DSM Nutritional Products Asia Pacific

Response to Food Standards Australia New Zealand Consultation Paper – Proposal P1028 “Infant Formula” published 23 February 2016 [05-16] (amended 4 May 2016)

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Preamble

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.

Overview

DSM Nutritional Products Pty Ltd, in response to FSANZ Consultation Paper P1028 on "Infant Formula", would like to offer comments pertaining to these questions published in *Attachment 1 – Summary of questions to submitters* and the corresponding *Supporting Documents 1 and 2*.

From Supporting Document 1 : Definitions and Nutrient Composition

No.	Section of the SD	Question
Q1.2	2.2	Q1.2: Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula? (1) "satisfies by itself the nutritional requirements of infants less than 6 months of age" (2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding " (3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age (4) no change
-	4.4	Comments regarding Section 4.4 "Long Chain polyunsaturated Fatty acids" and subsequent sub-sections of Supporting Document 1
Q1.5	4.5	What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale.
Q1.12	7.3.3.1	Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.
Q1.13	7.3.3.2	Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.
Q1.16	7.3.3.4	Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL? Please provide your rationale.

Q1.22	8.1.1	What is the justification to retain β-carotene as a provitamin A form?
Q1.24	9.1	Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.
Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
Q1.30	9.3	Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.

From Supporting Document 2 : Safety and Food Technology

No.	Section of the SD	Question
Q2.31	8.3	Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.
	9.1, 9.2	Processing Aids

DSM’s Comments to Supporting Document 1 : Definitions and Nutrient Composition

No.	Section of the SD	Question
Q1.2	***2.2***	***Q1.2: Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?*** ***(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"*** ***(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding "*** ***(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age*** ***(4) no change***

DSM's comments

DSM is of the opinion that Option (2) "*satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding*" is preferable as it reflects the fact that some children require the introduction of complementary foods earlier than others.

No.	Section of the SD	Question
-	*4.4*	***Comments regarding Section 4.4 "Long Chain polyunsaturated Fatty acids" and subsequent sub-sections of Supporting Document 1***

DSM's comments

The preliminary view of revised section 4.4 provides clarity with regard to specific n-3 and n-6 LC-PUFA of interest, in particular, DHA and AA, respectively. We fully agree with FSANZ's preliminary view "*that it is appropriate to maintain a maximum proportion of AA*[1] *and to replace the minimum ratio of total n-6 to total n-3 with a ratio of AA:DHA to avoid metabolic imbalance between the two LC-PUFA families*[2]". In addition, introducing a ratio of AA to DHA where AA is greater than or equal to DHA would bring Standard 2.9.1 into harmony with Codex STAN-72-1981.

However, regarding FSANZ's preliminary view "*that a minimum level of DHA is not supported by the evidence and that a guidance upper limit is sufficient*"[3], DSM would like to suggest for FSANZ to reconsider this position as we strongly believe a minimum level of DHA, with an equal or greater amount of AA, is scientifically justified and that the addition of both DHA and AA to infant formula, which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, should be mandatory.

FSANZ rightly points out that EFSA[4] found no developmental benefits *beyond* infancy, but that benefits *during* infancy are supported by convincing evidence[5]. EFSA therefore recommends addition of DHA to all infant formula and recently revised the EU regulations requiring mandatory addition of DHA (minimum 20 mg/100 kcal). The minimum level of 0.3% total fatty acids as DHA is considered as bringing benefits in eye and brain development. FAO/WHO granted a "convincing" level of evidence for a "critical role in retinal and brain development" for DHA in infants aged 0-24 months[6]. FAO/WHO Report 91 also established adequate intake levels of 0.20-0.36% of total fatty acids as DHA and 0.4-0.6% of total fatty acid as AA, similarly citing "convincing" evidence in support of these levels. EFSA gave a positive opinion for DHA (min 0.3% total fatty acid) and visual development in infants 0-12 months[7] and for DHA (min 100 mg DHA/day) and normal brain development from 0-24 months[8]. Furthermore, considering particularly Asian populations, recommendations from a recent Early

