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DSM Nutritional Products Asia Pacific

Response to Food Standards Australia New Zealand (FSANZ) 2ND Call for Submissions – Proposal P1028 “Infant Formula” published 26 April 2023

Submitted on 7 July 2023

Registered as DSM Nutritional Products Asia Pacific. Business registration Number: 53192777J (a division of DSM Singapore Industrial Pte Ltd, ACRA Registration No. 199100649D)

Submitters Details 1 & 2

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DSM Nutritional Products Asia Pacific is an affiliate of DSM Nutritional Products Ltd, the global market leader in the manufacturing and distribution of nutritional ingredients, in particular vitamins, carotenoids, polyunsaturated fatty acids and nutraceutical ingredients. Therefore, we have expertise in these nutrients and their uses. DSM Nutritional Products Ltd and its affiliate offices have actively participated in developing vitamins and minerals food fortification regulations or guidelines at the individual country, EU and Codex levels.

We thank the Foods Standards Australia and New Zealand (FSANZ) for extending the opportunity to comment on the Proposal.

1. Inclusion of Calcium Methylfolate as a permitted nutrient form of Folic Acid in the new Schedule 29-23 Permitted forms of Vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and foods for special medical purposes

For avoidance of ambiguity, the snip below from the document "2nd Call for Submission – Proposal P1028 26th April 2023", Page 123, is in reference.

[2] **After section S29—22**

Insert

S29—23 **Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes**

For sections 2.9.1—10(a), 2.9.2—4, 2.9.2—5, 2.9.2—6, 2.9.3—3(2)(c)(iii) and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, etc

Vitamin, mineral or electrolyte	*Permitted forms*
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5'-phosphate
Folic acid	Folate (excluding naturally occurring folate)

To include Calcium Methylfolate

New scientific evidence as assessed by EFSA (2020)[1], a Codex RASB, concludes that "the folic acid nutrient source Calcium-L-methyl-folate is safe, bioavailable and suitable for use in all foods intended for infants and young children". This folic acid nutrient source is the natural form as found in human milk. Based on the new scientific finding, the permitted uses for calcium-L-methyl-folate in the Advisory List of nutrient compounds CAC/GL 10-1079 was tabled under Proposal item 1.2 during the recent CODEX CCNFSDU 43rd meeting held on 10 March 2023 in Duesseldorf Germany[2] to be extended to include also Infant Formula Sec A, Follow-up Formula, PCBF and CBF, in addition to the current two FSMP permissions.

DSM would like to request FSANZ to review the permission of use of Calcium Methylfolate as a permitted form of Folic acid in light of the recent CODEX CCNFSDU 43rd meeting. The delegation had unanimously agreed to 'Proposal 1.2: Proposal to align the permitted uses of the

[1] Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food 10.2903/j.efsa.2020.5947

[2] https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCNFSDU&session=43

folic acid source Calcium-L-Methyl-Folate with those of N-Pteroyl-Glutamic acid in the Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CVG 10-1979) (Para 100 in the CCFSDU 43 Final Report[3]).

Para 101 states, "*CCNFSDU43 agreed to the recommendation of the PWG to revise the Advisory list of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies and submit the revision directly to CAC46 for adoption (Appendix V)*."

100. CCNFSDU43 agreed to the recommendation of the PWG to delete paragraph 9.5.2 from Standard CXS 73-1981 and submit the amendment directly to CAC46 for adoption (Appendix IV).

Proposal 1.2: Proposal to align the permitted uses of the folic acid source Calcium-L-Methyl-Folate with those of N-Pteroyl-L-Glutamic acid in the *Advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979) (submitted by Switzerland)

101. CCNFSDU43 agreed to the recommendation of the PWG to revise the *Advisory list of nutrient compounds* in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies and submit the revision directly to CAC46 for adoption (Appendix V).

[3] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-43%252FFinal%2BReport%252FREP23_NFSDUe.pdf

APPENDIX V

PROPOSED AMENDMENT TO *THE ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN* (CXG 10-1979)

(For adoption)

SECTION B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

All additions are shown in **bold underlined** font.

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	International and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
10. Folic acid								
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√
10.2 Calcium-L-methyl-folate		JECFA (2005)**; USP**	**√**	√	**√**	**√**	**√**	√

[1] CAC = Codex Alimentarius Commission
[2] IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[3] IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBF = Processed Cereal Based Foods for Infants and Young Children
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes other than Infant Formula

Calcium Methylfolate is not a new ingredient permitted in the Code. It was assessed in 2008 under Application A566 L-methylfolate, calcium[4] as a permitted form of folate for use in Foods for Special Medical Purposes as an alternative vitamin form of folate, as presently reflected in Schedule S29-20 Substances that may be added to food for special medical purposes[5]. It is noted that the risk assessment undertaken in A566 was for use in a range of foods excluding infant foods. It concluded that "As L-MTHF is bioequivalent to folic acid and raises no safety concerns, consumers would not be disadvantaged if L-MTHF were permitted as an alternative vitamin form of folate. In fact, consumers may consider there are potential benefits with

[4] https://www.foodstandards.gov.au/code/applications/Pages/applicationa566lmeth3419.aspx
[5] https://www.legislation.gov.au/Details/F2023C00451

fortifying food with a form of folate found naturally in the body, and which is unlikely to mask a Vitamin B12 deficiency."

EFSA Scientific Opinion evaluating Calcium methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processes cereal-based food[6] notes that "Having assessed the intervention study in healthy infants provided by the applicant, the Panel notes that overall the study did not indicate differences in growth and tolerance parameters in infants who consumed either an infant formula supplemented with the NS or with folic acid, and that no concerns were raised regarding safety or tolerability of the infant formula with the novel substance" and "concludes that the NS, calcium L-methylfolate, is safe under the proposed uses and use levels for infants and young children."

