

## CHAPTER 4: INFANT FORMULA FEEDING

This chapter reviews commonly used types of infant formula; recommended amounts to feed formula-fed infants in the first year; tips on bottle feeding; guidelines on the selection, preparation, and storage of infant formula; traveling with infant formula; warming bottles; and infant formula use when there is limited access to common kitchen appliances. Additional information is provided regarding milks and other food products inappropriate for infants. Counseling points related to the information presented in this chapter are found in Chapter 8, pages 161–167.

This chapter does not address the infant formula needs and feeding protocols for premature and low-birth-weight infants or infants with medical conditions requiring exempt infant formulas (see page 83 for more information regarding exempt infant formulas). Since nutritional management of these infants may be complicated by treatment for existing medical conditions, consult with and follow the recommendations of the infant's health care provider when counseling caregivers.

### Types of Infant Formulas

Breast milk is the optimal source of nutrition for the infant but, when breast milk is not available, iron-fortified infant formula is an appropriate alternative for the infant's first year of life. Infant formula is “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.”<sup>1</sup> The Food, Drug, and Cosmetic Act mandates that all infant formulas marketed in the United States provide the same nutrition for healthy, full-term infants.<sup>1</sup> Because infant formulas are often the only source of nutrition for infants, the Food and Drug Administration (FDA) monitors infant formula manufacturers very closely to assure the product provides the appropriate nutrition for all infants.<sup>2</sup>

A variety of infant formulas are available for healthy, full-term infants who are not breastfed or partially breastfed. These include cow's milk or soy-based infant formulas (iron-fortified), hypoallergenic infant formulas, and other infant formulas designed to meet the nutritional needs of infants with a variety of dietary needs (e.g., lactose-free or Kosher).

### Milk-Based Infant Formula

The most common infant formulas consumed by infants are made from modified cow's milk with added carbohydrate (usually lactose), vegetable oils, and vitamins and minerals. Casein is the predominant protein in cow's milk. Since the primary protein in breast milk is whey protein, rather than casein, some milk-based infant formulas have been altered to contain more whey. Despite that alteration, the protein in infant formula is significantly different from that in breast milk because of their different amino acid and protein composition. In milk-based infant formulas, about 9 percent of the kilocalories are provided by protein, 48–50 percent by fat, and 40–45 percent by carbohydrate. These infant formulas are lower in fat and higher in carbohydrate, protein, and minerals than breast milk.

### Iron-Fortified Infant Formula

The American Academy of Pediatrics (AAP) recommends that iron-fortified cow's milk-based infant formula is the most appropriate milk feeding from birth to 12 months for infants who are not breastfed or who are partially breastfed.<sup>3</sup>

Use of an iron-fortified infant formula ensures that formula-fed infants receive an adequate amount of iron, an important nutrient during the first year. Standard iron-fortified infant formulas are fortified with approximately 10 to 12 milligrams of iron, in the form of ferrous sulfate, per quart. Research shows that providing iron-fortified infant formula and cereal for the first 12 months of life, as done in the WIC and CSF

Programs, has been successful in reducing iron deficiency.<sup>4, 5, 6</sup> Iron deficiency is associated with poor cognitive performance and development in infants. See pages 24–25 for more information regarding iron deficiency.

### **Low-Iron Infant Formula**

In 1997, the AAP Committee on Nutrition recommended that the manufacture of infant formula containing less than 4 milligrams of iron per quart be discontinued.<sup>3</sup> Some of the most commonly used milk-based infant formulas are also available with reduced iron content. These low-iron infant formulas now contain approximately 5 milligrams of iron per quart of formula.<sup>7</sup>

There are no known medical conditions for which the use of iron-fortified infant formula is contraindicated. Some caregivers request low-iron infant formula for their infants because they believe that the iron in the infant formula causes gastrointestinal problems, such as colic, constipation, diarrhea, or vomiting. However, studies have demonstrated that gastrointestinal problems are no more frequent in infants consuming iron-fortified than low-iron infant formula.<sup>8, 9</sup>

As noted above, for the partially or non-breastfed infant, iron-fortified infant formula is the formula of choice to assure that an infant's iron needs are met.

### **Soy-Based Infant Formula**

Soy-based infant formulas were developed for infants who cannot tolerate infant formula made from cow's milk. These infant formulas contain soy protein isolate made from soybean solids as the protein source, vegetable oils as the fat source, added carbohydrate (usually sucrose and/or corn syrup solids), and vitamins and minerals. Soy-based infant formulas are fortified with the essential amino acid methionine, which is found in very low quantities in soybeans. In these infant formulas, 10 to 11 percent of the kilocalories are provided by protein, 45 to 49 percent by fat, and 41 to 43 percent by carbohydrate. All soy-based

infant formulas are fortified with similar amounts of iron as milk-based iron-fortified infant formulas.

The AAP has stated that soy-based infant formulas are safe and effective alternatives to cow's milk-based infant formulas, but have no advantage over them.

*Soy-based infant formulas may be indicated in the following situations:*<sup>10</sup>

- Infants with galactosemia (a rare metabolic disorder) or hereditary lactase deficiency
- Infants whose parents are seeking a vegetarian diet for their full-term infant or
- Infants with documented IgE-mediated allergy to cow's milk protein.

*The use of soy-based infant formulas has no proven benefit in the following situations:*<sup>10</sup>

- Healthy infants with acute gastroenteritis in whom lactose intolerance has not been documented
- Infants with colic
- Prevention of allergy in healthy or high-risk infants and
- Infants with documented cow's milk protein-induced enteropathy or enterocolitis.

### **Hypoallergenic Infant Formula**

A number of infant formulas have been developed and marketed for infants with allergies or intolerances to milk or soy-based infant formulas or those with a family history of allergies. Infant formulas manufactured and labeled for infants with allergies vary in the degree to which the allergy-causing protein has been modified. They may contain partially hydrolyzed protein, extensively hydrolyzed protein, or free amino acids. Extensively hydrolyzed and free amino acid-based infant formulas have been demonstrated to be tolerated by at least 90 percent of infants with documented allergies.<sup>11</sup> Currently available partially hydrolyzed infant formulas are not hypoallergenic and should not be used to treat infants with documented allergies.<sup>11</sup>

The prevalence of milk protein allergy in infancy is low, at 2 to 3 percent. However, food allergies may present in three ways:<sup>11</sup>

- Immunoglobulin E (IgE)-associated reactions, such as runny nose, wheezing, eczema, vomiting, and difficulty breathing;
- Non-IgE-associated reactions including diarrhea, malabsorption, colitis, or esophagitis; and
- Extreme irritability or colic.

