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Food Protection Program Policies, Procedures and Guidelines

Issue: Licensing and Testing Requirements for Frozen Desserts No: DU-01

This memorandum provides the Food Protection Program's policy on licensing and testing requirements for 105 CMR 500.000 *Good Manufacturing Practices for Food*.

I. Licensing Authority for Wholesale for Retail Frozen Dessert Manufacturers

The regulatory authority for inspection and licensing of frozen dessert establishments is stated in M.G.L. c.94, § 65G-U. The law states that frozen desserts manufacturers, **both retail and wholesale, shall be licensed and inspected by local boards of health.** Frozen desserts are further regulated in 105 CMR 500.000, *Good Manufacturing Practices for Food*. **All wholesale or retail frozen dessert manufacturers require licensing by the local board of health.**

A. Scope

What types of establishments are considered frozen dessert manufacturers?

1. Wholesale manufacturing plants that pasteurize raw milk and cream;
2. Wholesale manufacturers who purchase a pasteurized mix and manufacture ice cream;
3. **Retail manufacturers* who purchase a pasteurized mix and manufacture ice cream, soft-serve ice cream or frozen yogurt in a "frozen dessert freezing/dispensing machine."**

*It is important that the term *manufacturer* be understood as it pertains to frozen desserts. The term *manufacturer* or *frozen dessert manufacturer* as it appears in the regulations *includes any retail establishment operating a frozen dessert freezing/dispensing machine*. A "frozen dessert freezing/dispensing machine" is any machine that freezes, mixes and dispenses frozen desserts. **This includes soft serve machines frequently operated at the retail level. This means that all frozen dessert manufacturers, whether wholesale or retail, require licensing by the local board of health having jurisdiction.**

What types of establishments are not considered frozen dessert manufacturers?

1. *Stores and restaurants that purchase ice cream in bulk and scoop it, but do not make ice cream in a frozen dessert freezing/dispensing machine;*
2. *Retail stores that purchase ice cream or other frozen desserts in pre-packaged retail containers for re-sale to the public;*
3. *Vending machines that dispense packaged ice cream, novelties, etc.; and*
4. *"Dispensing only machines." Dispensing only machines are machines that dispense a prepackaged ready-to-use frozen dessert. These machines do not mix or freeze a mixture. They merely dispense it. Therefore the machine is not considered a manufacturing machine.*

B. Licensing of In-State and Out-of-State Frozen Dessert Establishments

M.G.L. c. 94, § 65G-U requires wholesale and retail in-state manufacturers of frozen desserts or frozen dessert mixes to be licensed and inspected by local boards of health. Application to local boards for licensing are to be made in February, and the license year is effective from March 1 through the end of February the following year. The Department of Public Health issues licenses for out-of-state wholesale frozen dessert manufacturers only. Fees for licenses and permits may be determined by each municipality. Pursuant to M.G.L. c.94 § 65H the license application shall include the following:

1. A statement that the applicant will manufacture such products only from pure and wholesome ingredients and only under sanitary conditions;
2. The location of each plant where products will be manufactured;
3. A statement as to where applicant will purchase frozen dessert mix and/or where applicant will purchase raw milk products, if a pasteurization plant; and
4. The brand and trade name(s) under which products will be sold.

C. Establishments for the Pasteurization of Ice Cream Mix and/or Frozen Yogurt Mix

Pasteurization plants processing ice cream, ice cream mix and frozen yogurt mix are licensed by local boards of health and may be inspected by the Massachusetts Department of Public Health (MDPH) or the local board of health. Whenever pasteurization is involved, the Food Protection Program has traditionally performed the inspections because of the complexity of pasteurization systems. M.G.L. c. 94, § 65J allows for enforcement to be administered by either the local board of health or MDPH. Monthly testing of the ice cream or frozen dessert mix is also required by 105 CMR 500.082(B). If the manufacturer maintains its own state approved laboratory, it must keep monthly testing results on file and available to local and state inspectors. Otherwise, monthly samples of mix must be tested at a MDPH approved laboratory and copies of the results must be submitted to the local board of health upon completion of analysis by the testing laboratory.

II. Policy on the Current 105 CMR 500.000, Frozen Desserts, Frozen Dessert Mixes and Ice Cream

The MDPH Food Protection Program is issuing the following interpretations to the current frozen dessert regulation. This policy is applicable to local boards of health frozen dessert programs and can be implemented immediately until further notice.

A. Testing and Testing Exemptions

The current language in 105 CMR 500.082(B) states that all manufacturers must have their frozen dessert products tested monthly by an approved laboratory. Section 500.082(B)(2) refers to seven categories of frozen dessert products. The intent is to require bacteriological testing for *dairy-based frozen desserts only*. Dairy-based frozen desserts such as ice cream, sherbet and frozen yogurt are frozen dessert products that contain dairy ingredients. *Non-dairy frozen desserts no longer require bacteriological testing*. Non-dairy frozen desserts, such as sorbet, water ices, Italian ice, slush and some frozen coffee beverages are frozen desserts that do not contain any dairy ingredients. These products do not pose the same potential for supporting pathogenic organisms as do frozen desserts that do contain dairy ingredients. **Therefore, testing of non-dairy frozen desserts is no longer required.** According to 105 CMR 500.082(B), all frozen dessert manufacturers (this includes soft serve dispensing machines and ice cream barrel freezers) shall have bacteriological tests performed on at least one dairy-based frozen dessert

product per month by a certified laboratory. The laboratory must submit copies of the results to the board of health upon completion of the analysis.

