IBFAN and Baby Feeding Law Group comments on EFSA's Draft Scientific Opinion on the essential composition of infant and follow-on formula. May 2014

The **International Baby Food Action Network** (IBFAN) is a global network of 273 groups in 168 countries working to end the suffering caused by inappropriate infant and young child feeding, strengthen and defend regulations that make products safer; stop irresponsible marketing and ensure that parents are not misled.

The **Baby Feeding Law Gro**up (BFLG) is a coalition of 22 leading UK health professional and lay organisations working to bring UK and EU legislation into line with the *International Code of Marketing of Breastmilk Substitutes* and subsequent World Health Assembly resolutions. The comments below are endorsed by BFLG members First Step Nutrition Trust, the National Childbirth Trust, the Royal College of Paediatrics and Child Health, Royal College of Midwives, La Leche League, Midwives Information Service, the Breastfeeding Network, the Association of Breastfeeding Mothers, Baby Milk Action, the Association for Improvements in the Maternity Services.

Specific Comments

Summary: Lines 31-33. Breastfeeding optimal for most infants

Breastfeeding is the optimal way to feed most infants, not just those deemed 'healthy'. The statement here on vitamin D and vitamin K may need qualification after review. Vitamin K stores may be low at birth but this does not mean breast milk does not provide an adequate supply and the statement on lines 2512-2522 contradicts this statement in the summary, and the different statement made in the conclusion (3176-3178) **IBFAN recommends deletion of the reference to 'healthy' and the bracketed reference to vitamin K**

Lines 37-38 The **Precautionary Principle** should be mentioned here in relation to the potential risk of additions to IF and FOF for which there is no agreed benefit or efficacy.

Lines 55-67. The report should place greater emphasis on the lack of reporting mechanisms for short or long-term health consequences and complications, direct or epigenetic, related to infant and young child feeding, given that this affects many of the assumptions made about the safety of ingredients. Many of the effects will by definition take some time to manifest. The rapid development of obesity in children requires and even more sensitive approach to these problems. The reporting also impacts on assessment of the safety of micronutrients such as DHA, where health problems have been reported in other countries. 98 reports were made to the US Food and Drug Administration (FDA) indicating that a subset of babies could not tolerate the

synthetic DHA used in formulas on the US market. FDA approval for DHA was given on condition companies carries out post-market surveillance. [1]

The panel infers that using current permitted maximum figures for micronutrient content of IF and FOF, intakes above current tolerable upper intake levels derived for young children are likely for some nutrients and that these may also be over-estimates for infants. The removal of maximum amounts for micronutrients in IF/FOF in this opinion is not justified adequately: there may be minimal evidence but without a maximum figure infants and young children may well be put at risk by large overages. There need to be a much clearer justification for the decision to no longer specify maximum levels.

Lines 82-88 Optional Ingredients: If the ingredients specified in this section have no necessity in IF or FOF the precautionary principle should be used and a clearer statement made that such ingredients should **not** be permitted for IF or FOF. Allowing the addition of optional ingredients opens the door to promotional claims. The EU should be working towards ensuing the highest possible standard for all formulas placed on the market.

Conversely – if an ingredient is considered important it should be in all formulas. As stated by the UK Scientific Advisory Committee on Nutrition in 2007: *"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."*

Lines 89-91 Formulas for Older babies IBFAN fully supports the Panel's conclusion that it not necessary to propose compositional requirements for formulas for older babies. IF are suitable for any fortified milk marketed for infants and young children.

