Wisconsin Department of Agriculture, Trade and Consumer Protection

Initial Regulatory Flexibility Analysis

Rule Subject: Milk and Milk Products

Adm. Code Reference: ATCP 65
Rules Clearinghouse #: Not assigned

DATCP Docket #: 13-R-06 and 13-R-13

Rule Summary

The department proposes a comprehensive revision to food safety rules ATCP 60, "Dairy Farms," and ATCP 80, "Dairy Plants." The objective of this proposed rule is to 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), accommodate advances in dairying and manufacturing dairy products, and continue ensuring the safety and quality of Wisconsin milk and milk products. FDA revises the PMO every two years and the department must periodically revise its dairy farm and dairy plant rules to ensure compliance with the PMO. States must meet PMO requirements in order for their grade "A" milk and milk products to be shipped in interstate commerce.

Consolidation of dairy farm and dairy plant rules into one rule

This rule revision consolidates ATCP 60 and 80 into a newly created ATCP 65, "Milk and Milk Products," recognizes the growing integration between Wisconsin dairy farms and dairy plants, where dairy plants are sometimes located directly on a dairy farm; and creates a more user-friendly "one-stop" rule for the dairy industry.

Revisions in general terminology and definitions

Wording was changed throughout to provide greater clarity and modernize terms. For example, references to "milk haulers" now refer to "bulk milk weigher and samplers", using the actual name of the license held by people who collect, sample, and transport milk. References to "inspectors" now refer to "division representative" to reflect the broader range of staff, *e.g.* sanitarians, food scientists, regulatory specialists who may conduct inspections. Definitions were also updated and revised, as necessary, to modernize terminology.

Clarification of licensing and fees

The rule clarifies that a license is required for each milk producer and each species of milk animal milked by a single producer. The rule clarifies that no more than one milk producer may have a grade "A" 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

clarifies that permitted restaurants do not need a separate dairy plant license if they prepare or process commercially pasteurized dairy products. The rule also exempts retail food establishments from requiring a dairy plant license if they process non-grade "A" dairy products made from commercially pasteurized dairy products solely for retail sale. The rule does not change licensing fees.

Dairy farm rule revisions

The following are among the dairy farm provisions contained in the rule:

- Prohibits locating milkhouse access driveways and doors such that animal waste could be tracked into the milkhouse.
- Clarifies that if a milk producer has more than one well, water from each well shall be tested at least once every two years.
- Recognizes the increasing adoption of modernized milking systems by incorporating PMO requirements for automatic milking installations, or robotic milking systems.
- Prohibits mixing or storage of human waste or septage with animal manure.
- Increases the inspection frequency of Grade "B" dairy farms from two years to one year.
- Slightly modifies the performance-based inspection requirements to ensure compliance with the PMO by prohibiting placement of farms in categories requiring inspection once or twice per year if they have been cited with any violation that presents an imminent health risk or if they've received a warning under s. ATCP 65.923(1) during the past year. Wisconsin issues a warning notice if an inspection finds a violation of a key violation. However, the rule expands the definition of a key violation to include instances when a farm receives one or more identical violations during two consecutive inspections, i.e. double debits.

Dairy plant rule revisions

The following are among the dairy plant provisions contained in the rule:

- Requires dairy plants to meet state water regulations and testing of water from a privately owned water system for compliance with safe drinking water requirements.
- Revises a current exemption related to overhead doors and electronic sliding doors in delivery areas, requiring Grade "A" plants to meet PMO requirements that the doors remain closed when not in use.
- Exempts dairy plants from having to clean certain reverse osmosis equipment after each day's use.
- Allows the department to authorize alternative temperature limits for storing non-Grade "A" milk and milk products.
- Exempts acid whey with at least minimum specified percent tritratable acidity or no more than a maximum specific pH from storage time and storage temperature requirements applicable to other dairy products.
- Requires dairy plants to develop a written recall plan for identifying and recalling dairy products should a food recall become necessary.

- Creates an exemption, in certain cases, from the requirement that dairy products shipped in bulk to a licensed food processing plant be pasteurized at the dairy plant where the product was manufactured.
- Allows dairy plants, at their discretion, to waive recovery of the cost of a rejected bulk load if the load is a direct ship load and contains milk from only one producer.

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 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.

If the proposed rule is adopted, some dairy producers may incur costs if they need to modify access to the milkhouse 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 or have been reported on the United States Department of Agriculture (USDA) repeat violator list for presenting for slaughter dairy cattle which yield carcasses that have tested positive for drug residues. 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). 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. This change is in response to information presented by industry. These two exemptions will result in cost savings for approximately 200 dairy plants.

The proposed rule also assists small businesses by consolidating dairy farm and dairy plant regulations into one rule.

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.

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