



Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL



ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

House Bill 5585 (Substitute H-1 as passed by the House)
Sponsor: Representative John Espinoza
House Committee: Agriculture
Senate Committee: Agriculture

Date Completed: 4-23-08

CONTENT

The bill would amend the Manufacturing Milk Law to do the following:

- **Revise the requirements for licensure under the Law.**
- **Require the money collected from license fees, fines, and other sources to be deposited into the Dairy and Food Safety Fund.**
- **Permit the Michigan Department of Agriculture (MDA) Director to impose a late fee of \$10 a day, up to \$100, for each day an application for a license renewal under the Law was late; charge a convenience fee; and collect from the applicant any cost associated with the method of payment.**
- **Permit the MDA Director to suspend a license or permit if a licensee or permittee committed certain violations.**
- **Include new standards for the pasteurization of milk, condensed milk, and whey, and the mixing of pasteurized milk products.**
- **Require a milk processing plant to provide certain minimum lighting levels and sufficient electrical power, and meet other requirements.**
- **Revise the requirements for cleaning equipment at a dairy plant.**
- **Revise certain requirements for the handling of retail packages and packaged dairy products.**

The bill would take effect 30 days after it was enacted into law.

Licensure

The Law requires the MDA to inspect all dairy farms at least every 12 months and dairy plants at least every six months. Under the bill, the MDA would have to inspect dairy farms at least every 12 months and dairy plants, receiving stations, and transfer stations every six months, or at time intervals as specified by the MDA Director.

Under the Law, a person may not produce, transport, wash milk tank trucks, process, label, or sell manufacturing milk or dairy products and may not manufacture single service containers and closures unless licensed or permitted under the Manufacturing Milk Law or the Grade A Milk Law.

The bill would remove those provisions, and instead would prohibit a person from doing any of the following without being licensed under the Manufacturing Milk Law or the Grade A Milk Law:

- Produce milk that is offered for sale.
- Collect milk samples for regulatory purposes.
- Wash milk tank trucks.
- Operate a milk transportation company that owns or operates a can milk truck.
- Process, label, distribute, or sell milk or manufactured dairy products, although a person operating a retail food establishment would be exempt from licensure under the Manufacturing Milk Law if he or she complied with certain

-- provisions under the bill and were licensed under the Food Law of 2000.

Those provisions would not prevent the sale, at wholesale or retail at a retail food establishment licensed under the Food Law, of milk or milk products that were packaged in final consumer packages at a facility licensed under the Manufacturing Milk Law.

A person licensed under the Grade A Milk Law and engaged in activities regulated under the Manufacturing Milk Law would be exempt from licensure under the Manufacturing Milk Law.

State agencies operating dairy facilities under a memorandum of understanding with the MDA would not be required to be licensed or permitted, or to provide producer security under the Law, but otherwise would be required to be in compliance with the Law.

Under the bill, "retail" would mean selling or offering for sale dairy products directly to a consumer. "Retail food establishment" would mean an operation that sells or offers to sell food directly to a consumer. Retail food establishment would include both a retail grocery store and a food service establishment, but would not include a food processing plant.

Exemptions

Frozen desserts manufactured from pasteurized mix in the soft form at retail food establishments licensed under the Food Law are exempt from the Manufacturing Milk Law.

The bill instead would exempt milk products manufactured at retail food establishments licensed under the Food Law if both of the following conditions were met:

- All ingredients contained in those products complied with the requirements of the Food Law.
- The milk products manufactured were not sold wholesale or to another business entity.

"Wholesale" would mean selling or offering to sell dairy products to retailers, jobbers, or distributors rather than directly to a consumer.

Application

The Law requires the MDA to issue an initial or renewal license or permit for regulated activities, other than a Grade A dairy farm, within 90 days after the applicant files a completed application. The bill would add an exception to that requirement for a bulk milk hauler/sampler license or permit.

Under the Law, "completed application" means an application complete on its face and submitted with any applicable licensing or permit fees as well as any other required information. The bill also would require any applicable fines to be submitted with an application for it to be considered complete.

Dairy and Food Safety Fund

The bill would require any fees, assessments, civil or administrative fines, and money from any other source collected by the MDA under the Law to be deposited into the Dairy and Food Safety Fund created under the Food Law.

The MDA could impose a late fee for a renewal application under the Manufacturing Milk Law. The fee would be \$10 for each business day an application was late, but the total late fee could not exceed \$100. The MDA could not issue or renew a license until any fees and fines had been paid. A hearing would not be required regarding the MDA's refusal to issue or renew a license under these provisions except as allowed under the Administrative Procedures Act. The MDA could charge a convenience fee and collect from the applicants any additional costs associated with the method of fee payment for the license or permit fees, not to exceed the costs of the MDA.