Note: Frozen yogurt is defined as a food that is prepared by freezing yogurt while stirring. Today, frozen yogurt is actually a cultured frozen dessert mix blend. Frozen yogurts may or may not contain active yogurt cultures. Laboratories should not run the standard plate count (SPC) test on frozen yogurts containing these “friendly” culture bacteria. Some frozen yogurt may have been pasteurized after culture was added. If it is known that a product labeled “frozen yogurt” does not contain live cultures, then the testing laboratory should perform the SPC. The coliform test is always run on frozen yogurts.

B. Enforcement Procedures per 105 CMR 500.000

The bacteriological limits for frozen desserts set forth in 105 CMR 500.083 are 10 coliform colonies per gram and 30,000 standard plate count (SPC) per milliliter for frozen dessert mixes (except in the case of bulk milk transport tank shipments, which must not exceed 100 coliform colonies per milliliter) and 20/30,000 for frozen desserts (except in the case of soft-serve products, which must not exceed 50 colonies per gram). **It is the responsibility of local boards of health to enforce monthly testing and reporting requirements for frozen dessert establishments, as well as to take appropriate actions when bacteriological violations have been found.**

The bacteriological standards are intended to provide guidance for enforcement and provide only one view of the total frozen dessert-manufacturing environment. The standards were never intended to be used as a rigid enforcement tool, especially on the first analysis. *It should be noted that the frozen dessert regulations **do not** consider one excessive count as a violation.* The presence of coliform is an indicator of inadequate operational sanitation and controls somewhere in the process. Bacteria counts slightly above the standards should only be a wake up call. It should alert the machine operator that something might not be right with cleaning, temperature, storage or handling. Intervention by the local boards of health at this point is often unnecessary.

In an effort to aid boards of health weighing the significance of bacteriological counts that have exceeded the standard, some commonly asked questions with MDPH’s answers follow:

Q. If a frozen dessert sample is reported to have a 30 coliform count, is this considered far worse than a coliform count of 20?

A. The coliform count is an indicator of a possible sanitation failure, not a confirmation that pathogens are present. In terms of the way bacteria grow; a count of 30 coliform does not exceed the standard by a significant margin. Bacteriological growth occurs at an exponential rate, not at a linear rate. Therefore, it is more meaningful to consider bacteria counts in terms of *doubling*. A two-generation increase, or two doublings, is considered significant. For example, a coliform count more than 80 would be considered significantly higher than a count of 20, the standard.

Q. Does a standard plate count (SPC) slightly above the standard of 30,000 colonies per milliliter present a public health concern?

A. The limit of 30,000 SPC is intended as a guideline. Usually the SPC represents harmless organisms, especially if there are no coliform associated with the sample. Spoilage organisms usually begin to affect the frozen dessert product in numbers much greater than 30,000. It usually takes counts of 1,000,000 or greater to create spoilage. According to 105 CMR 500.082, exceeding 30,000 once is not considered a violation. When a SPC is only slightly high, i.e.,

150,000, consider the company's track record. A telephone call to the owner to insure standard operating procedures have been followed may be all that is necessary. If previous counts have been satisfactory, request that the person in charge review their machine cleaning and sanitization and product handling procedures, and then just wait for the next month's results. Following the same logic of a two-generation increase, it would take an SPC of 120,000 or above to be considered "significantly high," as compared with 30,000, the standard.

Q. Do frozen dessert samples showing excess coliform contain pathogens that could make people sick?

A. As stated earlier, the coliform count is an indicator that pathogens might be present. Further testing is necessary to confirm actual pathogens. The overall risk to frozen dessert products is extremely low. The cold temperature simply does not allow for the growth of pathogens. In fact, there are very few reported food-borne illnesses associated with frozen dessert products - none reported to MDPH in recent years.

Q. What if counts continue to be reported in excess of the standards?

A. If the frozen dessert establishment has a history of slightly high counts or has some significantly high counts, the board of health should implement the resampling protocol stipulated in either 105 CMR 500.082(C), 500.082(D), or 500.082(E), or perform an inspection, or both. In accordance with 105 CMR 500.082(D), when a laboratory result shows a frozen dessert product is in excess of the bacteriological standards, the local health inspector may obtain or require additional testing in triplicate and may conduct an inspection to determine the cleanliness of the machine and/or establishment. It is deemed a violation if the majority of the three samples exceed bacterial limits. At this time the inspector may take action against the dispensing machine(s) and/or establishment responsible for the high counts.

Q. When should local health officials take enforcement action for high bacteria counts?

A. Slightly high counts aside, there are times when local enforcement action is warranted and should be taken. An inspection of the establishment and/or triplicate sampling shall be conducted:

- If there are repeated excess counts on the same machine;
- If there are significantly high counts (A count is considered significantly high if it exceeds the standard by a factor of four, or two doublings.); or
- If there is a combination of both high SPC and high coliform.

Also, review the establishment's cleaning and sanitizing procedures and check against manufacturer's specifications for the machine in use. Remember, if triplicates have been collected and the majority of triplicate samples exceed the standard, the local board of health must order the responsible machine shut down for cleaning and sanitizing. Reinstatement of shutdown machines should depend upon the results of recent inspections, corrections made or promised by the establishment and the overall compliance history of the establishment.

Q. During an inspection prompted by high bacteria counts what questions should be asked?

A. Ask if and how disassembly, cleaning, sanitizing and assembly of frozen dessert machines are performed as indicated by manufacturers' recommendation and at the required frequency. Also ask if the machine has been maintained properly. Often worn parts can lead to bacteria problems even when cleaning and sanitizing are completed properly. Review the establishment's cleaning

and sanitizing procedures and check against manufacturer's cleaning protocols for the machine. As always, common sense and professional judgment should be employed.