Committee on Nutrition

Commentary on Breast-Feeding and Infant Formulas, Including Proposed Standards for Formulas

The Committee on Nutrition published proposed standards for infant formulas in 1967 in anticipation of a review by the Food and Drug Administration (FDA) directed to all foods for special dietary use, including infant formulas. The infant formula standards published by the FDA in 1971 were similar to those proposed by the Committee.

Several developments have prompted the Committee to review the question of breast-feeding and formula standards. New developments relating to infant formulas reflect the interaction of one nutrient with another (e.g., protein with iron, vitamin E with unsaturated fats) that should be brought to the attention of pediatricians. Formulas for normal infants are being developed which use vegetable rather than milk protein as a base, and this requires modification of the standards for components of formulas.

Other agencies—including the Canadian Food and Drug Directorate and the Codex Alimentarius Committee on Foods for Special Dietary Uses—have been developing standards for infant formulas. The draft standards of these agencies raised questions that required review of the FDA standards for infant formulas. Their cooperation with the Committee has resolved most of the differences so that standards will be more nearly uniform.

The FDA will also be developing new regulations governing "medical" foods, i.e., foods for special dietary uses for specific medical conditions. This includes amino acid-modified products for children with amino acid disorders. Other special problems of infancy require special formulas either made by commercial companies or compounded in medical centers. The standard for normal infant nutrition should provide a reference base for formulas for children with these special nutritional problems. These reasons have prompted the Committee to revise and expand its recommendations on standards for infant formulas. The Committee also wishes to restate its position on breast-feeding.

BREAST-FEEDING

Infants grow most rapidly during the first 4 to 6 months of life. Nutrient requirements are most critical in this period, during which nutritional deficiencies can have lasting effects on growth and development.

Until the turn of the century, human milk provided by breast-feeding was the sole source of nutrients for infants from birth, and it remained the principal source during the period of rapid growth and high nutritional demand. When the mother's supply of milk was adequate and the baby could suckle successfully, growth and nutritional status of breast-fed infants became the reference standard; breast milk has not been improved on as a reference standard. The inability of some mothers to nurse successfully was an impetus to the use of modified cow's milk and to the development of present day infant formulas as a substitute. The convenience of formulas led to a decline in breast-feeding, a trend which continues throughout the world today.

Breast milk is bacteriologically safe. The immune globulins and white cells of colostrum and early breast milk confer substantial immunity to bacteriologic infections, particularly enteritis, which is especially significant for infants at risk. There is some clinical evidence suggesting that these immune substances provide protection from necrotizing enterocolitis.3

Certain nutrient interactions may result in some advantages of human milk over formulas. The low protein content of breast milk may favor better absorption of small quantities of iron, and the low iron content may provide the optimum for assuring a good immune reaction. The fat composition and the sodium and phosphorus content may be desirable. However, it should be
noted that these differences have not been proven to be advantageous in terms of general health and long-term consequences.4,5

The physical contact between mother and infant which breast-feeding entails is advantageous in that early physical contact between mother and infant promotes better interaction.6 However, the Committee wishes to caution that this may apply only when this contact is desired by the mother. The Committee also calls attention to some disorders that make breast-feeding unsuitable. Infants with certain genetic disorders are intolerant to human milk and require special diets; certain drugs and toxins that can harm the infant may be concentrated in human milk; and some mothers have an inadequate supply of milk or nipples unsuited for nursing.

The Committee reaffirms the recommendations for encouraging breast-feeding. However, some caution is needed against issuing dire warnings to mothers who cannot or do not wish to breast-feed; normal growth and development are possible without it. Important steps which will encourage breast-feeding include more adequate educational programs for adolescents and pregnant women and reinforcement by obstetricians, pediatricians, and nurses attending pregnant women. Changes in employment policies and in working conditions and provision of day-care centers at or near places of employment to make breast-feeding practical for working mothers will increase the frequency of breast-feeding. Such changes are urgently needed where the rural poor have migrated to urban areas in the United States and elsewhere. When breast-feeding is unsuccessful, inappropriate, or stopped early, infant formulas provide the best alternative for meeting nutritional needs during the first year.

