requirement, along with a penalty provision to be invoked if the producer has 3 drug residue violations within 12 months. These penalties are modified in the proposed rule and a penalty is created in sub. ATCP 65.922 (4) for milk producers whose milk sample yields a confirmed positive test result for drug residue in a second

separate 24-hour period within 12 months of the first violation. After the second offense, the proposed rule requires the license to be suspended for 5 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay a civil forfeiture or to discard one milk shipment; the milk producer must also complete participation in a drug residue prevention program and present a certificate of completion for the program within 180 days of receiving a warning letter. Milk producers whose milk sample yields a confirmed positive test result for drug residues in a third separate 24-hour period within 12 months of the first violation would have their milk producer license suspended for 10 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay two civil forfeitures or to discard two milk shipments; the milk producer would also have to develop and implement a Department-approved drug residue program and present documentation indicating that this program has been implemented for at least 90 days.

ATCP 65.928, Right of hearing.

ATCP 65.928 (3) contains a revised requirement the Department hold an informal hearing within 20 days, rather than 10 days, of receiving a hearing request. This change will bring the rule into compliance with ch. ATCP 1 (Administrative Orders and Contested Cases).

ATCP 65.928 (4) is revised to eliminate the 10 day requirement for requesting a contested case hearing, in conformance with Subch. III, ch. 227, Stats., and s. ATCP 1.03 (3) (a) 1. It is also revised to add that a request for a contested case hearing must follow the requirements in s. ATCP 1.06.

Small Businesses Affected

The proposed rule changes will impact dairy producers and dairy plants, many of which may be small businesses. The proposed rule does not substantially alter the vast majority of the requirements dairy-related businesses already meet. The rule does not increase license or permit fees. All Grade “A” dairy businesses, whether large or small, must meet regulations that are substantially in compliance with the FDA’s PMO in order to collect, sample, and transport Grade “A” dairy products and no special accommodation may be made for small businesses. The proposed rule does not make accommodations for small Grade “B” dairy businesses. The proposed rule allows Grade “B” businesses to seek variances from some requirements and incorporates more flexibility than for Grade “A” businesses. However, to protect food safety and the quality of Wisconsin milk and milk products, further flexibility based on business size is not possible. The rule proposes an increase in the frequency of inspection for Grade “B” dairy farms to more effectively ensure that these farms remain in compliance.

If the proposed rule is adopted, some dairy producers may incur costs if they need to modify access to the milkhous to avoid contamination with animal waste. A few milk producers may also be required to participate in a drug residue prevention program if they have milk samples test positive twice within 12 months. Some farms may need to have load-out doors installed to meet requirements for the location of bulk transport containers

that receive milk directly from the milking equipment (“direct ship” milking). Some on-farm dairy plants will have to construct an intervening room with two doors to minimize the likelihood of contaminants being tracked from the milking barn, milking parlor, or animal husbandry areas to the dairy plant. In general, the rule changes are expected to impact only a small number of dairy farms and dairy plants.

Some of the rule changes may result in cost savings or provide other benefits to industry. For example, the rule contains certain exemptions from dairy plant licensing for permitted restaurants and licensed retail food establishments. The rule also allows the Division of Food Safety (DFS) to authorize alternative temperature limits for storing non-Grade “A” milk or milk products. It exempts acid whey with specified percent titratable acidity or pH from storage time and storage temperature requirements applicable to other dairy products. It also exempts Grade “B” whey (not meeting the above requirements for acid whey) in specified situations from the storage time and temperature requirements. These changes are in response to information presented by industry.

Reporting, Bookkeeping and other Procedures

The proposed rule would not require any additional reporting or bookkeeping, but would require dairy plant operators to prepare a written recall plan.

Professional Skills Required

The proposed rule does not require any new professional skills by small businesses.

Accommodation for Small Business

All Grade “A” dairy farms and dairy plants, whether large or small, must meet regulations that are substantially in compliance with the Food and Drug Administration’s Pasteurized Milk Ordinance. No special accommodation for Grade “A” small dairy businesses may be made. Grade “B” dairy farms and dairy plants have more flexibility than Grade “A” dairy businesses, but Grade “B” dairy businesses also must meet certain requirements in order to produce safe, high-quality milk and milk products.

Conclusion

The provisions in this proposed rule will benefit Wisconsin's dairy industry and are expected to impose minor costs for only a few dairy farms and dairy plants.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

The Department will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this _____ day of _____, 2016.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Steven C. Ingham, Administrator,
Division of Food Safety