# Response to Request for Information on infant and follow on formula: Department of Health, August 2014

### 1. Mandatory ingredients

a) We do believe it to be appropriate for the EU to follow EFSA's recommendations regarding the composition of formulas. If it is considered that DHA is essential and safe then it should be a mandatory ingredient in specified amounts, provided such an addition reduces existing risks associated with artificial feeding and provided consumers are fully warned of risks on the label and any materials relating to the product.

However, we would welcome information about what systematic monitoring is in place to collect and analyze information on effects of formulas containing DHA.[1] Without such post market monitoring we cannot see how EFSA can conclude that there are no subsets of babies who cannot tolerate them. In the USA, where DHA enriched formulas have been widely marketed for a much longer time, and where products are not pre-approved by the FDA before being placed on the market,[2] 98 reports to the US Food and Drug Administration (FDA)[3] of adverse reactions only came to light following a Freedom of Information request. There are also indications that there may be unwelcome long term effects.[4] [5]

It is the opinion of Baby Milk Action, the Baby Feeding Law Group and IBFAN that all approved pre-authorised ingredients should be mandatory. It would be unethical to do otherwise. As the UK Government's Scientific Advisory Committee on Nutrition (SACN) said:

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[1] Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

[2] http://www.fda.gov/food/foodborneillnesscontaminants/peopleatrisk/ucm108079.htm#15

[3] *Replacing mother - Imitating Breast Milk in the Laboratory.* www.cornucopia.org FDA Q&A: www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/ConsumerInformationAboutInfantFormula/ucm108079.htm
FDA letter regarding the lack of post-market surveillance: http://info.babymilkaction.org/sites/info.babymilkaction.org/files/FDA Post market.pdf
Mead Johnson and Martek stop using DHA claims in the USA and Canada http://info.babymilkaction.org/news/policyblog/USA
*FDA Finalizes Rule Prohibiting Certain Nutrient Content Claims for DHA, EPA, and ALA Omega-3 Fatty Acids*
http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm394855.htm

[4] *The 10-year follow-up of a randomised trial of longchain polyunsaturated fatty acid supplementation in preterm infants: effects on growth and blood pressure. Arch Dis Child 2010;95:588–595. 588 doi:10.1136/adc.2009.167270* with responses http://adc.bmj.com/content/95/8/588/reply#archdischild_el_8934

[5] http://info.babymilkaction.org/news/policyblog/dhabriefing

*"There is no case for allowing the 'advertising' of follow-on formula... there is no scientific evidence demonstrating nutritional advantage of this product over infant formula...[both these] are breast milk substitutes as defined by the Code (which sets no upper infant age limit on this term)...We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods."*[6]

Aside from the fact that claims are inappropriate and misleading for all formulas and baby foods (in that they imply a health advantage over breastfeeding and family foods when there is none) if ingredients are common to all products there is no legal basis for a promotional claim.

2. Optional ingredients and claims on these ingredients

**The precautionary principle must be paramount in any decision related to products for infants and young children – not market driven innovation.** It is also critically important to recall the horizontal duty set out in the Lisbon Treaty that: "*A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."*

The notion that manufacturers should be allowed to add ingredients to products on the market before they have been proven to be safe and essential allows them to use babies in a mass uncontrolled trial for commercial purposes. This is extremely risky and should not be allowed.

Manufacturers should not add ingredients to formulas unless they have been given prior authorisation, that is based on carefully monitored, independently- funded research and analysis that meets the highest ethical criteria.

The potential for bias is present in all research. However, it is reduced if research is commissioned and funded by a disinterested party rather than one active in the market. Research carried out on babies - and babies under 12 weeks in particular - is fraught with ethical problems. Infants are an especially vulnerable group that do not consent on their own behalf so need special protection. Commercial involvement in such research also opens the door for coercion and inappropriate presentation of the risks. [8]

[6] http://www.sacn.gov.uk/pdfs/position_statement_2007_09_24.pdf

1. **A clear distinction should be made between research on adults and research on infants.**
2. **There should be no coercion to participate in the trial.**
3. The request for participation should be done by an independent person.
4. **The provision of free products through any trial should be considered an inducement for parents** to enrol their infants, especially parents living on a low income.

