GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

September 11, 2025

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically at www.regulations.gov

RE: Docket No. FDA–2025–N–1134, Infant Formula Nutrient Requirements; Request for Information

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) industry, with a mission to use science-based information to promote the consumption of and enable access to quality EPA & DHA from all sources for a positive impact on public health. 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 200+ members and partners represent the entire supply chain of EPA and DHA, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands, including infant formulas.

GOED appreciates the opportunity to provide information regarding Docket No. FDA-2025-N-1134, Infant Formula Nutrient Requirements. **GOED will focus on question #5. *What other nutrients (e.g., docosahexaenoic acid and arachidonic acid) or specifications for nutrients (e.g., ratio of linoleic acid to alpha-linolenic acid), if any, should we consider adding to 21 CFR 107.100?*** We understand that the FDA is interested in "…new scientific data or information related to infant formula nutrients, including international infant formula standards."

While breastfeeding is the ideal initial feeding method for providing nutrition to full-term infants and is recommended by major health organizations, including the World Health Organization,[1] for mothers who cannot or choose not to breastfeed, it is imperative that nutritionally complete infant formulas, providing similar benefits as human milk, are made available for their infants. While human milk composition varies, it provides insight into adequate fatty acid intakes for infants (Carlson et al, 2021). Such data was used, in part, to establish the DHA and ARA levels adopted by regulatory and standard setting bodies around the world.

Since 1985, the US infant formula nutrient specifications (21 CFR 107.100) have included only two requirements associated with fat and fatty acids: total fat must be between 3.3 and 6.0 grams per 100 Kcal (30% to 54% of energy) and linoleic acid (LA) must be at least 300 mg per 100 Kcal

[1] International Code of Marketing of Breast-Milk Substitutes

(2.7% of energy) with no maximum amount specified. In 2001, the FDA permitted the addition of DHA and ARA to infant formulas, but such addition is not required.

While most non-exempt infant formulas (i.e. for term infants) in the United States include DHA and ARA, some don't include the amounts/levels for proper infant development. To ensure formula fed infants are provided DHA and ARA at the required amounts/levels they need to thrive, GOED strongly recommends establishing requirements, as shown in the following table, for the mandatory addition of DHA and ARA to infant formula and thus the addition of both fatty acids to 21 CFR 107.100.

	Minimum (mg/100 kcal)	**Maximum (mg/100 kcal)**
DHA[a]	20	50
ARA[a]	20	50

[a]DHA and ARA to be added at a ratio from 1:1 to 1:2 of DHA to ARA

Scientific Support for Addition of DHA and ARA to Infant Formula

Following the June 4, 2025 meeting of the FDA Expert Panel on Infant Formula, three manuscripts were drafted and submitted for publication. While the manuscripts are still going through the peer review process, the first manuscript, entitled *FDA Expert Panel on Infant Formula "Operation Stork Speed" June 2025: Part 1, Nutrient Considerations*, includes a section on fats and fatty acids that was undoubtedly written by Expert Panel member Dr. J Thomas Brenna, who has a long history of being involved in conducting influential research on fatty acids, including research that contributed to the 2001 approval by the FDA for addition of DHA and ARA to infant formulas. The referenced manuscript begins to address the rationale for including DHA and ARA in infant formula.

DHA and ARA are most notable for their positive impact on neurodevelopmental outcomes, including visual and cognitive development.

In 2011, the European Commission, based on an opinion from the European Food Safety Authority (EFSA), authorized the claim *Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age,*[2] which provides support for the benefit of providing infants DHA in infant formula.

[2] Commission Regulation (EU) No 440/2011 of 6 May 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children's development and health

EFSA's *Scientific Opinion on the essential composition of infant and follow-on formulae*[3] provides support for the provision of pre-formed DHA to formula-fed infants in similar amounts as breast-fed infants based on the following:

- DHA is an essential structural component of the nervous tissue and the retina, and is involved in normal brain and visual development.
- The developing brain must accumulate large amounts of DHA in the first two years of life.
- The intake of preformed DHA generally results in an erythrocyte DHA status more closely resembling that of a breastfed infant than is achieved with ALA alone.