*All suspected cases of food allergy should be referred to a qualified health care professional for further diagnosis and treatment.*

The AAP recommends that the use of hypoallergenic infant formulas should be limited to infants with well-defined clinical indications.<sup>11</sup> If hypersensitivity is diagnosed, a physician may change the infant formula prescribed. The AAP states that formula-fed infants with confirmed cow's milk allergy may benefit from the use of hypoallergenic (extensively hydrolyzed or, if symptoms persist, a free amino acid-based infant formula) or soy-based infant formula.<sup>12</sup> Soy-based infant formula may be used for infants with IgE-associated symptoms. Improvement is usually seen in 2 to 4 weeks; however, the infant formula should be continued until at least 12 months of age. Hypoallergenic infant formulas made from extensively hydrolyzed protein or free amino acids may be used for infants with non-IgE-associated symptoms or those with a strong family history of allergy. Hypoallergenic infant formulas are significantly more expensive than either milk-based or soy-based infant formulas. In addition, their taste is altered significantly during hydrolysis of the protein and they may not be well accepted by some infants.

## Lactose-Free Infant Formula

Lactose is the major carbohydrate in cow's milk-based infant formulas. Lactose intolerance may lead to excess gas, diarrhea, or fussiness. A very small number of infants produce insufficient amounts of lactase, the enzyme needed to break down lactose.<sup>12</sup> Congenital lactase deficiency is extremely rare. Premature infants may have lower levels of lactase than term infants, proportional to their degree of prematurity, since lactase activity develops during the last trimester of pregnancy. Lactose intolerance may develop in later childhood (>2 years of age in some susceptible populations) or adulthood, but very few term infants have true lactose intolerance. Transient lactose intolerance may occur following acute diarrhea, but enzyme activity is restored quickly and switching to lactose-free infant formulas is usually not necessary.

Several cow's milk-based infant formulas are now available for infants with documented lactose intolerance. In addition, soy-based infant formulas are lactose-free and may be used for infants with documented lactose intolerance.

## Exempt Infant Formula

An exempt infant formula is one that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.<sup>13</sup> There are many varieties of specially designed infant formulas developed for infants with special medical conditions. For the most up-to-date information on infant formula composition and new products, refer to pharmaceutical company product information materials or contact the manufacturer. For more information regarding exempt infant formulas access FDA's Web site at <http://www.cfsan.fda.gov/~dms/inf-exmp.html>.

### **WIC Formula Database on the WIC Works Resource Center Website**

<http://www.nal.usda.gov/wicworks>

The Food and Nutrition Service (FNS), Department of Agriculture (USDA) developed an electronic database of infant formulas, exempt infant formulas, and medical foods that have been determined eligible for use in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Manufacturers benefit by having information about their WIC-eligible formulas readily available to all WIC State agencies and approximately 10,000 WIC clinic sites throughout the country. In turn, WIC agencies have access to an up-to-date formula database that will assist them in meeting the needs of participants.

## **Long-Chain Polyunsaturated Fatty Acids and Other Infant Formula Additives**

In recent years, infant formula manufacturers have begun to examine the benefits of adding a variety of nutrients and biological factors to infant formula to mimic the composition and quality of breast milk.<sup>14</sup> These include long-chain polyunsaturated fatty acids, nucleotides, prebiotics and probiotics.

### **Arachidonic Acid (ARA) and Docosahexaenoic Acid (DHA)**

Long-chain polyunsaturated fatty acids include the essential fatty acids, linoleic acid (abbreviated 18:2 n-6 or LA), and  $\alpha$ -linolenic acid (18:3 n-3 or ALA) along with their derivatives, arachidonic acid (20:4 n-6 or ARA) and docosahexaenoic acid (22:6 n-3 or DHA). Since formula-fed infants have been observed to have lower plasma levels of ARA and DHA, interest has arisen about the formula-fed infant's ability to synthesize these fatty acids.<sup>15</sup> ARA and DHA are major fatty acids

in the brain and retina. Research demonstrating better cognitive function in breastfed infants has led some to support the addition of ARA and DHA to infant formula. This issue remains controversial; the FDA's Life Sciences Research Office Expert Panel on Assessment of Nutrient Requirements of Term Infant Formulas does not recommend either a minimum or maximum content of ARA and DHA in infant formula.<sup>16</sup> FDA expects post-market surveillance to be conducted by infant formula manufacturers because previous studies on the effects of fatty acids in infant formulas on the growth and development of infants were based on short-term studies. Additionally, ARA and DHA were not ingredients in infant formula in the United States before early 2002. FDA treats the evaluation of the safety of ARA and DHA as new ingredients in infant formula as a judgment dependent on scientific data as well as time.<sup>17</sup> The AAP has taken no official position on their addition.<sup>15</sup> Most infant formula manufacturers currently offer products containing added ARA and DHA.

### **Nucleotides, Prebiotics, and Probiotics**

Nucleotides are metabolically important compounds that are the building blocks of ribonucleic acid (RNA), deoxyribonucleic acid (DNA), and adenosine triphosphate (ATP), and are present in breast milk.<sup>18</sup> It is thought that they may enhance immune function and development of the gastrointestinal tract and may be beneficial when added to infant formula.<sup>19</sup> Prebiotics are nutrients that support the growth of "good" bacteria in the intestine, while probiotics are these nonpathogenic bacteria, including Bifidobacteria and Lactobacilli. Since these organisms are present in the intestines of breastfed infants and may protect from infection by other pathogenic bacteria, researchers are studying the effect of adding them to infant formula. Although infant formula manufacturers are beginning to add these compounds to infant formula, more research is needed to confirm the benefits of adding nucleotides, prebiotics, and probiotics to infant formula.<sup>20</sup>

## Other Milks and Other Products

This section provides information on different milk and other products that are not appropriate substitutes for infant formula for infants, less than 12 months old, in the WIC and CSF Programs.