Approval for Construction

Under the bill, a milk plant operator would have to submit detailed plans to the MDA for approval before beginning new construction, remodeling, and equipment changes. Plans for new construction or remodeling would have to include a plan that provided for operational or physical isolation of the milk plant from sources of potential product contamination caused by animal production facilities located in close proximity to the milk plant. Retail or public viewing areas would have to be separated from processing areas by a solid floor-to-ceiling partition,

except that, as approved by the MDA Director, other equally effective means of protection could be used.

Security Device

Under the Manufacturing Milk Law, a licensee or applicant for licensure as a milk plant must provide a security device for the benefit of producers who may be damaged by a default in payment by the licensee. Accepted security devices include the following:

- An audited fiscal year end financial statement demonstrating the licensee's ability to meet certain minimum liquidity requirements.
- A commercial surety bond made payable to the MDA; a certificate of deposit, money market certificate, or other financial instrument that is issued or endorsed to the MDA; an irrevocable letter of credit filed with the MDA; life insurance policies that are issued or endorsed to the MDA; or other security acceptable to the MDA.

A licensee or applicant for licensure as a milk plant that does not provide security under those provisions must provide an agreement in which the milk plant prepays for its milk supply by means of cash payments before or at the time of delivery of milk products. Under the bill, the agreement would have to provide for cash payments before or at the time the milk was received at the plant.

"Cash payments", regarding those requirements, would mean a payment in cash or by check, money order, wire transfer, or draft for a sale in which the title to farm milk is transferred.

Under the Law, the MDA must revoke or deny a license for a milk plant if the licensee or applicant fails to provide one of the security devices described above. Milk plants that receive milk only from dairy farms under the same ownership as the milk plant are exempt from that requirement. The bill also would exempt milk plants that received milk only from dairy farms under the same sole proprietorship, the same registered partnership, or the same corporate ownership having the same registered name as the milk plant.

Suspension of License or Permit

The Manufacturing Milk Law permits the MDA Director summarily to suspend a license or permit upon determining that the licensee or permittee committed certain acts, which include offering for sale or selling milk or milk products suspected of contamination with any substance considered by the MDA to be an imminent or substantial health hazard.

The bill also would permit the MDA Director summarily to suspend a license or permit issued under the Law if a licensee or permittee offered for sale or sold milk or milk products that presented an imminent or substantial health hazard due to improper or unknown storage temperature or improper allergen labeling.

In addition, the MDA Director could suspend a license or permit upon determining that the licensee or permittee had offered for sale or sold milk or dairy products that were not pasteurized according to the requirements in the Law, except as otherwise permitted. (The Law permits unpasteurized milk to be used in the manufacture of cheese, only as allowed in certain Federal regulations.)

Milk Processing

The Manufacturing Milk Law requires all dairy plant by-products used for feeding purposes for farm animals to be pasteurized or derived from pasteurized products. The bill would require such pasteurization when specified by the MDA Director.

Under the bill, milk and dairy products could be aseptically processed as low-acid foods provided that they complied with the following requirements:

- All thermally processed milk and milk products that were packaged in hermetically sealed containers would have to be processed in a milk processing facility licensed under the Grade A Milk Law, the Manufacturing Milk Law, or the Food Law.
- All processors of acidified milk and milk products packaged in hermetically sealed containers would have to comply with the regulations of the Food and Drug Administration (FDA) in 21 CFR Parts 108, 110, and 114.

- All thermally processed milk and milk products that were packaged in hermetically sealed containers would have to comply with the regulations of the FDA in 21 CFR Parts 108, 110, and 113.
- Hermetically sealed packages would have to be handled to maintain product and container integrity.

(In Title 21 of the Code of Federal Regulations, Part 108 provides for an emergency permit that may be required if a food manufacturer, processor, or packer does not meet regulatory requirements regarding that food, before it may be introduced or delivered for introduction into interstate commerce. Part 110 relates to current good manufacturing practice in manufacturing, packing, or holding human food. Part 113 deals with thermally processed low-acid foods packaged in hermetically sealed containers. Part 114 provides good manufacturing practice for dealing with acidified foods.)

Under the Law, a person purchasing milk for resale or manufacture into another product must pay the producer in a manner and on dates set by the U.S. Department of Agriculture milk market administrator or as mutually agreed to by the producers, the dairy plant, and the MDA. The bill would remove the reference to the milk market administrator.

