

AMERICAN ACADEMY OF PEDIATRICS

COMMITTEE ON NUTRITION

PROPOSED CHANGES IN FOOD AND DRUG ADMINISTRATION REGULATIONS CONCERNING FORMULA PRODUCTS AND VITAMIN-MINERAL DIETARY SUPPLEMENTS FOR INFANTS

THE Food and Drug Administration is currently revising regulations governing composition and labeling of foods for special dietary uses. These proposed revisions should recognize changing practices in infant feeding, new information on nutritional requirements, and major advances in food technology. Of specific interest to the pediatrician is the fact that infant formula products are covered by these regulations. In the opinion of the Committee on Nutrition, it is of great importance that the standards established be consistent with sound nutritional practice and provide adequate levels of all nutrients, since during the first 6 months of life a majority of American infants receive virtually their total dietary intake from products in this category.

The Committee has given much study to the nutrient needs of infants and to the amounts of protein, vitamins, and minerals required for sound infant nutrition. It recognizes that adequate studies are not available to identify in many instances either optimal or safe minimal intakes of these substances. Nevertheless, it is our goal to insure that infant formulas are nutritious and as safe as modern technology and scientific knowledge can accomplish. This requires that the label information should fully inform the physician and the purchaser of the nutrient content of the formula and identify specifically any recognized nutritional inadequacies. The text which follows attempts to specify safe minimal levels of the nutrients contained in proprietary formulations of milk products and applies equally well to formulations with milk substitutes (soya, meat, etc.). The minimal values are not *recommended allowances* of these nutrients. Products which purport to be the sole source of nutrition

for infants and which provide less than these minimal specifications are to be so labeled as to identify the need for dietary supplementation.

In addition to proposing regulations governing infant formulas, the Food and Drug Administration has also published proposed revisions relating to formulation and content of vitamin and mineral supplements for infants. The nutritional considerations mentioned above apply with equal force to these products, and it is important that the two sets of regulations concerning these two types of products be consistent.

Average growth performance of full-term infants fed at the breast of well nourished mothers has not been exceeded by that of full-term infants consuming any artificial formulation. Therefore, average values of nutrients in human milk may be considered a rational basis for estimating minimal needs. Nevertheless, experience has proven that levels of several nutrients, notably vitamin D and iron, and possibly also of ascorbic acid, in human milk are even less than those necessary to support normal growth and state of health. In addition, the requirements of the breast-fed infant for vitamin E, thiamine, and vitamin B₆ may be different from those of infants fed formulas having compositions significantly different from that of human milk.

The use of the reference value 100 kcal* for specification of minimal amounts of vitamins and minerals is consistent with modern practice and implies a relation of nutrient needs to total metabolic activity. This

* Kilocalorie, the large calorie, is the calorie commonly used in diets as well as in nutritional and metabolic studies.

TABLE I
MINIMUM VITAMIN AND MINERAL LEVELS
PER 100 KCAL OF FORMULA
(VALUES GIVEN IN MILLIGRAMS, EXCEPT
WHERE OTHERWISE NOTED)

<i>Vitamins</i>	<i>Minimum Amount*</i>
Vitamin A (U.S.P. units)	250
Vitamin D (U.S.P. units)	40
Vitamin E (I.U.)	0.3
Ascorbic acid	8
Thiamine	0.025
Riboflavin	0.06
Niacin	0.25
Vitamin B ₆	0.035
Folic acid (μ g)	4
Pantothenic acid	0.3
Vitamin B ₁₂ (μ g)	0.15
<i>Minerals</i>	
Calcium	50
Phosphorus	25
Magnesium	6
Iron	1
Iodine (μ g)	5
Copper	0.06

* A number of values have been rounded out.

permits a comparison of these values among infants whose nutritional demands are changing as a function of growth. The tabular summary (Table I) which accompanies this text presents suggested minimal vitamin and mineral levels per 100 kcal. With the exceptions mentioned above, the amounts are similar to those found in human milk.

PROTEIN CONCENTRATION AND QUALITY

Human milk contains 1.8 gm of protein per 100 kcal, or 7.8% of the calories as protein (1.2 gm/100 ml and 66 kcal per 100 ml),¹ and available evidence indicates that, in a food which is the sole source of protein for an infant, such a level of protein is adequate when it is of quality comparable to that of human milk.

