

STANDARDS AND INDICATIONS FOR INDUSTRIALLY PRODUCED INFANT FORMULAS

Some Principles

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In December 1973, an article was published in the Medical Tribune, written by the Medical Tribune science editor, entitled "Baby feeds—are the big companies doing enough?" Apart from the content of the article, the question seems important and reflects what many people in general, including politicians, journalists, etc., are thinking of today. To this question can be added another one: are the pediatricians, especially pediatricians working in the field of nutrition, doing enough? Certainly, a lot of important research in infant nutrition has been done—and is still being done—by industrial scientists, in addition to the research done by university scientists. As, however, industrially produced infant formulas are available to more and more babies in the world, the responsibility of baby food manufacturers as well as of the pediatricians is really great.

Codex Alimentarius Commission has designated a special committee¹ to work out some basic rules for infant formulas, especially with regard to composition of single nutrients and to quality factors. There remain, however, certain problems with respect to infant feeding with industrially produced infant formulas, where it probably will be difficult to arrive to any (official) statements by this

committee. Some of the problems are of practical importance and involve terminology and classification of infant formulas. Other problems concern food ingredients, which may be used in the production of such formulas. In addition the ethical aspects of sales promotion—a field of growing interest during recent years—will be commented upon in this article.

Terminology and Classification of Infant Formulas

General terminology. Terminology of the product is a question of practical importance, especially with respect to comparison between different products on a national as well as an international level. Still today—in spite of the work by the Codex Committee—many names are used for products designed for bottle feeding of infants such as "infant milks", "infant formulas", "milk dried preparations", "milk mixtures", "breast or mother's milk substitutes", etc. etc. Other more specific terms are "humanized" infant formulas, "adapted milks", etc.

It would according to my opinion be of great value (for the pediatricians, for the producers as well as for the consumers) if one could agree upon a term that is common for all kinds of bottle feeding products (primarily liquid or after reconstitution) and that could be trans-

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¹ Codex committee on foods for special dietary uses.

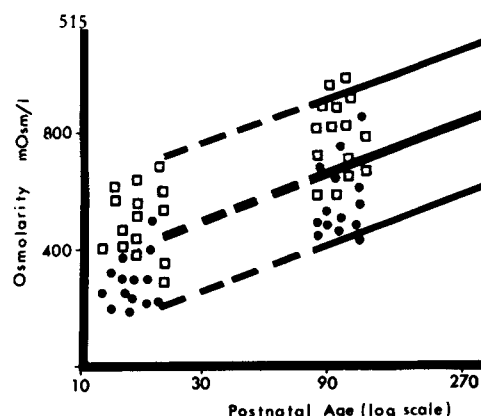


Fig. 1. Renal concentration capacity in early infancy. Symbols: \square , Fullterm; \bullet , Preterm infants. Regression lines (Mean \pm 2 S.D.) according to Winberg (*Acta Paediatr Scand*, 48: 318, 1959). From Svenningsen & Lindquist, 1971.

lated into most languages. For this purpose the term infant formula seems to be the most adequate (in German Formula-Diät für Säuglinge, in French Formule pour Nourissant, in Swedish Formulakost, etc.).¹

There exist in many countries today two types of infant formulas, so-called starting milks and follow-up milks, or better expressed: starting formulas and follow-up formulas. Starting formulas ("Anfangsnahrung") are intended to be used during the first 4–6 months of life. Consequently they should completely cover the nutritional requirements at this age as they are the only or main food of the infant. Follow-up formulas ("Dauernahrung") are used for the following months of infancy and they are intended to be used together with increasing amounts of different semisolid and solid foods: at this age—second part of infancy—ordinary cow's milk replaces more and

more (varying in different countries) the industrially produced formulas. As the follow-up formula is just a part of a mixed feeding scheme, the composition of follow-up formulas may vary according to feeding habits in different countries and in different parts of the world.² The manufacturers should be asked to indicate for each product which category applies.

The above-mentioned proposals about classification of infant formulas refer only to conventional infant formulas (designed for healthy babies) and not to so-called therapeutic formulas designed for treating babies with different disorders.

The term humanized (adapted) formula. The terminology used for that type of starting formula intended to be used especially during the immediate postnatal adaptation period—when different organ functions are less well developed—needs some specific comments. It is now well known that within the normal development of renal as well as of other important organ functions, there is a wide biologic variation in the rate of maturation. This is illustrated in Fig. 1 and Fig. 2, showing the renal concentration capacity and the renal acidifying capacity, respectively, in early life (15, 17). It seems thus not appropriate to refer to means when different organ functions are under consideration in relation to the metabolic load of a formula. The infants of interest in this connection are those on the *minus* side of the normal range.