Recently, commercial formula companies affirmed a policy that proscribes advertising and promotional practices which might discourage mothers from breast-feeding. Physicians, nurses, and other health aides attending pregnant and postpartum women, as well as salespersons promoting formulas, should not unconsciously encourage a negative attitude toward breast-feeding, particularly where its discontinuance may increase the risk of malnutrition. These persons are in a position to actively encourage breast-feeding.

MILK-SUBSTITUTE FORMULAS

The Committee believes the development of milk-substitute formulas for infants is important to child health. The supply of milk protein is marginal and its costs are increasing. Cheaper and more available substitutes that are nutritionally safe are welcome as a means of assisting in the prevention of malnutrition. However, there is a risk of fostering other forms of malnutrition if the new products do not provide all nutrients needed by the infant. The nutritional problems to be resolved in making formulas from vegetable proteins are more complicated because milk used as a base for formulas contains nutrients that are not provided by vegetable proteins.

The Committee has adopted a single standard that applies to both milk-based and milk-substitute formulas. Where experience with milk-based formulas has disclosed no deficiency, the Committee has proposed minimum standards that avoid the need for supplementation of these formulas but require supplementation only of milk-substitute formulas, e.g., with vitamin K, inositol, etc.

SPECIAL FORMULAS FOR MEDICAL PURPOSES

The FDA presently includes infant formulas and special dietary products under its regulation section 125. This section deals with label statements concerning nutritional properties of foods used for special dietary purposes. The FDA is developing new regulations that will allow special products to be labeled for use in specific medical conditions with a warning that the product is to be used only under medical supervision, i.e., as medical foods. This concept is extremely valuable in marketing products for patients with phenylketonuria, uremia, lactose intolerance, or other conditions requiring medical foods which might be harmful if used by the normal consumer.

The Committee recommends that the FDA create two categories of infant formulas: one for normal infants (which is the subject of this report) and one for infants with specific medical conditions, e.g., amino acid disorders, malabsorption, low birthweight (less than 2,500 gm). This second category would separate the regulation of products for infants (less than 12 months of age) from those of medical foods for older children and adults. This separation is desirable inasmuch as infant formulas are likely to provide the sole or major nutritional source for the infant, whereas medical foods for an older child or adult usually provide only a fraction of the day's diet.

Information understandable to the parent about the indications and use of products should be provided by label inserts. The label of any product is to be used only under medical supervision.
clearly indicate what volumes should be fed to meet nutritional needs. Requirements (Table I) are based on calories, not volume of intake. Medical foods are discussed in more detail in a companion paper on diets for children with amino acid disorders.

**INFANT FORMULA STANDARDS—GENERAL COMMENTS**

The present standards apply to formulas prepared for healthy infants from birth (2.5 to 4.0 kg) to 12 months of age (8 to 10 kg). The recommended minimum nutrient levels proposed by the Committee are summarized and compared with those required under the FDA regulations of 1971 in Table I. The Committee recommends that a formula contain these nutrients at the levels proposed before it can be labeled as “infant formula.” The proposed standards in this statement are also useful guidelines for nutritionists or physicians who must prepare formulas for infants with specific nutritional problems.

Unmodified cow’s milk and evaporated milk at usual dilutions do not meet the proposed standards. While normal growth occurs with the use of cow’s milk, iron deficiency and hyperphosphatemia are common complications. Vitamin C supplements are needed. The high salt and saturated fat content of cow’s milk may have adverse effects on later health, although this has not as yet been proven. Its high protein and mineral content increase the risk of dehydration and hypernatremia whenever diarrhea or other conditions increase the demand for water.

**CALORIC DENSITY, OSMOLARITY, AND RECONSTITUTION OF CONCENTRATED PRODUCTS**

Infant formulas generally have a caloric density of 670 kcal/liter* (20 kcal/oz). Formulas having a caloric density of significantly lower or higher than this must be labeled clearly to show the reason for the change in concentration; in some instances these products will be regarded as “medical” formulas for specific management of special clinical conditions, to be used only under medical supervision.

Osmolarity of most mammalian milk is approximately 300 mOsm/liter. Hyperosmolar formulas may be a factor in causing necrotizing enterocolitis. Until more evidence is presented, the Committee recommends that formulas for normal infants have concentrations no greater than 400 mOsm/liter without a warning statement on the label.

Some formulas are concentrated when sold and require addition of water. Errors in dilution may cause hyper- or hypo-osmolar states. Directions for dilutions must be explicit.

If a special formula is incomplete (e.g., fat or carbohydrate is excluded), explicit directions for supplementation should be provided.

**PROTEIN**

The Committee reaffirms its proposal that formulas must provide a minimum of 1.8 gm/100 kcal of protein having a PER† at least 100% that of casein. Where a protein has a PER less than 100% that of casein, the level should be increased to compensate for the lower PER. For example, a protein with a PER 75% that of casein would have to provide at least 2.4 gm of protein per 100 kcal (1.8/0.75). No proteins with a PER less than 70% that of casein can be used.

The question of which protein reference standard to use is disputed. The Committee continues to believe casein is most appropriate for testing purposes. Others have recommended 1.8 gm of protein per 100 kcal, but tentatively have proposed egg protein, not casein, as the reference protein, with a cut-off at 70% the PER of egg protein. Egg protein contains more methionine-cysteine than casein and promotes more rapid weight gain in rats per gram of protein eaten, i.e., it has a higher PER than casein because rats have a greater need for methionine-cysteine. Normal healthy infants do not have this high requirement for the sulfur-containing amino acids. In the opinion of the Committee, the use of the egg protein standard artificially raises the quality required; application of this standard would eliminate soy protein, which is equal to human milk in promoting growth of human infants.

The Canadian standards for infants recommend 1.8 gm/100 kcal but a minimum PER of 85%, not 70%, that of casein. This higher standard also eliminates use of soybean protein formulas, unless supplemented with methionine.

*Throughout this report “liter” is used as a reference volume rather than “quart,” in anticipation of our adopting the metric system. For regulatory purpose, the Committee recommends that either liter or quart be allowed as a volume reference because no harm will result from using them interchangeably for these purposes and added costs can be avoided in this way.

†PER is the **protein efficiency ratio** derived from rat weight gain per gram of protein fed. The PER of a test protein may be expressed as a percent of the PER of a casein or other protein standard which has a high biological value.
<table>
<thead>
<tr>
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<th>CON 1974 Recommendations:</th>
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<tr>
<td>Chloride (mg)</td>
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*Retinol equivalents.
†Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.
‡Milliequivalent for 670 kcal/liter of formula.

The protein in a formula may be derived from a single source or from a mixture of protein sources, or it may be supplemented with L-amino acids or acceptable hydrolysates. The manufacturing processes must be standardized so that protein quality can be consistently assured in the formula. The "chemical score" is a useful guide for those introducing new protein sources, and a chemical score at least 70% is desirable when the provisional reference pattern adopted by FAO/WHO is used. Any new protein proposed for use in formulas for normal infants should be given appropriate laboratory tests and animal and clinical trials before being released for use by normal infants without medical supervision.

The need to assure adequate quantities of protein is obvious, and the need to conserve protein is becoming more clear as world supplies of animal proteins become scarce and more expensive. Therefore, the ability to use appropriately tested vegetable protein sources must not be proscribed by regulation. The possibility that
formulas containing higher protein have some disadvantage has been suggested, particularly in relation to iron absorption.

The level of protein in human milk is about 1.6 gm of protein per 100 kcal. Most commercial formulas in the United States today use 2.3 gm of protein per 100 kcal. The minimum quantity and quality proposed in these standards (1.8 gm/100 kcal) promoted growth and development equal to that of human milk when studied under carefully controlled conditions. This standard satisfied the Committee as meeting infant needs for growth by generally accepted criteria.

The Committee has proposed a maximum protein level of 4.5 gm/100 kcal. There is no evidence that protein levels in excess of the minimum 1.8 gm/100 kcal, when given to normal infants, confer any advantage. Increasing protein intake increases solute load. Special purpose formulas designed for further modification (e.g., meat-base formula) may have protein levels greater than this figure. Because these formulas are recommended for use under medical supervision, the higher protein concentration should be permitted, if appropriate labeling information is provided. When the formula is designed to be modified by addition of calories that would bring the protein content within the range of 1.8 to 4.5 gm/100 kcal, the information regarding modification must be explicit.

