

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BOARD OF HEALTH

NOTICE OF ADOPTION  
OF AMENDMENTS TO ARTICLE 115 OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter (the “Charter”) and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice of intention to amend Article 115 (Prescription Formula Preparation Facilities) of the New York City Health Code (the “Health Code”) was published in the City Record on June 20, 2008, and a public hearing was held on July 21, 2008. No written comments were received and no testimony was given. At its meeting on September 17, 2008, the Board of Health adopted the following resolution.

**STATUTORY AUTHORITY**

These amendments to the Health Code are promulgated pursuant to §§558 and 1043 of the Charter. Sections 558(b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department’s authority extends. Section 1043 grants the Department rule-making authority.

**STATEMENT OF BASIS AND PURPOSE**

The Board of Health, at its meeting on October 24, 2007, adopted a resolution repealing and reenacting Article 115 of the New York City Health Code (Prescription Formula Preparation Facilities). At the request of the Department’s Bureau of Food Safety and Community Sanitation (BFSCS), the Board of Health further amended §115.17 (g) and §115.21(f) of the Health Code to enable prepared powdered infant formula to be held in storage at temperatures of 40°F or lower.

The Production and Clinical Services Department of Food and Nutrition, Presbyterian Hospital, brought to the attention of the BFSCS that Article 115’s required temperature for holding prepared powdered infant formula at 37°F is lower than that prescribed by the American Dietetic Association’s guidelines. The Administrator of Presbyterian’s Department of Food and Nutrition wrote that:

Our clinical care practice needs to be evidence based. The major reference we have used is the 2004 publication by the American Dietetic Association Infant Feedings: Guidelines for Preparation of formula and Breastmilk in Health care Facilities. This reference states in Chapter 4 - Formula Preparation and Handling: Dedicated refrigerators with adequate chill capacity (4°C, 40°F) for infant feedings in the formula room and on the patient care units are recommended. This reference also states: Care should be taken to avoid freezing temperatures (0°C, 32°F) or excessive heat (35°C, 95°F) in stock storage areas. While the code addresses mixed infant formula (not shelf stable products) we have found that attempting to maintain refrigerators at <37°F has resulted in freezing of the mixed formula in our refrigerators.

Further review by the Department found that both the ADA guidelines and the UN Food and Agriculture Organization and World Health Organization recommendations for cooling and maintaining reconstituted powdered infant formula to prevent infection with certain microorganisms, including, but not limited to, *E. sakazakii*, are to initially cool prepared powdered formula to 35°F to 40°F (2°C to 4°C) within one hour of preparation, and then to store formula under refrigeration at temperatures below 41°F

(5°C). Refrigerated storage, at temperatures lower than 41°F (5°C), is sufficient to prevent or slow growth of harmful bacteria.

Currently, Health Code §115.21(f) provides that “prescription infant formula prepared from a powdered food base shall be cooled to 37 degrees Fahrenheit (2.8 degrees Celsius) within one hour of preparation, and maintained at 37 degrees Fahrenheit (2.8 degrees Celsius).” In addition, labeling requirements in Health Code §115.17(g) provide that prescription formula be labeled with information that it be kept “under refrigeration at or below 40 degrees Fahrenheit (4.4 degrees Celsius), except that prescription formula for infants prepared with a powdered food base shall be maintained at temperatures below 37 degrees Fahrenheit (2.8 degrees Celsius)...”

Accordingly, to be consistent with WHO and ADA guidelines, and to maintain nutritional quality of prepared formula, the Board of Health amended the required holding temperature for prepared powdered formula from 37°F (2.8°C) to 40°F (4°C). The Department believes this amendment will continue to promote a safe and nutritional product

**References:**

*Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities*, Robbins, Beker, ed.; Pediatrics Nutrition Practice Group, American Dietetic Association, 2004.

*Safe Preparation, Storage, and Handling of Powdered Infant Formula*. World Health Organization with Food and Agriculture Organization of the United Nations, 2007.

International Food Safety Authorities Network, *INFOSAN Information Note No. 1/2005-Enterobacter sakazakii, Enterobacter sakazakii in powdered infant milk formula*

US Centers for Disease Control and Prevention, *MMWR*, April 12, 2002/51(14); 298-300: Enterobacter sakazakii Infections Associated with the Use of Powdered Infant Formula----Tennessee, 2001.

**Statement Pursuant to Charter § 1043**

This proposal was not included in the Department’s regulatory agenda because the need for the amendment became known after publication of the regulatory agenda.

The amendment is as follows:

Matter underlined is new

Matter to be deleted is indicated by [brackets].

RESOLVED, that subdivision (g) of §115.17 of Article 115 (Prescription Formula Preparation Facilities) of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, adopted by resolution on the twenty-fourth of October, two thousand seven, be, and the same hereby is, amended, to be printed together with explanatory notes, to read as follows:

**§115.17 Labeling of containers.** Each container of prepared prescription formula for an individual shall be labeled with the following information:

\* \* \*

(g) A statement that the prescription formula shall be kept under refrigeration at or below 40 degrees Fahrenheit (4.4 degrees Celsius)[, except that prescription formula for infants prepared with a powdered food base shall be maintained at temperatures below 37 degrees Fahrenheit (2.8 degrees Celsius)];

\* \* \*

Notes: Subdivision (g) of §115.17 was amended by resolution adopted on xxxx deleting the labeling requirement for holding prepared powdered formula at temperatures lower than other prepared formula.

RESOLVED, that subdivision (f) of §115.21 of Article 115 (Prescription Formula Preparation Facilities) of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, adopted by resolution on the twenty-fourth of October, two thousand seven, be, and the same hereby is, amended, to be printed together with explanatory notes, to read as follows:

**§115.21 Packaging and sterilization.**

\* \* \*

(f) Prepared infant prescription formula shall be properly cooled to and maintained at or below 40 degrees Fahrenheit (4.4 degrees Celsius) within one hour of preparation, except that prescription infant formula prepared from a powdered food base shall be cooled to 37 degrees Fahrenheit (2.8 degrees Celsius) within one hour of preparation, and maintained at [37 degrees Fahrenheit (2.8 degrees Celsius)] or below 40 degrees Fahrenheit (4.4 degrees Celsius).

Notes: Subdivision (f) of §115.21 was amended by resolution adopted on xxxx deleting the requirement for holding prepared powdered formula at temperatures lower than other prepared formula.