

Appendix E

Minutes to Pelletized Ice Cream Meeting June 27, 2008

To: State Weights and Measures Directors, NCWM Laws and Regulations Committee and Other Interested Parties

On June 27, 2008, a meeting was held at NIST in Gaithersburg, Maryland, to discuss issues related to the sale of packaged Pelletized Ice Cream (an attendance list is attached). The participants included state and local officials from Maryland, New York, and Pennsylvania (including a representative of the NCWM L&R Committee), officials from the Food and Drug Administration, two producers of pelletized ice cream and a representative of the International Dairy Foods Association (International Ice Cream Association). The International Dairy Foods Association (IDFA), based in Washington, DC, represents the nation's dairy manufacturing and marketing industries and their suppliers. IDFA is composed of three constituent organizations; the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plants, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 % of the milk, cultured products, cheese, and frozen desserts produced and marketed in the United States. IICA's members that manufacture and sell pelletized ice cream product are: Dippin' Dots, Unilever/Good Humor Breyers, Kemps, and MolliCoolz. Carol Hockert, Chief of the NIST Weights and Measures Division, Lisa Warfield, David Sefcik, Elizabeth Gentry, and Ken Butcher from NIST also attended.

Background Information

Pelletized ice cream is a unique and novel product that entered the market in 1988 with Dippin' Dots, which was predominantly sold in food service venues direct to consumers. Packaged pelletized ice cream entered the retail marketplace about 2 years ago. A suggested definition for Pelletized Ice Cream is: "beads of ice cream which are quick-frozen with liquid nitrogen." The beads are relatively small, but can vary in shape and size. As with other types of ice cream, the pellets are produced in several flavors and they are frequently mixed with pieces of cookies, brownies or dough and other inclusions. Pelletized ice cream products meet the federal standard of identity (SOI) for ice cream as specified in 21 CFR §135.110. The product is made using pasteurized mix consisting of one or more of the prescribed dairy ingredients, sweeteners, stabilizer and flavoring. The ice cream mix is stirred via pumping and spraying action as the droplets are frozen at very low temperatures using liquid nitrogen. The freezing process results in small round shaped beads or pellets of ice cream that meet the required 4.5 pounds per gallon weight requirements set forth in the SOI for ice cream. By itself, the density of pelletized ice cream is higher than other ice creams because the product contains much less air than regular ice cream. It was noted that using the 4.5 pound density in the FDA's standard of identity is not an effective tool for determining the accuracy of fluid measure because, due to the higher density of pelletized ice cream, a package could easily meet the weight requirement and still not contain the fluid measure declared on the label. Because density variations occur when inclusions are added to packages of pelletized ice cream and, because the inclusions (e.g., cookie bits) themselves vary in size and weight, using gravimetric testing to verify the declared volume of a sample may not be practical. At least two manufacturers label their packages by net weight and the others label their packages in terms of fluid measure. The manufacturers that label their packages by fluid measure include the air surrounding the pellets in their net quantity of contents statement. At least four of the five known producers of pelletized ice cream are currently selling their packaged product in retail stores and their producing facilities are located in California, Florida, Kentucky, and Minnesota. At least one other manufacturer sells this product from bulk as a ready-to-eat food in mall kiosks, sports stadiums and other venues.

Pelletized ice cream products in the market are currently labeled by both weight and volume as follows:

Dippin' Dots - Weight (Dippin' Dots Pouches and product for export), and Volume (Orblets and bulk food service)

Kemps/Hood - Volume (Itty Bits)

Good Humor - Breyer's/Unilever - Weight (Popsicle Shots)

MolliCoolz - Weight (MolliCoolz)

Pelletized Ice Cream must be sold by Fluid Volume

The International Ice Cream Association (IICA) reported that there was a consensus among the manufacturers that pelletized ice cream should be labeled and sold on the basis of fluid volume in accordance with Subsection 1.7.1. Factory Packaged Ice Cream and Similar Frozen Products in the Method of Sale of Commodities Regulation in NIST Handbook 130. That Subsection reads “Ice cream, ice milk, frozen yogurt and similar products shall be kept, offered, or exposed for sale or sold in terms of fluid volume.” FDA officials at the meeting agreed with industry’s recommendation. When a food is frozen and it is sold and consumed in a frozen state, the declaration must express the volume at the frozen temperature. FDA regulations also permit fluid ounces to be used when “there is a firmly established general consumer usage and trade custom of declaring the contents of a ...solid, semisolid, or viscous product by fluid measure.” For ice cream there is a firmly established consumer usage and trade custom of selling ice cream and similar frozen products by volume. (See below for regulatory references.)

