

CURRENT MARKETING AND USE OF POWDERED INFANT FORMULA IN THE UNITED STATES

BACKGROUND

Infant formulas are products intended for use solely as a food for infants (individuals not more than 12 months of age) because of their simulation of human milk or their suitability as a complete or partial substitute for human milk. Infant formulas are marketed in the United States in three forms, as powdered, liquid concentrate, and liquid ready-to-feed products. Powdered formulas for infant feedings have been available since the late 1800s, with introduction of liquid concentrates in the early 1950s and ready-to-feed products about 1960. Following introduction of liquid formulas, the proportion of infant formula sold in powdered form declined, with the lowest proportion of sales from about 1970 to 1980; since 1980, the proportion of powdered infant formula sales has increased (Fomon, 2001). Based on 1999 dollar sales from Information Resources, Inc., powdered infant formula accounts for approximately half (49%) of the infant formula market in the United States. In most other countries, most infant formula is sold in powdered form.

On a cost-per-feeding basis, powdered infant formulas are less expensive than liquid formulas. Comparison of retail prices of a small, convenience sample of powdered, concentrate, and ready-to-feed infant formulas in the Washington, DC area in November 2002, suggests that cost-per-feeding of powdered infant formula is about 67% of the cost of ready-to-feed and 82% of the cost of concentrate.

The following sections of this paper describe types of infant formulas currently marketed in the United States, preparation of powdered products for feeding, and administration of infant formulas in health care settings.

CURRENTLY MARKETED INFANT FORMULAS

Federal regulations (21 CFR 107.100) require minimum and, in some cases, maximum levels of nutrients for infant formulas marketed in the United States. These regulations do not specify ingredients to be used in infant formulas but, like all foods, ingredients used in infant formulas are generally recognized as safe (GRAS) food ingredients or approved food additives.

Infant formulas are formulated to contain protein (nitrogen), carbohydrate, and fat ingredients to provide for the energy and macronutrient needs of infants. Micronutrients are added to formulations either as individual ingredients or as ingredients of vitamin and mineral premixes. Types and forms of infant formulas currently marketed in the United States and macronutrient ingredients listed in product label ingredient statements are described in the paragraphs that follow.

Products for Term Infants

The energy density of most formulas for term infants is 20 kcal/oz (670 kcal/L). Formulas with greater energy density (24 kcal/oz) have higher levels of macronutrients but micronutrients are provided at the same concentrations per 100 kcal as in the 20 kcal/oz formulas.

Milk-based infant formulas are consumed by the majority of term infants. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-feed forms. Various cow milk-derived products (e.g., nonfat milk, casein, combinations of casein and whey proteins, or partially hydrolyzed whey protein concentrate) provide protein for these formulas. Lactose, corn syrup solids, sucrose, or corn maltodextrin provide carbohydrates and vegetable oil blends provide fat.

Soy protein-based formulas are consumed by about 25% of term infants in the United States. The soy protein is a specific protein isolate fortified with L-methionine; combinations of corn maltodextrin, sucrose, or corn syrup solids provide carbohydrate; and vegetable oil blends provide fat. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-feed forms.

Protein hydrolysate-based formulas are often consumed by infants with milk allergy or intolerance to intact protein. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-feed forms. Enzymatically hydrolyzed casein, fortified with selected amino acids, provides nitrogen; combinations of corn syrup solids, maltodextrin, or sucrose provide carbohydrate; and vegetable oil blends provide fat. One protein hydrolysate-based product also includes medium chain triglyceride (MCT) oils as a fat source.

Amino acid-based formula may be consumed by infants who do not tolerate formulas based on cow milk proteins, soy protein isolate, or casein hydrolysates. One amino acid-based formula is currently marketed in the United States and it is marketed only in powdered form. This formula contains corn syrup solids, free amino acids, and a vegetable oil blend as sources of macronutrients.

Products for Preterm Infants

Premature infant formulas are consumed by many infants born preterm. They are marketed only in ready-to-feed form. Energy concentrations of these formulas are 24 kcal/oz and 20 kcal/oz. They also contain higher concentrations of protein and certain micronutrients to meet the needs of preterm infants. These formulas contain nonfat milk, whey protein concentrate, corn syrup solids, lactose, vegetable oil blends, or MCT as sources of macronutrients.