Section 4 Methodological considerations

Lines 581-592. The panel has assumed the average amount of formula consumed in the first 6 months of life as equivalent to 500kcal/day, based on average energy requirements. The panel states that whilst intakes are generally higher, the minimum contents they propose based on this will meet the needs of virtually all infants under 6 months of age. This is used throughout when calculating recommendations. The panel should however also consider the amount of formula that manufacturers recommend on their products for infants, as this is relevant when discussing upper levels and health consequences. For example, formula manufacturers typically recommend 5 bottles of milk of 210ml/bottle for infants per day from 4-6 months, and this is equivalent to 1050ml milk and almost 700kcal. We would like to see greater discussion about how recommendations made here based on nutritional adequacy of formula feeding and current practices by formula companies might be reconciled. As an example, there is currently no proposal to provide a maximum level for iodine in formula and a suggested minimum of 15µg/100kcal is proposed. The UL for iodine for children 1-3y suggested by the SCF is 200µg/day, and therefore considering that many infants may receive about 1000ml/700kcal worth of formula a day, a maximum level of 25-30µg/100kcal would be a prudent limit, despite lack of clarity of evidence for infants. This prudent approach should be used throughout to

[1] *Replacing mother - Imitating Breast Milk in the Laboratory.* www.cornucopia.org FDA Q&A: www.fda.gov/Food/FoodSafety/Product- FDA letter regarding the lack of post-market surveillance: http://info.babymilkaction.org/sites/info.babymilkaction.org/files/FDA Post market.pdf

ensure that recommended intakes are considered and that wherever possible the precautionary principle is used to specify potential high intakes.

Lines 593-600 Follow-on Formula As noted by the report (line 3157) Food Standards Agency and Departments of health in the UK, IF is suitable throughout the first year of life, when babies are not breastfed. WHO have also pointed out that FoF is not necessary. In addition, the ingredients and composition of IF and FoF are similar. Therefore it would be simpler, and cause much less confusion for parents, if the two products were combined with the compositional requirements for IF used throughout.

The equivalent energy, protein, amino-acids, fat and fatty acids and carbohydrates (line 1621) proposals for IF/FOF in this report support this one standard. The confusion over the iron content of formula as IF/FOF or as a milk used in the first 12 months of life (lines 2071-2074) also support one standard for IF across the first year of life.

Section 5.1.5 Health consequences

Line 684. Imitating Breastmilk We welcome the confirmation that clearly states that Breastmilk changes continuously and that IF cannot imitate it with respect to its energy and protein content. This should be repeated in the summary as formula manufacturers frequently suggest that their products are similar to breastmilk.

Section 5.2.5 Health consequences Plant Proteins as protein sources for IF and FOY

5.2.5.3 Line 818. **Isoflavins etc** This sentence does not provide adequate protection to infants and the panel should be more specific as to what 'as low as is feasible' means in terms of the concentrations of these substances in IF/FOF. Without clear guidance manufacturers will determine what they believe to be 'feasible'.

Section 5.2.6.4 Amino Acid reference Pattern Line 952 – 954 Follow-on formulas It is noted that *"FOF can be used as the principal liquid element of a progressively diversified diet of infants in place of breastmilk,"* We support this confirmation that FOF FoF is a breastmilk substitute and should be classified as such when implementing the *International Code of Marketing of Breastmilk Substitutes* and subsequent WHA Resolutions in the IF and FoF Directive 2006/141/EC.

Section 5.4.5.2.2 Sucrose, glucose and fructose

Lines 1427-34 Sugars We note that it is considered appropriate that sucrose may be added to IF containing hydrolysed protein to camouflage the taste of the hydrolysate. We note that in lines 500-502 the report states that this opinion will not address composition requirements for IF for infants with special nutritional requirements or CMPA, and fully hydrolysed formula are foods for special medical purposes. We are unclear why hydrolysed formula are therefore being discussed here. We also do not agree that as complementary foods may contain other sugars that that is a rationale for them to be included in FOF. In order to reduce risk to oral health and to ensure that FOF, as a breast milk substitute, is more closely aligned to breast milk composition, it would seem sensible to maintain the same restrictions on carbohydrates in If as FOF.

The negative effects of sucrose, glucose and fructose on taste preference and particularly their cariogenic potential in babies who are developing teeth, should not be dismissed. We do not see

why IF and FoF based on milk proteins should contain sucrose, glucose or fructose. Lactose has lower cariogenic potential and advantages in mineral absorption.

