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Dear Janine,

Subject: Codex Committee on Nutrition and Foods for Special Dietary Uses: Proposed Draft Revised Standard for Follow-Up Formula (CODEX STAN 156-1987)

I am writing to you in response to conversations at the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) 17 November 2016 meeting in Canberra. At this meeting, colleagues representing the area of Omega-3 research made a number of comments relevant to the proposed draft Revised Standard for Follow-Up Formula (CODEX STAN 156-1987). CMA takes this opportunity to submit further relevant information for your consideration, as head of the Australian delegation, to the 38th Session of the CCNFSDU to be held in Germany 5-9 December 2016.

Based on the below summary of information, it is recommended Australia take the following position:

- Minimum docosahexaenoic acid (DHA, 22:6n-3) levels in infant formula be a mandatory requirement. It is acknowledged that there is difficulty in setting a minimum requirement on something that can be taken up voluntarily, therefore it is proposed that there is a body of evidence to support setting a mandatory requirement that provides for a minimum level of DHA in infant formula.
- The minimum level of 0.3% of total fatty acids for the addition of DHA should be put forward by Australia. This is consistent with the principles governing the addition of optional ingredients in FUF.
- Should a mandatory requirement not be feasible, then the optional addition of DHA at the minimum level of 0.3% of total fatty acids should be taken.
- It is recommended that the level of arachidonic acid (20:4 n-6) be equal to or higher than DHA content. Recent studies demonstrate the importance of balancing the amounts of ARA and DHA as too much DHA may suppress the benefits provided by ARA.[1]

[1] Hadley et al. 2016, 'The Essentiality of Arachidonic Acid in Infant Development', *Nutrients vol. 8, no. 4* *doi:10.3390/nu8040216*

CMA makes further comment on the Australian position for Part 1: Essential Composition of Follow-Up Formula for Older Infants (6-12 Months) Recommendation 5: Optional Ingredients - DHA:

It is suggested that the current weight of scientific evidence does not support the current position Australia has taken: that is "Australia supports the Chairs' compromise proposal not to set a minimum and to include a statement in the footnote". It is acknowledged that there is difficulty in setting a minimum standard on something that can be taken up voluntarily, therefore it is recommended that minimum DHA levels in infant formula be a mandatory requirement.

While challenges in establishing a global minimum standard are stated – the Australian position should reflect the body of evidence guiding infant nutrition and development in this country. For the establishment of global health policy, it is imperative to meet the needs of the most vulnerable and preserve the status of the well-nourished.

It is recommended that Australia adopt the position that there is a body of evidence to support a mandatory minimum level of DHA in infant formula. The minimum level of 0.3% of total fatty acids for the addition of DHA is consistent with the principles governing the addition of optional ingredients in FUF.

Setting a minimum level of 0.3% DHA in FUF at the Codex level ensures that those infants lacking in DHA are provided meaningful levels if fed formula. It also sets an evidence-based benchmark from which higher national/regional standards for FUF can be established, as needed, based on local dietary patterns and cultural practices.

As noted in 3.3.3.3 of the proposed revision of the FUF standard, "when any of these ingredients or substances is added to formula it shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk".

Without providing for a minimum level in the standard, it will be left to national authorities to systematically evaluate the available evidence and determine an appropriate level for addition. This is a very resource intensive exercise and appears unnecessary given that at least two groups (FAO and EFSA), both considered a Codex Recognized Authoritative Scientific Body (RASB), have established minimum DHA levels based on the intended effect of supporting retinal and brain development.

The FAO report 91 concludes there is a convincing level of evidence that DHA plays a critical role in retinal and brain development from 0-24 months and probable evidence that an adequate intake level of 10-12mg/kg bw DHA from 6-24 months is associated with these developmental benefits.[2]

EFSA has concluded that "…a cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of total fatty acids and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months" (EFSA, 2009). This conclusion confirms that benefits occur during the period of interest and are applicable to infants regardless of feeding from birth, or after weaning from breast milk, which are the

[2] FAO (2010) Fats and fatty acids in human nutrition: Report of an expert consultation. FAO Food and Nutrition Paper 91 http://foris.fao.org/preview/25553-0ece4cb94ac52f9a25af77ca5cfba7a8c.pdf

exact scenarios for use of FUF. EFSA recommends between 20 and 50 mg/100kcal for infant and follow-on formula.