[1] SD1, Section 4.4.4 AA, Paragraph 3
[2] SD1, Section 4.4.5 Ratios of DHA, AA and LC-PUFA, Paragraph 5
[3] SD1, Section 4.4.3 DHA, Paragraph 5
[4] FSA, 2014a. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760, 106 pp. doi:10.2903/j.efsa.2014.3760.
[5] of SD1 Attachment A1.1 Section 3.4.4.
[6] FAO, 2010. Fats and fatty acids in human nutrition. Report of an expert consultation. FAO Food and Nutrition Paper, 91.
[7] EFSA, 2009. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Mead Johnson Nutritionals on DHA and AA and visual development. The EFSA Journal (2009) 941, 1-14
[8] EFSA, 2014b. 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. EFSA Journal 2014;12(10):3840, 8 pp. doi:10.2903/j.efsa.2014.3840

Nutrition Academy Workshop indicate that "a supply of 100 mg DHA/day should continue during the second half of infancy"[9]

While some meta-analyses [10, 11] may not corroborate with conclusions drawn by recognized authoritative scientific bodies (RASBs), it is important to highlight that results of meta-analyses are often inherently constrained by inclusion criteria designed to create a fairly homogenous dataset. The heterogeneity of study designs due to dose of DHA/AA, duration of supplementation, age of infants at initiation of supplementation, and outcome measures typically precludes meta-analysis of the total evidence base. Referring to the earlier meta-analyses, Simmer[10] and colleagues excluded nearly half the studies identified as irrelevant (i.e. 10 of 25 trials) and Sun[11] and co-workers only considered cognitive outcomes when assessing neurodevelopmental benefits, disregarding the significant evidence base for improvements in visual development. In contrast, RASBs such as EFSA and FAO/WHO not constrained by the need to consider a homogeneous dataset, as they assess each individual study for its own merit, and thus their conclusions tend to be more comprehensive.

There are also large nutritional compositional gaps with regard to DHA levels between human milk – the gold standard comparison for compositional requirements, and ruminant-based milk. The reported world-wide average for DHA in human milk is 0.32%±0.22[12]. Due, at least in part, to fatty acid deficiencies of the maternal diet[13], 25% of reported human milk levels fall below this average, with most of these not less than 0.15% total fatty acids as DHA[14]. In a world-wide survey of human milk DHA and AA levels previously conducted by FSANZ[15], all samples contained at least 0.1% DHA and only 10 of 35 publications reported DHA levels below 0.2% of fatty acids thus confirming that a minimum DHA level naturally exists (i.e. not below 0.1% of total fatty acids) and that the minimum is near or above 0.3%. With regard to Australian mothers, in particular, available data suggests that DHA levels are highest in breast milk during the first 12 weeks, averaging 0.26% of total fatty acids[16,17]. Based on one Australian report[17], it would appear that breast milk DHA levels decline during the course of lactation to about 0.2% by 30 weeks. However, this observation is inconsistent with more recent data from women living in Europe indicating that DHA and AA remains consistent throughout lactation[18,19].

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[9] Koletzko B et al., 2014. Current Information and Asian Perspectives on Long-Chain Polyunsaturated Fatty Acids in Pregnancy, Lactation, and Infancy: Systematic Review and Practice Recommendations from an Early Nutrition Academy Workshop. Ann Nutr Metab 65:49–80.
[10] Simmer K, Patole SK, Rao SC. Cochrane Database of Systematic Reviews 2011, Issue 12. Art. No.: CD000376.
[11] Sun H, Como PG, Downey LC,et al. 2015. J Perinatology 35:867-74
[12] Brenna TJ, et al., 2007. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. AJCN 85:1457-64.
[13] Michaelsen KF, et al., 2011. Food sources and intake of n-6 and n-3 fatty acids in low-income countries with emphasis on infants, young children (6–24 months), and pregnant and lactating women. Maternal and Child Nutrition 7 (Suppl. 2), pp. 124–140
[14] Brenna TJ, et al., 2007. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. AJCN 85:1457-64
[15] FSANZ (2007) Application A532 Final Assessment Report, Ratio of Long Chain Polyunsaturated Fatty Acids in Infant Formula Products. Report prepared by Food Standards Australia New Zealand, Canberra http://www.foodstandards.gov.au/code/applications/Documents/A532%20LCPUFAs%20FAR%20FINAL.pdf
[16] Stoney RM, et al. 2004. Clin Exp Allergy 34:194-200
[17] Makrides et al., 1995
[18] Grote et al., 2015
[19] Marangoni et al., 2000

Ruminant milks, including cow's milk, on the other hand, are poor substitutes for human milk. DHA is not provided by any ruminant milk and AA in cow's milk is reported to only be 0.05% of total fatty acids vs 0.47% in human milk[20]. Substituting human milk with cow's milk in the form of infant formula will only further diminish the DHA and AA content of the infant's diet. Thus, reliance on the fat quality of cow's milk alone is insufficient to meet DHA and AA requirements as the sole or principle source of nourishment for infants.