### Whole Cow's Milk

The AAP Committee on Nutrition recommends that whole cow's milk not be fed to infants during the first year of life.<sup>21</sup> Breast milk or iron-fortified infant formula is recommended instead of cow's milk for a number of nutritional and medical reasons.

*Whole cow's milk is not recommended for infants for the following reasons:*<sup>20</sup>

- **Inappropriate nutrient content** – Research indicates that it is difficult for infants to consume a balanced diet, with adequate nutrients, when whole cow's milk replaces breast milk or iron-fortified infant formula.<sup>21</sup> Infants fed whole cow's milk have low intakes of iron, linoleic acid (an essential fatty acid), and vitamin E and excessive intakes of sodium, potassium, chloride, and protein. These nutrient intakes are not optimal and may alter an infant's nutritional status, with the most dramatic effect on iron status. Infants over 6 months old require good sources of iron in their diets; there is very little iron in whole cow's milk. The composition of whole cow's milk (i.e., high calcium, high phosphorus, and low vitamin C) may inhibit an infant's ability to absorb iron from different complementary foods, including iron-fortified infant cereals.
- **Microscopic gastrointestinal bleeding and blood loss** – Cow's milk has been shown to cause microscopic bleeding and blood loss from an infant's immature gastrointestinal tract when fed to infants in the first 6 months of life<sup>22</sup> and to a lesser extent between 6 and 12 months.<sup>23</sup> These problems disappear at about 12 months.<sup>24</sup> This bleeding promotes the development of iron deficiency anemia. Studies show that iron deficiency in early childhood may lead to long-term changes in learning and behavior that might not be reversed even with iron supplementation

sufficient to correct iron-deficiency anemia<sup>25</sup>

- **Stress on the kidneys** – Cow's milk is difficult for a young infant's immature kidneys to process because of its concentrated protein, sodium, potassium, and chloride and resulting high renal solute load (see page 30 for more information regarding renal solute load). The renal solute load of infants fed whole cow's milk is two to three times higher than that of formula-fed infants.<sup>26</sup> Even older infants may have a problem with the load of these nutrients on the kidneys and be at greater risk for developing dehydration.<sup>27</sup> The possibility of developing dehydration as a result of a high renal solute load is greatest during: an acute illness when intake is lower, especially if there is fever; when the diet is calorie dense, that is, high in calories but low in volume of food/fluid; and when renal concentrating ability is decreased, as in chronic renal disease and diabetes.<sup>28</sup>
- **Hypersensitivity (allergic) reactions** – Cow's milk contains proteins that may cause hypersensitivity (allergic) reactions in the young infant due to his immature gastrointestinal tract.

Given these concerns about cow's milk, the recommended choices to use in meeting an infant's nutritional needs are breast milk and iron-fortified infant formulas (for those not breastfed or partially breastfed). Encourage caregivers to breastfeed or keep their infants on iron-fortified infant formula until 12 months old.

### Low-Fat or Skim Cow's Milk

Pediatric nutrition authorities agree that skim milk (fresh liquid, reconstituted nonfat dry milk powder, or evaporated skimmed milk) or low-fat milk (1 or 2 percent low-fat milk) should not be fed to infants.<sup>20, 21, 29</sup> These milks contain insufficient quantities of fat (including linoleic acid), iron, vitamin E, and vitamin C; and excessive protein, sodium, potassium, and chloride. The amount of protein and minerals in low-fat and skim milk is even higher than in whole cow's milk; these milks place a strain on an infant's kidneys in the same way as does whole cow's milk.

Fat, as found in sufficient amounts in breast milk and infant formula, is needed to meet an infant's energy needs for growth and for proper development of the nervous system. Increased publicity of the association between high-fat diets and heart disease has led some caregivers to believe that they should feed their infants skim or low-fat milk to prevent obesity or atherosclerosis later in life. However, feeding skim or low-fat milk to infants and children up to age 2, in an attempt to prevent heart disease from developing later in life, is not considered appropriate.<sup>30</sup> According to the AAP, consumption of skim or low-fat milk is not recommended in the first 2 years of life because of the high protein and electrolyte content and low caloric density of these milks.<sup>30</sup>

### Evaporated Cow's Milk

Homemade formulas made from evaporated milk are not recommended in the first 12 months of life.<sup>29</sup> Evaporated whole milk is whole cow's milk from which approximately 60 percent of the water has been removed. This milk is fortified with vitamin D but remains low in the same nutrients as whole cow's milk and low in folate if the milk is boiled. Evaporated milk can also be made from skim cow's milk. Before the development of infant formulas, evaporated whole milk was used to make a homemade infant formula which was thought to be easier for an infant's kidneys and digestive system to handle than plain whole cow's milk. However, the disadvantages of evaporated milk formulas are now considered similar to those of whole cow's milk.

### Sweetened Condensed Milk

Sweetened condensed milk is not an appropriate food or beverage for infants.<sup>29</sup> This milk product has a high sugar concentration and similar disadvantages to whole cow's milk. It is made by adding sugar to whole cow's milk and then evaporating water from the milk. When undiluted, this milk contains seven times the carbohydrate content of evaporated whole milk.

### Goat's Milk

Goat's milk is **not** recommended for infants.<sup>29</sup> Goat's milk contains inadequate quantities of iron, folate, vitamins C and D, thiamin, niacin, vitamin B6, and pantothenic acid to meet an infant's nutritional needs. Some brands of goat's milk are fortified with vitamin D and folate, but other brands may not be fortified. This milk also has a higher renal solute load compared to cow's milk and can place stress on an infant's kidneys. This milk has been found to cause a dangerous condition called metabolic acidosis when fed to infants in the first month of life.

