

CONSIDERATION OF THE PLACE OF “GOOD NIGHT” MILK PRODUCTS IN THE DIET OF INFANTS AGED 6 MONTHS AND ABOVE

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1. The Scientific Advisory Committee on Nutrition (SACN) Subgroup on Maternal and Child Nutrition (SMCN) was asked by the Department of Health to advise on the risks associated with the use of “Good Night” milk products for infants six months of age and above. The advice was sought in response to enquiries raised by health professionals and other non-governmental organisations about the use of these products and their potential impact on infant nutrition and health.
2. The Committee considered the place of these products in the diet of infants, identifying any potential risks or benefits associated with their use.

Background

3. Government policy in the UK has consistently supported breastfeeding as important in the promotion of maternal and infant health. The Department of Health currently recommends exclusive breastfeeding for the first six months of an infant’s life, with continued breastfeeding thereafter alongside appropriate complementary foods.¹ Infant formula is the only alternative to breastmilk considered suitable for infants younger than one year of age. Follow-on formula can be given from six months of age, but there is no nutritional justification for this change². The composition, marketing and labelling of infant formula and follow-on formula is regulated by European Directive and United Kingdom Statute. The composition and labelling of cereal-based processed weaning foods is similarly regulated.
4. Under the International Code of Marketing of Breastmilk Substitutes, a breastmilk substitute is defined as “*any food being marketed or otherwise presented as a partial or total replacement for breastmilk, whether or not suitable for that purpose*”.³ The definition is therefore based on the

¹ Department of Health (2003b) ‘*Infant Feeding Recommendation*’
http://www.breastfeeding.nhs.uk/en/docs/FINAL_QA.pdf

² Department of Health (2002) Scientific Review of the Welfare Food Scheme. No.51. London, TSO

³ Shubber, S. (1998) The International Code of Marketing of Breast-milk Substitutes. Nijhoff Law Specials, Volume 40. Kluwer Law International.

manufacturer's suggested use of the product rather than its composition. It does not specify an upper limit to infant age.

5. On the basis of this definition, formulas and liquid complementary foods specifically marketed as suitable for the feeding of infants and young children who could otherwise be breastfed are considered as breastmilk substitutes.⁴⁵
6. Infant formula manufacturers Cow & Gate and HiPP Organic have both recently introduced products described as "Good Night" milks. The products are represented as helping to settle babies at bedtime and are marketed for use as a bedtime liquid feed from a bottle or feeding cup.

HiPP Organic's Good Night Milk Drink

7. HiPP Organic's Good Night Milk Drink is described on the package as a "*milk based meal of organic Follow-on milk with added organic cereals*". The product differs from typical infant formulas and follow-on formulas in that it has added ingredients (pre-gelatinised rice flour, whole-grain oatmeal and organic corn starch), which makes the drink more viscous than other formula milks (see Annex 1 for a full list of ingredients). The Follow-on Formula Regulations do not specify an amount of added starch, but it is not a prohibited ingredient. HiPP Organic's product is also labelled as containing gluten.
8. Annex 2 shows that the nutrient density of this product broadly mirrors that of follow-on formula. However, the product has a higher energy density (76 kcal per 100ml) and slightly lower vitamin C content (2.13mg per 100 kJ) than that specified by the Infant Formula and Follow on Formula Regulations. The company states, on their website, that their product "*meets the nutritional and legal criteria for cereal based weaning foods. It is made with 25% cereals and 75% follow-on milk*".
9. The company also makes statements about the product, which could be interpreted as claims. For example, the following claims are made on the product packaging, and/or on the company's website:

"...to help soothe and settle babies at the end of the day, in readiness of a good night's sleep..."

"It is also gentler and easier for tiny tummies to digest than cow's milk!" (HiPP Organic)

Cow and Gate's Good Night Milk

10. Cow & Gate's Good Night Milk is marketed as a "*thicker specially formulated follow-on formula*". As with HiPP Organic's product, Cow and Gate Good Night

⁴ Shubber, S. (1998) The International Code of Marketing of Breast-milk Substitutes. Nijhoff Law Specials, Volume 40. Kluwer Law International.

⁵ WHO (2008) The International Code of Marketing of Breast-milk Substitutes: Frequently asked questions. Updated version 2008.

Milk also has added ingredients (galacto-oligosaccharides, polyfructose, rice flakes and potato starch), making the drink more viscous than other formula milks (see Annex 1). Cow and Gate's product is labelled as gluten-free.