Apart from DHA and AA, human milk contains an abundance of the dietary precursors of these fatty acids, alpha-linolenic acid (ALA) and linolenic acid (LA), respectively. However, the amount of DHA and AA produced in vivo from dietary precursors ALA and LA in human milk or complementary diets is minuscule[21] relative to the demands of growth and development, and the rate of production declines throughout early infancy[22]. Thus relying on endogenous production of DHA and AA cannot fill the gap caused by insufficient direct intake[23].

Due to the limited availability and intake of foods rich in DHA and AA, the Codex Working Group (WG) for the revision of follow-up formula (FUF), representing older infants 6-12 months inclusive, has recognized DHA among fatty acids as "…*of global concern for this age group*."[24]. While we are cognizant that the current FSANZ P1028 consultation is intended to discuss only infant formula (0-6 months), Standard 2.9.1 Division 3 and the subsequent sub-divisions on compositional requirements (ie. 2.9.1-9 – 12) addresses both Infant formula and follow-on formula, thus making this observation by the Codex WG relevant to this section of the discussion on fat requirements. Although published data regarding the intake of DHA and AA by infants living in Australia and New Zealand is limited, a recent study[25] summarized available Australian intake data for children and adults 2 years and above. It was estimated that pregnant and nursing women likely consume an average of 51 of the recommended 200 mg DHA per day and children 2-11 years consume 150 mg *total* n-3 LC-PUFA of which approximately 50% may be DHA, thus falling below intake recommendations for children 6 months and above[26,27]. If both maternal and young child intake of DHA is limited in Australia, it is probable that infant intake is also limited likewise and would benefit from a standardized inclusion of DHA in infant formula.

In light of the evidence above, we therefore respectively request FSANZ to consider establishing a **mandatory addition of DHA at a minimum level of 0.3% of total fatty acids, together with equal or greater levels of AA**, in keeping with various RASB recommendations

[20] Zou X, 2013. Lipid Composition Analysis of Milk Fats from Different Mammalian Species: Potential for Use as Human Milk Fat Substitutes. J. Agric. Food Chem 61:7070−7080.
[21] Pawlosky RJ, et al. 2006. Compartmental Analyses of Plasma 13C- and 2H-Labeled n-6 Fatty Acids Arising from Oral Administrations of 13C-U-18:2n-6 and 2H5-20:3n-6 in Newborn Infants. Pediatr Res 60: 327–333.
[22] Carnielli VP, Simonato M, Verlato G, et al. (2007) Synthesis of long-chain polyunsaturated fatty acids in preterm newborns fed formula with long-chain polyunsaturated fatty acids. Am J Clin Nutr 86:1323-30.
[23] Brenna TJ. 2016. Nutr Rev 74:329-336
[24] Codex Consultation paper March 2016
[25] Meyer BJ. Nutrients. 2016 Feb 24;8(3). pii: E111. doi: 10.3390/nu8030111.
[26] FAO, Report 91
[27] EFSA, 2010. EFSA Journal 8(3):1461. [107 pp.]. doi:10.2903/j.efsa.2010.1461

and the world-wide average of DHA in human milk as the best option to support the health and development of infants.

No.	Section of the SD	Question
Q1.5	***4.5***	***What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale.***

DSM's comments

DSM agrees with the with the current approach of FSANZ to allow the continued use of novel sources of fat (e.g. DHA form algal oil) when these forms have demonstrated their safety and suitability for infant feeding. Therefore we consider that the pre-assessment of novel foods and novel sources of ingredients are sufficient to manage any potential risks. We also consider that the Editorial note appended to "Table to clause 23" in the former Standard 2.9.1 suggesting consultation of Standard 1.3.4 for algal DHA and fungal AA source identity standards to be important guidance that should be maintained and made explicit in the new Code under "Standard 2.9.1-11 Infant Formula and follow-on formula – fat – further requirements*" or as deemed appropriate by FSANZ. Below is a suggested text to the qualifier:

" **Refer to Standard 1.3.4 Identity and Purity for Specifications on Supplementary fatty acids*"

docosa
(ARA),

No.	Section of the SD	Question
Q1.12	***7.3.3.1***	***Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.***
Q1.13	***7.3.3.2***	***Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.***

DSM's comments

DSM agrees with FSANZ's nutrition assessment conclusion that the higher minimum of Vitamin C at 2.5mg/100kJ is unlikely to pose a risk to infant health.