Except for a controversial position of the European Union not requiring the addition of ARA, there is consensus among regulatory authorities to require ARA in infant formula when DHA is added. Presently, there is insufficient data to support the idea that infants fed formula containing only DHA (without ARA) will result in long-term developmental outcomes that are similar to those of their breastfed peers. Likewise, it is unknown if infants who are not receiving ARA through infant formula or follow-on formula will grow and develop in the same way as those who are breastfed or receiving ARA through fortified formula. To address these concerns, clinical studies to determine the nutritional adequacy and safety of infant formula containing DHA without the concomitant addition of ARA are necessary. Until such time that those studies are conducted, there should be a requirement for addition of ARA to infant formula.

Infant nutrition experts endorse the inclusion of both DHA and ARA in infant formula and GOED refers you to the following references.

Brenna JT. Arachidonic acid needed in infant formula when docosahexaenoic acid is present. Nutr Rev. 2016 May;74(5):329-36. doi: 10.1093/nutrit/nuw007. Epub 2016 Mar 24. PMID: 27013482.
https://pubmed.ncbi.nlm.nih.gov/27013482/

Crawford MA, Wang Y, Forsyth S, Brenna JT. The European Food Safety Authority recommendation for polyunsaturated fatty acid composition of infant formula overrules breast milk, puts infants at risk, and should be revised. Prostaglandins Leukot Essent Fatty Acids. 2015 Dec;102-103:1-3. doi: 10.1016/j.plefa.2015.07.005. Epub 2015 Sep 21. PMID: 26432509.
https://pubmed.ncbi.nlm.nih.gov/26432509/

Koletzko B, Carlson SE, van Goudoever JB. Should Infant Formula Provide Both Omega-3 DHA and Omega-6 Arachidonic Acid? Ann Nutr Metab. 2015;66(2-3):137-138. doi: 10.1159/000377643. Epub 2015 Mar 7. PMID: 25766858.
https://pubmed.ncbi.nlm.nih.gov/25766858/

[3] 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
https://www.efsa.europa.eu/en/efsajournal/pub/3760

Koletzko B, Bergmann K, Brenna JT, Calder PC, Campoy C, Clandinin MT, Colombo J, Daly M, Decsi T, Demmelmair H, Domellöf M, FidlerMis N, Gonzalez-Casanova I, van Goudoever JB, Hadjipanayis A, Hernell O, Lapillonne A, Mader S, Martin CR, Matthäus V, Ramakrishan U, Smuts CM, Strain SJJ, Tanjung C, Tounian P, Carlson SE. 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 Jan 1;111(1):10-16. doi: 10.1093/ajcn/nqz252. PMID: 31665201. https://pubmed.ncbi.nlm.nih.gov/31665201/

International Term Infant Formula Standards and Regulations Relevant to DHA and ARA

United States

While DHA and ARA are not included in 21 CFR 107.100, and thus not required to be added to infant formula, both fatty acids are permitted for addition to non-exempt (i.e. term) infant formula. The first Letter of No Objection for both DHA and ARA is dated May 17, 2001 and is for the intended use of DHA and ARA in term infant formula, at a maximum level of 1.25% each of the total dietary fat and at a ratio ranging from 1:1 to 1:2 (DHA:ARA). Subsequent Letters of No Objection followed, which provides evidence of a long history of safe use. A summary of sources of DHA and ARA associated with FDA Letters of No Objection for use in non-exempt (i.e. term) formula is provided in the following table.

Table: Sources of DHA and ARA Associated with FDA Letters of No Objection for Use in Non-Exempt (i.e. Term) Formula

GRN No.	Date of Closure	Substance	Intended Use
41	May 17, 2001	DHASCO (docosahexaenoic acid-rich single-cell oil) and ARASCO (arachidonic acid-rich single-cell oil)	DHA and ARA in term infant formula, at a maximum level of 1.25% each of the total dietary fat and at a ratio ranging from 1:1 to 1:2 (DHA:ARA)
94	April 18, 2006	Docosahexaenoic acid-rich oil from tuna (DHA-rich tuna oil) and arachidonic acid-rich oil from Mortierella alpina (AA-rich fungal oil)	ARA at a mean level of 0.4% of total fatty acids and DHA at a mean level of 0.15% of total fatty acids in term infant formula
553	June 19, 2015		For use as an ingredient in term