Volumetric Test Method and Air Measurement Issues

Once it was agreed that the appropriate method of sale for pelletized ice cream is by fluid volume, discussion moved to whether or not the air surrounding the beads is to be included as part of the fluid declaration. The IICA again reported that there was a consensus among the manufacturers that the air surrounding the beads should not be included as part of the fluid volume of the ice cream (“air-excluded”). To enforce the “air-excluded” standard, the water displacement method for ice cream novelties in Section 3.12. could be used if appropriate modifications were made to ensure the ice cream pellets can be completely and properly submerged. Some states and industry have tried alternative head-space methods and have substituted glycerin for water in the displacement procedures with some limited success. Pelletized ice cream can melt quickly but some states have reported that their tests indicate that with careful handling and strict temperature regulation of the water, the melting can be limited. Reducing melting is crucial to volume determinations because FDA requires that the volume of ice cream be determined while in a frozen state. After ice cream melts, it cannot be refrozen and tested because any air that the product contained is lost. There is also a need to develop a practical means to keep the pellets immersed in the test fluid so that their volume can be accurately determined. One approach which shows promise is to place the beads in a weighted nylon mesh bag (the volume displaced by the bag and weight are deducted). The IICA reported that in testing pelletized ice cream with added inclusions such as cookie pieces, cookie dough or brownies caused inaccurate results due to water absorption by the inclusions. But more testing and a collaborative study are needed before any one test method can be proven to provide reliable results. The group discussed the possibility of using screening tools or audit type tests to reduce destructive testing and to reduce the need to have inspectors collect samples and transport them to a testing laboratory.

It was during this discussion a potential problem with the “air-excluded” net content declaration surfaced. For nutritional labeling purposes, manufacturers must also state the serving size in volume using household measures such as “tablespoon” or “cup” in the nutrition facts panel. Because the air will have to be subtracted from the total volume of the ice cream on the net content label, a consumer who were to measure out the total number of household ½ cup measures of ice cream (with air) would find a greater number of servings than what would be calculated by dividing the total net contents by 4 fl oz. The difference between the two volumes with or without air could be as much as 50 %. While this may not be a significant issue for individual serving size containers, it could be a problem when pelletized ice cream is sold in multiple serving containers. The potential problem is that consumers might be confused or misled by the apparent discrepancies in the declarations. Several suggestions were offered to address the potential problem such as having the manufacturer provide special label information explaining the reason for the difference in volumes, but it became clear during the discussion that this issue would have to be formally submitted to the FDA nutritional labeling experts for resolution. The FDA representatives who attended the meeting were experts in package labeling and standards of identity but could not respond to questions on nutritional labeling. They asked that a written request be submitted to FDA requesting a prompt interpretation of its regulations. IDFA agreed that it would draft and send a request for interpretation to FDA before the NCWM Annual Meeting.

If FDA requires an “air-included” standard (i.e., the air surrounding the pellets is included in the fluid volume of the ice cream), the volume of the ice cream declared in the net quantity statement and the nutritional label serving size

would be in approximate agreement. A test procedure to verify the volume of ice cream sold on this basis would be simpler to develop and verify than the water displacement method in Handbook 133. This test could be as simple as pouring the pelletized ice cream into a chilled cylinder and then taking a direct reading of the volume from the graduations on the cylinder. The suitability of the test equipment in either test would be crucial so that the combined uncertainties of the calibrated test equipment and the uncertainty of the test method do not exceed $\frac{1}{6}$ of the Maximum Allowable Variation.

The IDFA representative will send a letter to FDA requesting an interpretation of its regulations in regard to whether the air is to be included in the volume of the ice cream and how industry will be expected to provide nutritional information on packages. Once FDA issues a response, IDFA will collaborate with state weights and measures officials and NIST to develop the appropriate test procedures. At this point, NIST will host a second meeting of weights and measures officials, industry and the FDA to move forward on the next steps needed. Once the industry receives notice from FDA on how they will have to package and label pelletized ice cream, the pelletized ice cream manufacturers will need a reasonable period of time to make the necessary changes to packaging for declaration of the net contents in fluid volume (from weight to volume or from volume of product with “air-included” to “air-excluded”). This will include package redesign, and the ability to use up existing inventory of packaging and product in storage and in the market place. Because the shelf life of ice cream can range from 12 to over 18 months, inventories of product may be extensive. IICA asked that during this time period of determining the proper net content declaration and measurement tool if weights and measures officials could consider using regulatory enforcement discretion for pelletized ice cream products.

This report was sent to all state weights and measures officials and other interested parties. It will be presented to the Laws and Regulations Committee at National Conference of Weights and Measures during its 93rd Annual Meeting in Burlington, Vermont – July 13 to 17, 2008.

References:

NIST Handbook 130 – 2008 Edition – Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality - Uniform Regulation for the Method of Sale of Commodities, pages 104-105.

1.6. Fluid Milk Products. – All fluid milk products, including but not limited to milk, lowfat.

1.7. Other Milk Products. – Cottage cheese, cottage cheese products, and other milk products that are solid, semi solid, viscous, or a mixture of solid and liquid, as defined in the Pasteurized Milk Ordinance of the U.S. Public Health Service, as amended in 1965, shall be sold in terms of weight.

1.7.1. Factory Packaged Ice Cream and Similar Frozen Products. – Ice cream, ice milk, frozen yogurt, and similar products shall be kept, offered, or exposed for sale or sold in terms of fluid volume.

CFR TITLE 21--FOOD AND DRUGS Section 101.105 Declaration of net quantity of contents when exempt.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

To participate in the work on pelletized ice cream please contact: Lisa Warfield at NIST at lisa.warfield@nist.gov or at (301) 975-3308 or Cary P. Frye at the International Dairy Foods Association at cfrye@idfa.org or at (202) 220-3543.

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