Problems are compounded by publication bias where trials with negative outcomes are less likely to be published. Public health policy, especially in the area of infant and young child feeding, should be predominantly informed by independent, publicly financed studies that are in the public domain and subjected to a rigorous peer review process.

We support EFSA's observation that adding unnecessary ingredients to formula puts an unnecessary burden on the delicate metabolism of infants is an important one.

1) b should be the preferred option, allowing all ingredients to be agreed through independent scrutiny and harmonised across the EU.

2) It is the view of the BFLG and IBFAN that nutrition claims should not be allowed for any foods for infants and young children. Currently manufacturers make many promotional, idealising and misleading claims about their products on websites and media advertising aimed at both the public and health professionals.

**SMA** for example is currently highlighting how its 90 years of experience in making infant formula has introduced many of these ingredients, still making claims about efficacy for many of them.[9]

**SMA** make extravagant claims for its **Comfort Milk** for an ingredient now reported by EFSA to have no efficacy:

*'One recent study has shown that average daily crying time was reduced from 23.6 minutes when infants were fed a non-SN-2 enriched formula to 3.8 minutes a day when fed an SN-2 enriched formula'.*

**Aptamil** makes a series of claims for *prebiotics* and arachidonic acid in its first infant milk on its health professional website in an article by dietitian Luise Marino [10] and still make claims for a range of health benefits of prebiotics in first infant formula.[11]

In its '*formula comparison chart'* Aptamil includes prebiotics, taurine, arachidonic acid and nucleotides in its list of 'ingredients' for comparison, suggesting that their presence in breast milk and formula milk is 'equivalent'.[12]

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5. **If a randomized control method is used, then this must be justified** and parents must fully understand the methodology of the research.
6. **Parents must be provided with the fullest possible information which** include the short and long-term risks .
7. Parents must not be recruited before birth. Decisions about baby feeding may alter after birth.
8. Parents must not be under any pressure to use or continue to use a formula milk because they are in a research study.
9. Long term follow up to assess any untoward effects is essential

[9] https://www.smamums.co.uk/home/90-years-experience-181.aspx

[10] https://www.aptamilprofessional.co.uk/breastfeeding/articles/article/specific-prebiotics-reduce-atopic-dermatitis

[11] https://www.aptamilprofessional.co.uk/our-products/baby-0-6-months/aptamil-first-milk

[12] https://www.aptamilprofessional.co.uk/pdf/Aptamil-milk-comparison-chart-June13201306171226.pdf

We recommend that the all promotional claims of foods for infants and young children will be reviewed on the basis of the EFSA review and outlawed. Nutrition and health claims for optional ingredients are routinely used by manufacturers to suggest their products have advantages that make them *'closer to breast milk.'* Such claims are misleading.

Health professionals in particular are often confused by the conflicting information they receive and unaware that there are no procedures for holding manufacturers to account for misleading information in professional journals. It is essential that all information for HCPs objective, accurate and expert. The halting of promotional claims is an essential safeguard.

**3. Protein hydrolysates as protein sources for infant formula and follow on formula**

a) It is important to distinguish between partially and extensively hydrolysed protein in infant formula. Formulas which contain extensively hydrolysed protein are used under medical supervision for children with cows' milk protein allergy and are foods for special medical purposes usually obtained on prescription. Partially hydrolysed protein (100% whey protein) is used in a number of formula available over the counter, one of which may makes claims for a reduction in the risk of eczema in infants from atopic families (SMA HA). Others are marketed as being 'easier to digest' (Aptamil Comfort milk, Cow & Gate Comfort milk (these products are identical in composition) and SMA Comfort) but do not make claims about allergies. There is no convincing evidence to support claims that partially hydrolysed proteins in milk prevent colic, wind, GI disturbance, constipation or regurgitation in infants (Crawley & Westland, 2014).