### Soy-Based (Soy Milks) and Rice-Based (Rice Milk) Beverages

Beverages made from soy, rice, or other grains or nuts are not equivalent to infant formulas or breast milk and are not appropriate for infant consumption.<sup>31</sup> Although most are fortified with vitamins A, D, and B12, riboflavin, calcium, and zinc, these beverages lack appropriate amounts of kilocalories, protein, and fat needed by infants for adequate growth.<sup>31</sup> Use of these milks can be dangerous to an infant's health. Marasmus and malnutrition have been reported in infants fed these beverages as the whole or major source of nutrition.<sup>31</sup>

### Sweetened Beverages Fed From a Bottle

Infants should **never** be given sweetened beverages (e.g., soda, fruit drinks, powdered beverages, sweetened teas) because they are associated with a higher risk for developing early childhood caries and childhood obesity. These beverages lack appropriate amounts of kilocalories, protein, and other key nutrients and displace breast milk or infant formula in the infant's diet.<sup>32,33</sup> See page 114 for more information regarding sweetened beverages.

## Feeding Infant Formula in the First Year

The amount of infant formula needed by an infant over a 24-hour period will vary depending on the infant's age, size, level of activity, metabolic rate, medical conditions, and other source(s) of nutrition (breast milk and/or complementary food). Infants have the ability to regulate their food intake relative to their nutritional needs. In doing so, they express signs of hunger and satiety and expect their caregiver to respond to these cues. Thus, unless medically indicated otherwise, infants should be fed on demand, i.e., fed when they indicate their hunger, and not forced to follow a strict feeding schedule, nor to finish a bottle when no longer hungry. Infants placed on strict feeding schedules in the early months of life stand a greater chance of being either overfed or underfed.

### Hunger and Satiety Cues

Infants, especially newborns, may not be consistent or follow a timed schedule as to when and how often they want to eat. A healthy infant eventually establishes an individual pattern according to his or her growth requirements. It is normal for infants to have fussy times; an infant may cry and just want to be held, to suck, or need to be changed; or may not be hungry. Thus, encourage caregivers to watch for and respond appropriately to the infant's cues of hunger and satiety or fullness. Caregivers should look for the following common signals of hunger and fullness in their infants.<sup>34</sup>

#### Signs of Hunger

An infant who is hungry may:

- Wake and toss
- Suck on a fist
- Cry or fuss or
- Appear like he or she is going to cry.

Caregivers should respond to the early signs of hunger and not wait until the infant is upset and crying from hunger.

#### Signs of Fullness

Encourage the caregiver to feed the infant until he or she indicates fullness. Signs of fullness include:

- Sealing the lips together
- A decrease in sucking
- Spitting out the nipple and
- Turning away from the breast or bottle.

Some infants may eat less than the portions offered if they are not hungry. A caregiver should never force an infant to finish what is in the bottle. Infants are the best judge of how much they need. They may want to eat less if they are not feeling well and may want more if they are in a growth spurt.<sup>35</sup>

*If you perceive that a caregiver is frustrated or having difficulty coping with an infant's fussiness or crying, refer him or her to a health care provider for further assessment and assistance.*

#### Feeding Frequency and Amount

Newborn formula-fed infants are generally fed infant formula as often as exclusively breastfed infants are fed for a total of 8 to 12 feedings within 24 hours. These young infants need to be fed small amounts of infant formula often throughout the day and night because their stomachs cannot hold a large quantity. If a newborn infant sleeps longer than 4 hours at a time, the infant should be awakened and offered a bottle. See page 59 for more information regarding the sleepy infant.

From birth to 6 months of age, infants grow rapidly and will gradually increase the amounts of infant formula they can consume at each feeding, the time between each feeding, and the total amount of infant formula consumed in 24 hours. Encourage parents or caregivers to prepare 2 ounces of infant formula every 2 to 3 hours at first. More should be prepared if the infant seems hungry, especially as the infant grows.<sup>36</sup>

The partially breastfed infant will consume less infant formula than given in these examples,

depending on the frequency of breastfeeding. At 6 months old, infants begin to shift from dependence on breast milk or infant formula as the primary nutrient source to dependence on a mixed diet including complementary foods. Thus, the consumption of breast milk or infant formula tends to decrease as the consumption of complementary foods increases.

### **Sleepy or Placid Infant**

An exception to using the demand feeding approach is for a young infant who is sleepy or placid. Some infants may either fall asleep after feeding on a bottle for a short time, may not be easy to wake for feeding every 2 to 3 hours, or do not show signs of hunger normally. To assure that such infants obtain sufficient nourishment, it is advisable for mothers to wait no more than 4 hours (or sooner if the infant's health care provider indicates) between feedings until the infant's first well check up (between 2 and 4 weeks old). At that time, the infant's health care provider should be consulted to determine whether to recommend continuation of that practice based on the infant's weight gain.

*To wake a sleepy infant, a mother can try these methods:*

- Stroking the infant's cheek with the nipple
- Holding the infant in an upright position (sitting or standing) while supporting the chin with one hand, several times
- Rubbing or stroking the infant's hands and feet
- Unwrapping or loosening blankets
- Giving the infant a gentle massage
- Undressing or changing the infant's clothing or diaper or
- Playing with and talking to the infant.

Feeding throughout the night is not usually necessary for the older infant with a normal growth rate. *Refer an infant, whose caregiver complains of the infant's sleepiness or lack of hunger signs, to a health care provider for further assessment.*

### **Formula Feeding Tips**

Caregivers can help their formula-fed infants have a positive feeding experience by feeding in a relaxing setting. *Encourage caregivers to:*

- Find a comfortable place in the home for feeding;
- Interact with the infant in a calm and relaxed manner in preparation for and during feeding (e.g., by cuddling and talking gently to the infant); and
- Show the infant lots of love, attention, and cuddling in addition to feeding - reassure them that doing so will decrease fussiness and will not "spoil" the infant.