The quality of a protein will vary with source and method of processing. If a quantity of formula which supplies 100 available kilocalories as customarily or usually prepared for consumption contains less than

1.8 gm of protein of quality equivalent to that of casein (Protein Efficiency Ratio),² or when the quality of the protein expressed as a fraction of that of casein multiplied by the gram protein per 100 kcal is less than 1.8, or if the protein quality is less than 70% of that of casein, the following statement should appear on the label: "This product should not be used as the sole source of protein of the infant diet."

VITAMIN A

No cases of vitamin A deficiency in breast-fed infants have been reported in the United States. The total vitamin A potency of human milk, though variable, averages 250 U.S.P. units per 100 kcal. Several early clinical studies attempted to determine the vitamin A requirements of infants consuming artificial formulations; evaluation of these results is complicated because the vitamin A preparations used were of uncertain potency and stability. A minimal level of 250 U.S.P. units of vitamin A per 100 kcal is therefore recommended for infant formulas.

VITAMIN D

The Committee has recommended an intake of vitamin D of 400 U.S.P. units per day and, at the same time, recognized that normal linear growth without rickets occurs with intakes below this value. The evidence available suggests that a minimum of 250 U.S.P. units be supplied per day;³ and, when this value is considered in relation to the amount of formula ordinarily consumed, a level of 40 U.S.P. units per 100 kcal appears to be an appropriate value.

VITAMIN E

Human milk contains approximately 2 I.U. of vitamin E per liter (0.3 I.U. per 100 kcal).⁴ Although levels of vitamin E in blood of term infants are low, they rise rapidly when the infant is breast-fed, and biochemical evidence of vitamin E deficiency has not been reported in breast-fed infants. Because an increased intake of poly-

unsaturated fatty acids (PUFA) results in an increased vitamin E requirement, formula products with two, three or more times the PUFA content of human milk (approximately 6% of calories) have a depleting effect on the infant's body stores of vitamin E. Such products should probably be supplemented with vitamin E. However, until the relation between vitamin E requirement and PUFA intake is established quantitatively for the infant, the value of 0.3 I.U. of vitamin E per 100 kcal is recommended as a tentative minimum.

ASCORBIC ACID

The requirement for ascorbic acid during early infancy, like the requirement for vitamin B₆, is dictated to a great extent by level of dietary protein. Under these circumstances, needs are determined in relation to tyrosyluria (hypertyrosinemia) rather than to an antiscorbutic effect. Ascorbic acid has been linked to protein metabolism since 1939 when incomplete metabolism of aromatic amino acids was demonstrated in premature infants.⁵ Recently the syndrome of transient hypertyrosinemia of the newborn has been reviewed and both clinical and dietary aspects of the problem discussed.⁶ This report refers to an unpublished survey of 15,000 infants in which it was determined that 10% of full-term infants had mild tyrosinemia during the first week of life while 30% of premature infants had severe tyrosinemia.

Tyrosinemia of the newborn is related to maturity at birth and protein content of diet and generally remits with age. Tyrosinemia is reduced by a decrease in protein intake or, in some instances, by administration of appropriate amounts of ascorbic acid.

The evidence discussed above indicates that the relative need for ascorbic acid during early postnatal life may be greater than later on. The ascorbic acid content of human milk varies from 2 to 10 mg per 100 ml (3 to 15 mg per 100 kcal). The recommended minimal level, 8 mg per 100 kcal, is consistent with the known antiscorbutic properties of human milk and provides ade-

quate protection against hypertyrosinemia in infants receiving formulas with conventional protein contents.

THIAMINE, RIBOFLAVIN, AND VITAMIN B₆

Average levels of thiamine and riboflavin in human milk are 0.025 and 0.06 mg per 100 kcal, respectively, and no cases of clinical thiamine deficiency have been reported in breast-fed American infants in the past 25 years. In addition, a review by an FAO/WHO expert group supports the position that the level of thiamine and riboflavin in human milk is adequate and consistent with sound nutrition.⁷ It is proposed that artificial formulas contain no less than 0.025 mg of thiamine and 0.06 mg of riboflavin per 100 kcal. In formulas supplying more than 40% of the calories from carbohydrate, the level of thiamine should be increased proportionately.