Conversion of Calcium Methylfolate to Folic acid equivalents

The EFSA AFC Panel concluded that folic acid and calcium L-methylfolate have similar bioavailability at equimolar doses of supplementation (EFSA AFC Panel, 2004). Therefore, the amount of calcium L-methylfolate to be added to meet the compositional requirements for folate can be calculated on the basis of the respective molecular weights of calcium L-methylfolate (497.5 g/mol) and folic acid (441.4 g/mol)[6]. Table 1 from the EFSA Scientific Opinion June 2022[7] offers a comparison on the chemical nomenclature and identity.

As such, based on the current minimum requirement of Folic acid in Infant Formula listed in Schedule 29 – 5,

2.4 ug Folic acid per 100 kJ is equivalent to $\frac{497.5}{441.4} \; x \; 2.4 = \mathbf{2.7}$ ug Calcium Methylfolate on an equimolar basis.

DSM is in agreement with the current preference of FSANZ to retain the unit of measurement for Folic acid as ug per 100kJ based on the conversion proposed above.

[6] doi: 10.2903/j.efsa.2020.5947, EFSA Journal 2020;18(1):5947

[7] doi: 10.2903/j.efsa.2022.7452, EFSA Journal 2022;20(8):7452

Table 1: Identity of folic acid, 5-MTHF-glucosamine and CaLMF

	Folic acid	5-MTHF-glucosamine	CaLMF
Synonyms	Pteroylmonoglutamic acid (PGA)	(6S)-L-5-methyltetrahydrofolic acid, glucosamine salt; (6S)-5-methylfolate, glucosamine salt	N5-Methyl-tetrahydrofolic acid, calcium salt; 5-Methyltetrahydropteroylglutamate, calcium salt
Chemical name (IUPAC)	L-Glutamic acid, *N*-[4-[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl) methyl]amino]benzoyl]-	L-Glutamic acid, *N*-[4-[[[(6*S*)-2-amino-3,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl] methyl]amino]benzoyl]-, compound with 2-amino-2-deoxy-D-glucose (1:2)	L-Glutamic acid, *N*-[4-[[[(6*S*)-2-amino-3,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl]methyl] amino]benzoyl]-, calcium salt
Molecular formula	$C_{19}H_{19}N_7O_6$	$C_{20}H_{25}N_7O_6.2C_6H_{13}NO_5$	$C_{20}H_{25}N_7O_6.Ca$
Molecular weight	441.4 g/mol	817.80 g/mol	497.5 g/mol
CAS Registry number	59–30-3	1181972–37-1	129025–21-4

2. Removal of the prohibition on the use of ITF (Inulin type fructans) and/or GOS with LNnT in Standard 2.9.1 – 12 Restrictions on addition of inulin-type fructans and galato-oligosaccharides

For avoidance of ambiguity, the snip below from the document "2nd Call for Submission – Proposal P1028 26th April 2023", Page 104, is in reference.

2.9.1—12 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

(1) If an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only *inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only *galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

(2) Infant formula and follow-on formula to which an inulin-type fructan or a galacto-oligosaccharide is added must not contain lacto-N-neotetraose as an added substance.

DSM would like to draw FSANZ's attention to Application A1265 – 2'-FL DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt for use as nutritive substances in infant formula products[8]. We note from the Call for Submissions that FSANZ is proposing in the draft variation to the Code to remove the current prohibition in Standard 2.9.1 on the use of ITF and/or GOS with LNnT.

As per Para 2.2.6 of the Call for Submissions on Application A1265, the amendment is proposed on the basis that "LNnT is a HMO and is permitted to be added to IFP at concentrations consistent with human milk. LNnT has no known chemical or biological characteristics different from other permitted HMOs that would lead to adverse outcomes in infants. Consistent with FSANZ's assessment for the removal of the prohibition for 2'-FL with ITF and/or GOS (see Application A1251), FSANZ is satisfied that there are no public health and safety concerns with the combination of ITF and/or GOS in IFP with LNnT at current permitted maximum use amounts". As such, DSM would like to seek clarity if the draft Infant Formula Standards 2.9.1 would incorporate the variations introduced in Attachment A of the above-mentioned Application A1265, specifically repealing subsection 2.9.1 – 7(2) (Page 28).

[8] https://www.foodstandards.gov.au/code/applications/Documents/A1265%20CFS%20Report.pdf

Schedule

Standard 2.9.1—Infant formula products

[1] Subsection 2.9.1—7(2)

Repeal the subsection.

3. Minimum voluntary Docosahexanoic acid (DHA) levels for Infant formula (0-6 mths) and Follow-up Formula for older infants (6-12 mths)

DSM references section 4.5.3 on Docosahexanoic acid (DHA) of the document "Supporting Document 2 Nutrient Composition for Infant Formula Products Proposal P1028 – Infant Formula 2nd CFS", Page 36.

DSM notes that FSANZ has adopted the preferred option of retaining the voluntary permission for DHA addition. The draft Schedule S29-4 Infant formula products—limits on fatty acids that may be present in infant formula and follow-on formula does not reflect any minimum content when DHA is added as an optional ingredient, only a GUL of 7 mg/100kJ was adopted.

On the contrary, DSM would like to petition for FSANZ to reconsider their position with relation to DHA on the basis of these key fundamentals, namely, the guiding principles for the addition of optional ingredients laid out in CODEX Standard CXS 72-1981, human milk DHA levels, clinical trial data establishing efficacious levels of DHA (+ ARA) addition into formulas and lastly, expert recommendations from RASB based on the totality of the body of evidence.

The Codex Infant Formula Standard CXS 72-1981 Para 3.2.1 permits the addition of optional ingredients to formulas for infants "*in order provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies*." Para 3.2.2 states that "*the formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.*"

As such, it is appropriate to look to human milk DHA levels, and clinical trial data establishing efficacious levels of DHA (+ ARA) addition into formulas in order to establish minimum levels in formula. In addition, expert recommendations should be consulted.

In the absence of a scientifically substantiated minimum amount, there is a risk that products containing an optional ingredient may not contain sufficient quantities shown to elicit a physiological benefit in the target population.

3.1 The physiological function of DHA in Infants – integral to brain and eye structure and function

DHA is essential for normal brain and eye development because it is a structural component of the nervous tissue and retina[9,10]. During the last trimester of pregnancy and for the first 18 months of life, DHA And ARA rapidly accumulate in the cerebral cortex[11]. Evidence continues to emerge demonstrating the importance of these two fatty acids for the healthy structure and function of the brain as well as gene expression and signalling pathways. Given the rapid development of the brain during pregnancy and the first two years of life, neurodevelopment is particularly vulnerable to nutrient deficiencies. Multiple trials have shown that higher plasma or red blood cell DHA levels are positively correlated with neurodevelopment outcomes.

3.2 Breastmilk as the Gold Standard – Human Milk *always* contains DHA

Human milk is considered the preferred source of nutrition for healthy infants[12]. Human milk always contains both ARA and DHA, and breastmilk content provides an estimate of the range of inclusion levels and ratios that are to be added to formulas to achieve blood levels and functional outcomes more closely resembling those of populations of breastfed infants[13],[14].

Global human milk mean levels have been reported in two highly-cited publications[13,14]. These papers report global human milk mean levels of DHA to be between 0.32 – 0.37% of total fatty acids, respectively, with an ARA:DHA ratio of approximately 1.5:1. The level of 0.32% DHA equates to approximately 20mg/100kcal (4.8mg/100kJ) depending on the fatty acid content of the infant/follow-on formula. EFSA has established an adequate intake level of 100mg DHA per day for Infants (0-12mths) based on clinical evidence and breastmilk levels. Formula fed infants will not meet these recommended levels without the use of pre-formed DHA fortified formula containing *adequate* quantities.

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[9] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2013). Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. *EFSA Journal* 11 :3408, 103 pp. doi:10.2903/j.efsa.2013.3408

[10] 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*. 12: 3760, 106 pp. doi: 10.2903/j.efsa.2014.3760.

[11] Basak, S., Mallick, R., Banerjee, A., Pathak, S., & Duttaroy, A. K. (2021). Maternal Supply of Both Arachidonic and Docosahexaenoic Acids Is Required for Optimal Neurodevelopment. *Nutrients. 13*(6), 2061

[12] World Health Organization (2002). Infant and Young Child Nutrition: Global Strategy on Infant and Young Child Feeding. Fifty Fifth World Health Assembly, Geneva.

[13] Brenna, J.T., B. Varamini, R.G. Jensen, D.A. Diersen-Schade, J.A. Boettcher, and L.M. Arterburn. (2007). Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr. 85: 1457 – 1464

[14] Fu, Y., X. Liu, B. Zhou, A.C. Jiang, and L. Chai. (2016). An updated review of worldwide levels of docosahexaenoic and arachidonic acid in human breast milk by region. *Public Health Nutr.* 19: 2675 – 2687

3.3 Clinical Trials Data – Infants fed formulas without *adequate* preformed DHA have lower DHA status as compared to breastfed infants and infants fed formulas with adequate preformed DHA

Although DHA can be synthesized from the essential fatty acid alpha-linolenic acid (ALA), autopsy studies show that the frontal lobes of infants fed formulas without added ARA and DHA have a lower percentage of total omega 3 fatty acids and DHA compared to breastfed infants[15]. Most clinical trials measure red blood cell DHA levels as an acceptable biomarker for DHA status of neuronal tissues[16]. Infants fed preformed DHA have higher erythrocyte DHA levels compared to infants provided ALA alone in a dose dependent manner (DHA levels studied: 0mg, 17mg 34mg, 51mg per 100kcal)[17]. A trial comparing the red blood cell DHA (RBC DHA) levels among infants fed follow-on formulas with two different levels of DHA (~5mg/100kcal vs. ~15mg/100kcal) and breastfed infants found that infants fed the higher dose of DHA had RBC DHA levels similar to breastfed infants whereas those fed the lower dose (~5mg/100kcal) had levels signi**fi**cantly lower than the higher dose group (~15mg/100kcal) and the breastfed infants[18]. This suggests that low levels of DHA added to infant formulas are not adequate to achieve erythrocyte levels similar to breastfed infants.

[15] Byard, R. W., Makrides, M., Need, M., Neumann, M. A., & Gibson, R. A. (1995). Sudden infant death syndrome: effect of breast and formula feeding on frontal cortex and brainstem lipid composition. *Journal of paediatrics and child health.* 31(1), 14–16.
[16] Kuratko, C. N., & Salem, N., Jr (2009). Biomarkers of DHA status. *Prostaglandins, leukotrienes, and essential fatty acids.* 81(2-3), 111–118.
[17] Colombo, J., Carlson, S. E., Cheatham, C. L., Shaddy, D. J., Kerling, E. H., Thodosoff, J. M., Gustafson, K. M., & Brez, C. (2013). Long-term effects of LCPUFA supplementation on childhood cognitive outcomes. *The American journal of clinical nutrition.* 98(2), 403–412.
[18] Visentin, S., Vicentin, D., Magrini, G., Santandreu, F., Disalvo, L., Sala, M., Fasano, V., & González, H. F. (2016). Red blood cell membrane fatty acid composition in infants fed formulas with different lipid profiles. *Early human development.* 100, 11–15.

3.4 Clinical trials data - Infants fed formulas with preformed ARA and DHA at appropriate levels and ratios have improved visual and neurodevelopmental outcomes compared to infants fed formulas without preformed ARA and DHA

Many studies have demonstrated improved visual and neurodevelopmental outcomes among infants fed infant formulas with added ARA and DHA compared to infants fed a standard infant formula[19,20,10,21]. A recent Cochrane review[20] also concluded neurodevelopmental benefits when infants were fed formulas with added DHA and ARA. The majority of studies showing these benefits have included 0.32 - 0.36% DHA and 0.64% - 0.72% ARA, although some studies with lower levels have also reported benefits. While it is true that the results did not consistently show a benefit, it is important to understand that there is heterogeneity among the measures tested and doses/ratios of DHA and ARA used[20]. The importance of *levels* and *ratios* are demonstrated in the DIAMOND study[21]. In this clinical study, infants were fed formulas containing a range of DHA with varying ARA:DHA ratios for the first year of life and were followed from 6 weeks to 9 years of age. The sustained attention score of infants significantly improved as DHA levels increased from 0mg DHA/100kcal to 17 and 34mg/100kcal as long as the ratio of ARA to DHA was within 1:1 – 2:1. When compared to the no LC-PUFA control group, benefits in physiology, various aspects of cognition, and attention were reported up to 5 years of age in those that received at least 17 mg/100 kcal DHA with the ARA:DHA ratio of 1:1 – 2:1. If the ARA:DHA ratio is less than 1:1, the benefits were typically not observed. Brain imaging (MRI) studies at 9 years of age were consistent with these results and showed that the addition of DHA and ARA at effective levels and ratios during infancy had long lasting positive effects on brain structure and functions[17,,22]. This is reflected in a scientific opinion published by EFSA (2014)[23] where "The Panel concludes that a cause-and-effect relationship has been established between the consumption of DHA and contribution to normal brain development. The following wording reflects the scientific evidence: "*DHA contributes to normal brain development*"."

[19] Koletzko, B., K. Bergmann, J.T. Brenna, P.C. Calder, C. Campoy, M.T. Clandinin, J. Colombo, et al. (2020). 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.* 111: 10 – 16.

[20] Jasani, B., Simmer, K., Patole, S. K., & Rao, S. C. (2017). Long chain polyunsaturated fatty acid supplementation in infants born at term. *The Cochrane database of systematic reviews.* 3(3), CD000376.

[21] Colombo, J., D.J. Shaddy, E.H. Kerling, K.M. Gustafson, and S.E. Carlson. (2017). Docosahexaenoic acid (DHA) and arachidonic acid (ARA) balance in developmental outcomes. *Prostaglandins Leukot Essent Fatty Acids.* 121: 52 – 56.

[22] Lepping, R. J., Honea, R. A., Martin, L. E., Liao, K., Choi, I. Y., Lee, P., Papa, V. B., Brooks, W. M., Shaddy, D. J., Carlson, S. E., Colombo, J., & Gustafson, K. M. (2019). Long-chain polyunsaturated fatty acid supplementation in the first year of life affects brain function, structure, and metabolism at age nine years. *Developmental psychobiology.* 61(1), 5–16.

[23] Scientific Opinion on the substantiation of a health claim related to DHA and contribution to normal brain development pursuant to Article 14 of Regulation (EC) No 1924/2006 10.2903/j.efsa.2014.3840

The Cochrane review[20] also included nine studies examining visual acuity among infants fed formulas with added ARA and DHA compared to infants fed standard formula. Meta-analysis revealed a significant benefit of supplemented formulas for visual evoked potential (VEP) scores at 12 months of age and one study continued to show improvements in VEP scores through 3 years of age[24,25,20]. Meta-analyses of other visual acuity outcomes showed no effect[20]. This may be due to differences in the tools used to measure visual acuity, but also in the doses of DHA utilized in the studies[26]. This is reflected in scientific opinion published by EFSA (2009)[27] where "the panel concludes that there is a cause-and-effect relationship between intake of infant formulas with added DHA at the efficacious level of ~0.3% of total fatty acids and visual acuity at 12 months of age. This led to the adoption of a health claim reflecting the scientific evidence that "*DHA contributes to the visual development of infants*".

3.5 Experts and RASBs recommend including both ARA and DHA in formulas intended for infants at efficacious *levels* and *ratios*.

Recommendations regarding the ARA and DHA content of formulas intended for infants have been published by recognized authoritative scientific bodies (e.g., CAC/CCNFSDU, EFSA, FAO, ANSES/AFSSA) and other scientific experts and expert groups (e.g., European Academy of Pediatrics, French Society of Pediatrics)[28,29Error! Bookmark not defined.13,19,30]

Most of the published opinions of authoritative and international expert groups are in consensus recommending both DHA and ARA, and for the content of DHA not to exceed the content of ARA. Specifically, these bodies concluded that either

a) both DHA and ARA should be added to formulas for infants at levels representative of human milk, with ARA content at least equalling DHA content, or,

[24] Auestad, N., Montalto, M. B., Hall, R. T., Fitzgerald, K. M., Wheeler, R. E., Connor, W. E., Neuringer, M., Connor, S. L., Taylor, J. A., & Hartmann, E. E. (1997). Visual acuity, erythrocyte fatty acid composition, and growth in term infants fed formulas with long chain polyunsaturated fatty acids for one year. Ross Pediatric Lipid Study. *Pediatric research.* 41(1), 1–10.

[25] Connor, S. L., Taylor, J. A., & Hartmann, E. E. (1997). Visual acuity, erythrocyte fatty acid composition, and growth in term infants fed formulas with long chain polyunsaturated fatty acids for one year. Ross Pediatric Lipid Study. *Pediatric research.* 41(1), 1–10.

[26] Decsi, T., Marosvölgyi, T., & Szabó, É. (2023). Docosahexaenoic Acid in Formulas for Term Infants: The Way from Pioneer Idea to Mandatory Dietary Recommendation. *Life (Basel, Switzerland).* 13(6), 1326

[27] Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Mead Johnson Nutritionals on DHA and ARA and visual development. *The EFSA Journal* (2009) 941, 1–14 https://doi.org/10.2903/j.efsa.2009.941

[28] FAO (Food and Agriculture Organization of the United Nations). (2010). Fats and fatty acids in human nutrition: Report of an expert consultation. FAO Food and Nutrition Paper 91.

[29] AFSSA (Agence Française de Sécurité Sanitaire des Aliments). (2010). Opinion of the French food safety agency on the update of French population reference intakes (ANCs) for fatty acids. AFSSA – Request no. 2006-SA-0359.

[30] Tounian, P., M. Bellaïche, and P. Legrand. (2021). ARA or no ARA in infant formulae, that is the question. *Arch Pediatr.* 28: 69 – 74.

b) that these nutrients are *optional*, but if DHA is added then ARA also should be added at levels at least equal to DHA.

These published opinions confirm that consumption of ARA- and DHA-supplemented formulas by infants is safe, with DHA at up to 0.5% of total fat intake and ARA at least the level of DHA. Several expert publications have concluded that clinical evidence supporting the safety and suitability of formulas supplemented with DHA but not ARA is lacking[19,13,30]

3.6 Regulatory Status of DHA and ARA Addition to Infant Formula in major jurisdictions

In 2020, an international panel of 25 experts published a position paper of the European Academy of Paediatrics recommending that infant and follow-on formula should contain DHA between 0.30 – 0.5% of total fatty acids, or at a minimum of 20 mg/100 kcal (4.8 mg/100kJ). They strongly recommend that ARA be provided at least equal to the DHA content[19].

EFSA, in their 2014 opinion concluded that DHA should be considered a mandatory nutrient in infant and follow-on formula (minimum 20 mg/100 kcal)[9]. This is reflected in the EU Regulations EU (2016/217)[31] , Annex II (Article 2(2) Compositional requirements for Follow-on Formula and Infant Formula (Annex I), specifies a minimum content of DHA at 4.8 mg/100kJ (20 mg/100kcal), maximum 12 mg/100kJ for both categories. (See *Figure 2*)

The CODEX Draft Standard for Follow-Up Formula for Older Infants (FuFOI) for 6-12 months[32], which overlaps partially with Standard 2.9.1 Infant Formula (0-12mths) specifies that a minimum content of 20 mg/100kcal (4.8 mg/100kJ) of DHA should be reached when DHA is added to follow-up formula for older infants (6-12mths), and ARA content should reach at least the same concentration as DHA. Although this standard applies for older infants, it is likely that it reflects the current thinking and conclusions on the efficacy of DHA and ARA in 0-12mth Infant population. (See Figure 1)

[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0127-20230317 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 (Text with EEA relevance)

[32] REPORT OF THE FORTY-THIRD SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES https://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-43%252FFinal%252520Report%252FREP23_NFSDUe.pdf

Figure 1: CODEX Draft Standard for FuFOI, Optional Ingredients, DHA (See yellow highlight)

Docosahexaenoic acid[21)]

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

21) If docosahexaenoic acid (22:6 n-3) 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 arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their population.

Figure 2: Compositional Requirements referred to in Article 2(2) Follow-On Formula (6-12mths) and Annex I, Compositional Requirements referred to in Article 2(1) Infant Formula (0-6mths)

5.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

▼B

4.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

4.7. 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.

While FSANZ's current option of a voluntary DHA addition with no minimum amount does not pose any significant hurdles to manufacturers importing from or exporting to EU, China or CODEX-reliant markets, it may unintentionally create an unequal playing field for local manufacturers should they not wish to maintain multiple SKUs or recipes to accommodate various markets. Considering that a relatively large proportion of Infant formula and toddler milks are exported to China, Hong Kong, Taiwan, Vietnam and Korea[33], the Chinese GB 10766-2021 requirements for Follow-on Formula (6-12mths) specifies a minimum content of 3.6 mg/100kJ DHA when added, maximum of 9.6 mg/100kJ[34]. This further adds to the complexity for local manufacturers.

A market survey[35] of newly launched infant formula (0-6mths), follow-on formula (6-12mths) and growing up milks (1-4years)* in Australia and New Zealand between Jan 2018- June 2023, found a total of 197 new launches over the 5 year period. The average DHA content for Infant Formulas was 4.62 mg/100kJ with a median of 3.64 mg/100kJ. For Follow-on Formula, the average content was 3.44 mg/100kJ with a median of 3.39mg/100kJ. For both, median and average levels were below the RASB recommended levels of 4.8 mg/100kJ (20mg/100kcal). A possible implication may be that infants in Australia and New Zealand are not receiving adequate intakes of DHA and ARA based on the amounts present in the formulas shown to confer physiological beneficial outcomes same as that of breastfed infants. Therefore, specifying a minimum amount of DHA that should be added will ensure that efficacious levels are present for the intended population.

Table 1: DHA levels of Infant Formula (0-12mths) and Growing up milk (1-4 years) launched in ANZ from 2018-2023

Category	*n*	Average DHA (mg/100 kJ)	Median DHA (mg/100 kJ)	Max DHA (mg/100 kJ)	Min DHA (g/100 kJ)
Baby Formula (0-6 mths)	66	4.62	3.64	19.56	0.69
Baby Formula (6-12 mths)	55	3.44	3.39	8.098	0.71
Growing Up Milk (1-4 yrs)*	76	5.82	4.80	42.49	0.44
Grand Total	197				

**Growing up milk (1-4 years) = Formulated Supplementary Food for Young Children*

[33] Infant Nutrition Council, Draft Export Control Rules 2020 – Milk and Milk Products,

[34] GB 10766-2021 National Food Safety Standards Older Infant Formula

[35] Mintel GNPD 2023, search details "ANZ, Baby formula (0-12 mths) Growing up milks (1-4 years)

Conclusion with relation to DHA and ARA addition to Infant formula

DHA and ARA levels in formulas for infants should be in alignment with human milk levels, clinical data defining safe and effective levels and ratios, and expert recommendations.

- Global human milk data show mean levels of DHA to be between 0.32 – 0.37% of total fatty acids, respectively, with an ARA:DHA ratio of approximately 1.5:1[13,14]
- Clinical data show evidence of efficacy at a minimum level of ~0.3% DHA, with ARA:DHA ratios of 1:1 – 2:1. The clinical data also show that these levels are safe and nutritionally suitable.
- Most expert recommendations are for formulas for infants to contain 0.30% - 0.5% DHA or a minimum of 20 mg/100 kcal (4.8mg/100kJ), and ARA at least equal to DHA (1:1 – 2:1). Most regulatory requirements like CODEX, EU, China GB, align with expert recommendations.
- Most major regulations consider DHA to be optional, but when added, ARA must also be added to at least the same level.
- DHA levels present in Infant Formula, Follow-on Formula are *below* the demonstrated, recommended, efficacious levels in Australia and New Zealand over the last 5 years. This may not achieve the intended public health effect of bringing the DHA status of formula-fed infants closer to that of breast-fed infants.