The bill would prohibit packaged fluid dairy products that exceeded the sell-by date from being reused in any dairy products regulated by the Grade A Milk Law or the Manufacturing Milk Law unless the MDA approved a protocol for such reprocessing. The protocol would have to include consideration of storage temperatures, bacterial counts, age past the sell-by date, sight and smell grading qualities, added ingredients, and any other factors the MDA Director considered critical.

Packaged fluid dairy products that had left the control of a dairy plant but were returned or delivered to a dairy plant, commonly referred to as "returned products", could not be reprocessed into milk or milk products regulated under the Grade A Milk Law or the Manufacturing Milk Law.

The bill would require milk and milk products to be advertised as specified in the Food Law.

Bulk Hauler/Sampler

The bill would require a licensed bulk milk hauler/sampler to ensure that milk over 96 hours old was not picked up from a dairy farm. Goat milk, however, could be stored for seven days, and sheep milk could be frozen for extended storage and transportation.

Pasteurization

The Law provides standards for the pasteurization of milk and milk products, including required temperatures and pasteurization times. The bill also would require all milk and milk products, including milk solids, whey, nonfat dry milk, condensed milk, cream, skim milk, and other milk products, as well as eggs, egg products, cocoa, cocoa products, emulsifiers, stabilizers, vitamins, and liquid sweeteners to be added before pasteurization. All those additions would have to be done in a sanitary manner that prevented the contamination of the added ingredient or the milk or milk product. Ingredients that could be added after pasteurization would be those flavoring ingredients and other ingredients that had been found to be safe and suitable, and would include:

- Ingredients permitted by the CFR standards of identity when considering a standardized milk or milk product.
- Fresh fruits and vegetables added to cultured milk and milk products, if the resultant equilibrium pH level (4.6 or below when measured at 75° F) of the finished product were reached without undue delay and were maintained during the shelf life of the product.
- Ingredients subjected to prior heating or other technology that had been demonstrated to the FDA to be sufficient to destroy or remove pathogenic microorganisms.
- Ingredients having a water activity of 0.85 or less.
- Ingredients having a high acid content (pH level of 4.6 or above when measured at 75° F) or high alkalinity (pH level greater than 11 when measured at 75° F).
- Roasted nuts.

- Dry sugars and salts.
- Flavor extracts having a high alcohol content.
- Safe and suitable bacteria cultures and enzymes.
- Ingredients that had been found to be safe and suitable by the FDA.

All milk and milk products would have to be pasteurized, prior to the entrance into reverse osmosis (RO), ultra-filtration (UF), evaporator, or condensing equipment, and would have to be performed in the milk plant where the processing was done. If the product were whey, however, pasteurization would not be required if the product were acid whey (with a pH of less than 4.7) or if it were processed in RO or UF equipment at temperatures at or below 45° F.

In addition, if the product were raw milk for pasteurization, it could be concentrated by the use of RO or UF membrane filtration without pasteurization before entering the equipment, provided that the following sampling, testing, design, installation, and operational criteria were met:

- Before processing, all raw milk supplies were sampled and tested for antibiotic residues in accordance with the provisions of the Law.
- The RO or UF filtration system was designed and operated to assure that milk or milk product temperature was maintained at or below 45° F throughout the process, provided that the product temperature could rise above 45° F for not more than 15 minutes, and if the product temperature rose above 50° F, the product would have to be diverted immediately until it again was below 45° F. The diverted product would have to be discarded, immediately cooled to below 45° F, or immediately pasteurized.
- The RO or UF system was equipped with temperature monitoring and recording devices that complied with the applicable specifications outlined in the Grade A Milk Law. At a minimum, milk or milk product temperature would have to be monitored and recorded before entering the system, before entering each stage of the modules in series that contained cooling, and the retentate stream before any final cooler and upon exiting the system.
- If the RO or UF system were not designed, installed, and operated in accordance with the above criteria, the

raw milk or milk product would have to be pasteurized before entering the RO or UF system.

All condensed milk and milk products transported to a milk plant for drying would have to be repasteurized at the milk plant before they were dried.

If condensed whey containing at least 40% total solids had been partially crystallized by cooling, it could be transported to a separate milk plant for drying without repasteurization, provided that the following conditions were met:

- The condensed, partially crystallized whey was cooled and maintained at 45° F or less.
- Milk tank trucks used to transport the whey were washed and sanitized immediately before filling and were sealed after filling until unloading.
- Separate unloading pumps and pipelines were provided and used only for the unloading of the condensed, partially crystallized whey. Those pumps and pipelines would have to be cleaned and sanitized as a separate cleaning circuit.