11. Again, the nutrient density of this product broadly mirrors that of follow-on formula (Annex 2), although the product has a slightly lower thiamin content (13.6µg per 100 kJ) than that specified by the Commission Directive 2006/141/EC on Infant Formula and Follow-on Formula (Annex 2).
12. Cow & Gate make the following statements about the product which could be interpreted as claims:

"Help settle your baby at bedtime"

"...thicker than regular follow-on milk and gentle on your baby's tummy"

SACN's assessment of the products

13. Regardless of the compositional differences described above, both products are labelled "Good Night" milk. They are marketed for identical purpose and either could replace breastmilk as the infant's last feed before sleep.
14. The Committee's view, therefore, is that both products are breastmilk substitutes. Continued breastfeeding as part of a diversified diet is recommended beyond six months. Either product could be used inappropriately to replace breastmilk, thus undermining continued breastfeeding. The risks associated with *not* breastfeeding are well established. In this context, the Committee noted that the Cow & Gate product carries an "Important Notice" as do other follow-on formulas.
15. The Committee has not identified published evidence that the use of any follow-on formula offers any nutritional or health advantage over the use of infant formula among infants artificially fed. Moreover it has not identified any scientific evidence that either "Good Night" milk product offers advantage over the use of currently available follow-on formula or infant formula. Specifically the Committee are unaware of published scientific evidence to support the statements made about "*settling the baby for the night*", or being "*gentler on the baby's tummy*".
16. The Committee is concerned that such statements encourage parents to believe that it is desirable for a baby to sleep longer at an age when healthy infants show considerable variation in normal sleeping behaviour. There is also a risk that mothers may consider the product suitable for "settling" their infant more than once a day and use these products on occasions additional to bedtime, or even use them to "settle" infants younger than six months. With regard to HiPP Organic's product, such unintended use would be contrary to advice that gluten-containing products should not be given to infants under six months of age.⁶

⁶ Department of Health (2008) '*Weaning: Starting on solid food*' http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4117080

17. Another concern is that the products could encourage parents to put their baby to bed immediately after bottle-feeding. This would result in prolonged tooth exposure to a feed rich in carbohydrates leading to the development of nursing bottle caries. The Committee recognises that both companies advise cleaning the baby's teeth after the last feed at night though such practice would appear at variance with the "settling" routine suggested on Cow & Gate's product.
18. HiPP Organic Good Night Milk Drink is described by the manufacturer as a complementary food. This creates a risk that mothers might use the product to replace more energy dense foods during weaning, thus threatening the normal process of dietary diversification.
19. The Committee noted that HiPP Organic's product states it to be "*suitable from 6 months to 3 years of age, as an alternative to the evening Follow-on milk feed or meal*". It does not consider the product suitable as a meal replacement for young children.
20. The manufacturer of HiPP Organic recommends that the product is reconstituted using procedures, which differ from those used to prepare infant formula and follow-on formula. The 2005 Infant Feeding Survey⁷ showed that a high proportion of mothers do not follow the recommended procedures when preparing formula⁸. The introduction of new methods seems likely to confuse parents further and create additional risk.

Conclusions

21. The Committee is concerned that the claims made could undermine breastfeeding, as either product could replace or displace the night-time breastfeed. In light of the current recommendations to continue breastfeeding beyond six months, the Committee considers both products to be breastmilk substitutes, which should be labelled and marketed appropriately.
22. The Committee was unable to identify any published scientific evidence to support a claim that "Good Night" milks offer nutritional or other health advantage over the use of infant formula or follow-on formula.
23. The Committee is concerned that the use of these products to "settle" babies at night could promote poor dental hygiene.
24. The Committee does not agree with HiPP Organic's statement that its product is suitable for young children as an alternative to the evening meal.

⁷ Bolling K, Grant C, Hamlyn B, Thornton A. (2007) Infant Feeding Survey 2005. The Information Centre

⁸ Department of Health 'Bottle Feeding' leaflet (2007)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4123619

Annex 1 – Product Ingredients

The ingredients lists for both products are given below:

a) HiPP Organic ‘Good Night Milk Drink’

Ingredients: Organic Follow-on milk (75%) [organic skimmed milk powder, organic lactose, organic vegetable oils (palm, rapeseed, sunflower), organic corn starch, calcium phosphate, calcium carbonate, vitamin mix (vitamin C, vitamin E, vitamin A, vitamin D), iron diphosphate, zinc oxide, potassium iodate], organic pregelatinised rice flour (13%), organic whole-grain oatmeal (13%), emulsifier (soya lecithin), thiamin (vitamin B1)

b) Cow & Gate ‘Good Night Milk’

Ingredients: Lactose*, Skimmed Milk*, Vegetable Oils, Prebiotic Fibres (Galacto-Oligosaccharides*, Polyfructose), Rice Flakes, Potato Starch, Calcium Carbonate, Vitamin C, Magnesium Citrate, Emulsifier (Soya Lecithin), Taurine, Choline Chloride, Iron Sulphate, Zinc Sulphate, Cytidine 5'-Monophosphate, Adenosine 5'-Monophosphate, Uridine 5'-Monophosphate, Inosine 5'-Monophosphate, Vitamin E, Niacin, Guanosine 5'-Monophosphate, Folic Acid, Copper Sulphate, Pantothenic Acid, Vitamin A, Vitamin D, Beta-Carotene, Biotin, Vitamin B12, Vitamin B6, Thiamin, Manganese Sulphate, Potassium Iodide, Vitamin K, Sodium Selenite, Contains: *Milk, Soya