			infant formula at a maximum use level of 1.25% of dietary fat (maximum of 0.5% of total fat DHA)
677	May 2, 2017	Docosahexaenoic acid oil produced in Schizochytrium sp.	Intended for use as an ingredient in non-exempt (term) infant formula (ages from birth to 12 months) in accordance with current good manufacturing practices and in combination with a source of arachidonic acid
730	March 30, 2018	Arachidonic-acid rich oil from Mortierella alpina strain LU 166	Ingredient in milk-and soy-based infant formulas. The maximum level for non-exempt term infant formula is 0.75% ARA by weight of total fatty acids in combination with docosahexaenoic acid (DHA) at a ratio ranging from 1:1 to 2:1
731	April 6, 2018	Docosahexaenoic acid oil produced in Schizochytrium sp.	For use as an ingredient in term infant formula at a maximum level of 0.5% total fat as DHA and in combination with a safe and suitable source of ARA. The ratio of DHA to ARA would range from 1:1 to 1:2
776	October 26, 2018	Algal oil (35% docosahexaenoic	Ingredient in non-exempt infant

		acid) from Schizochytrium sp. strain FCC-1324	formulas for term infants at use levels up to 0.5% (wt/wt) of fatty acids as DHA in combination with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA
777		Algal oil (55% docosahexaenoic acid) from Schizochytrium sp. strain FCC-3204	Ingredient in non-exempt infant formulas for term infants at use levels up to 0.5% (wt/wt) of fatty acids as DHA in combination with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA
862	June 15, 2020	Algal oil (40% docosahexaenoic acid) from Schizochytrium sp. strain ONC-T18	Ingredient in non-exempt infant formula for term infants at levels up to 0.5% (w/w) of total fat as DHA with the provision that algal oil will be used in infant formula in combination with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA
933	November 13, 2020	Algal oil (≥36% DHA from Schizochytrium sp. strain DHF	Ingredient in non-exempt infant formula for term infants at a maximum level of 0.5% of total fat as DHA in combination

			with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA
1008	February 25, 2022	Algal oil (≥45% DHA) from Aurantiochytrium limacinum TKD-1	As an ingredient non-exempt infant formula for term infants at a maximum level of 0.5% (w/w) of total fat as DHA in combination with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA
1115	September 18, 2023	Fungal oil (≥40% ARA) from Mortierella alpina strain AF	Intended for use as an ingredient in non-exempt infant formula for term infants at levels providing up to 0.75% of fat as ARA M. alpina oil will be used in combination with a safe and suitable source of DHA at a ratio ranging from 1:1 to 2:1 ARA:DHA
1236	June 10, 2025	Algal oil (≥40% DHA) from Aurantiochytrium limacinum H Sc-01	Intended for use as an ingredient in non-exempt infant formula for term infants at a maximum level of 0.5% (w/w) of total fat as DHA in combination with a safe and suitable source of ARA at a ratio ranging from 1:1 to 1:2 of DHA to ARA

Codex Alimentarius

The Codex Alimentarius is not a regulatory body, rather a standard setting body. However, it's relevant to the current discussion because there are countries that adopt, in part or in full, Codex standards as their own regulation(s). Codex considers the age of an infant to be 0 to <6 months and an older infant to be 6-12 months. Under the Codex Alimentarius standard, DHA, and thus ARA, are optional ingredients for addition to infant formulas.

Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants CXS 72-1981

Docosahexaenoic acid*

Unit	Minimum	Maximum	GUL**
% of fatty acids	-	-	0.5

*If DHA is added to infant formula, ARA contents should reach at least the same content as DHA. The content of EPA should not exceed the content of DHA.

**Guidance upper levels (GULs) are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

Standard for Follow-Up Formula for Older Infants and Products for Young Children CXS 156-1987

Docosahexaenoic acid*

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	30
mg/100 kJ	-	-	7

*If DHA is added to follow-up formula for older infants, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and ARA contents should reach at least the same content as DHA. The content of EPA should not exceed the content of DHA.

European Union

The EU considers infants to be <12 months of age,[4] and infant and follow-on formulas are foods used by infants.