Transitional formulas are consumed by many preterm infants as they approach hospital discharge and after discharge. They are provided in ready-to-feed and powdered forms for hospitals and powdered form on the general market. The energy concentration of these formulas is 22 kcal/oz and they contain higher concentrations of certain nutrients than formulas for term infants. These formulas contain nonfat milk, whey protein concentrate, maltodextrin, lactose, or vegetable oil blends as sources of macronutrients.

Human milk fortifiers are nutritional supplement products that may be added to breast milk to supplement its nutrient content. One human milk fortifier product is sold in liquid ready-to-feed form. It is essentially the same in composition as 24 kcal/oz preterm formulas. Two products are marketed in powdered form. These products contain corn syrup solids and milk proteins with or without MCT as energy sources. Addition of these powdered human milk fortifiers results in minimal volume increment to the fluid volume consumed by the preterm infant.

Products for Infants with Metabolic Disorders and Other Special Populations

Metabolic infant formulas are formulated for use by infants with disorders of amino acid metabolism such as phenylketonuria, maple syrup urine disease, tyrosinemia, or other inherited metabolic disorders. Metabolic infant formulas and other products for infants with special nutritional needs are available only in powdered form. These formulas contain corn syrup solids, blends of vegetable oils, and selected balance of amino acids. Each is formulated without the primary offending amino acid(s) for the specific disorders. Unlike other formulas, these products are not intended to be fed as the sole source of nutrition to infants with metabolic disorders.

Products for Older Infants

Follow-up or follow-on formulas are iron-fortified, cow milk-based or isolated soy protein-based products intended for use by older infants (>6 months) and toddlers consuming solid foods. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-feed forms. The nutrient concentrations of formulas for older infants must meet the nutrient requirements for formulas fed to younger infants. They typically contain higher levels of calcium and phosphorus than formulas for younger infants.

PREPARATION OF POWDERED INFANT FORMULAS FOR FEEDING

Like all powdered food products, powdered infant formulas are *not* sterile and contain bacteria. Good manufacturing practice is critical to assure production of safe formulas. In addition, proper preparation, storage, delivery, and disposal of infant formulas are also critical for prevention of food-borne infections.

Instructions on Product Labels

Infant formula manufacturers are required by Federal regulation (21 CFR 107.20) to provide instructions for preparation and use on their product labels. These regulations specify that product labels for powdered products must include instructions for 1) storage of infant formula before and after the container has been opened, 2) “sterilization” of water, bottle, and nipples when necessary for preparing infant formula for use, and 3) dilution of the formula, when appropriate (directions for powdered infant formula must include the weight and volume of powdered infant formula to be reconstituted). Statements 1) cautioning against improper preparation or use of an infant formula and 2) indicating that parents should consult their physicians about use of infant formulas are also required.

Instructions for product storage before and after the powdered product has been opened are similar to the following label statement.

- “Store unopened cans at room temperature. Cover opened can tightly with a plastic lid and store in a cool, dry place. Do not refrigerate or freeze. Use contents within 1 month of opening to ensure freshness.”

Examples of instructions for preparation and use on labels of currently marketed infant formulas include statements such as the following. A single set of instructions is given for infants of all ages.

- “Bring water to a boil then cool to 100° F (40° C). Pour desired amount of water into bottle. Feed immediately, or cover and refrigerate bottled formula to be used within 24 hours.”
- “Boil water for 5 minutes. Cool to a warm temperature (120-130° F). Pour desired amount into feeding bottle. Store in refrigerator until used. Use within 24 hours after mixing.”
- “Bring water for formula to a rolling boil (approximately 1 minute), then let cool to lukewarm temperature. Feed immediately, or cover and refrigerate bottled formula until needed. Use within 48 hours.”
- “Ask your baby’s doctor about infant formula use, including the need to boil water for formula, bottle, and nipple assembly. Pour desired amount of warm water into bottle. Feed immediately or cover and refrigerate prepared formula. Use within 48 hours. Throw away prepared formula left in feeding bottle or cup within one hour after feeding begins.”

Preparation of Formula in Infant Health Care Facilities

Physical facilities and practices for preparation of infant formulas vary widely among intensive health care facilities treating ill infants. The American Dietetic Association (ADA) published guidelines in 1991 for preparation, storage, and administration of safe infant formulas in health care facilities (The American Dietetic Association, 1991). This reference is currently being updated; an abbreviated version with a revision date of November 2002 is available at <http://www.eatright.org/formulaguide.html>.