A number of specialised milk products available on prescription are available which contain extensively hydrolysed proteins, the review of these products is now being undertaken by The British Dietetic Association Paediatric Group and they will report on specialised milk products in Autumn 2014 (contact: sarahwestondietitian@gmail.com). Previous work done by First Steps Nutrition Trust on specialised milks in 2013 highlighted the following products available as foods for special medical purposes, but there may have been market changes since then:

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| Extensively hydrolysed peptide-based infant formula suitable from birth | Aptamil Pepti 1<br>Cow & Gate Pepti-junior<br>Mead Johnson Nutramigen LIPIL 1<br>SHS Nutricia Pepdite<br>SHS Nutricia Pepdite MCT<br>SHS Nutricia Infatrini Peptisorb |
| Extensively hydrolysed peptide-based formula for older infants | Aptamil Pepti 2<br>Mead Johnson Pregestimil LIPIL |

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|---|---|
| | Mead Johnson Nutramigen LIPIL 2 |
| | SHS Nutricia Pepdite 1+ |
| | SHS Nutricia Pepdite MCT 1+ |

NICE (2008)[13] make a statement that there is insufficient evidence to suggest that infant formula based on partially or extensively hydrolysed cows' milk protein can help prevent allergies. This topic is currently under review by COT for SACN and will report later this year.

b) The protein source for all the milks available over the counter with partially hydrolysed protein is 100% whey protein from cows' milk.

c) Comfort milks are more expensive than standard infant formula: currently Comfort milks retail at £1.16 - £1.50/100g compared to 94p-£1.11/100g for standard first infant formula. SMA HA is the most expensive partially hydrolysed formula currently available over the counter at £1.50/100g.

Despite SMA HA being more expensive than Nestlé's standard SMA formula it has reportedly offered it to health facilities at the same price. This is effectively a promotional discount to try to gain tacit health service endorsement for the product and to encourage its routine use. We believe that the term should not be permitted. (It is not permitted in North America, where Nestlé markets the formula for general use with the promotional name 'Good Start'.)

d) SMA HA makes a number of claims related to hypoallergenicity that can be seen here and some of which is repeated below:

https://www.smahcp.co.uk/sma-products/ha-infant-milk/ha-infant-milk/product-2068.aspx?catid=21&accepted=true

*SMA® H.A. is a Hypo-Allergenic infant milk designed to reduce the risk of developing allergy to cows' milk proteins. It is nutritionally complete with Omega 3 & 6 LCPs. It should be used from the first formula feed onwards, either in combination with breast milk or when only formula-feeding.*

*Babies who have a family history of allergy (for example a parent or a sibling with allergy) may develop an allergic response to the protein in cows' milk. Most infant milks contain long chains of cows' milk proteins. In SMA H.A. these proteins have been broken up into smaller pieces, which reduce the risk of your baby developing an allergic response.*

- *Clinically proven to reduce the risk of eczema by over 50% in 'at risk' infants[1]*
- *Use from the first formula feed*
- *Omega 3 & 6 LCPs*
- *Easy to digest*

A summary of the evidence and current recommendations related to this product and the claims can be found in the report Infant Milks in the UK (May 2014) [14]

[13] http://www.nice.org.uk/guidance/ph11

d) The Baby Feeding Law Group has made several complaints about the legality of the HA claim which is widely used in Europe. HA claims can imply that products marked as 'HA' or 'Hypoallergenic' will not cause allergies and may even prevent them. [15]

Nestlé broke into the US infant formula market in 1988 with *Carnation Good Start HA* formulas. Several allergic babies suffered from anaphylactic shock as a result, prompting nine US States and the Food and Drug Administration to investigate. Attorney General Robert Abrams found that the advertisements used could mislead even medical professionals since the company cited studies that did not adequately support its claims. He concluded that the claims were *"Misleading, deceptive and unfair"* and that while the word *'hypoallergenic'* means *'less likely to cause allergic reaction'* many consumers interpret the word to mean that the formula could *not* cause an allergic reaction. Mr Abrams referred to Nestlé's *"eagerness to break into the lucrative US infant formula market"* and said that *"those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irresponsible conduct."*