**FAT AND ESSENTIAL FATTY ACIDS**

Fat provides about 50% of the calories in human milk, including 5% as essential fatty acids (principally linoleic acid). FDA regulations provide for a minimum of 15% of calories from fat (1.6 gm/100 kcal) with 2% of total calories as essential fatty acids, i.e., linoleic acid in the form of a glyceride. The Committee recommends that these minima be increased to 3.3 gm of fat per 100 kcal (30% of calories) and 300 mg of linoleic acid per 100 kcal (approximately 2.7% of total calories) to provide a fat to carbohydrate ratio within a range that is customary in infant diets. Excess linoleic acid produces excessive peroxidation and increases vitamin E requirements; however, the Committee cannot, from present evidence, set an upper limit of linoleic acid content of the diet. In human milk, linoleic acid comprises 8% to 10% of the fat.

The Committee recommends a maximum of 6 gm of fat per 100 kcal (54% of calories), which will still ensure sufficient carbohydrate and protein to avoid ketosis or acidosis caused by excess fat. Special formulas—those that are free of fat, low in fat, or low in carbohydrate and high in fat (ketogenic diets)—should be treated as "medical formulas." The Committee also recommends that no more than 1% of calories be derived from fatty acids that are longer than 20 carbon atoms to avoid possible toxicity from excessive amounts of certain oils, such as rapeseed or some fish oils.

**CARBOHYDRATE**

In most formulas 40% to 50% of calories are provided as carbohydrate. Lactose is the carbohydrate in human and cow's milk and supplies most or all of the carbohydrate in milk-based formulas. Other carbohydrates (such as dextrins, maltoses, corn syrup solids, and sucrose) are used in infant formulas, especially when milk protein (of which traces may be found in lactose) is to be avoided by allergic infants. When carbohydrates other than lactose are used, the type of carbohydrate in the formula must be identified and its efficacy for growth of healthy infants ascertained.

**VITAMINS**

The Committee reaffirms its recommendations in the 1967 statement and agrees with those adopted by the FDA, with the noted amendments.

**Niacin**

A minimum of 250μg/100 kcal of niacin is recommended by the Committee. The FDA has used a standard of 800μg/100 kcal of niacin equivalents, which includes dietary tryptophan, a precursor of niacin. The protein level in formulas as recommended by the Committee provides the tryptophan that supplies the niacin equivalents. The Committee feels a specific recommendation for niacin is desirable.

**Vitamin B₆**

The minimum recommendation for vitamin B₆ (pyridoxine) remains at 35μg/100 kcal. In addition, at least 15μg for each gram of protein is recommended in recognition of an increasing requirement for pyridoxine as protein content increases.

**Vitamin A**

A maximum level of 750 IU/100 kcal of vitamin A (4,800 IU/liter) is proposed. This is intended mainly for those formulas where intake is likely to be low, i.e., 300 to 400 ml of formula per day, during the first weeks of life, and for infants who do not absorb fat well. In such instances, even when consuming a full liter of formula, the maximum amount of vitamin A would be well below the prescription level, i.e., 10,000 IU.
Although most formulas contain 62 IU of vitamin D per 100 kcal (400 IU/liter), a maximum of 100 IU/100 kcal is proposed; this would provide 670 IU/liter of formula. Technically, this amount of vitamin D would exceed the maximum allowed without prescription under existing FDA regulations, i.e., 400 IU per person per day. However, this higher level of vitamin D should be allowed in formulas for low-birthweight infants (2.5 to 3.5 kg) whose intake is low or whose absorption of fat is poor. Infants receiving 300 to 400 ml of formula per day would receive only about 125 to 160 IU of vitamin D from formula with 400 IU/liter; but, with 640 IU/liter of formula, these infants would receive 200 to 275 IU of vitamin D daily, which should meet daily requirements. This higher level of vitamin D per 100 kcal is also useful in providing adequate vitamin in more dilute formulas that sometimes must be fed to some infants for a limited period. Supplemental vitamin A and D are needed for extremely small infants or infants with steatorrhea.

Vitamin K

Normally, vitamin K is present in milk-based formulas in sufficient quantities to prevent deficiency, and the bacterial flora engendered by milk-based formulas in healthy infants apparently contribute to an adequate vitamin K supply. Consequently, supplementation of milk-based formulas with vitamin K is apparently unnecessary. The Committee recently recommended that soy isolate and other milk-substitute formulas contain a minimum of 8 µg of vitamin K per 100 kcal. The Committee has again reviewed evidence and now suggests that 4 µg/100 kcal (the minimum level in commonly used milk-based formulas) is sufficient for normal infants. Consequently, supplementation of milk-based formulas with vitamin K is apparently unnecessary. The Committee recently recommended that soy isolate and other milk-substitute formulas contain a minimum of 8 µg of vitamin K per 100 kcal. The Committee has again reviewed evidence and now suggests that 4 µg/100 kcal (the minimum level in commonly used milk-based formulas) is sufficient for normal infants. Consequently, supplementation of milk-based formulas with vitamin K is apparently unnecessary. The Committee recently recommended that soy isolate and other milk-substitute formulas contain a minimum of 8 µg of vitamin K per 100 kcal.

The requirements for biotin by infants is not known, but the vitamin is essential in many metabolic pathways. Biotin deficiency can be produced in animals fed a biotin-free diet, but deficiency in humans has been observed only under exceptional circumstances. Biotin is present in many foods, including human and cow’s milk, and is manufactured in the intestine by bacteria. The recommendation for biotin is a minimum of 1.5 µg/100 kcal, less than that found in human milk but approximating that in commonly used milk-based formulas. This lower intake has not been attended by any signs of biotin deficiency.

Choline

The requirement for choline also is not known. Choline deficiency has been described in young mammals and has resulted in liver and kidney damage. Choline is a constituent of lecithin and sphingomyelin, and it is present in human and cow’s milk. Normally, common used milk-based formulas provide about 7 mg/100 kcal or 45 mg of choline per liter. Choline is present in human milk and tolerated with no adverse reactions, and deficiencies in mammals produce serious effects; therefore, the Committee recommends the inclusion of at least 7 mg of choline per 100 kcal in infant formulas. Choline may have to be added to milk-substitute formulas to attain the minimum level, depending on the ingredients used.

Inositol

Inositol is a ubiquitous compound present in foods in substantial amounts, particularly in human and cow’s milk. It is a critical constituent of brain, heart, and skeletal muscle phospholipids. Inositol deficiency has been demonstrated only in a few species of mammals. The Committee recommends 4 mg/100 kcal (26 mg/liter), which is the amount commonly found in milk-based formulas. This is less than the amount found in human milk (25 mg/100 kcal); but, because there is no evidence for inositol deficiency, the amount found in milk-based formula is recommended as a minimum. Amounts equal to that found in human milk should be allowed.
posed for these three electrolytes because development of new formulas could result in levels that might be too low for nutritional adequacy or too high for safety. The proposed minima are based on average levels found in human milk; these minima are sufficient to meet the growth needs and leave little residual for excretion in urine. Maximum levels are those provided in cow’s milk and constitute a significant solute load but one that can be excreted (in isotonic urine, 300 mOsm/liter) by the normal infant. Levels near the minima probably are preferable.

The ratio of sodium to potassium (expressed in mEq) should not exceed 1.0 and the ratio of sodium plus potassium to chlorine should be at least 1.5. Ideally, ratios similar to those in human milk should be used (sodium to potassium, 0.5; sodium plus potassium to chlorine, 2.0). In humans and experimental animals, the ratio of sodium to potassium influences blood pressure in certain hypertensive or hypertensive-prone states. Use of the sodium to potassium ratio found in human milk will reduce the possible risk of excess sodium to cause an increase in blood pressure in infants at risk. Use of the recommended sodium plus potassium to chlorine ratio will provide a balanced mixture for urinary excretion an acid-base regulation.

Calcium and Phosphorus

The Committee recommends the same minimum levels for calcium and phosphorus in infant formulas as published in 1967, and that the ratio of calcium to phosphorus be no less than 1.1 and no more than 2.0. A ratio of calcium to phosphorus within this range assures an alkaline ash diet similar to that found in all mammalian milks.