The design and operation of pasteurization equipment and all appurtenances would have to comply with the applicable standards, specifications, and operational procedures of the Law.

The Law requires dairy products made or sold in the State to comply with certain standards for holding temperature, bacterial limits, somatic cell count, drug residues, sediment, and other factors. The bill would require raw milk for frozen desserts to have a maximum freezing point of -0.530° on the Horvet scale.

The bill would remove requirements that pasteurized condensed milk, condensed skim milk, and pasteurized condensed whey contain less than a certain amount of phosphates.

The bill would revise the temperature requirements for whey for condensing, which currently must be held at 45° F or less, or 145° F or greater, with some exceptions. The bill would reduce the minimum hot holding temperature from 145° F to 135° F.

Currently, pasteurized condensed whey must be cooled to 45° F or less during crystallization, within 18 hours of condensing. The bill would require pasteurized condensed whey and whey products to be cooled to 50° F or less during crystallization, within 72 hours of condensing.

The bill also would eliminate the bacterial limit for pasteurized condensed whey, which currently may not exceed 50,000 bacteria per gram.

Under the Law, sterilized or aseptic products may contain no viable bacteria. The bill would delete reference to viable bacteria and state, "Refer to 21 CFR 113.3(e)(1)". (Under that Federal regulation, commercial sterility of thermally processed food means the condition achieved by the application of heat that renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution and viable microorganisms, including spores, of public health significance.)

Milk Processing Plant

The Law requires a person who owns or operates a plant receiving milk for manufacturing into a dairy product to meet certain requirements, including equipping the plant with adequate and well-distributed lighting. The bill would require that the lighting be of at least 50 foot-candles where dairy products were graded or examined for condition and quality such as a can milk receiving room dumping area; 20 foot-candles at working surfaces in rooms for manufacturing, processing or packaging of dairy products or washing of equipment and utensils; five foot-candles in all other rooms, including storage rooms and coolers; or as specified by the MDA Director. Light intensity would have to be measured at a distance of 30 inches from the floor with a light meter.

The Law also requires a person who owns and operates a milk processing plant to maintain conveniently located and adequate toilet facilities that comply with certain requirements. The bill would require the toilet facilities to be located in the processing plant.

The bill also would require a person who owned and operated a milk processing plant to provide adequate electrical power for on-demand support of lighting, cooling, heating, agitation, and ventilation systems.

Currently, a milk processing plant owner or operator must ensure that product storage tanks or vats comply with certain requirements. The bill would require an owner or operator to ensure that pasteurized milk and milk product storage tanks were cleaned and sanitized at least every 72 hours. Pasteurized ice cream storage tanks could be cleaned and sanitized at least every 120 hours, subject to the following:

- Ice cream storage tanks would have to be equipped with a seven-day recording device complying with certain specifications in the Grade A Pasteurized Milk Ordinance.
- Once withdrawal of ice cream mix from the tank commenced, no further additions of mix could be made except in the first 24 hours following the beginning of the withdrawal. Records of the products produced from that tank would have to be maintained.
- All standard plate counts, coliform counts, and pathogen counts on finished product and ice cream mix produced from that storage tank could not exceed legal standards.

A warning notice would have to be issued following the first test result that did not meet the legal standards for standard plate count or coliform. Any count not meeting the legal standards in the next three test results would require implementation of the 72-hour cleaning and sanitizing provision described above. That provision would remain in effect until the plant demonstrated to the MDA Director its ability to remain in compliance with the legal standards.

Dairy Plant

Except as otherwise provided under the Law, a dairy plant owner or operator must dismantle all equipment after each day's use, except for that designed for clean-in-place (CIP) cleaning, and thoroughly clean the equipment by using dairy cleaners, detergents, sanitizing agents, or other similar materials approved for dairy or food

service use that will not contaminate or adversely affect the dairy products.

The bill would revise that provision to require an owner or operator to dismantle all equipment that was not designed for mechanical or clean-in-place cleaning, and thoroughly clean and sanitize all equipment after each day's use, using the same cleaning agents currently provided, except that the bill would remove the reference to dairy cleaners.

The Law requires a dairy plant owner or operator to provide a covered or enclosed receiving, washing, and sanitizing facility at each site that receives or ships milk or dairy products in milk tank trucks. The bill would retain that provision for all newly licensed or newly or extensively remodeled facilities. An owner or operator would have to meet that requirement or provide means to protect the milk during the sampling and transferring process that were acceptable to the MDA Director.

