GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

30 August 2021

Food Standards Australia New Zealand (FSANZ)
submissions@foodstandards.gov.au

RE: Proposal P1028 – Infant Formula Products Consultation Paper 2 Nutrient Composition

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

GOED thanks Food Standards Australia New Zealand (FSANZ) for the opportunity to provide comments on Proposal P1028– Infant Formula Products Consultation Paper 2 Nutrient Composition. During the 2016 consultation on infant formula, GOED recommended a mandatory minimum addition of DHA to infant formula similar to that implemented in the EU[1] per the recommendation of the European Food Safety Authority (EFSA)[2]. While GOED continues to believe a mandatory minimum addition of DHA is prudent, we respect FSANZ's position and write with a focus on the Guidance Upper Limit (GUL) for DHA.

GOED supports FSANZ's current proposal to retain the current voluntary permission for DHA, provided the content of DHA does not exceed the arachidonic acid (AA) amount and the content of eicosapentaenoic acid (EPA) does not exceed the content of DHA. Furthermore, we support a GUL for DHA and recommend setting it at 7 mg/100 kJ (30 mg/100 kcal), not 0.5% of total fatty acids.

In the consultation document, FSANZ supports aligning with Codex and expressing the GUL as mg/100 kJ, but then presents the GUL as a percent of total fatty acids. The following two bullets present the conflicting positions.

[1]COMMISSION DELEGATED REGULATION (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2016%3A025%3AFULL

[2]EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7);3760. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3760.pdf

- Under the "Proposed Approach" for "5.2 Units of Expression," it states, "Based on alignment with Codex STAN 72-1981 and the Codex Draft Standard for FUF, FSANZ proposes to express the amounts of fatty acids in terms of mg/100 kJ. This applies to LA, ALA and DHA. Limits on lauric acid, myristic acid, and erucic acid will still be prescribed as a percentage of fatty acids."
- Under the "Proposed Approach" for "5.4 Long chain polyunsaturated fatty acids and other LC-PUFA, ratios and sources," it states, "Based on further alignment with Codex STAN 72-1981 and the conclusions of the 2016 nutrition risk assessment, FSANZ proposes to retain the current voluntary permission for DHA, provided the content of DHA does not exceed the AA amount. When DHA is present, the amount should be controlled with a GUL, by adopting the Codex GUL for DHA of 0.5% total fatty acids."

Adopting a GUL for DHA of 7 mg/100 kJ (30 mg/100 kcal), in alignment with the Draft Revised Standard for Follow-Up Formula (CXS 156-1987) – Draft Essential Composition and Quality Factors –held at Step 7[3], versus 0.5% total fatty acids serves to accommodate the wide range of energy needs of this age group. As detailed in "Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes[4]," infants' energy requirements vary by sex and age and range from 1,800 kJ (430 kcal)/day for one month old girls to 3,500 kJ (837 kcal)/day for 12 month old boys, translating to 126-245 mg of DHA/day.

Setting the GUL based on total fatty acids means that the wide range of energy requirements of infants will not be taken into consideration. The "Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes" includes an adequate intake (AI) for fat of 30-31 grams/day for 0-12 month old infants. For a GUL of 0.5% total fatty acids, this would translate to 150-155 mg DHA per day, an amount associated with ~2200 kJ/day, which meets the needs of only 1-2 month old infant boys and 4 month old infant girls.

In addition to supporting a GUL for DHA of 7 mg/100 kJ (30 mg/100 kcal), GOED recommends that when DHA is added to infant formula that a minimum of 4.8 mg/100 kJ (20 mg/100 kcal) be required. This level corresponds to that discussed by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to ensure a benefit.

GOED's final comment relates to Koletzko et al., 2020[5], which seems to have been misinterpreted in the consultation paper. The misinterpreted information in question is from a bulleted list and reads as follows – "*High DHA may lead to adverse effects such as reduced AA*

[3] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-40%252FREPORT%252FREP19_NFSDUe.pdf

[4] https://www.nhmrc.gov.au/file/3321/download?token=RHlu4kNJ

[5] Koletzko B, Bergmann K, Brenna JT, et al. Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Paediatrics and the Child Health Foundation. Am J Clin Nutr 2020;111:10–16.

levels in brain tissue suboptimal neurodevelopment, poor growth and immune development." As written, it seems that high DHA levels alone may lead to the listed outcomes. This is not true and the sentence in the original publication provides the required qualification – "the provision of high DHA intakes without balanced amounts of AA may induce undesirable effects in infants, such as reduced AA concentrations in brain tissue, suboptimal neurodevelopment, and potentially also adverse effects on growth and immune development (64)" – to interpret the information correctly. GOED asks that any future discussions on this information be considered in light of how it is presented in the original publication and not as presented in the consultation.

Thank you in advance for consideration of our comments.

Sincerely,

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs