Infant & Young Child Feeding n Nutrition in Perspective 透視嬰幼兒餵哺與營養

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# The New European Union Regulations on Compositional, Labelling and Marketing of Breastmilk Substitutes: Lowering the Maximum Protein Level

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Breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants<sup>1</sup> . For babies who cannot breastfeed, infant formula is the only alternative to breastmilk in providing the sole source of nutrition in the first few months, before the introduction of complementary food. Standard infant formula is essentially cow milk-based (or goat



milk-based) and manufactured with reference to the nutritional content of breastmilk. Manufacturers have to adhere to international or national compositional standards for infant formula, e.g. Codex standards<sup>2</sup>, European Union (EU) standards.

In the light of the latest scientific evidence, EU revised its regulations on the composition, labelling and marketing of breastmilk substitutes in 2016, which will come into force in February 2020<sup>3</sup>. It asserts that "the essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data". The new regulations are devised based on the Scientific Opinion on the Essential Composition of Infant and Follow-on Formulae issued by the expert panel of the European Food Safety Authority (EFSA) in 2014<sup>4</sup>. Among other changes, the new regulations will lower the permitted maximum protein level of infant formula (IF)<sup>a</sup>, i.e. stage 1 formula, and follow-on formula (FF)<sup>b</sup>, i.e. stage 2 formula. This article discusses the changes in IF and FF based on intact cow or goat milk-based protein and the scientific rationales.

#### Note:

a. Infant formula is a food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding.b. Follow-on formula is a food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants.

#### Human Milk Protein versus Infant Formula Protein

Human breast milk has a very low protein content (mature milk: 0.9 g/100ml) compared to other animals' milk (e.g. cow:3.4g/100ml; rats:12 g/100ml)<sup>5</sup> . Yet, its proteins are of high quality and their utilization is efficient. Breast milk proteins change continuously to suit the infant's circumstances. A meta-analysis of breastmilk protein content of mothers who delivered term babies showed mean levels of 1.8 g/100 ml, 1.3 g/100ml and 0.9 g/100 ml during the 1<sup>st</sup>, 2<sup>nd</sup>, and 10–12<sup>th</sup> postnatal weeks respectively<sup>6</sup>. Colostrum (the first milk) has higher protein content than mature milk due to its high concentration of non-digestible protective proteins, viz. secretory IgA, lactoferrin and lysozyme, which constitute a proportion of the whey protein. The easily digestible nutritional protein, alpha-lactalbumin, makes up a major whey fraction.<sup>7</sup>

In addition, human milk has high levels of non-protein nitrogen (NPN), such as free amino acids (e.g. taurine), peptides and nucleotides. While newborns have very limited capacity to synthesise taurine and nucleotides, they are essential for optimal growth. Taurine enhances fat absorption, visual development and liver functions. Nucleotides act as precursors of DNA, RNA and co-enzymes involved in protein synthesis and bioactive metabolic regulators in a wide range of physiological processes<sup>8</sup>.

Infant formula is a product of fixed composition. Its protein content, in terms of quality and quantity, can by no means replicate that of human milk.

# Latest Evidence on Infant Formula Protein:

#### <u>Maximum Protein Intake</u>

Accumulating evidence suggested that high protein intake in infancy was associated with increased growth. In a multi-centre European randomised controlled trial (RCT), infants were randomly assigned to feed on cow milk-based IF and FF with low protein content (IF: 1.77 g /100 kcal; FF: 2.2 g /100 kcal) or those with high protein content (IF: 2.99 g /100 kcal; FF: 4.4g /100 kcal) in the first year. They were followed up for growth. At 24 months of age, the weight-for-length z score of infants in the lower protein group was 0.20 (95% CI: 0.06,0.34) lower than that of the higher protein group and did not differ from the breastfed reference group<sup>9</sup>. Subsequently, a systematic review concluded that higher protein intake in infancy and early childhood was associated with increased growth/body mass index (BMI) in childhood<sup>10</sup>.



Despite the above, the ESFA Expert Panel considered the role of protein in the reported increased growth rate and higher BMI in childhood still controversial and more research would be required. On the other hand, it found no scientific evidence of a physiological need for protein intakes at 3 g/100 kcal (the current EU's permitted maximum

protein level for IF) in infancy. Furthermore, a review showed the current protein intakes of European infants were generally well above the requirements<sup>4</sup>.

#### Minimum Protein Intake to Ensure Growth and Development

The protein content of infant formula should ensure adequate growth and development of healthy infants. The Expert Panel reviewed a number of studies which examined the safety and suitability of IF based on intact cow's milk protein with protein contents of 1.8 – 1.9 g/100 kcal. For example, the study described above found no statistically significant difference in weight-for-length and BMI at 24 months between the group of infants fed low protein formulae (IF: 1.77 g /100 kcal; FF: 2.2 g /100 kcal) in the first year and the breastfed reference groups<sup>9</sup>. Based on the available evidence, the Panel regarded a minimum protein intake of 1.8 g/100 kcal from IF and FF (containing intact milk protein) as adequate to ensure infant growth and development.

## **Changes to the EU Regulations<sup>3</sup>:**

In the new regulations, the requirements for energy, amounts for fat and carbohydrate will not differ significantly from those in the current regulations. Regarding proteins, cow's milk, goat's milk and isolated soy protein are considered safe and suitable protein sources for use in IF and FF containing intact protein. However, the safety and suitability of each specific IF or FF containing protein hydrolysates will need to be established by clinical evaluation in the target population before use. The permitted maximum protein level will be reduced from the current 3 g/100 kcal for IF and 3.5 g/100 kcal for FF to 2.5 g/100 kcal for both IF and FF based on cow's milk and goat's milk protein.

Under the new regulations, EU maintains that "nutrition and health claims are promotional tools that are used by companies in commercial communications". Given the unique role of infant formula in infant diet, the use of nutrition and health claims for infant formula will be prohibited.

	Current		New	
	EU regulation		EU regulation	
	Minimum	Maximum	Minimum	Maximum
	(g/100kcal)	(g/100kcal)	(g/100kcal)	(g/100kcal)
Infant formula	1.8	3.0	1.8	2.5
Follow-on formula	1.8	3.5	1.8	2.5

#### **Local Scene**

In Hong Kong, the requirements on nutritional composition and nutrition labelling of infant formulae came into effect in December 2015. All locally marketed infant formulae must fulfill a set of nutritional composition requirements. All formulae marketed for infants and young children under 3 years old must provide a nutrition label accordingly. Under the local regulation, the permitted protein content of infant formula is 1.8 to 3 g/100kcal, according to the Codex standards<sup>11</sup>.

# **Practical Tips for Parents:**

With its unique composition of nutrients, breastmilk provides the optimal nutrition to support growth and development of infants. Parents are encouraged to pursue their breastfeeding goals with support from health professionals, significant others and the community at large.

For babies who cannot breastfeed, IF (Stage 1 formula) is the only alternative for the first 6 months. While it is advisable for 6 to 12-month-old babies to continue with IF (Stage 1 formula), some parents may choose to switch to FF (Stage 2 formula) after 6 months. Nonetheless, from the nutritional perspective, there is currently inadequate scientific evidence to suggest a need for Stage 2 formula.<sup>12</sup> Besides, before the new EU regulations become fully effective and other national / international standards follow suit, FF generally has higher protein level compared to IF. With the accumulating evidence suggesting the association between high protein intake in infancy and increased growth / BMI, parents are encouraged to continue breastfeeding or Stage 1 formula while giving their child adequate complementary food after 6 months.

#### Key messages:

• Human milk's proteins are of high quality and their utilization is efficient. It contains easily digestible proteins and high levels of non-protein nitrogen, such as taurine and nucleotides. Infant formula can by no means replicate the composition of human milk.

母乳含優質和高使用效率的蛋白質;它包含容易消化的蛋白質及高含量的非蛋白質氮如牛磺酸和 核苷酸。嬰兒配方奶絕不能完全複製母乳的天然成分。

- Infant formulae's composition should be safe and suitable to meet the nutritional requirements and promote the growth and development.
  嬰兒配方奶粉的成分必須恰當及符合安全,以滿足嬰兒的營養需求和促進成長發展。
- In the light of the latest scientific evidence, the new EU regulations has revised the essential composition of infant formula and follow-on formula including the following:
  - The permitted maximum protein level will be reduced for formulae based on cow's milk or goat's milk protein (intact protein). The experts consider that there is no evidence of a physiological need for such high protein intakes and the protein intakes of their infants are well above the requirements.
  - > The use of nutrition and health claims for infant formula will be prohibited.

根據最新的科學證據·新的歐盟法規已修訂有關嬰兒配方奶和較大嬰兒配方奶的基本成分要求· 當中包括:

降低由牛奶或羊奶蛋白提煉的嬰兒配方奶的最高蛋白質含量。專家認為現時沒有科學證據支持嬰兒需要有如此高的蛋白質攝入量,而且調查顯示當地嬰兒的蛋白質攝入量遠超過所需。
 禁止將營養和健康聲稱用於嬰兒配方奶。

## **Further Reading:**

- ✓ First Steps Nutrition Trust. Statement on "Changes to the compositional, labelling and marketing regulations for breastmilk substitutes that come into force in February 2020". Issued in Nov 2019. Link: <u>https://www.firststepsnutrition.org/statements</u>
- ✓ Press release on "EFSA updates advice on infant and follow-on formulae". Issued by EFSA on 24 July 2014. Link: <u>https://www.efsa.europa.eu/en/press/news/140724</u>
- ✓ Factsheet for parents "Recommendation on Formula Milk Feeding for Young Children". Family Health Service, Department of Health, HKSAR. Link: <u>http://s.fhs.gov.hk/g3kj3</u>

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Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3664059/pdf/FNR-57-21083.pdf

- 11. Pamphlet on Nutritional Composition and Nutrition Labelling of Infant Formula. Centre for Food Safety. Link: <u>https://www.cfs.gov.hk/english/food\_leg/food\_leg\_Formula\_Products\_for\_Infants.html</u>
- 12. Factsheet for parents "Recommendation on Formula Milk Feeding for Young Children". Family Health Service, Department of Health, HKSAR.

Link: http://s.fhs.gov.hk/g3kj3

Views expressed in this article are the author's and do not necessarily reflect the opinion or position of the BFHIHKA.

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