Section 5.4.5.2.3 Maltodextrins and starches Line 1441 Although maltodextrins and starches have the advantage of producing lower osmolality in products than mono- and disaccharides, the Panel have not set out any other reason for their use and they do not appear in breastmilk. These sources have been shown to be advantageous for young babies and should be avoided where possible. Evidence on the most suitable sources of carbohydrates in soy formula is needed. We believe that the carbohydrates in all formula used in infancy should be based on those ingredients present in breast milk where there is no rationale otherwise. There is a risk associated with the use of sugars with greater cariogenic potential than lactose in products aimed at infants in the first year of life and prudency would suggest that these are therefore not used.

Section 5.4.6.2.2 Sucrose, glucose and fructose Lines 1583 -5 The addition of sucrose, fructose or honey to FoF has not been sufficiently justified. There is a danger of inducing caries in the infant's first teeth and developing a stronger preference for sweet foods.

Section 5.4.6.2.4 Starches Lines 1597 -1606 Section 5.4.5.2.3. does not demonstrate that starches or maltodextrins are beneficial in the infant's diet, or that infants up to one month of age can tolerate 2g/100ml starch in the formula. It is noted that 2 more undigested carbohydrates reached the colon with increasing complexity of the carbohydrates. (1450)" Further evidence is required to ascertain any potential disadvantages of the addition of starch or maltodextrins to formula milk and until they are proved to be safe, lactose should provide the carbohydrate component of IF and FoF based on milk proteins.

Section 6 Minimum content of micronutrients in IF and FOF

Line 1631. We agree with the concerns of First Steps Nutrition Trust that the panel now only proposes to provide minimum values for micronutrients, whilst understanding that evidence on upper levels is limited. It is well known that in order to ensure the minimum value of micronutrient content after a period of storage that overages are used by manufacturers to allow for nutrient degradation. Koletzko & Shamir (2006)[2] highlighted the fact that babies given the freshest formula milks might get dangerously high doses of some vitamins. Interactions between nutrients means that a high amount of one micronutrient could adversely affect absorption of another and this is picked up throughout this report. In order for member states to have clarity and consistency over compositional criteria and to be able to clearly highlight analysis which may show that OF/FOF are not meeting appropriate compositional values, minimum and maximum values should be specified for all those micronutrients where there are known health risks associated with high intakes.

Section 6.7.5 Health consequences

Lines 1992-1995. Iron We wholly disagree that the lack of evidence should allow there to be no maximum level for iron in IF/FOF. The section 6.7.5 highlights some potentially serious consequences of iron overload in iron replete infants and children and it is clearly stated that active excretion of iron is minimal and that iron replete infants might be at risk for negative

[2] Koletzko & Shamir (2006) *British Medical Journal* 332, 621-622

health consequences if given extra iron. We ask the panel to consider carefully providing a maximum level of iron for IF and FOF.

Section 6.7.6 Recommendations

Lines 2071-2074. This section suggests that an infant formula used throughout the whole of the first year of life should have a different minimum iron content to that specified for infant formula. The recommendation in many areas is that only a first infant formula is used throughout the first year of life and this again suggests that it would be most useful to only have one standard for all infant milks across the first year. It is not clear from this statement how a manufacturer will respond to adding iron to formula since it appears to contradict the evidence given earlier for the amount of iron needed in infancy.

Section 6.1.4.6 Recommendations

Line 2340. Risks of Aluminium We appreciate that the terms of reference are to consider the essential composition of IF/FOF rather than components for which there is no essentiality, but we would very much like to see a short section on aluminium in formula before the section on vitamins to summarise current evidence on the high content of aluminium in many formula and to make a recommendation that these levels should be reduced by manufacturers as a matter of urgency.

Section 6.15.4 Health consequences

Lines 2384-2386. Vitamin A An upper level for vitamin A in IF/FOF should be specified to ensure that as a minimum, actual likely intakes do not exceed the UL of 800µg/day for children 1-3y suggested by SCF. Using potential real intakes of up to 700kcal/day of formula based on recommended feeds by manufacturers as the prudent figure, an upper maximum level of 110-120µg/100kcal should be set. Vitamin A degrades in formula milk and overages are needed to meet minimum content after shelf-life. A maximum value should ensure that infants given the freshest formula do not (at the very least) exceed amounts suggested as a potential risk for 1-3 year olds.

