



**SUBMISSION TO FSANZ**

**Consultation Paper – Proposal P1028  
(Infant Formula)**

**FROM NU-MEGA INGREDIENTS PTY LTD**

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## 1. INTRODUCTION

Nu-Mega Ingredients Pty Ltd is a wholly owned subsidiary of Clover Corporation Ltd <sup>1</sup>. Nu-Mega is a world class supplier of Omega-3 DHA as functional food ingredients, including the HiDHA® micro-encapsulated tuna oil, a rich source of Omega-3 DHA.

Clover Corporation Ltd began as a family owned Australian research-based company in 1988. Publicly listed on the Australian Securities Exchange in 1999, Clover evolved from being a research and development, manufacturing and marketing company to one concentrating on forming strategic relationships focused on technology, new product development and commercialisation.

Today we continue to focus on improving human health through nutrition and have become a global leader in the delivery of stable omega-3 and omega-6 products in to the infant nutrition and medical foods market with a reputation of excellence and quality.

## 2. RECOMMENDATIONS FROM NU-MEGA INGREDIENTS

Nu-Mega Ingredients appreciate the opportunity to comment on the consultation paper for the potential revision of the Regulation of Infant Formula in the Australia New Zealand Food Standards Code as this will have important implications for our clients and consumers in the future.

Nu-Mega Ingredients supports the importance of continuous review and revision of the compositional requirements of infant formula products within the Code to ensure that infants/toddlers are provided with the required level of nutrition to support normal development.\* Nu-Mega Ingredients would like to see international evidence-based information and recommendations considered when reviewing the compositional requirements of infant formula products.

\*Nu-Mega Ingredients supports breastfeeding being the recommended method to feed an infant, however in the absence of breastfeeding a nutritious and safe substitute to breast milk is required.

In response to the FSANZ's preliminary view detailed within Section SD1 (4.4) relating to Long chain polyunsaturated fatty acids (LC-PUFAs);

*"FSANZ considers that a mandatory minimum amount of DHA is not supported and retaining the voluntary permission is appropriate and is unlikely to pose a risk to infant health. Maintaining this voluntary permission would not impact on the manufacture of infant formula."*

Nu-Mega would like to draw attention to the recent legislative change on 2<sup>nd</sup> February 2016 to the compositional requirements within the European Union (EU) infant formula regulation<sup>2</sup> which supports the mandatory addition and minimum levels of docosahexaenoic acid (DHA) within infant formula whereby;

**DHA becomes a mandatory ingredient at a minimum of 20mg/100kcal and up to 50mg/100kcal for 0-12 month infant formula products (and ARA becomes an optional ingredient)**

The European Food Safety Authority (EFSA) have previously acknowledged the scientific substantiation of DHA as an important compositional requirement in infant formula for the normal development of eyes and brain in infants;

Based on EFSA review of substantial clinical data provided by Mead Johnson Nutrition, the European Union Parliament approved the Article 14 Health Claim – "DHA contributes to the visual development in infants" for infant formula products 0-12 months based on a minimum DHA fortification level of 0.3% of the total fatty acids<sup>3</sup>.

In October 2014, after review of DSM Nutritional Products health claim related to docosahexaenoic acid (DHA) and contribution to normal brain development, the EFSA expert panel concluded that a cause and effect relationship has been established between the consumption of DHA and contribution to normal brain development. For infants/children (0-24 months), a minimum 100mg DHA per day in one or more servings being required<sup>4</sup>.

In light of the recent EU legislative changes to infant formula compositional requirements and the scientific substantiation supported by EFSA, Nu-Mega encourages FSANZ to review the basis for DHA to be considered as a mandatory compositional component at minimum level of 20mg/100kcal within the Code for infant formula products (0-12 months).

### 3. REFERENCES

1. Clover Corporation – see [www.clovercorp.com.au](http://www.clovercorp.com.au)
2. European Union Commission Regulation (EU) No. 2016/127 of 25 September 2015
3. European Union Commission Regulation (EU) No. 440/2011 of 6 May 2011
4. EFSA Journal 2014; 12(10): 3840 [8 pp]