The Committee has defined requirements for vitamin B₆ during infancy⁸ and suggested a level of 20 µg of vitamin B₆ per gram of protein in infant formulas. A minimal value of 0.035 mg per 100 kcal of a formula containing 1.8 gm of protein per kilocalorie seems appropriate.

NIACIN

Human milk contains an average of 0.25 mg niacin per 100 kcal and 0.55 mg niacin equivalents (from 1.8 gm protein) per 100 kcal. This amounts to a total of 0.80 mg niacin per 100 kcal of human milk. The recommended dietary allowance of the Food and Nutrition Board⁹ for infants is 0.60 mg niacin per 100 kcal. This includes the calculated amount of niacin available from tryptophan in dietary protein (niacin equivalent). Unless the protein supplies less than 0.55 mg niacin equivalent from tryptophan, a content of 0.25 mg of niacin per kcal is adequate.

FOLIC ACID

Folic acid deficiency during infancy is characterized by low levels of folate in serum or blood, morphologic changes in neutrophils, and, in the severe stage, me-

galoblastic anemia. It is more common among low birth weight infants.^{10,11} Low stores at the time of birth, infection, diarrhea or malabsorption, low dietary intake, rapid weight gain, and vitamin C deficiency contribute to the development and manifestations of a folic acid deficiency state.

Estimations of folic acid content of milk products are technically difficult, and results of measurements in different laboratories are not always consistent. This issue has received comment by the Committee and others.¹² On the basis of best available data, a minimal intake of 4 μ g per 100 kcal appears satisfactory and in keeping with the average content of human milk.¹³

PANTOTHENIC ACID

Clinical evidence of pantothenate deficiency has not been reported in infants consuming human milk or cow milk formulas. Since human milk contains about 0.3 mg per 100 kcal, there is reason to recommend this as a minimal level.

VITAMIN B₁₂

A dietary deficiency of vitamin B₁₂ is unknown in infants in the absence of a specific morbid state. Therefore the amount available in human milk, up to 1 μ g per liter, appears adequate (0.15 μ g per 100 kcal).

PHOSPHORUS AND CALCIUM

Von Sydow reported that human milk did not provide sufficient phosphorus, 150 mg per liter, to meet the growth needs of infants weighing less than 2,000 gm.¹⁴ Such infants, while consuming adequate amounts of vitamin D, developed chemical or growth rickets characterized by reduced serum levels of phosphorus and calcium, an increase in serum level of alkaline phosphatase, and roentgenographic changes compatible with rickets. Growth rickets occurs as a result of reduced stores of minerals at birth, dietary deficiency, and increased demands for minerals due to rapid growth.

From observations on stable strontium balance in infants,¹⁵ it has been concluded that the ion limiting skeletal mineralization

in the human infant is phosphate. It appears that phosphorus may be limiting for the human infant at a level below 150 mg per liter of milk (25 mg per 100 kcal).

The effect of limiting dietary calcium has not been studied in human infants, and the minimal level of calcium required in the diet independent of phosphorus and vitamin D has not been examined. In the absence of such data, and recognizing the adequacy of human milk to support excellent bone growth, calcium content of the diet at the level in human milk is presumed adequate and amounts to 50 mg per 100 kcal.

MAGNESIUM

The content of magnesium in human milk, 6 mg per 100 kcal, is adequate for normal nutrition, and is proposed as the minimum level for infant formulas.

IRON

The human infant will become deficient in iron if only the amount available in human milk, 0.02 mg per 100 kcal, is supplied during the first 12 months of life. A formula must contain 1 mg of iron per 100 kcal if it is to meet the minimum requirement of the infant.

COPPER

While hypocupremia is recognized, it is secondary to primary disturbances in protein metabolism with loss of copper protein complexes. Attempts to produce copper deficiency during infancy have been unsuccessful.

