UP International

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[redacted], July the 30th, 2021

Proposal P1028 – Infant formula

Consultation paper 2 – Nutrient Composition

UP International answers

FOREWORD

The present document summarizes comments proposed by UP International on FSANZ's open consultation, which aims to change the food code related to Infant Formula Products: Infant formula and Infant formula for Special Dietary Uses (IFPSDU). When relevant, propositions of answers to each specific question are displayed in the table below.

<table>
<tr><th></th><th>Questions</th><th>Commentaries</th></tr>
<tr><td colspan="3">General question related to the Consultation paper</td></tr>
<tr><td>1.</td><td>In addition to your submissions from previous consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence of practical barriers and quantify impacts where possible.</td><td>
<u>DHA</u>: The proposed approach by FSANZ is to align with Codex STAN 72-1981, but it is not compatible with Regulation (EU) 2016/127. Indeed, as shown in the example below, to be compliant with EU regulation, the quantity of DHA should be at least at 0,5% of fatty acids, which is the GUL proposed by FSANZ. European infant formula could therefore not be delivered to Australia, because it would not be correct to deliver infant formula with an amount of DHA always at, or above, the GUL value.
<table>
<tr><th></th><th></th><th colspan="2">Regulation (UE) 2016/127</th><th colspan="2">FSANZ proposed option</th><th rowspan="2">Typical EU Infant formula</th></tr>
<tr><th></th><th></th><th>Minimum</th><th>Maximum</th><th>Minimum</th><th>Maximum or GUL</th></tr>
<tr><td>Lipids</td><td>g/100 kJ</td><td>1,1</td><td>1,4</td><td>1,05</td><td>1,4</td><td>1,2</td></tr>
<tr><td>Fatty acids (FA)</td><td>g/100 kJ</td><td></td><td></td><td></td><td></td><td>1,14</td></tr>
<tr><td>DHA</td><td>mg/100 kJ</td><td>4,8</td><td>12</td><td></td><td></td><td>5,75</td></tr>
<tr><td>DHA</td><td>% FA</td><td></td><td></td><td></td><td>0,5</td><td>0,504</td></tr>
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Therefore, we beg FSANZ to consider another option compatible with Regulation (EU) 2016/127. For example, to set a maximum for DHA at 8 mg/100 kJ. It would be lower than the EU maximum, but still achievable and compatible.

<u>Medium chain triglycerides</u> (MCTs): The current Standard 2.9.1 permits MCTs to be present only as a natural constituent of a milk-based ingredient of that formula; or as a component of a processing aid in the preparation of a permitted fat-soluble vitamin. Keeping this restriction would prevent commercialization of formulas following the European regulation or Codex and containing vegetable oils that naturally contain MCTs.
Please, see in page 6 a more detailed answer with a proposed adjustment of the current standard 2.9.1 regarding the use of MCTs in formulas for healthy infants.
These constraints linked to DHA and MCT content would lead to the development of specific formulas in the Australian and New Zealand market.
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	Questions	Commentaries
2.	With the proposed approaches for Standard 2.9.1 or Schedule 29 in this Consultation paper, will small or large businesses be disproportionately impacted if a new permission or restriction does not align with international regulations or standards? If so can you specify how by providing quantitative evidence where possible?	If the constrain about DHA is kept as proposed, European food business operators will be impacted because they may not all have the possibility to develop and produce specific infant formulas for Australia and New Zealand.
	Questions about the minimum LA requirement. (Section 5.3)	
3.	Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale and any supporting evidence.	We support the proposed approach of FSANZ to express the amounts of fatty acids, including LA, in “mg/100 kJ” instead of “% total fatty acids”.
4.	Are there any technical issues related to increasing the LA minimum in Standard 2.9.1 to align with the higher EU 2016/127 level of 120 mg/100 kJ?	There is no technical issue related to increasing the LA minimum to 120 mg/100 kJ.
5.	Can you provide data on the LA levels in commercially available infant formula internationally? This information can be provided as ‘Commercial in confidence’ if required.	See the cover letter with confidential data.
	Questions about setting separate maximum iron levels for soy-based infant formula. (Section 7.3.3.5)	
6.	Do you support setting a separate iron maximum for soy-based infant formula? Please provide your rationale and evidence to support your answer.	
	Questions about setting a separate phosphorus range for soy-based infant formula. (Section 7.4.1)	