Main ingredients that contribute to carbohydrate content in infant formula, follow-on formula and “Good Night” milk products					
HiPP Organic			Cow & Gate		
Infant Formula*	Follow-on Formula**	“Good Night” product***	Infant Formula^	Follow-on Formula^^	“Good Night” product^^^
Organic lactose	Organic lactose	Organic Lactose	Lactose	Lactose	Lactose
		Organic Corn Starch	Dietary fibres (galacto-oligosaccharides, polyfructose)	Prebiotic fibres (galacto-oligosaccharides, polyfructose)	Prebiotic fibres (galacto-oligosaccharides, polyfructose)
		Organic pre-gelatinised rice flour		Glucose syrup	Rice flakes
		Organic wholegrain oatmeal			Potato starch

* HiPP Organic “Infant Milk”

** HiPP Organic “Follow-on Milk”

*** HiPP Organic “Good Night Milk Drink”

^ Cow & Gate “Complete Care: First Infant Milk from newborn”

^^ Cow & Gate “Complete Care: Follow-on Milk for babies from six months”

^^^ Cow & Gate “Good Night Milk”

Annex 2 - Nutritional Information

Values below are given per 100 kJ for each product, and compared to the essential composition for follow-on formula* (Directive 2006/141/EC) and weaning foods** (Directive 2006/125/EC).

Value	Essential composition of Follow-on Formula* (per 100kJ)		HiPP Organic 'Good Night Milk Drink' (per 100kJ)	Cow & Gate 'Good Night Milk' (per 100kJ)	Essential composition of processed cereal-based foods** [see note below] (per 100kJ)
	Min	Max			
Energy (per 100ml)	250 kJ 60 kcal	295 kJ 70 kcal	320 kJ 76 kcal	295 kJ 70 kcal	
Protein	0.45 g	0.8 g	0.63 g	0.61 g	Protein content: max 1.3g Added protein: min 0.48g
Total Carbohydrate of which:	2.2 g	3.4 g	2.97 g	3.05 g	If sucrose, fructose, glucose syrups or honey are added the max amount of added CHO from these sources: 1.2g Added fructose: max 0.6g
sugars (lactose)	1.1 g	-	1.94 g	2.37 g	
Total Fat Of which:	0.96 g	1.4 g	1.03 g	1.02 g	Max fat content: 1.1g
saturates	-	-	0.31 g	0.44 g	
Fibre	-	-	0.06 g	0.27 g	
Sodium	5 mg	14 mg	6.25 mg	6.78 mg	Max: 25mg
Vitamin A	14 µg (RE)	43 µg (RE)	22.5 µg (RE)	20.0 µg (RE)	14 – 43 µg (RE)
Vitamin D	0.25 µg	0.75 µg	0.31 µg	0.47 µg	0.25 – 0.75 µg
Vitamin E	0.1 mg	-	0.22 mg	0.26 mg	Max: 0.73mg
Vitamin C	2.5 mg	7.5 mg	2.13 mg	2.71 mg	Max: 6.09mg
Thiamin (vit B1)	14 µg	72 µg	31.3 µg	13.6 µg	Min: 25 µg
Calcium	12 mg	33 mg	25.3 mg	25.8 mg	Min: 20mg
Phosphorus	6 mg	22 mg	21.9 mg	15.6 mg	-

Value	Essential composition of Follow-on Formula* (per 100kJ)		HiPP Organic 'Good Night Milk Drink' (per 100kJ)	Cow & Gate 'Good Night Milk' (per 100kJ)	Essential composition of processed cereal-based foods** [see note below] (per 100kJ)
	Min	Max			
Iron	0.14 mg	0.5 mg	0.34 mg	0.37 mg	Max: 0.73mg
Zinc	0.12 mg	0.36 mg	0.16 mg	0.24 mg	Max: 0.49mg
Iodine	2.5 µg	12 µg	3.44 µg	3.73 µg	Max: 8.5 µg
Potassium	15 mg	38 mg	24.1 mg	27.5 mg	Max: 39 mg (applies to product as sold)

* Commission Directive 2006/141/EC on Infant Formula and Follow-on Formula

** Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children

Note: Compositional requirements given are for that category of processed cereal-based foods referred to in Article 1(2)(a)(ii) of Directive 2006/125/EC as “cereals with an added high protein food which are or have to be reconstituted with water of other protein free liquid”.

Note also that Annex 1 to Directive 2006/125/EC requires that, for processed cereal based foods, the amount of cereal and/or starchy root shall not be less than 25% of the final mixture on a dry weight for weight basis.

Figures provided per 100kJ. This relates to product ready for use, marketed as such or reconstituted as instructed by the manufacturer.