Enforcement Guidance: Frozen Dessert Law

Pasteurization Requirements for Dry Frozen Yogurt Mixes that contain Allowed Live Yogurt Cultures

This document is guidance for Pennsylvania Department of Agriculture (PDA) employees involved in the administration and enforcement of the Frozen Dessert Law (31 P.S. §§ 417-1 – 417-14) and its attendant regulations (7 Pa. Code Chapter 39). This document will also be made available to impacted regulated entities and the general public, and will be identified by PDA in the regular listing of Non-Regulatory Public Documents it is required to disseminate under Executive Order 1996-1 (titled Regulatory Review and Promulgation).

A. Background.

The regulation at 7 Pa. Code § 39.5 (titled Standards for frozen dessert mix) requires retail manufacturers of frozen desserts to obtain the frozen dessert mix (“mix”) only from a holder of a PDA-issued milk products permit. It also requires that the mix be pasteurized and held in storage at a temperature of 45°F or less. Under current regulations, when a dry frozen yogurt mix is reconstituted with pasteurized milk or water by a retail manufacturer of frozen desserts, the reconstituted mixture must then be re-pasteurized.

Pasteurization kills live bacterial cultures, and the re-pasteurization described in the preceding sentence would kill any live yogurt cultures that were intentionally added by the retail manufacturer of the frozen dessert mix and, in so doing, eliminate any benefit from the addition of these live yogurt cultures to the frozen yogurt mix. This Enforcement Guidance addresses the limited circumstances under which a retail manufacturer of frozen desserts may reconstitute a dry frozen yogurt mix containing live yogurt cultures with pasteurized milk or water without that reconstituted mixture having to be re-pasteurized before it is flavored and frozen.

This Enforcement Guidance is reasonable in that: (1) the safety of the end product – frozen yogurt mix that has been reconstituted from a dry mix with pasteurized milk or water and that contains live yogurt cultures – is preserved; (2) PDA retains extensive regulatory oversight with respect to this frozen dessert mix; (3) the current regulatory reference at 7 Pa. Code § 39.5 cites to a regulatory subchapter that has been repealed and supplanted by new regulations at 7 Pa. Code Chapter 59a; (4) the regulations at 7 Pa. Code Chapter 59a adopt the standards of the U. S. Food and Drug Administration’s Grade “A” Pasteurized Milk Ordinance – a document which allows for the addition of certain ingredients which have been found safe and suitable after pasteurization; and (5) it is the intention of PDA to move forward with a regulatory promulgation project that will correct and update 7 Pa. Code § 39.5 and formalize the terms of this Enforcement Guidance.
Among the “safe and suitable” ingredients that the Grade “A” Pasteurized Milk Ordinance allows to be added to milk or milks products without the need for re-pasteurization are: (1) ingredients subjected to prior heating or technology demonstrably sufficient to remove or destroy pathogenic organisms; and (2) ingredients having a water activity of 0.85 or less.

PDA issues the following.

**B. Enforcement Guidance.**

If all of the following conditions are met, frozen yogurt mix that has been reconstituted from dry frozen yogurt mix with pasteurized milk or water from an approved source need not be re-pasteurized after any live yogurt cultures and/or other “safe and suitable” ingredients as described above are added. These conditions are:

1. The reconstitution is accomplished with pasteurized milk or pasteurized milk products, and/or with water from a PDA-approved source.

2. If the reconstitution is accomplished with pasteurized milk or pasteurized milk products, these come from single-use packaging and the contents of that packaging are used in their entirety in a single day’s production.

3. If the reconstitution is accomplished with pasteurized milk or pasteurized milk products, the pasteurized milk or pasteurized milk products used in the reconstitution are held at a temperature of 38° F or lower at all times.

4. The dry frozen yogurt mix (other than flavorings) comes from aseptically packaged single batched containers.

5. Any sweeteners and flavorings are stored in a manner to prevent contamination.

6. The reconstituted frozen yogurt mix is cooled to a temperature of 38° F or lower within 60 minutes of reconstitution.

7. The reconstituted frozen yogurt mix is frozen within 48 hours following reconstitution.

8. If reconstituted frozen yogurt mix is not frozen, it is date-marked in a manner acceptable to PDA, and the date of preparation and required disposal date are indicated on any prepared product.

9. The frozen yogurt produced from the reconstituted frozen yogurt mix is being manufactured to be served directly to the consumer at retail in single serving containers that will be consumed at the time of purchase.

10. The frozen yogurt is completely used in a single day’s production or within 24 hours, whichever is later, and is discarded at the end of that period.
11. Records are maintained for each batch, with a tracking system that allows easy traceability of the ingredients used, time/date made and the amount left /discarded.

12. All other applicable regulations are complied with, and the frozen yogurt mix is handled and maintained in accordance with the Food Code (7 Pa. Code Chapter 46).

PDA will evaluate the efficacy of this Enforcement Guidance on an ongoing basis.