### **Guidelines on Feeding From a Bottle**

To make bottle feeding safe and comfortable for infants, encourage caregivers to do the following:

- Wash their hands with soap and water before feeding.
- Hold the infant in their arms or lap during the feeding (with the infant in a semi-upright position with the head tilted slightly forward, slightly higher than the rest of the body, and supported by the person feeding the infant). The infant should be able to look at the caregiver's face. If an infant's head is tilted back or lying flat down, the liquid could enter the infant's windpipe and cause choking.
- Hold the bottle still and at an angle so that the end of the bottle near the nipple is filled with infant formula and not air. This reduces the amount of air swallowed by the infant.
- Stroke the infant's cheek gently with the nipple to stimulate the "rooting" reflex. This will cause the infant to open his or her mouth to initiate feeding.
- Ensure that the infant formula flows from the bottle properly by checking if the nipple hole is an appropriate size (if the bottle is held upside down, the falling drops should follow each other closely and not make a stream). The nipple ring on the bottle should be adjusted so that air can get into the bottle (otherwise the nipple may collapse).



- Burp the infant at any natural break in or at the end of a feeding to eliminate swallowed air from the stomach. Try to avoid stopping to burp an infant after every couple of ounces because this can be disruptive to the feeding. An infant can be burped by gently patting or rubbing the infant's back while he or she is held against the front of the caregiver's shoulder and chest or held and supported in a sitting position in the caregiver's lap. Burping at natural breaks during feeding helps to slow the feeding, thereby lessening the amount of air swallowed, and may help to reduce gastroesophageal reflux and colic in some infants (see pages 139–140 for more information regarding reflux and colic). A small amount of spitting up is common in formula-fed infants. The breaks in feeding are also good times for the caregiver to socialize with (e.g., talk gently and smile at) her infant.

Throughout infancy, it is especially important that formula-fed infants be fed in a position that both minimizes their chances of choking and allows them physical and eye contact with their caregivers. When an infant is held closely and can establish eye contact with the caregiver, bonding between the two is enhanced. Older infants may prefer to hold the bottle themselves while in the caregiver's arms or lap or while sitting in a high chair or similar chair. See Figure 5 on page 90 for more tips for feeding an infant with a bottle.

*See pages 123–124 for information regarding weaning an infant from the bottle.*

### **Propping the Bottle Is Not Recommended**

It is never appropriate to prop a bottle to feed an infant by placing a bottle supported by a pillow or something similar in the infant's mouth.

*Caregivers should avoid propping the bottle because:*

- Liquid in the bottle can accidentally flow into the lungs and cause choking;
- Infants tend to contract ear infections because fluid enters the middle ear and cannot drain properly;

- Infants may overfeed; or
- Infants do not receive human contact, which is important to make them feel secure and loved.

It is not advisable to give infants a bottle (whether propped or not) while the infant is lying down at nap or bedtime<sup>31</sup> or while the infant is lying or sitting in an infant car seat, carrier, stroller, infant swing, or walker. In addition to possibly causing choking and ear infections, these practices can lead to dental problems if there is milk, fruit juice, or a sweetened beverage in the bottle. See pages 132–133 regarding early childhood caries.

## **Selection, Preparation, and Storage of Infant Formula**

To assure that infant formula is safe for consumption, the infant formula must be properly selected, prepared, and stored and bottles must be properly sanitized.

### **Selecting Cans of Infant Formula**

*Encourage caregivers to take these steps when selecting and using cans of infant formula:*

- Check the infant formula's expiration date on the label, lid, or bottom of the can. If the expiration date has passed, then the infant formula has expired and should not be used.
- Do not select cans of infant formula that have dents, leaks, bulges, puffed ends, pinched tops or bottoms, or rust spots. These characteristics indicate that the product quality may be diminished and the product is unsafe.
- Store cans of infant formula in a cool, indoor place – not in vehicles, garages, or outdoors.

**Figure 5: Tips on Feeding With a Bottle**



### **Preparing and Storing Bottles:**

- Ensure that bottles and accessories are clean and sanitary.
- Do not allow bottles of breast milk or infant formula to stand at room temperature to prevent spoilage. Refrigerate prepared bottles until ready to use.
- For those infants who prefer a warm bottle, hold the bottle under running warm (not hot) water immediately before feeding.
- Shake a bottle of breast milk before feeding because breast milk separates when it is stored.
- Never use a microwave oven to heat bottles of breast milk or infant formula. They may explode or the milk may get too hot. Since the liquid heats unevenly, it can be much hotter than it feels. Microwave heating can destroy special substances in breast milk.
- Do not put cereal or other foods in a bottle. This practice replaces breast milk or infant formula with food that may not be needed by the infant, teaches the infant to eat complementary foods (solids) incorrectly, and increases the infant's risk for choking.
- Throw out unused breast milk or infant formula left in a bottle and wash the bottle with soap and hot water immediately. Clean and sterilize bottles and accessories before reusing them.

### **Feeding the Infant:**

- Feed the infant when he indicates hunger. Respond to the early signs of hunger. Do not wait until the infant is upset or crying.
- Gently and slowly position the infant to prepare for a feeding.
- Feed the infant in a smooth and continuous fashion. Follow the infant's lead on when to feed, how long to feed, and how much to feed. Avoid disrupting the feeding with unnecessary burping, wiping, juggling, and arranging.
- Always hold the infant during feedings. Propping the bottle is never appropriate. Propping a bottle may cause ear infections and choking. It also deprives the infant of important human contact.
- Hold the infant's head a little higher than the rest of the body to prevent milk from backing up in the ear and causing an ear infection.
- Do not offer the bottle at nap time or let an infant carry a bottle around. Allowing an infant to sleep with a bottle may lead to tooth decay.
- Wait for the infant to stop eating before burping. Burp by gently patting or rubbing the infant's back while the infant is resting on your shoulder or sitting on your lap.
- Continue to feed the infant until he or she indicates being full. Signs of fullness include sealing the lips, spitting out the nipple, and turning away from the breast or bottle.
- Never force an infant to finish what is in the bottle. Infants are the best judge of how much they need.
- An older infant may be fed a bottle while sitting in a high chair.
- Before opening a can of infant formula, wash the can lid with soap and water to remove bacteria, dust, insect parts, and other substances that could contaminate the infant formula when opened. Rinse soap off thoroughly with water so that soap does not get into the infant formula.