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

[4] Article 2(2)(a) of Regulation (EU) No 609/2013

compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

- Mandatory addition of DHA (minimum: 4.8 mg/100 kJ or 20 mg/100 kcal; maximum: 12 mg/100 kJ or 50 mg/100 kcal), but not ARA
- Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2% of the total fat content for n-6 long-chain polyunsaturated fatty acids (1% of the total fat content for arachidonic acid (20:4 n-6)).
- The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

China

China considers the age of an infant to be 0 to <6 months and an older infant to be 6-12 months. DHA, and thus ARA, are optional ingredients for addition to infant formulas.

GB 10765-2021 National Food Safety Standard: Infant Formula
GB 10766-2021 National Food Safety Standard: Older Infant Formula

	Indicators			
	/100 kJ		/100 kcal	
	Minimum	Maximum	Minimum	Maximum
DHA* (mg)	3.6	9.6	15	40
ARA (mg)	Not specified	19.1	Not specified	80

*If DHA is added to infant or older infant formula, at least the same amount of ARA shall be added. The amount of EPA shall not exceed the amount of DHA.

Australia

- Australia considers infants to be 0 to 12 months of age. Infant formula is for infants 0 to <6 months of age and follow-on formula is for infants 6-12 months of age.
- Schedule 29 allows for the use of DHA in infant formula products up to 12 mg/100 kJ.
- Food Standards Code – Standard 2.9.1 requires that infant formula and follow-on formula must have an ARA content equal to or more than DHA content and an EPA content no greater than DHA.
- Note that the revised regulation for infant formula products came into effect on 13 September 2024 and applies in Australia only. New Zealand opted out of this standard under Annex D of The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System.

Canada
From October 23, 2024 - January 22, 2025, Health Canada ran a consultation on proposed compositional requirements for infant foods and foods currently regulated as foods for special dietary use. Proposed compositional requirements were provided for the proposed category of infant formulas (0-12 months), which are currently regulated as human milk substitutes under Division 25 of the Food and Drug Regulations (FDR). DHA is listed as an optional ingredient.

	Minimum (per 100 kcal)	Maximum (per 100 kcal)
DHA* (mg)	0	50

*If DHA is added, ARA contents should reach at least the same level as DHA. The content of EPA should not exceed the content of DHA.

South Korea
According to MFDS Notice No. 2025-56, on August 26, 2025, the South Korean Ministry of Food and Drug Safety promulgated revisions to the Food Code with changes to infant formula effective on January 1, 2028. Among the changes to infant formula is the mandatory inclusion of DHA (unknown level). A fully translated document was not available in advance of submitting these comments, so the ARA requirements, if any, are unknown.

Indonesia (available upon request)
Per BPOM Regulation 01/2018 on Control of Processed Food for Special Nutritional Purposes, DHA is an optional ingredient in infant formula (birth to <6 months) and follow-up formula (6-12 months).

- Infant formula
  - DHA:
    - Minimum: 0.2% of fatty acids
    - Upper Reference Limit (highest value of nutrient content obtained based on considerations of meeting infant nutritional needs and a history of safe use, but not based on risk assessments): 0.5% of fatty acids
  - ARA: The addition of DHA to infant formula must be accompanied by the addition of ARA at a ratio of 1:1-2.
  - EPA content must not exceed the DHA content.
- Follow-up formula
  - DHA:
    - Minimum: 0.2% of fatty acids
    - Upper Reference Limit: 0.9% of fatty acids
  - ARA: The addition of DHA to infant formula must be accompanied by the addition of ARA at a ratio of 1:1-2.
  - EPA content must not exceed the DHA content.

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

To summarize, GOED strongly recommends establishing requirements, as shown in the following table, for the mandatory addition of DHA and ARA to infant formula and thus the addition of both fatty acids to 21 CFR 107.100.

	Minimum (mg/100 kcal)	Maximum (mg/100 kcal)
DHA[a]	20	50
ARA[a]	20	50

[a]DHA and ARA to be added at a ratio from 1:1 to 1:2 of DHA to ARA

Thank you for the opportunity to submit comments. Should you have any questions, please do not hesitate to contact me at harry@goedomega3.com.

Sincerely,

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