Pertaining to maximum limits, DSM is of the view that it should be increased to 17 mg/ 100 kJ in alignment with Codex, given that this increase is very unlikely to pose a risk for infant health.

Studies have demonstrated ascorbic acid's ability to increase iron absorption. Keeping iron levels low and increasing its bioavailability is definitively beneficial as unabsorbed iron has been shown to have adverse effects on the gut microbiome by increasing pathogen abundance and inducing intestinal inflammation[28]. Additionally, there is some concern that regulation of iron absorption is immature in infants. In adults, iron homeostasis is primarily controlled through tightly regulated changes in iron absorption, meaning absorption decreases if iron status increases, which makes overload unlikely. However, in infants, this might not necessarily be the case which would also support low levels of iron with high bioavailability[29].

Pertaining to Q1.13 on retaining the current Standard 2.9.1 minimum iron level at 0.2 mg/kJ and maximum level at 0.5 mg/kJ instead of aligning with Codex at a minimum level of 0.1 mg/kJ, and no GUL, DSM is of the opinion that instead of retaining the higher minimum level between the two, it might be more useful to increase iron bioavailability by choosing appropriate forms of iron, reducing phytate content and/ or adding absorption enhancers such as ascorbic acid. Given the negative effects of unabsorbed iron in the gut and the fact that regulation of iron absorption is thought to be immature in infants as outlined in the preceding paragraph, this is probably the safer option to adopt the lower minimum of 0.1 mg/kJ.

[28] Jaeggi, T., G. A. M. Kortman, D. Moretti, C. Chassard, P. Holding, A. Dostal, J. Boekhorst, H. M. Timmerman, D. W. Swinkels, H. Tjalsma, J. Njenga, A. Mwangi, J. Kvalsvig, C. Lacroix and M. B. Zimmermann (2014 epub). "Iron fortification adversely affects the gut microbiome, increases pathogen abundance and induces intestinal inflammation in Kenyan infants." *Gut 2015;64:5 731-742*

[29] Lönnerdal, B. and S. L. Kelleher (2007). "Iron metabolism in infants and children." Food and Nutrition Bulletin 28(4): S491-S499

No.	Section of the SD	Question
Q1.16	***7.3.3.4***	***Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL? Please provide your rationale.***

DSM's comments

Yes, DSM supports FSANZ's preliminary view to adopt alignment with the higher Codex minimum (2.5 μg/100 kJ) and maximum (GUL 14 μg/100 kJ) amounts for iodine as compared with current standard.

Iodine is essential for the healthy function of the thyroid stores and uses iodine to produce the iodine containing hormones thyroxine and triiodothyronine (thyronine). These hormones play a key role in regulating metabolism, metabolic rate, and body temperature. They are also essential for brain and nervous system development in the foetus and young child.

In Australia and New Zealand, with the identification of the re-emergence of iodine deficiency, it has been identified as one of the key micronutrients mild-moderatly deficient in the diet of infants and toddlers in New Zealand[30]. The study by Skeaff et al.[31] outlines the importance of iodine fortification in infant formulas. The iodine status of formula-fed infants was mildly deficient as compared to breast-fed infants who were moderately deficient. The latter indicates low breast milk iodine concentrations and therefore poor iodine status in breast-feeding women. By comparison, formula-fed infants had a better iodine status arising from the fortification of iodine in infant formulas. Inadequate intakes during this crucial time of development can have negative consequences as iodine is needed for normal thyroid activity, vital for brain development in the first 2 years of life. It was also acknowledged in P230 Section 15.1.3 on the limitations of the mandatory fortification proposal that "FSANZ will consider these issues as part of a future review of Standard 2.9.1 – Infant Formula Products."

[30] FSANZ P230 – Consideration of mandatory fortification with Iodine for New Zealand (12 February 2008)
[31] Skeaff S.A. et. al. (2005) Are breastfed infants and toddlers in New Zealand at risk of Iodine deficiency ? Nutrition 21(3): 325-331.