## Sterilizing Water and Bottles

Infants 3 months of age and younger are more likely to contract illnesses from micro-organisms in bottles and nipples that are improperly cleaned, cleaned in contaminated water, or filled with contaminated water. Therefore, for infants less than 3 months old, glass or hard plastic bottles and bottle parts (nipples, caps, rings) should first be thoroughly cleaned using soap, hot water, and bottle and nipple brushes, and then either be sterilized in boiling water for 5 minutes, as indicated in Figures 6a, 6b, and 6c, pages 93–95, or washed in a properly functioning dishwasher machine. If disposable plastic bottle liners are used, the bags should be discarded after one use and the nipples, rings, and caps sterilized in boiling water or washed in a dishwasher until the infant is at least 3 months old. After 3 months, unless otherwise indicated by a health care provider, bottles should be thoroughly washed using soap and hot water and bottle and nipple brushes or cleaned in a dishwasher.

As a precaution, it is generally recommended to boil the water used for infant formula preparation during the first 3 months of life.<sup>29</sup> Caregivers should consult their health care providers regarding whether the water used for preparing infant formula or for feeding should be boiled for the infant older than 3 months. If a caregiver is in doubt about the safety of the water supply or if there are reports in the community about the water supply being contaminated, he should find an alternate source of clean water and consult his health care provider as soon as possible.

Caregivers can boil water to make infant formula by bringing the water to a rolling boil, boiling it for 1–2 minutes, and then letting it cool.<sup>20, 37</sup> See pages 35–39 regarding the use of different types of water, including well water, and water safety.

The terminal sterilization of infant formula, which involves filling clean bottles with properly diluted infant formula first and then boiling all the formula-containing bottles in water, is not recommended because

boiling destroys certain nutrients (e.g., folate and other water-soluble vitamins).

## Preparing Infant Formula

Powdered infant formula is prepared by mixing one unpacked level scoop of dry powder to 2 ounces of sterile water. Concentrated infant formula is prepared by adding equal parts of water to concentrated liquid. Ready-to-feed infant formula is ready for the infant to consume. These preparations will yield an infant formula that is approximately 20 calories per ounce. See Figures 6a, 6b, and 6c on pages 93–95 for a checklist of instructions for preparing ready-to-feed, liquid concentrated, or powdered iron-fortified infant formula.

General guidelines for infant formula preparation are provided; however, the caregiver should always follow the manufacturer's instructions for preparation. Although infant formula cans include written instructions for preparation, caregivers may not be able to read or understand those instructions. If they are unable to read English but can read another language, printed instructions should be provided in their own language. Infant formula preparation instructions designed in picture format can be used for low-literacy or illiterate participants.

It is very important to prepare infant formula properly. Increasing the water-to-formula ratio is never recommended because it will yield a lower-calorie formula, which will not meet the infant's calorie requirements. Decreasing the water-to-formula ratio may be recommended for infants who are failing to thrive, but it should only be done when recommended by the infant's health care provider. Infants consuming incorrectly reconstituted infant formula may develop serious health problems. Under-diluted infant formula (containing too little water) puts an excessive burden on an infant's kidneys and digestive system and may lead to dehydration. This problem becomes worse if the infant has increased fluid needs due to fever or infection. Over-diluted infant formula (containing too much water) may contribute to growth problems, nutrient

deficiencies, and water intoxication. See pages 28–29 for more information regarding water needs for infants. *If the caregiver has any questions or concerns about infant formula preparation, refer him or her to their infant's health care provider.*

### Special Concerns

Infant formula is a safe and effective alternative for infant nutrition when breastfeeding is impossible or impractical. However, healthcare professionals should be aware that powdered infant formulas are not commercially sterile products. Powdered infant formulas are heat-treated during processing, but unlike liquid infant formula products they are not subjected to high temperatures for sufficient time to make the final product commercially sterile. A concern about possible *Enterobacter sakazakii* (*E. sakazakii*) infections led the Food and Drug Administration to issue an alert to healthcare professionals in April 2002. For more information see <http://www.cfsan.fda.gov/~dms/inf-ltr3.html>. *E. sakazakii* is a microorganism belonging to the family of the *Enterobacteriaceae* which may cause sepsis, meningitis, or necrotizing enterocolitis among infected infants. According to the FDA, “clusters of *E. sakazakii* infections have been reported in a variety of locations over the past several years among infants fed milk-based powdered infant formula products from various manufacturers... The literature suggests that premature infants and those with underlying medical conditions may be at highest risk for developing *E. sakazakii* infection.”<sup>38</sup>

### Storing Infant Formula

Prepared infant formula is a highly perishable food that must be stored properly for safe consumption.

*The following guidelines are recommended to prevent spoilage of infant formula:*


Store bottles of prepared infant formula in a properly functioning refrigerator until ready to use. Bacterial growth is reduced when infant formula is kept in a refrigerator at temperatures at 40 degrees Fahrenheit or below. (Use a special thermometer to test if the refrigerator is at the appropriate temperature.) Caregivers should always consult their health care provider and follow the manufacturer's label instructions for infant formula storage procedures. In general, it is recommended that caregivers:


- Use refrigerated bottles of concentrated or ready-to-feed infant formula within 48 hours of preparation or
- Use refrigerated bottles of powdered infant formula within 24 hours of preparation.
- Opened cans of concentrated or ready-to-feed infant formula should be covered, refrigerated, and used within 48 hours. Freezing infant formula is not recommended.
- Powdered infant formula should be tightly covered and stored in a cool, dry place and used within a month after opening.
- Discard any infant formula remaining after a feeding. The mixture of infant formula with saliva provides an ideal breeding ground for disease-causing micro-organisms.
- Infant formula that is removed from refrigeration should be used within 1 hour or discarded.<sup>39</sup>
- Before reusing any bottles or their parts, they should be cleaned and sanitized as described under “Sterilizing Water and Bottles” on page 91.

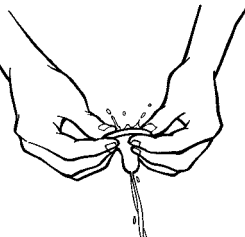
### Traveling With Infant Formula

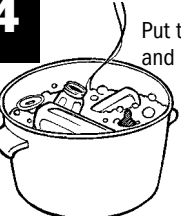
When traveling, caregivers can take along a can of powdered infant formula and separate water in clean bottles (or sterilized bottles for infants under 3 months old). Then, the infant formula can be mixed up to make single bottles when needed. Alternately, single servings of ready-to-feed infant formula can be used. It is not recommended to travel with bottles of prepared infant formula held at room temperature.