Aptamil Comfort, Cow & Gate Comfort and SMA Comfort make no claims related to hypoallergencity but promote their products as reducing colic, wind, GI disturbance, constipation and regurgitation. [16]

Interestingly, a Danone representative invited to present information on formulas to a multi-disciplinary health service group admitted that Cow & Gate Comfort and Aptamil Comfort have different packaging and pricing, but are exactly the same milk powder, Aptamil being positioned as a 'premium' product.

e) The suitability of formula manufactured from protein hydrolysates should be demonstrated on a case by case basis through clinical studies, using the hydrolysates alongside any other additional ingredients used in the product. There is currently no recommendation that these products have efficacy, however many parents use them when they erroneously believe that normal infant behaviours such as vomiting, back arching and crying are related to milk intolerance. Those children who have CMP should be managed and treated medically, not through over the counter sales, and health professionals need better training to support families with infants around safe infant feeding. Often over-feeding of standard formula leads to conditions mis-interpreted as intolerance for example.

It is important to note these partially hydrolysed milks are frequently advertised to health professionals in adverts making claims and giving references which would not stand up to scrutiny, but which cannot be assessed critically by an external body.

f) If it is deemed too disruptive to remove these products from the market whilst clinical trials are undertaken we would like to see strict guidance on the claims that can be made for products and the advertising of these products to health professionals.

**4. Maximum amounts of nutrients**

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[14] http://www.firststepsnutrition.org/pdfs/Infant_milks_May_2014_final_NEW.pdf pp 68-73
[15] BFLG letter to Hazel Blears, regarding the Legality of Nestlé's HA claims.
[16] http://www.firststepsnutrition.org/pdfs/Infant_milks_May_2014_final_NEW.pdf pp 68-73

We strongly support the maintenance of maximum values for micronutrients in formula and clarity about how the new 'target' values can be used in terms of a 'minimum'. It is particularly important that maximum figures are put in place since, due to the degradation of some micronutrients over time, manufacturers already have to use overages to ensure average values at the end of shelf-life. See information from *First Steps Nutrition Trust* on sell by dates. More work is needed on products at the beginning and end of shelf-life to consider to ensure that overages and micronutrient degradation over relative long time periods do not put infant health at risk.

**5. Nutrition and health claims in infant formulae**

a) **Lactose** The three over the counter lactose free formula currently available claim to have lactose contents of <7mg/100ml (<10mg/100kcal). Aptamil Lactose free claims to have <0.06mg/100ml. All would therefore be able to claim to be lactose free under the Commission suggestion.

Great care must be taken to ensure that any statement regarding the presence or absence of lactose – or any other ingredient – is presented in a low key, clear way that is not in any way promotional. The ingredients panel should be used effectively.

b) **DHA LCP**

We support the suggestion that products containing DHA LCPs carry a clear statement that these must be put in all formulas by law. With this in place it makes no sense to allow an additional claim about the presence of DHA LCP. Such a claim will always be highly promotional and undermining of breastfeeding, not only for eruopean consumers but for consumers where these products are exported.

As mentioned before, the US Food and Drug Administration has recorded adverse reactions to formula containing LCPs and has also referenced research showing adverse reactions, including sleep apnea. Accordingly, including LCPs as a compulsory ingredient will remove the option of feeding formula-fed infants with products without these ingredients. Labels should therefore include a warning of possible adverse reactions and advice to seek medical help if these are encountered.

c) The current COT review relating to allergy in infancy will provide guidance on the current evidence available relating to the usefulness of partially hydrolysed formula in prevention of allergy. Currently there is only one formula in the UK which is marketed on this basis and clarity from COT/SACN later in the year will hopefully allow clarity over the evidence the company currently presents. An overall review of all evidence for products is likely to be more useful than a case by case analysis of smaller amounts of data relating to one product.