The ADA guidelines specify that all infant formulas should be prepared by trained, healthy personnel using aseptic technique in a specific location devoted to infant formula preparation (preferably a separate room with little risk of microbial or chemical contamination). The guidelines present detailed information for minimizing the potential for microbial contamination and growth during infant formula preparation, storage and use in health care facilities.

ENTERAL ADMINISTRATION OF INFANT FORMULAS IN GENERAL HEALTH CARE AND NEONATAL INTENSIVE CARE SETTINGS

Infants will often need to be fed by more than one route or method during hospitalization. While many in-hospital settings have developed guidelines for general enteral feedings, it remains particularly difficult to determine optimal introduction and advancing of enteral feedings in preterm infants and in seriously ill infants.

General enteral feeding approaches and indications for their use are discussed by Wessel (1994). Guidelines for enteral delivery of infant feedings are suggested by The American Dietetic Association (1991, revised 2002).

Nipple Feeding

Nipple feeding from breast or bottle requires an infant to have a coordinated gastrointestinal tract response, including established sucking and swallowing reflexes and efficient gastric emptying and motility. The suck-swallow reflex develops generally at 34 to 36 weeks of gestational age and stable preterm infants can begin nipple feeding around this time. Formulas for preterm infants or fortified human milk are the most common feedings although other formulas may be indicated for certain medical conditions and for older, ill infants (Wessel, 1994).

Facility-prepared feedings must be fed within four hours of preparation, or covered and stored under refrigeration for not more than 24 hours after preparation. Any warming before feeding should be accomplished in less than 15 minutes. For infants being nipple fed, any product remaining in the bottle one hour after the start of nipple feeding should be discarded (The American Dietetic Association, 1991, revised 2002).

Tube Feeding

Infants without adequate physiologic function to undertake nipple feeds (infants generally younger than 34 weeks gestational age, very sick infants, or infants requiring mechanical ventilation) will require either parenteral or tube feeding regimens. Decisions to use the infant's intestinal tract for nutrient absorption will generally encompass products fed via tube, by continuous or intermittent (bolus) delivery through the nasogastric, orogastric, or transpyloric routes. Less often, gastrostomy feeding tubes inserted trans-abdominally directly into the stomach may be used. The choice will depend on the gastrointestinal development and the health/disease status of the infant. Continuous delivery is commonly used for very small infants and infants who have difficulty with bolus feedings or intermittent placement of feeding tubes. It is generally used with transpyloric feedings, as well as with some gastrostomy feedings. Rates of delivery may be very slow (a few ml/hr) for very small or very sick infants (Wessel, 1994).

Facility-prepared feedings must be fed within four hours of preparation, or covered and stored under refrigeration for not more than 24 hours after preparation. For intermittent (bolus) enteral tube feeding, facility-prepared formula should be packaged in amounts needed for one feeding or for a four-hour period. For continuous enteral tube feeding, hang-time for facility-prepared infant formula should not exceed four hours. (The American Dietetic Association, 1991, revised 2002).

SUMMARY

At present, powdered infant formulas account for 49% of the infant formula market in this country. Many infant formulas are available in multiple forms (powdered, liquid concentrate, and liquid ready-to-feed); however, amino acid-based formula and formulas for infants with metabolic disorders and other special infant populations are available only in powdered form. Although human milk fortifiers are available in both ready-to-feed and powdered forms, use of the powdered form adds less to the volume that the infant must consume. General preparation instructions and guidelines for preparation of powdered infant formulas in health care facilities are presented. Approaches and guidelines for administration of enteral feedings in health care settings are also presented.

REFERENCES

The American Dietetic Association. 1991. Preparation of formula for infants: guidelines for health care facilities. Chicago: The American Dietetic Association. 100p. An abbreviated on-line revision [November 2002] is available at <http://www.eatright.org/formulaguide.html>.

Fomon, SJ. 2001. Infant feeding in the 20th century: formula and beikost. *Journal of Nutrition*. 131:409S-420S.

Information Resources, Inc. 1999. Infoscan 1999 Annual Data. Chicago, Illinois: Information Resources Inc.

Wessel, JJ. 1994. Feeding methodologies. In: Nutritional care for high-risk newborns (Rev. Ed.). S Groh-Wargo, M Thompson, J Cox, editors. Chicago: Precept Press. p. 206-219.