**Figure 6a:**  
**Preparation Checklist for Standard Ready-to-Feed Iron-Fortified  
 Infant Formula (using glass or hard plastic bottles)**


**1**  Wash your hands, arms, and under your nails, very well with soap and warm water. Rinse thoroughly. Clean and sanitize your workspace.


**2**  Wash bottles and nipples, using bottle and nipple brushes, and caps, rings, and preparation utensils in hot soapy water before using. Rinse thoroughly.


**3**  Squeeze clean water through nipple holes to be sure they are open.


**4**  Put the bottles, nipples, caps, and rings in a pot and cover with water. Put the pot over heat, bring to a boil, and boil for 5 minutes. Remove with sanitized tongs, allow the items to cool, and air dry.

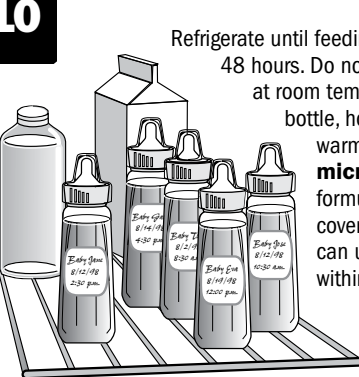
**5**  Wash the top of the can with soap and water and rinse well to remove dirt. Wash the can opener with soap and hot water.

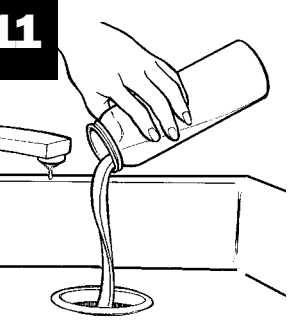
**6**  SHAKE CAN WELL and then open the can.

**7**  Pour the amount of ready-to-feed formula for one feeding into a clean bottle. Do not add water or any other liquid.

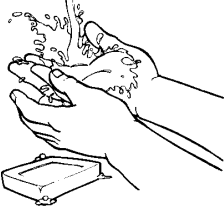
**8**  Attach nipple and cap and SHAKE WELL. Feed prepared formula immediately.


**9**  If more than one bottle is prepared, put a clean nipple right side up on each bottle and cover with a nipple cap. Label each bottle with the baby's name and the date and time that it was prepared.


**10**  Refrigerate until feeding time. Use within 48 hours. Do not leave formula at room temperature. To warm bottle, hold under running warm water. **Do not microwave bottles.** If formula is left in the can, cover and refrigerate open can until needed. Use within 48 hours.

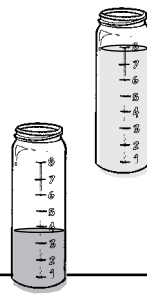
**11**  Throw out unused formula left in bottle after feeding or which has been unrefrigerated for 1 hour or more. Store unopened cans in a cool, dry indoor pantry shelf. Use before the expiration date.

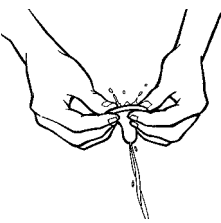
**Figure 6b:**  
**Preparation Checklist for Standard Liquid Concentrated Iron-Fortified Infant Formula**  
**(using glass or hard plastic bottles)**


**1**  Wash your hands, arms, and under your nails, very well with soap and warm water. Rinse thoroughly. Clean and sanitize your workspace.

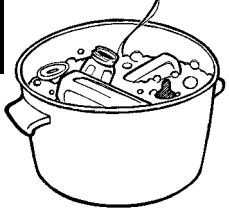
**7**  **SHAKE CAN WELL** and then open the can.


**2**  Wash bottles and nipples, using bottle and nipple brushes, and caps, rings, and preparation utensils in hot soapy water before using. Rinse thoroughly.

**8**  Pour needed amount of formula into a clean bottle using ounce markings to measure formula and add an equal amount of cooled boiled water. Thus, if 4 oz. of formula is poured into the bottle, 4 ounces of water should also be added.


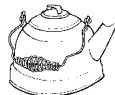
**3**  Squeeze clean water through nipple holes to be sure they are open.

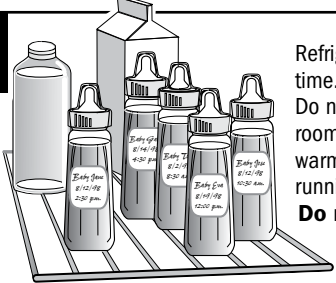
**9**  Attach nipple and ring to the bottle and **SHAKE WELL**. Feed prepared formula immediately. If formula is left in the can, cover and refrigerate can until needed. Use within 48 hours.


**4**  Put the bottles, nipples, caps, and rings in a pot and cover with water. Put the pot over heat, bring to a boil, and boil for 5 minutes. Remove with sanitized tongs, allow the items to cool, and air dry.

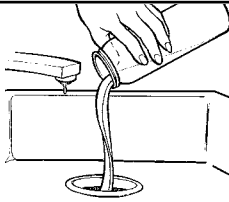
**10**  If more than one bottle is prepared, put a clean nipple right side up on each bottle and cover with a nipple cap. Label each bottle with the baby's name and the date and time that it was prepared.

**5** For formula, bring water to a very bubbly boil. Keep boiling it for a minute or two, then let it cool. Use this water to mix the formula. Use water from a source approved by the local health department. If tap water is used for boiling, collect only cold tap water allowed to run for 2 minutes first.


 **BOIL**  **COOL**


 Refrigerate until feeding time. Use within 48 hours. Do not leave formula at room temperature. To warm bottle, hold under running warm water. **Do not microwave bottles.**


**6**  Wash the top of the can with soap and water and rinse well to remove dirt. Wash the can opener with soap and hot water.


**12**  Throw out unused formula left in bottle after feeding or which has been unrefrigerated for 1 hour or more. Store unopened cans in a cool, dry indoor pantry shelf. Use before the expiration date.