Graham and co-workers have recently described copper deficiency in a limited number of children fed a milk formula low in copper during recovery from kwashiorkor.^{16,17} The syndrome produced in these children resembled that described by Cartwright and co-workers in swine fed copper deficient diets.¹⁸

A reasonable minimum figure for copper is 0.06 mg per 100 kcal, the amount available in human milk.

IODINE

The content of iodine in human milk will not meet the infant's needs when ma-

ternal intake of this element is inadequate. This occurs in many geographic regions where endemic goiter is found. The minimal needs of the infant can be calculated from measurements of iodine content of human milk in goiterous regions and study of the supplements needed to prevent goiters. Available evidence indicates a safe minimal level in formulas is 5 μg per 100 kcal.

GENERAL CONSIDERATIONS

The minimal levels of nutrients identified in the foregoing section apply only to the needs of term infants in good health and cannot be considered as providing safe levels in formulations designed for total dietary intake by premature, low birth weight, or ill infants. The specific nutritional needs of such subjects must be assessed by the physician. Modifications of these formulas by the addition of protein, vitamin or mineral supplements will, in general, be necessary; or, formulations containing higher levels of specific nutrients may be recommended to meet the special needs of these infants.

Improvements in food technology promise the appearance of new infant formulas containing novel types of protein combined with new sources of carbohydrate and lipids. In addition, modifications of milk or other proteins may permit preparation of formulations with either enhanced nutritional value or even in decreased nutritional value. For example, modification of proteins may also remove certain trace elements for which no previous essentiality had been demonstrated. While the Committee welcomes potential benefits to infant nutrition afforded by new products, it believes that properly designed and conducted clinical trials of these products should be mandatory prior to marketing. In the past new formulations have occasionally been sold to the public without prior evidence of efficacy, and occasionally to the detriment of a considerable population of infants. It must be demonstrated that a new formulation does not increase the nutrient requirements for specific substances.

When used for infant feeding, a formula

prepared from cows milk (including evaporated and powdered) in essence becomes a complete or partial substitute for human milk. Under these circumstances it would be desirable that milk products represented as an ingredient of infant formulas comply with the minimum standards set forth above. They are, however, specifically exempted by present and proposed regulations and pediatricians should be alert to the need to supplement formulas made from cows milk with (at least) ascorbic acid and iron.

Approximately 600,000 infants per year are fed formulas prepared from evaporated milk. By 3 months of age about 750,000 infants are receiving fluid milk. As a prophylaxis against rickets, we have endorsed the continued addition of vitamin D to fluid and evaporated milk. The Canadian Food and Drug Directorate has recently permitted the addition of ascorbic acid to evaporated milk as a prophylactic measure against scurvy.

VITAMIN AND MINERAL SUPPLEMENTS

Levels of vitamins and minerals in preparations designed for administration as supplements for infants should provide an intake of each nutrient which is consistent with our knowledge of nutritional requirements and should be sufficient to allow for individual variability in dietary habits and food intake. Levels in excess of the maximum levels set forth in Table II appear to have no nutritional advantage for the normal infant. The maximal levels chosen except those for iron and Vitamin D are in general twice the amount present in 1 liter of human milk. This allows an excess considered safe yet permits an infant consuming a formulation devoid of a particular nutrient to receive through a supplement twice the estimated minimal need. Preparations containing more than these amounts should be considered as therapeutic rather than supplemental. Supplements should not provide levels of nutrients which are so low as to be of little value in helping to meet the infant's requirements. The assignment of minimal levels at values approximately one-

TABLE II
SUGGESTED ALLOWABLE MAXIMAL AND MINIMAL
AMOUNTS IN VITAMIN AND
MINERAL SUPPLEMENTS
VITAMIN CONTENT IN MANUFACTURERS' RECOMMENDED
DAILY DOSAGE
(VALUES GIVEN IN MILLIGRAMS, EXCEPT
WHERE OTHERWISE NOTED)

<i>Vitamins</i>	<i>Minimum</i>	<i>Maximum</i>
Vitamin A (U.S.P. units)	850	3,400
Vitamin D (U.S.P. units)	100	400
Vitamin E (I.U.)	1	10*
Ascorbic acid	25	100
Thiamine	0.15	0.6
Riboflavin	0.2	0.8
Niacin	2.0	8.0
Vitamin B ₆	0.15	0.6
Folic acid (μ g)	12	50
Pantothenic acid	1	4
Vitamin B ₁₂ (μ g)	0.5	2
<i>Minerals</i>		
Calcium	150	600
Phosphorus	75	300
Magnesium	25	100
Iron	4	16
Iodine (μ g)	20	80
Copper	0.25	1

* This level is higher than twice the level in 1 liter of human milk to permit supplementation when diets have increased content of polyunsaturated fatty acids.

quarter of the maximum levels will insure against this.