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	Questions	Commentaries
7.	Do you support setting a separate phosphorus range for soy-based infant formula? Please provide your rationale and evidence to support your answer.	
Other comments about the Consultation paper		
8.	Comment about the calculation of energy	S29−2 states that the energy content must be calculated using energy contributions from **fat, protein, and carbohydrate** with the relevant energy factors set out in S11−2. S11-2 defines energy factors for carbohydrate (excluding unavailable carbohydrate) and for unavailable carbohydrate (including dietary fibre). Because S29-2 does not mention unavailable carbohydrate, and because carbohydrate is defined as available carbohydrate in Standard 1.1.2, our understanding is that unavailable carbohydrate must not be taken into account in the calculation of energy for infant formula products. However, in the section 6.2 of this consultation, it is written: “It is FSANZ’s expectation that all companies will apply the energy factors for available and unavailable carbohydrates in subsection S11−2(2) to their products and to apply both factors in accordance with the proportion of oligosaccharides directly absorbed in the small intestine.” Therefore, a clarification is needed in S29-2 to specify whether unavailable carbohydrates must be taken into account, or not, in the calculation of energy.

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	Questions	Commentaries
9.	Comment about folic acid/folate	FSANZ proposes to express the requirements for folic acid/folate as µg folic acid/100 kJ. In Europe, 1 µg food folate = 0.6 µg folic acid. To avoid further misunderstanding and questions about if we have to apply the factor of 0.6 or not, would it be possible to replace the name “folate” by “folic acid” in S29?
10.	Comment about permitted forms of L-carnitine	FSANZ proposes that L-carnitine should be permitted as L-carnitine hydrochloride and L-carnitine tartrate. Will pure L-carnitine still be allowed? Pure L-carnitine is a form commonly used in infant formulas.
11.	Inconsistency about selenium	For selenium: on page 90 of the consultation paper, FSANZ proposes to increase the maximum level to 2.0 µg/100 kJ which would align with EU 2016/127. However, in the Appendix 1, page 123, FSANZ proposes to align the maximum with Codex STAN 72-1981 (2.2 µg/100 kJ). Could you please clarify which value should be considered?

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Medium chain triglycerides

Context:

Medium chain triglycerides (MCTs) are defined by Standard 2.9.1 as fats that contain fatty acids of 6–12 carbon chains. The current Standard 2.9.1 permits MCTs to be present only as a natural constituent of a milk-based ingredient of that formula; or as a component of a processing aid in the preparation of a permitted fat-soluble vitamin. Codex STAN 72-1981 and EU 2016/127 do not include any statement about MCT. It is also acknowledged in the consultation that MCTs are naturally present in many foods including dairy products, coconut and palm (kernel) oils. During previous consultation, FSANZ received 6 comments, 3 in favor of maintaining the current restrictions and 3 in favor of their removal.

In the absence of new data and considering the possible safety concerns associated with long term consumption of MCTs, FSANZ intend to maintain the current restriction.

Comment:

We agree that MCTs are not predominant in human milk, however, considering FSANZ definition (C6 to C12), they are naturally present in human milk at a range of about 3 to 10 % of total fatty acids (Delplanque et al., 2018).

For decades, infant formulas have been made with vegetable oils that naturally contain MCTs ranging from about 0.1 to 16.5% of total fatty acids (Delplanque et al., 2015) and no health issue related to MCT content in infant formula has been reported. For example, in France, 60 out of 98 infant formulas contain coconut oil, a natural source of MCTs. Moreover, 10 FSMP for CMA and fat malabsorption report additional MCTs in their ingredient list with a MCT content between 19 and 58% of total fatty acids.

We share the FSANZ point of view that long term consumption by healthy infants of formulas having a high MCT content may have negative health consequences. However, this has been reported with high MCT concentration of about 40% or more of total fatty acids (Borum, 1992; Łoś-Rycharska et al., 2016; Taylor et al., 2015; Whyte et al., 1986; Wu et al., 1993).

As stated by Łoś-Rycharska et al., “the use of preparation containing an **additive of MCT** has its limitations” (Łoś-Rycharska et al., 2016).

Therefore, we support an adjustment of the current standard 2.9.1 for healthy infants in order to forbid the voluntary addition of MCTs as such but to allow the use of vegetable oils naturally containing MCTs, by adding the following in the below paragraph:

> “Standard 2.9.1 permits MCT to be present only as a natural constituent of a milk-based ingredient of that formula; **or as a natural constituent of vegetable oil**; or as a component of a processing aid in the preparation of a permitted fat-soluble vitamin.”

The removal of existing restrictions on MCTs would align Standard 2.9.1 with Codex STAN 72-1981 and EU regulation 2016/127/EU. In contrast, keeping these restrictions on MCTs would prevent commercialization of European or Codex formulas containing vegetable oils that naturally contain MCTs.

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References

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