Based on the above, DSM proposes that formulas for infants (0-12mths) should contain, when added, a minimum level of 20 mg/100 kcal (4.8 mg/100kJ) DHA, with ARA:DHA at a ratio of 1:1 – 2:1.

4. Permission of use of Tocopherols in Infant and Follow-on Formula

DSM references section 3.3.2 Ascorbyl palmitate (304), tocopherols concentrate, mixed (307b) and other tocopherols (308 & 309) of the document "Supporting Document 1 Food technology for Infant Formula Products Proposal P1028 – Infant Formula 2nd CFS", Page 18.

For avoidance of doubt, the excerpt is extracted below :

> Tocopherols concentrate, mixed (307b) has the higher MPL of 30 mg/L for the draft Codex FUF, compared to 10 mg/L in the Code. The draft Codex FUF standard also is linked to two other tocopherols – tocopherol, d-alpha (307a) and tocopherol, dl-alpha (307c) – singly or in combination. But neither of these tocopherols are permitted in the Code for any food classes so they are not considered further for permissions for IFP. If specific permission is sought for these alternative forms of tocopherols they will require separate assessment outside of this proposal, i.e. an application.

With relation to the statement that "*But neither of these tocopherols are permitted in the Code for any food classes so they are not considered further for permissions for IFP*", DSM would like to bring to attention Schedule 15 Substances that may be used as food additives[36] S15-5 Table of permissions for food additives, category 0 (Preparations of food additives) and category 2 Edible oils and oil emulsions, where tocopherol, d-alpha, concentrate (307) is permitted at MPL, GMP. See Figure 3.

The EU Regulation for Food Additives (EC) No. 1333/2008, Annex II, Part E, Authorised Food additives and Conditions of use in Food Categories, 13.1.1 Infant Formula and 13.1.2 Follow-on Formulae[37], permits the use of E307 Alpha-tocopherol at a maximum permitted level of 10 mg/kg (alone or in combination with E306, E308, E309). The (EU) No. 231/2012[38] defines E307 as dl-alpha-tocopherol. See Figure 4 and Figure 5.

For completeness, the draft CODEX Standard for Follow up Formula for older infant and products for young children, Section A : Follow-Up formulation for Older infants (6-12mths) which overlaps with the FSANZ Infant Formula Standards, has provisions for the *direct addition* of tocopherol, d-alpha (INS 307a) and tocopherol dl-alpha (INS 307c) at a maximum of 3 mg/100ml singly or in combination. See Figure 6.

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[36] https://www.legislation.gov.au/Details/F2021C00607

[37] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1333-20230322 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance)

[38] https://op.europa.eu/en/publication-detail/-/publication/a42dd9b2-b63f-438b-a790-1fa5995b7d41

A summary on the provisions for tocopherols in EU, CODEX, and FSANZ is provided in Table 2 below.

Table 2: Summary of provisions of use for tocopherols in Infant Formula, Follow-on formula and general food and beverage in EU, CODEX and FSANZ

	EU			CODEX			FSANZ		
Additive	E-	F&B	IF, FO	INS	F&B	IF, FO	INS	F&B	IF, FO
d-alpha-tocopherol	n.a.	N	N	307a	Y	IF: N; FO: Y	307	Y	N
dl-alpha-tocopherol	E307	Y	Y	307c	Y	IF: N; FO: Y	n.a.	N	N
Mixed tocopherol	E306	Y	Y	307b	Y	Y	307b	Y	Y

Y : Yes ; N : No ; N.A. : Not available
IF : Infant Formula (0-6 mths) corresponding to Category 13.1.1
FO : Follow-up formula (6-12mths) corresponding to Category 13.1.2

Given the above, DSM would like to petition for FSANZ to review its position with relation to tocopherol, d-alpha, concentrate (307) and tocopherol, dl-alpha (INS 307c) in permitting its use as an antioxidant in Infant Formula Products in the Code, in alignment with the draft CODEX FUF standard which FSANZ is aware of, and the EU Food Additive Regulation (EC) No. 1333/2008.

Figure 3: FSANZ Schedule 15 – Substances that may be used as Food Additives. D-alpha-tocopherol (307) is permitted as an additive in 2 categories

Permissions for food additives

INS (if any)	*Description*	*MPL*	*Conditions*
0	**Preparations of food additives**		
	Additives permitted at GMP		
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1 000	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1 000	
216	Propyl p-hydroxybenzoate (propylparaben)	2 500	
218	Methyl p-hydroxybenzoate (methylparaben)	2 500	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	350	
243	Ethyl lauroyl arginate	200	
304	Ascorbyl palmitate	GMP	
307	Tocopherol, d-alpha-, concentrate	GMP	
307b	Tocopherols concentrate, mixed	GMP	
308	Synthetic gamma-tocopherol	GMP	
309	Synthetic delta-tocopherol	GMP	

Permissions for food additives

INS (if any)	*Description*	*MPL*	*Conditions*
2	**Edible oils and oil emulsions**		
160b	Annatto extracts	20	
304	Ascorbyl palmitate	GMP	
307	Tocopherol, d-alpha-, concentrate	GMP	
307b	Tocopherols concentrate, mixed	GMP	
308	Synthetic gamma-tocopherol	GMP	
309	Synthetic delta-tocopherol	GMP	

As at 3 June 2021 Schedule 15

Authorised Version F2021C00607 registered 08/07/2021

Figure 4: REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE Council of 16 December 2008

▼M2

13	**Foods intended for particular nutritional uses as defined by Directive 2009/39/EC**	
13.1	**Foods for infants and young children**	
	INTRODUCTION PART, APPLIES TO ALL SUBCATEGORIES	
		The maximum levels of use indicated refer to foods ready for consumption prepared following manufacturers' instructions
		E 307, E 325, E 330, E 331, E 332, E 333, E 338, E 340, E 410, E472c and E 1450 shall be used in conformity with the limits set in the Annexes to Directive 2006/141/EC
13.1.1	**Infant formulae as defined by Directive 2006/141/EC**	
		Note: For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used

▼M2

Category number	E-number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	Restrictions/exceptions
	E 270	Lactic acid	*quantum satis*		only L(+)-form
	E 304(i)	L-ascorbyl palmitate	10		
	E 306	Tocopherol-rich extract	10	(16)	
	E 307	Alpha-tocopherol	10	(16)	
	E 308	Gamma-tocopherol	10	(16)	
	E 309	Delta-tocopherol	10	(16)	

13.1.2	**Follow-on formulae as defined by Directive 2006/141/EC**				
		Note: For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used			
	E 270	Lactic acid	*quantum satis*		only L(+)-form
	E 304(i)	L-ascorbyl palmitate	10		
	E 306	Tocopherol-rich extract	10	(16)	
	E 307	Alpha-tocopherol	10	(16)	
	E 308	Gamma-tocopherol	10	(16)	
	E 309	Delta-tocopherol	10	(16)	
	E 322	Lecithins	1 000	(14)	
	E 330	Citric acid	*quantum satis*		
	E 331	Sodium citrates	2 000	(43)	
	E 332	Potassium citrates	*quantum satis*	(43)	

Figure 5: COMMISSION REGULATION (EU) No 231/2012 Laying down specifications for food additives listed in Annex II and III to the Regulation (EC) No. 1333/2008

E 307 ALPHA-TOCOPHEROL

Synonyms	dl-α-Tocopherol; (all rac)-α-Tocopherol
Definition	
Einecs	233-466-0
Chemical name	DL-5,7,8-Trimethyltocol; DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula	$C_{29}H_{50}O_2$
Molecular weight	430,71
Assay	Content not less than 96 %
Description	Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light
Identification	
Solubility	Insoluble in water, freely soluble in ethanol, miscible in ether
Spectrophotometry	In absolute ethanol the maximum absorption is about 292 nm
Specific rotation	$[\alpha]_D^{25}$ 0° ± 0,05° (1 in 10 solution in chloroform)
Purity	
Refractive index	$[n]_D^{20}$ 1,503-1,507
Specific absorption in ethanol	$E_{1cm}^{1\%}$ (292 nm) 71-76 (0,01 g in 200 ml of absolute ethanol)
Sulphated ash	Not more than 0,1 %
Lead	Not more than 2 mg/kg

Figure 6: Food additives permitted for use in Follow-up formula for older infants - tocopherol (INS 307a, 307c)

4. Food Additives

The following additives are permitted[22]:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	

5. Permission of food additives in nutrient preparations

DSM references section 3.3.14 Silicon dioxide (amorphous) (551) Page 21 and Appendix 1 "Summary of submitter comments and FSANZ responses for Food Additives" page 37-38 of the document "Supporting Document 1 Food technology for Infant Formula Products Proposal P1028 – Infant Formula 2nd CFS",

For avoidance of doubt, the excerpt is extracted below :

Other issues raised.	Questioned the inconsistency of FSANZ approach to addressing permissions for food additives in nutrient preparations. It is noted that if the substances are either functioning as a processing aid carrier and is already permitted or is a permitted form of vitamins, minerals or electrolytes than it is already permitted and so no additional permission for use in nutritive preparations is required. It notes that FSANZ has explicitly proposed permissions for use of INS 333 [calcium citrates] and INS 341 [actually only 341(iii), tricalcium phosphate] in nutrient preparations, when both these food additives are generally permitted processing aids (carriers). It has noted that FSANZ has explicitly not permitted a number of such food additives (e.g. INS 414, 551, 421, 1450 and 301) [listed in section D – Advisory list of food additives for special nutrient	DAN INC FCG	The reason for adding permissions for these two specific food additives with very specific condition statements was to ensure consistency with the EU Regulations 1130/2011 (amending (EC) 1333/2008, Annex III, part 5, section B), as explicitly requested by industry submitters including INC to the CP1 2021. This was to ensure regulatory certainty for use of food additives in nutrient preparations and alignment with the EU Regulations, including using the same condition statements. FSANZ is also proposing to add permissions for the use of sodium ascorbate (INS 301) for use in nutrient preparations to be consistent with EU

Issue	Comment	Submitter(s)	FSANZ Response
	forms within Codex CAC/GL 10-1979] since they are also generally permitted processing aids.		Regulations and CXG 10-1979 since its technological purpose appears to be most appropriate as an antioxidant food additive (due to Codex Guideline CXG 36-1989) and not as a processing aid carrier. However, if industry agree that there is no need to add such permissions for substances performing the technological purpose as processing aid carriers into the Code then FSANZ is comfortable removing them. It notes that permission has been added for use of silicon dioxide (also listed in CXG 10-1979) as an anti-caking agent food additive (not carrier) for nutrient preparations to ensure regulatory certainty.

DSM notes FSANZ's intention in providing regulatory certainty in the Code for 2 additives – sodium ascorbate (INS 301) and Silicon dioxide (INS 551) for use in nutrient preparations with the same condition of use statements and maximum limits. However, DSM notes that this creates confusion and ambiguity within the Code as well as in relation to the other 3 food additives which are permitted for use as nutrient carriers under CODEX Guidelines CXG 10-1979, Part D

While FSANZ's position is clear with regard to the 5 food additives (Gum Arabic INS 414, Silicon dioxide INS 551, Mannitol INS 421, Starch sodium octenyl succinate INS 1450, Sodium ascorbate INS 301) that these "*can be considered as generally permitted processing aids in the Code so no changes to the Code are required*[39]" and therefore, the maximum limits of use are at GMP,

[39]Page 22, 2.3.4 Discussion Additives in nutrient preparation CP1 Safety and food technology P1028, May 2021

the recent proposal by FSANZ above stipulates limits for 2 of the food additives – sodium ascorbate at 50 mg/L (in FUF) and Silicon dioxide at 10 mg/L (with the note 'May only be added as part of a nutrient preparation'). The use scenario, *as part* of a nutrient preparation, or *in* a nutrient preparation are essentially the same manner by which the additive or carrier would be present in the finished product i.e. the infant formula, as noted by the unit of expression per litre (L). This is incongruent within the Code itself to have two conflicting limits.