Starting formulas which are developed for use especially during the immediate postnatal adaptation period are in certain countries called humanized infant formulas, in other countries adapted infant formulas. There seems to be a general agreement today that the term "humanized" is not a very good term. An infant formula can never be humanized. It should therefore be of great value if this term could be abandoned and replaced by the term adapted. For the same reasons the term fully adapted should be deleted because a formula can, of course, never be fully adapted.

¹ Cf. definition of formulated foods by AMA Council on Foods and Nutrition: Formulated foods are mixtures of two or more foodstuffs or ingredients, other than seasonings, processed or blended together (1).

² It may be noted that the 27th World Health assembly has in a resolution on infant nutrition and breast-feeding requested the Director-General to promote and further support activities related to the preparation and use of weaning foods based on local products (WHA 27/43, 23 May, 1974).

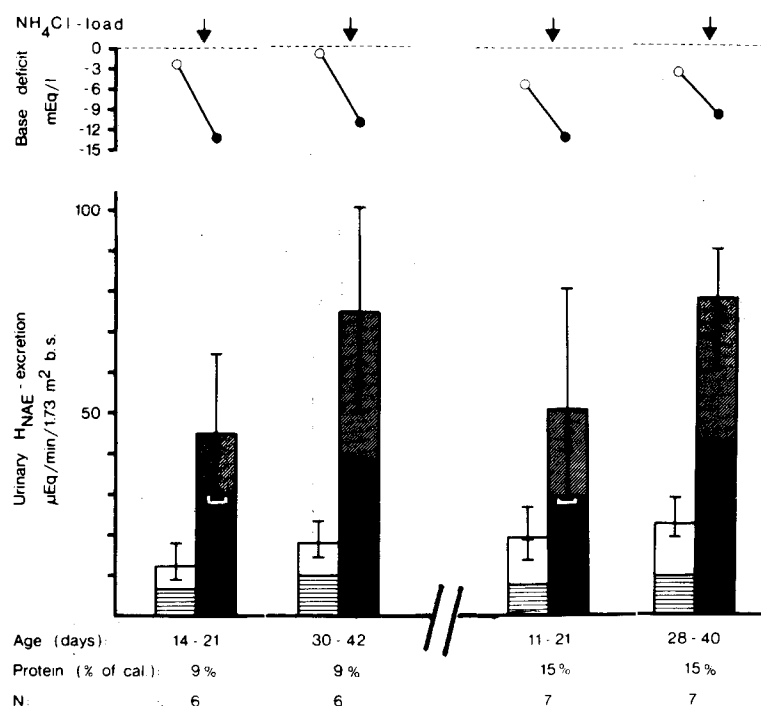


Fig. 2. Influence of protein intake on plasma deficit and urinary H⁺-excretion before and during induced acidosis in preterm infants at 1-3 weeks and 4-6 weeks, respectively, of postnatal life. Symbols: Preloading and maximum plasma base deficit (mean) ○—●, urinary H⁺NAE (mean and range) ▨ ▨, H⁺TA (mean) ▨ ▨ and H⁺NH₄⁺ (mean) ▨ ▨. Note: the low hydrogen excretion capacity during the first 2-3 weeks of life and the wide range of this capacity, notable also at 4-6 weeks of life. From Svenningsen & Lindquist, 1974.

Definition of adapted formulas. Today there is no internationally accepted definition of adapted (or humanized) formulas. The meaning of such a term may vary from country to country and from one manufacturer to another. It would therefore be of great value if from an international point of view one could agree upon a definition of the term adapted formula, i.e. which requirements should be fulfilled for an infant formula to be called adapted.

Generally speaking, an adapted formula should be similar in composition and appearance to human milk. Such a formula should thus not be permitted to contain starch (or flour). Acidification by addition of dl-acid should not be permitted and one wonders whether acidification should be permitted at all.

The adapted infant formula should fulfill certain requirements with respect to the concentration of different nutrients (protein, lipids, carbohydrates, minerals) and, furthermore, certain quality criteria should be fulfilled. Last year the Committee on Nutrition of

the German Pediatric Society has published its definition of an adapted formula (3) and this seems in most respects to be a sound base for further discussions of this matter.

Comments on Some Ingredients in Infant Formulas

As mentioned before, the Codex Committee has stated in the present draft, that infant formulas should meet the nutritional requirements of normal infants. Consequently, the draft contains recommendations about the content (minimum and sometimes maximum level) for the most important single nutrients, and also certain quality criteria. These considerations seem to have been mainly accepted by the pediatricians and therefore they don't need to be discussed here.