The conclusions of FAO Report 91 endorsing the critical role and benefits of DHA at a specific intake range are irrefutable and based on strength of evidence definitions developed and applied by WHO/FAO. The Expert Panel for Report 91 was instructed to adhere to principles of evidence review and strength of evidence grading that are described in detail in their report. Specifically, the following was required of the Panel "In developing their conclusions and recommendations, the authors of the background papers were asked to use the four criteria levels (convincing, probable, possible or insufficient) of the "strength of evidence" developed and applied by the joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Disease (WHO, 2003). The strength of evidence was reviewed and evaluated again during the Expert Consultation to arrive at recommendations and conclusions and to establish requirement levels. As was the case in the past, only evidence that warranted the levels of evidence "convincing" and "probable" were used to formulate recommendations." (FAO Report 91).

While certain meta-analyses (e.g., Simmer et al., 2011; Sun et al. 2015) are often cited to refute the fact that brain and retinal development are furthered by a specific intake range of DHA, none of these publications have implemented the level of rigor, scrutiny, and expertise associated with the establishment and activities of an FAO or EFSA expert panel. To consider these meta-analysis publications on the same level as guidance and recommendations from an RASB is unprecedented. Narrowing of the evidence base to exclude studies that may not fit a predefined meta-analysis question likely explains discrepancies between single meta-analysis publications and RASB recommendations.

Further, guiding principles for the composition of infant formulas (COMA, 1996) advise that when assessing infant formula nutritionally, "All studies should be interpreted in light of outcomes of healthy infants exclusively breastfed for four to six months, rather than the composition of human milk. In the absence of adequate data, consideration should be given to including a breastfed reference group in studies." The reported world-wide average for DHA in human milk is 0.32%±0.22 (range 0.06 to 1.4%) and for ARA is 0.47%±0.13 (range 0.24 to 1.0%).

Using human milk levels as a reference is consistent with the principles laid out in 3.3.2.2. Human milk contains DHA and ARA along with an abundance of the dietary precursors of these fatty acids, alpha-linolenic acid (ALA; 18:3 n-3) and linoleic acid (LA; 18:2 n-6), respectively. However, the contribution of human milk to the complementary diet decreases dramatically during the first year of life. Intake of ALA and LA from dietary sources other than human milk is limited among older infants and young children in both developing (Michaelsen et al., 2011) and developed (Ghisolfi et al., 2013) countries. These observations are clearly delineated in section 5.5.1 of the eWG's current agenda paper.

Furthermore, the Chair notes, "Almost all eWG members agreed that dietary intakes of α-linolenic acid were considered to be inadequate on a global scale (7CM; 1CMO; 3CO)." The amount of DHA and ARA produced from precursors is small, relative to the demands of growth and development (Brenna, 2016). It has been recently noted that "…none of the many studies to date has found equivalent DHA and ARA status in developing infants fed 18-

carbon fatty acids [3] compared with infants fed LCPUFAs, and this is particularly true for DHA" (Carlson and Colombo 2016).

Intake of DHA by infants and young children in developing countries are also estimated to be insufficient. Thus, given the limited global intake of ALA and the limited rate of conversion of ALA to DHA, the assertion that in vivo production of sufficient DHA to support developmental needs, is not substantiated.

Finally, it is worth clarifying whether a minimum level for DHA would be consistent with legal precedents. The Chairs have noted that "…minimum values for optional ingredients have not been established for any other optional ingredients listed in either the Codex Infant Formula Standard, or the proposed draft Standard for Follow-up Formula (REP16/NFSDU Appendix III)". While this statement accurately describes these two standards, minimum values for optional ingredients for this age group is not unprecedented. The Codex Guidance on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991) provides for optional addition of vitamins and minerals and notes the following: "6.6.1.3 If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food."

We thank you for the opportunity to provide this information for your consideration ahead of the 38th meeting of the CCNFSDU. Should you require any further supporting information, please feel welcome to contact the CMA.

Yours sincerely,

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Head, Regulatory Affairs
CMA

Assoc. Professor Barbara Meyer
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Lalen Dogan
Chair, Omega-3 Centre

[3] In this context, "18-carbon fatty acids" refers to alpha-linolenic acid (ALA; 18:3 n-3) and linoleic acid (LA; 18:2 n6)

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicine and healthcare products industry, representing members across the supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines and healthcare products of the highest quality.
CMA is the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

References for Recommendation 5:

Committee on Medical Aspects of Food and Nutrition Policy (COMA), 1996. Guidelines on the nutritional assessment of infant formulas. UK Department of Health Report on Health and Social Subjects, Number 47.

EFSA, 2009. EFSA Journal 941:1-14.

Food and Agricultural Organization of the United Nations (FAO), 2010. FAO Food and Nutrition Paper 91.

Forsyth et al., 2016. Ann Nutr Metab 69(1):64-74

Ghisolfi J,et al., 2013. Public Health Nutr 16(3), 524–534.