Packaging Requirements

Currently, retail packages must be labeled as specified in 21 CFR Part 101 (which pertains to food labeling), 9 CFR Part 317 (which includes standards of identity and composition), and subpart N of 9 CFR Part 381 (dealing with poultry products inspection), all of which are adopted by reference, and as specified under certain sections of the Federal Food Code adopted by the Food Law.

The bill instead would require retail packages to be labeled as specified in 21 CFR Part 101, which would be adopted by reference, and as specified under the Food Law.

Currently, a person who packages dry milk must ensure that a lined container is not lined more than one hour before the container is filled. Under the bill, that provision would not apply if the container were provided adequate protection from contamination.

The Manufacturing Milk Law requires a person who owns or operates a plant to keep all products under refrigeration at temperatures of 40° F or lower after packaging and until ready for shipment. The

bill would increase the maximum allowable temperature to 45° F.

Definitions

The bill would define "advertise" or "advertisement" as a presentation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of milk or milk products.

The bill would define "approved laboratory" as a laboratory that has been evaluated by the MDA and is approved to perform tests on manufactured milk and milk products.

"Dairy animal" would mean any domesticated lactating mammal, including a cow, goat, sheep, water buffalo, or other hooved mammal, that is managed and milked to obtain milk for human consumption.

"Dairy farm" would mean any place or premises where one or more dairy animals are kept for milking purposes, and from which a part or all of the milk is provided, sold, or offered for sale.

"Dairy plant" would mean any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, packaged, or prepared for distribution. That definition would replace the current definition of dairy plant under the Law, i.e., a milk plant, transfer or receiving station, cheese plant, frozen desserts plant, or other plant receiving dairy products or processing dairy products into manufactured dairy products.

Currently, "distributor" means a person other than a producer or processor who offers for sale or sells to another for resale at retail milk or dairy products. Under the bill, that term would mean a person other than a producer or processor who offers for sale, holds for sale, or sells at wholesale milk or dairy products.

Under the Law, "first receiving point" means the dairy plant where the milk is first received for processing and manufacturing. The term does not include receiving stations and transfer stations. Under the bill, the term would not include receiving and

transfer stations for producer security requirements only.

The bill would define "food service establishment" as a fixed or mobile restaurant, coffee shop, cafeteria, short order cafe, luncheonette, grill, tearoom, sandwich shop, soda fountain, tavern, bar, cocktail lounge, nightclub, drive-in, industrial feeding establishment, private organization serving the public, rental hall, catering kitchen, delicatessen, theater, commissary, food concession, or similar place in which food or drink is prepared for direct consumption through service on the premises or elsewhere, and any other eating or drinking establishment or operation where food is served or provided for the public. Food service establishment would not include any of the following:

- A motel that serves continental breakfasts only.
- A bed and breakfast that has 10 or fewer sleeping rooms, including sleeping rooms occupied by the innkeeper, one or more of which are available for rent to transient tenants.
- A bed and breakfast that has at least 11 but fewer than 15 rooms for rent, if the bed and breakfast serves continental breakfasts only.
- A child care organization regulated under the child care licensing Act, unless the establishment is carrying out an operation considered by the Director to be a food service establishment.

(That definition is the current definition of "food service establishment" under the Food Law.)

Under the bill, "registered name" would mean either a name that is registered as "doing business as" at the county clerk's office in the county in which the producer or processor resides or a name that is registered with the State of Michigan as a legal entity registered to do business within the State under an assumed name. The term would include incorporations, corporations, limited liability companies, limited liability partnerships, and similar entities.

Currently, "sanitary standards" includes standards for dairy equipment formulated by the United States Department of Agriculture

(USDA) or the FDA. The bill instead would include general sanitary construction standards for dairy equipment formulated by the USDA or the FDA, if sanitary standards are not available for a particular piece of equipment.

MCL 288.570 et al.

Legislative Analyst: Curtis Walker

FISCAL IMPACT

The bill would result in a small saving for the State since it would allow the Michigan Department of Agriculture to assess a late fee and pass on the costs of convenience charges for transactions to fee payers. The bill also would redirect revenue from all fees, assessments, fines, or money collected under these provisions to the Dairy and Food Safety Fund, instead of the General Fund, where it currently is deposited. According to the MDA, approximately \$60,000 is collected annually in fee revenue, \$15,000 is collected in fines, and it expects to collect less than \$1,000 annually in late fees. This means that about \$75,000 would be deposited into the Dairy and Food Safety Fund instead of into the General Fund. The Dairy and Food Safety Fund is used to administer dairy and food programs in the MDA.

Fiscal Analyst: Jessica Runnels

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.