However, certain ingredients in infant formulas to cover the requirements of various single nutrients are still the subject of controversial interest. The use of such ingredients needs to be further discussed including development of sound recommendations.

Table 1. Main components and H^+ regulating processes in acid-base economy

Components	Processes
1. Acid/base potentials of the diet	Gastrointestinal acid/base absorption
2. Intestinal processes	
3. Tissue growth	
4. Intermediate metabolism	Endogenous H^+ -production
5. Variation in compartmental size	
6. Intercompartmental redistribution	Renal tubular HCO_3^- -reabsorption
7. Kidney function	Transcellular acid/base transport
	Net acid excretion

In an individual with a normal acid-base balance (NAB), the net acid input to the kidney (NAI), influenced by components 1-6, is equal to the net acid excretion from the kidney (NAE) influenced by component 7, or

$$NAB = NAI - NAE$$

From Lindquist & Svenningsen, 1973.

An infant formula should, of course, not contain any ingredient that during a special period of life could be harmful to the baby, e.g. gluten. The introduction of gluten was discussed by ESPGA¹ at a round table conference already in 1969 in Interlaken, and the conclusion was: no gluten before the age of 4 months (12).

Furthermore, infant formulas should not contain ingredients, even if they are harmless, if they have no meaning in infant nutrition. Such ingredients could mislead the consumer about the quality and the nutritional value of the product. This refers especially to starting formulas. An example of an ingredient that according to my opinion should be discussed in this respect is honey; so far no convincing evidence has been presented about the nutritional meaning of including honey in such formulas.

In discussing ingredients in infant formulas consideration should also be given to acidification of milk.

The disadvantages of acidified formulas have been discussed especially during recent years against the background of our present knowledge about the less well de-

veloped buffer capacity of the kidney during the first weeks of life. It is now known that lactic acid (l-form) as well as citric acid are normal metabolites of the body. The capacity of newborns to metabolize these acids is limited when given in great amounts. However, acidified formulas do not contain such acids in great amount in relation to the homeostatic capability of the young infant. Furthermore, it is quite clear that acidification of the formula is a minor factor as compared to other factors of the total acid-base economy of the body provided dl-forms are not used. Table 1 shows a survey of different factors operating in this economy (9). From Fig. 3 it is quite evident that the most important factor is surplus (excess) protein. This figure shows the incidence of late metabolic acidosis in relation to protein intake in early life; in preterm infants (appropriate for gestational age) this was found to be 10.3%, 24.5% and 37.5% at a protein intake of 2.4 g, 3.3 g and 5.7 g/kg/d, respectively (16).

Another drawback of acidification of infant formulas has been shown to be somewhat adverse influence on fat absorption (5), which in turn could lead to an adverse effect also on mineral absorption, especially calcium. It should, however, be noted that other factors probably are of greater importance with respect to fat absorption in young babies. In summary these are the fatty acid composition of the fat, the amount of fat fed and the triglyceride structure of the fat (19). The fat absorption is also to a great extent depending on the age (5) and the maturity of the infant; in prematures fed with cow's milk formula (impaired) fat absorption has been found to be correlated with low bile acid levels (14).

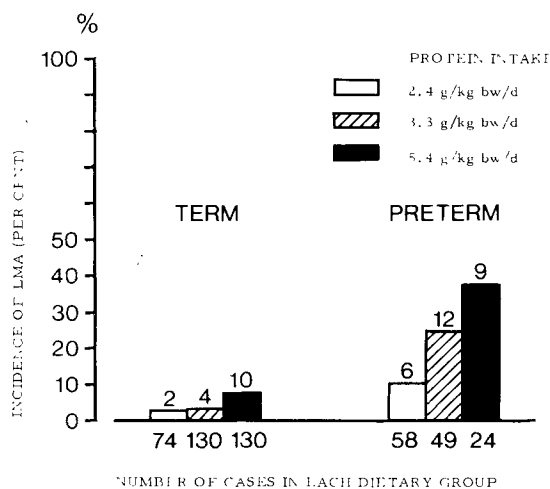


Fig. 3. Incidence of Late Metabolic Acidosis (LMA) during the first weeks of life in term and preterm infants in relation to protein intake. The figures below the columns give the total number in each group and figures above the numbers with LMA. An infant was considered to have LMA whenever a base excess value below -8.0 mEq/l was found and confirmed twice (after 24 and 48 hours). From Lindquist & Svenningsen, 1973.

¹ European Society for Pediatric Gastroenterology.

