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28 August 2019

Food Standards Australia New Zealand
Mr Mark Booth, CEO
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Via Email: submissions@foodstandards.gov.au

Dear Mr Booth,

Call for submissions – Application A1155 2'-FL and LNnT in infant formula and other products

The Royal Australasian College of Physicians (RACP) welcomes the Food Standards Australia and New Zealand (FSANZ) call for submissions on application A1155 2'-FL and LNnT in follow-on formula.

The RACP is Australia and New Zealand's largest medical college, representing over 25,000 physicians, including 4,500 paediatricians, across over 30 specialties. Our members routinely work with newborns, infants, young children and their families. The RACP has previously made submissions to the FSANZ commenting on the regulation of infant formula products for special dietary use and expressing concern over the regulation of marketing of infant formula in Australia, including labelling of infant formula products.

We have consulted with members of our Paediatrics and Child Health Division and its Paediatric Policy Advisory Committee to provide the following general comments about application A1155.

We approach this application from the principle that if infants are unable to receive breastmilk for whatever reason, they should be fed the best possible alternative. This consideration is reinforced given growing evidence of the importance of the microbiome particularly during the first 1000 days.[1]

Human milk composition should be the primary reference for the composition of infant formula products. Human milk oligosaccharides (HMOs) are a major component of human milk and are present in higher amounts than protein, and 2'FL and LNnT are two of the most abundant HMOs present in human milk. These compounds are already available in infant formulas in the USA and across Europe where the evidence around the addition of these two HMOs has also been discussed and reviewed. Given these considerations and the

[1] Robertson RC, Manges AR, Finlay BB, Prendergast AJ. The Human Microbiome and Child Growth - First 1000 Days and Beyond. Trends Microbiol. 2019;27(2):131-147

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adequate evidence for the safety of these two compounds, we agree with the FSANZ that HMOs are safe to add to infant formula products at the levels proposed.

However, our support for this application is subject to some caveats and concerns.

Firstly, the evidence of benefits from addition of these HMOs is not as well established as the evidence on safety. While there is some evidence of positive impacts on microbiome, gut integrity and immune modulation from laboratory animal and in-vitro studies, the biological process underlying this association is not well understood. For instance, one recent study[2] which found positive associations between consuming HMO-supplemented formula and lower parent-reported morbidity and medication use (as a secondary outcome finding) cautiously concluded that these findings 'warrant confirmation in future studies.'

Secondly, and related to the above, as there are no clear and demonstrable clinical benefits to the infant consuming these products, it is likely that the addition of these compounds could be used primarily as a marketing exercise, to allow the manufacturer to claim closer biosimilarity to human breast milk. We therefore recommend that the FSANZ maintain its vigilance around any potentially problematic and misleading marketing tactics arising from approval of this application.

We would also like to highlight the following considerations which may be relevant to how information on the addition of these two compounds should be presented to the consumer:

- Use of the common name of 'HMO' in consumer information on these products is warranted given that this term, along with 'HiMO' or 'human milk oligosaccharides' or 'human identical milk oligosaccharides' tend be common terms used in scientific journals and medical congresses. Use of the term 'HMO' is also more likely to facilitate greater consumer understanding and informed choice compared to a more technical name such as Lacto-N-neotetraose which may unnecessarily alarm some consumers
- The compounds to be added are produced by a genetically engineered micro-organism. While the additional DNA is added as a plasmid, rather than being integrated into the E Coli DNA, this will be an issue for some consumers. Information about this should therefore be made available to consumers so that they can exercise a choice, should they have concerns about genetically modified organisms (GMOs).

The RACP thanks FSANZ for the opportunity to provide feedback on this application. Should you require further information or wish to discuss this further, please contact [redacted], Senior Policy Officer at Policy@racp.edu.au or [redacted].

Yours sincerely

Prof Paul Colditz
President, Paediatric & Child Health Division

[2] Puccio G, Alliet P, Cajozzo C, et al. Effects of Infant Formula With Human Milk Oligosaccharides on Growth and Morbidity: A Randomized Multicenter Trial. J Pediatr Gastroenterol Nutr. 2017;64(4):624–631.