Iron

The precise requirement for iron and the optimum means for providing it to the infant remain uncertain. Iron deficiency is not common in term infants fed human milk, which contains about 0.15 to 0.2 mg/100 kcal (1 to 1.5 mg/liter). Iron availability may be less in formulas with higher protein concentrations; iron deficiency is more common in infants fed 2.4% protein (3.6 gm/100 kcal) than in those fed 1.5% protein (2.3 gm/100 kcal) in a milk formula. Fortification of both types of milk with 8 mg of iron per liter abolished the deficiencies.

The Committee earlier recommended that infants receive at least 1 mg of iron per kilogram per day from either cereal or formula supplemented with at least 1 mg of iron per 100 kcal, or from some other source. This supplement reduces the incidence of iron deficiency in populations at risk. The Committee is aware that the level of iron in most iron-supplemented formulas (i.e., 12 mg/liter) may be more than is necessary to prevent iron deficiency.

The Committee recommends that all formulas contain at least the lower level of iron found in human milk (0.15 mg/100 kcal or 1 mg/liter) and that the iron be in a bioavailable form. The Committee also reaffirms its recommendation that infants at risk for iron deficiency be given formulas supplemented with iron between 1 and 2 mg/100 kcal (approximately 6 to 12 mg/liter). The Committee feels that new studies are needed to compare the metabolism of iron in formulas at 0.15 and 1 mg/100 kcal under different conditions. The form of iron added to a formula affects its availability. The type and level of protein in a formula modifies the requirement. The weight and maturity of the infant at birth affect iron stores and requirement. A more detailed statement is being published by the Committee on iron fortification of formulas and foods for infants, older children, and adults.

Zinc

Marginal to deficient intakes of zinc by some young infants and children in the United States have been reported. Based on data on zinc levels in human and cow’s milk, as well as other nutritional information, the minimum requirement for zinc by the infant is approximately 0.5 mg/100 kcal (3.2 mg of zinc per liter). Absorption of zinc from soy-based formulas may be less efficient than from milk-based formulas because of the presence of phytate in soy protein; but, present evidence is insufficient to make specific recommendations for additional zinc in soy-based formulas.

Copper

Current evidence does not warrant any change in the copper level required in formulas for full-term infants.

Manganese

The requirement for manganese is not known, and no clinical evidence of deficiency has been reported in infants. The levels of manganese in human and cow’s milk are quite low. The Committee recommends 5μg/100 kcal of formula, approximately the level in commonly used milk-based infant formulas.

OTHER NUTRIENTS IN FORMULAS

Our knowledge of nutrition continues to increase, and information about other essential
nutrients for infants may be forthcoming. The Committee proposes that regulations make provision for the addition of other nutrients to infant formulas if they are demonstrated to be of nutritional value, considered nutritionally safe, and included at levels reasonably related to those in human milk. Therefore, the Committee recommends that regulations on the content of infant formulas not be limited to the nutrients listed in Table I. Rather, this list should be used to ensure that nutrients now known to be essential are in all infant formulas and that the list can be easily amended as new information becomes available.

CONCLUSIONS

This statement proposes recommendations toward increasing the practice of breast feeding. Specific recommendations made for standards of infant formulas as to calorie, protein, fat, vitamin, and mineral levels apply to both milk-based and milk-substitute infant formulas. Such formulas, when used in place of breast-feeding, must supply most or all of the nutrients infants require during the first weeks or months of life.

The minimum levels of nutrients per 100 kcal recommended for formulas provide good growth and development in healthy, full-term infants; distinct hazards may be encountered at levels below these. However, no significant advantage is to be gained by providing levels in excess of these minima in normal infants. Recommendations for maximum levels are made only where quantities in excess lead to toxicity; generally, levels near the minima recommended are most desirable because they are the most likely to reflect the composition of human milk, and the least likely to result in any undesirable nutrient to nutrient interaction.

The recommendations also can be used as reference standards for formulas for special dietary uses of “medical” formulas. The Committee recommends that “medical” formulas be classified by FDA into a special group under the paragraph dealing with infant formulas.

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REFERENCES

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