Adequate acidification of a formula with l-acid thus appears to be relatively harmless. The main indications for use of such formulas in feeding normal infants are in situations when good hygienic conditions and adequate storage conditions are not available (4), e.g. in certain geographic localities. It may be noted also that acidification of formulas increases the likelihood that such milk will be used for infant feeding rather than for general family consumption. In areas of the world where there is a general food shortage there is a danger that foods intended for infants may be consumed by other members of the family.

Composition of Infant Formulas with Respect to Future Health. Some Current Problems

The composition of infant formulas should also be looked upon with respect to future health of the baby. An example of a current problem is the addition of sucrose to infant formulas. This has not only bearing on the importance of keeping the mouth of the infant as free from sucrose as possible after the eruption of the teeth in order to reduce the development of caries. Furthermore, it is important not to accustom the children to a sweet taste; in this way the craving for snacks and other sugar containing products later on in life could perhaps be prevented. In addition it has been questioned whether an excessive intake of carbohydrates could not provoke an increased insulin production which might become permanent (13).

Another similar example concerns the relationship between infant diet and the development of atherosclerosis, a problem that during recent years has been the subject of growing interest (for references, see 8, 11).

Our knowledge so far about this relationship does not seem to argue for a marked change in the fat composition of infant formulas. The main reason for this is the generally good experience of nutrition of infants (not breastfed) according to present principles. Minor modifications of the fatty acid composition can, however, not be regarded as unjustifiable, provided they are based on valid experi-

mental studies and do not imply any harm to the baby. Such a modification that has been discussed is a reduction to very low values of lauric and myristic acids as these fatty acids have in animal studies been shown to be strongly atherogenic (10, 20). The same fatty acids have also been shown to be most potent in raising the serum cholesterol level in the human being (2, 7). Another possible modification is a moderate increase of linoleic acid (e.g. to 6% of total calories, i.e. to the same value as is found in the breastmilk of mothers whose diet is rich in polyunsaturated fat); together these two changes will have a slightly depressing effect on the serum cholesterol level (6).

Although thus minor modifications could be discussed with respect to the relationship between infant (and childhood) diet and the development of atherosclerosis later on in life certainly much more research remains to be done before we are ready for general statements on this point.

Enrichment of Infant Formulas

Generally speaking, one could say that if there is a possibility to prevent deficiency disorders in infants through enrichment of infant formulas, this possibility should be considered. In practice, however, enrichment involves often not only nutritional but also technological problems (e.g. influence on keeping quality). Enrichment of infant formulas is thus an example of a field where a research cooperation between university and industry scientists is desirable.

Ethical Aspects on Sales Promotion

During recent years the ethics of sales promotion have in many countries come under lively discussion, especially with respect to possible conflicts vis-à-vis the propaganda for breastfeeding. It is true, that most infant formula producers say in their advertising today that human milk is best for the baby. It is, however, important that the producers in their sales promotion behave in such a way that this statement will have a real meaning and not appear to be hypocrisy. It would be of great advantage if one could agree upon certain basic ethical rules. These rules should protect

the mothers against unduly persuasive advertising for formula products, especially starting formulas.

The rules clearly need to be more strict in the third world (the preindustrialized countries) than in economically advanced countries. In the former countries any kind of advertising that could give the mother the impression that an infant formula is as good for the baby as her breast milk must be avoided. This applies above all to starting formulas. Very often the mothers cannot afford to continue—when once started—to feed their babies formula products as instructed by the manufacturers. They then dilute the formula products too much, which means that the babies are not given calories and essential nutrients in sufficient amounts, leading to malnutrition. Furthermore, bottle feeding under defective hygienic circumstances often leads to diarrhoea, which in turn contributes to the development of malnutrition. The Protein Advisory Group of the United Nations System also emphasizes the critical importance of breastfeeding under the sociocultural and economic conditions, which prevail in many developing countries (18).

The following proposals are made:

1. Preferably only adapted formulas should be recommended during the first month(s) of life. Beside fulfilling certain nutritional requirement it is desirable that such formulas have an appearance and a consistency resembling human milk. If they contain starch (or "Schleim" or gum preparations) they will have a thicker consistency, which makes the mother believe that such a formula gives a better satiety feeling than breast milk. When the babies cry—which they often do—the mothers believe that this depends on hunger. She is then tempted to buy such a formula, believing that this will be better for her baby.

2. The term "humanized" should be abandoned and replaced with adapted.

3. Advertising about starting formulas should preferably be directed to professional personnel: doctors, nurses, dietitians, nutri-

tionists, etc. rather than to the consumers (or more correctly expressed, to their mothers).

4. For reasons of hygiene and expense referred to above advertising must especially be restricted in developing countries.

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