**Figure 6c:**  
**Preparation Checklist for Standard Powdered Iron-Fortified  
 Infant Formula (using glass or hard plastic bottles)**


**1**  Wash your hands, arms, and under your nails, very well with soap and warm water. Rinse thoroughly. Clean and sanitize your workspace.


**2**  Wash bottles and nipples, using bottle and nipple brushes, and caps, rings, and preparation utensils in hot soapy water before using. Rinse thoroughly.

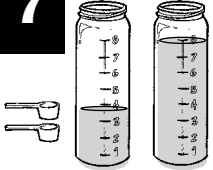
**3**  Squeeze clean water through nipple holes to be sure they are open.


**4**  Put the bottles, nipples, caps, and rings in a pot and cover with water. Put the pot over heat, bring to a boil, and boil for 5 minutes. Remove with sanitized tongs, allow the items to cool, and air dry.


**5**  For formula, bring water to a very bubbly boil. Keep it boiling for a minute or two, then let it cool. Use this water to mix the formula. Use water from a source approved by the local health department. If tap water is used for boiling, collect only cold tap water allowed to run for 2 minutes first.

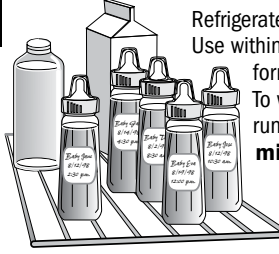
**BOIL**  **COOL**

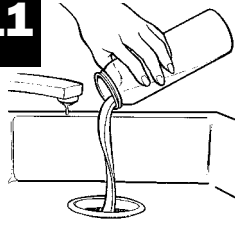
**6**  Remove plastic lid; wash lid with soap and clean water and dry it. Write date on outside of plastic lid. Wash the top of the can with soap and water, rinse well, and dry. Wash the can opener with soap and hot water. Open the can and remove scoop. Make sure that the scoop is totally dry before scooping out powdered formula. Only use the scoop that comes with the formula can.


**7**  For each 2 ounces of cooled boiled water added to a clean bottle, carefully add 1 level scoop of powdered formula. Thus, if 8 ounces of water is poured into the bottle, 4 level scoops of formula should be added.


**8**  Attach nipple and ring to the bottle and **SHAKE WELL**. Feed prepared formula immediately.

**9**  If more than one bottle is prepared, put a clean nipple right side up on each bottle and cover with a nipple cap. Label each bottle with the baby's name and the date and time that it was prepared.

**10**  Refrigerate until feeding time. Use within 24 hours. Do not leave formula at room temperature. To warm bottle, hold under running warm water. **Do not microwave bottles.**

**11**  Throw out unused formula left in bottle after feeding or which has been unrefrigerated for 1 hour or more.

**12**  Make sure that no water or other liquid gets into the can of powder. Cover opened can tightly and store in a cool dry place (not in the refrigerator). Use within 4 weeks after opening to assure freshness.

**13**  To be used again, the scoop should be washed with soap and hot water, rinsed thoroughly, and allowed to air dry. When making formula again, the scoop should be totally dry before using it to scoop powder out of the can. Store unopened cans in a cool, dry indoor pantry shelf. Use before the expiration date.

## Warming Infant Formula

*The following guidelines are recommended to warm refrigerated infant formula:*

- For infants who prefer a warmed bottle, warm the bottle immediately before serving.
- A safe method of warming a bottle is to hold it under running warm tap water. Shake the bottle before testing the temperature. Always test the temperature before feeding to make sure that it is not too hot or cold (test by squirting a couple of drops onto the back of your hand).
- Warm only as much infant formula as you think will be needed for a feeding.
- Never use a microwave oven to warm infant formula because this practice is dangerous. Liquid in a bottle may become very hot when heated in a microwave oven and remain hot afterwards even though the bottle feels cool. Infants have been seriously burned while being fed liquids warmed in microwave ovens. Covered bottles, especially vacuum-sealed and metal-capped bottles of ready-to-feed infant formula, can explode when heated in a microwave oven.

## Guidelines for Using Infant Formula When There Is Limited Access to Common Kitchen Appliances

The following guidelines regarding use of standard milk- and soy-based infant formulas are recommended for caregivers with limited access to a refrigerator or stove (or when their own appliances are not functioning properly; e.g., a caregiver's refrigerator is not working and not keeping foods at or below 40 degrees Fahrenheit).

*If there is no access to a refrigerator:*

- Use powdered infant formula instead of 32 ounce ready-to-feed cans or 13 ounce concentrated cans. The latter two are designed for the preparation of multiple bottles of infant formula at one time and require use of a refrigerator for storage. Alternately, ready-to-feed infant formula in 8 ounce servings can be used.

- Follow instructions for properly sanitizing bottles and water (see pages 91 and Figure 6c, page 95).
- Prepare one bottle at a time, if powdered infant formula is used; fill it with the approximate amount of infant formula that the infant can consume at one feeding. Make sure to scoop the powder out of the can using a clean, dry scoop when preparing infant formula. Make sure no liquid enters the can because it will facilitate the growth of bacteria and spoilage of the infant formula. See Figure 6c, page 95, for more detailed instructions.
- Use infant formula immediately after it is prepared or after a ready-to-feed can or nursette is opened.
- Discard any infant formula left over after a feeding or infant formula that has been sitting at room temperature for more than 1 hour.<sup>39</sup>

*If there is no access to a stove or dishwasher:*

- Nursette bottles are the ideal packaging of infant formula to use for infants less than 3 months old when a stove or a dishwasher (for sterilizing bottles and their parts and boiling the water) is not available.

## Guidelines for Using Infant Formula After a Natural Disaster or Power Outage

The Centers for Disease Control and Prevention (CDC) recommends the following after a natural disaster or power outage:<sup>40</sup>

- Use ready-to-feed infant formula if possible.
- Use bottled water to prepare powdered or liquid concentrated infant formula.
- If bottled water is not available, use boiled water. Use treated water (treated with chlorine or iodine to disinfect it per manufacturers directions) to prepare infant formula only if bottled or boiled water is not available.



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