CONCLUSION

This memorandum presents suggested safe minimal levels for vitamin and mineral content of formulas designed to provide total nutrition for infants. These levels must not be equated with recommended daily allowances; rather, they represent levels below which distinct hazards may be encountered. In addition, maximal and minimal values for vitamin and mineral supplements are suggested. The maximal levels will provide intakes close to ideal. A supplement containing less than the stipulated minimal levels will probably serve no useful purpose.

CHARLES U. LOWE, *Chairman*
DAVID BAIRD COURSIN
FELIX P. HEALD

MALCOLM A. HOLLIDAY
DONOUGH O'BRIEN
GEORGE M. OWEN
HOWARD A. PEARSON
CHARLES R. SCRIVER
L. J. FILER, JR., *Consultant*
O. L. KLINE, *Consultant*

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COMMITTEE ON NUTRITION

BABY FOOD AS SPECIAL DIETARY FOODS

“**B**ABY FOODS” have been regarded as “Food for Special Dietary Uses” under federal Food, Drug, and Cosmetic Act regulations that have been in effect since 1942. The current revision of the FDA regulations proposes to continue this classification (Federal Register, December 14, 1966; 31 F.R. 15730).

A recent article in the *New England Journal of Medicine*¹ objects to classifying infant foods as “Food for Special Dietary Uses” in the recently proposed revision of the federal Food and Drug regulations. The authors appear to be unaware that “baby foods” have been regarded as “Food for Special Dietary Uses” for a quarter of a century. The proposed revisions make no substantive changes in the current regulations affecting “baby foods.”

In practical terms, this section of the regulations provides that if a food represented by the manufacturer for use by infants, specifically those less than 12 months of age, contains two or more ingredients, these shall be listed on the label. The label needs to indicate the specific plant or animal source of each ingredient and the common or usual name of each ingredient, including spices, flavorings, and colorings. This is important since typical “baby foods” may contain as many as 10 to 12 ingredients in addition to the principal one. They may combine a variety of additives, including flavoring agents, preservatives, antioxidants,

emulsifiers, nutrients, and special fat ingredients.

Special feeding problems are of common occurrence in pediatric practice. It is impossible for the physician to identify the cause of food idiosyncrasy unless he has knowledge of the specific nature of all food consumed. There can be no question, therefore, that physicians and parents have need for fully informative labeling of foods offered for infants and small children. The present and proposed labeling requirements provide this information.

The Committee is informed that the classification of “baby foods” as “Food for Special Dietary Uses” is a deterrent to the sale of these products in certain countries where this designation limits distribution to drug outlets rather than food stores. The Committee takes no position on this aspect of classification; it does strongly urge retention of a requirement for fully informative labeling to protect American infants.

The Committee on Nutrition of the American Academy of Pediatrics endorses without reservation the language and the intent of the current regulations 125.5 and the revision, 125.4(a) and (b).² The net effect of these regulations will be to maintain fully informative labeling of commercially prepared infant food to the end that knowledge of the food content by physician and parent will insure safety, health, and sound nutrition for the infant.

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Acknowledgment

The author wishes to thank Dr. Strother Walker for statistical advice and Dr. Henry K. Silver for reviewing the manuscript.

CORRECTION

An error was made in the Committee on Nutrition report in the November issue of *PEDIATRICS* (40:916, 1967). On page 919 the first sentence in the paragraph on iron should read:

The human infant will become deficient in iron if only the amount available in human milk, 0.2 mg per 100 kcal, is supplied during the first 12 months of life.

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Pediatrics 1967;40:916

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the World Wide Web at:

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