It is noteworthy to mention that the CODEX Guidelines CXG 10-1979 Advisory List, Part D, permits a maximum level of 75 mg/kg Sodium Ascorbate in the ready-to-use format. FSANZ has adopted a similar level of maximum 50 mg/L sodium ascorbate in FuF (6-12 months). This poses an analytical challenge to distinguish which sodium ascorbate was present from its use in a nutrient preparation (for example polyunsaturated fatty acids powders) and which was present as a direct addition into the infant formula recipe to comply with the respective limits. To add to the complexity, Sodium ascorbate is a permitted form for Vitamin C and is permitted for infant formula fortification, which presents an additional challenge in distinguishing the origins in a finished product.

With regard to Silicon dioxide (INS551) maximum use limits, DSM notes that both the Code and CODEX Advisory List Part D are aligned at maximum 10 mg/L in the ready-to-use format. An overview is presented in the table below.

Food Additive (INS)	CP1[40], 2016 Consultation[41] as Processing aid carriers	CFS2	CODEX Advisory List, Part D	(EC) No. 1333/2008 Annex III, Part 5, Section B
Gum Arabic (INS 414)	GMP	Not expressly permitted	10 mg/kg	10 mg/kg
Silicon dioxide (INS 551)	GMP	10 mg/L	10 mg/kg	Not set at RTU level (10, 000 mg/kg in *nutrient preparation*)
Mannitol* (INS 421)	GMP	Not expressly permitted	10 mg/kg	3 mg/kg
Starch sodium octenyl succinate (INS 1450)	GMP	Not expressly permitted	100 mg/kg	100 mg/kg for Vitamin preparations in RTU 1,000 mg/kg for PUFA preparations in RTU
Sodium ascorbate** (INS 301)	GMP	50 mg/L (FuF only)	75 mg/kg	1 mg/L for Vitamin D 75 mg/L for PUFAs

[40] FSANZ 2021 Consultation Paper 1, Supporting Document 1 - Food Additives

[41] FSANZ 2016 Consultation – Infant Formula, Supporting Document 2 – Safety & food technology

*as a carrier for Vitamin B12 dry powders
**in Vitamin D preparations and coating of nutrient preparations containing polyunsaturated fatty acids

The format that FSANZ has presented on Page 131 of the CFS2 (see Figure 7) may cause unintended regulatory ambiguity for parties who are unfamiliar with the discussion on P1028 and FSANZ's position with relation to these 5 food additives being viewed as processing aids, not food additives. DSM fully agrees and is clear with FSANZ's position in 2016, subsequently reiterated in FSANZ 2021 Consultation Paper 1, SD 1 Food Additives that "*these 5 Food additives are "permitted at GMP in the Code and as such, can be considered as processing aids under the Code. (…) Therefore, these substances can be used as processing aids (i.e. carriers) in nutrient preparations for infant formula product. No changes to the Code are required to permit their continued use and the proposed changes to carry-over provisions will not impact their use (as generally permitted processing aids, which can include the technological purpose of carrier).*"

DSM would like to urge FSANZ to reconsider the manner by which the regulatory permissions on the above are expressed in the draft regulations namely in the consistency. DSM is of the view that if Sodium Ascorbate, Silicon dioxide are stated in its use as part of a nutrient preparation, for consistency, the other 3 food additives (Gum Arabic, mannitol and starch sodium octenyl succinate) should also similarly be stated. Conversely, if the latter 3 are not explicitly stated, the former 2 additives should also be excluded to minimise ambiguity.

Figure 7: Draft Schedule 15—Substances that may be used as food additives

13.1	***Infant formula products***		
270	Lactic acid	GMP	
300	Ascorbic acid	50 mg/L	See Note 1, below.
301	Sodium ascorbate	50 mg/L	See Note 1, below.
302	Calcium ascorbate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
307b	Tocopherols concentrate, mixed	30 mg/L	See Note 1, below
308	Gamma-tocopherol	10 mg/L	
309	Delta-tocopherol	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrates	GMP	
332	Potassium citrates	GMP	
338	Phosphoric acid	450 mg/L	Not for follow-on formula
339	Sodium phosphates	450 mg/L	Not for follow-on formula
340	Potassium phosphates	450 mg/L	Not for follow-on formula
407	Carrageenan	300 mg/L	Only in a liquid product
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	Only in a liquid product that contains hydrolysed protein
440	Pectins	10 000 mg/L	See Note 1, below
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
472c	Citric and fatty acid esters of glycerol	7 500 mg/L	Only in a powdered product
		9 000 mg/L	Only in a liquid product
500	Sodium carbonates	2 000 mg/L	
501	Potassium carbonates	2 000 mg/L	
524	Sodium hydroxide	2 000 mg/L	
525	Potassium hydroxide	2 000 mg/L	
526	Calcium hydroxide	2 000 mg/L	
551	Silicon dioxide (amorphous)	10 mg/L	May only be added as part of a nutrient preparation
1412	Distarch phosphate	5 000 mg/L	See Note 2, below.
1413	Phosphated distarch phosphate	5 000 mg/L	See Note 3, below.
1414	Acetylated distarch phosphate	5 000 mg/L	See Note 4, below.
1422	Acetylated distarch adipate	5 000 mg/L	See Note 5, below.
1440	Hydroxypropyl starch	5 000 mg/L	See Note 6, below.

=== End of submission ===