Section 6.16.2 Lines 2409-2411 Vitamin D There is evidence from a recent systematic review to suggest that there is a strong positive correlation between exclusive breastfeeding and infant vitamin D status (Thiele et al, 2013[3]) and there is considerable debate about variables related to vitamin D in breast milk which require greater discussion here. Levels will vary and may be inadequate in some situations, but the blanket assertion that breast milk does not contain sufficient vitamin D to prevent rickets even if the mother takes vitamin D supplements is misleading and goes against policy and experience in many areas. This section needs to be re-written to reflect a greater review of the literature.

A 2013 systematic review by Thiele et al. found that *"a strong positive correlation exists between maternal vitamin D intake during exclusive breastfeeding and infant serum 25-hydroxyvitamin D levels."* They conclude that when maternal vitamin D intake or production is sufficient, vitamin D transfer via breastmilk is adequate to meet infant needs. However, the author continues, *"in the*

[3] Thiele et al (2013*) J Hum Lactation*, 29, 163-170.

reviewed studies, doses up to 10 times the current recommended daily intake of vitamin D were needed to produce sufficient transfer from mother to breastfed infant." [4]

Vitamin D is present in breastmilk in the fat and the aqueous fraction. The bioavailability of vitamin D in breastmilk is different from added vitamin in food or infant formula.
This sentence needs correction: *"The mean vitamin D content of breast milk in healthy women has been reported to be in the range 0.25-2.0 µg/L (0.04-0.31 µg/100 kcal)* [5]There is general agreement that human milk does not contain sufficient vitamin D to prevent rickets, even if the mother takes vitamin D supplements.[6]

It is also in opposition to: Lawrence Ruth A, *Breastfeeding a guide for the medical profession*[7] which on page 135 "*clearly the levels vary and may be inadequate in human milk in some situations, especially in cold climates in the winter with little sunshine and for dark skinned individuals*." A clear relationship between maternal intake and breastmilk content was presented in Maternal infant vitamin D relationships during breast-feeding. [8] **This should be reflected in the summary.**

Section 6.16.56 Recommendations

Lines 2449-2450. We would like to see a maximum level of vitamin D in formula milk suggested based on the UL of 25µg/day of between 3-4µg/100kcal to allow for typical formula intakes of 700kcal/day.

Section 7 Maximum content of micronutrients in IF and FOF

Lines 2896-2928. We do not believe that the statements provide adequate justification for no longer setting maximum amounts of micronutrients in IF/FOF and would urge the panel to consider setting these at the very least for those nutrients for which there may be a risk associated with high intakes.

Section 8.2 There are no reports of adverse effects occurring with the current specifications of choline in IF Inositol

Lines 2988-2999/3056-3057. The report should clearly recommend that ingredients are added ONLY when their efficacy is proven by independently funded and systematically reviewed evidence. If no such evidence is available such ingredients should not be permitted. To do otherwise is to use babies in a mass uncontrolled trial.

Section 8.6 'Probiotics' and 'synbiotics'

Lines 3134 -5 Probiotics. We are pleased that the Panel notes the lack of convincing evidence of benefit for the addition of "probiotics" and/or "synbiotics" to IF or FOF concluding that they are not necessary. The addition of these ingredients has been used as excuse not to follow WHO

[4] Thiele DK1, Senti JL, Anderson CM. Maternal vitamin D supplementation to meet the needs of the breastfed infant: a systematic review. J Hum Lact. 2013 May;29(2):163-70. doi: 10.1177/0890334413477916. Epub 2013 Mar 4
[5] Dawodu and Tsang, 2012
[6] Olafsdottir et al., 2001
[7] 7th edition 2011 Mosby/Elsevier
[8] Rothberg AD, Pettifor JM, Cohen DF, Sonnendecker EW, Ross FP. J Pediatr. 1982 Oct;101(4):500-3.

safety recommendations on reformulation, exposing infants to risks from inherent contamination.