No.	Section of the SD	Question
Q1.22	***8.1.1***	***What is the justification to retain β-carotene as a provitamin A form?***

DSM's comments

Further clarification from FSANZ is sought for as to its use as a food colour in Infant Formula – specifically, if Beta-Carotene is no longer a permitted form of Pro-Vitamin A, can it still be permitted as a colour in Infant formula? We noted that "*the Code also permits various chemical forms of beta-carotene for use in Infant formula as a colour*[32]" and that "*regardless of whether it is for colouring or nutritional purposes, the revised Code requires that beta carotene should be counted as contributing to the Vitamin A content of Infant Formula*". We would like to seek further guidance on the reference in the revised code pertaining to the use of beta carotene as colour in infant formula as outlined above. In short, "Is beta-carotene still permitted as a colour additive in infant formula?"

[32]Section 7.2.1 Vitamin A, Para 3

No.	Section of the SD	Question
Q1.24	***9.1***	***Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.***

DSM's comments

Indeed, the physiological importance of choline for infant development has been widely recognized and acknowledged by scientific bodies as an important starting material for the biosynthesis of several metabolite that play key roles in fetal development, particularly the brain. As a main constituent of cellular membrane, the phosphotidylcholine is required for cell division and growth with subsequent effects on brain structure and function. Compositionally, human milk differs in its choline composition from bovine- and soy-based formulas as it contains greater amounts of total choline relative to soy-derived formulas and has higher amounts of phosphocholine than either of the latter two. The differences in choline composition (and bioavailability) between human milk and formulas appears to adversely affect the choline status of neonates[33].

As such, DSM agrees with FSANZ's view that Choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7 – 12 mg/100kJ to bring the standard to alignment with Codex.

No.	Section of the SD	Question
Q1.27	***9.2***	***Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.***
Q1.30	***9.3***	***Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.***

DSM's comments

In accordance with the conclusions of expert bodies[34], DSM agrees with FSANZ's preliminary view that mandatory inclusion of L-carnitine (at 0.3-0.8 mg/100kJ) and Myo-inositol (at 1.0-9.5 mg/100kJ GUL) in infant formula in alignment with CODEX is scientifically supported.

[33] Caudill, M. A. (2010). "Pre- and Postnatal Health: Evidence of Increased Choline Needs." *Journal of the American Dietetic Association* **110**(8): 1198-1206.

[34] Life Sciences Research Office (LSRO), American Society for Nutritional Sciences. Assessment of Nutrient Requirements for Infant formula. J Nutrition 1988; 128(Supp): 2059S-2298S.

DSM'S Comments to Supporting Document 2: Safety and Food Technology

No.	Section of the SD	Question
Q2.31	***8.3***	***Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.***
-	***9.1, 9.2***	***Processing Aids***

DSM's comments

DSM agrees with FSANZ's position that the carry-over principle for food additives should not apply to Infant Formula provided that exclusions are granted to allow the use of nutrient carriers in special nutrient forms. This is based on the understanding that these are considered under Section 9 "Processing Aids" of Supporting Document 2, as processing aids in the Code, and not as food additives.

Herein outlined in Section 9.2 "Comparison between Code and Codex Permission", DSM affirms FSANZ's interpretation and conclusion with regard to

> "*CODEX Advisory List (CAC/GL 10-1979) for specific food additives (gum arabic, silicon dioxide, mannitol, starch sodium octenyl succinate and sodium ascorbate) which have the technological function as carriers for nutrient. As such, these nutrient carriers are considered as processing aids in the Code, not food additives. These 5 substances are all Schedule 2 food additives in Standard 1.3.1. (section S16 – 2 of the revised code), so are generally permitted processing aids.*
>
> *All Schedule 2 food additives in Standard 1.3.1 (section S16 – 2 of Schedule 16 in the revised Code), are also generally permitted processing aids due to subclause 3(b) of Standard 1.3.3 (section 1.3.3 – 4 in the revised Code). This means these substances may be used as processing aids in the manufacture of infant formula*"

DSM would like this interpretation – in the form of the suggested sentence below – to be made explicit in the Code, reflected either in Standard 1.3.1 or Standard 1.3.3 or whichever FSANZ deems appropriate, to provide clarity and allow for the unambiguous interpretation on the use of the above food additives in nutrient preparations for infant formula :

> *"All Schedule 2 food additives in Standard 1.3.1 (section S16 – 2 of Schedule 16 in the revised Code) in nutrient preparations are allowed to be carried-over as processing aids in infant formula in accordance with the provisions set out in subclause 3(b) of Standard 1.3.3 (section 1.3.3 – 4 in the revised Code)."*

END OF SUBMISSION

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