

Call for Submissions – Proposal P1028:

Restricting Probiotics in Infant Formula

Ref: 5.4 L(+) lactic acid producing microorganisms (page 42):

FSANZ's preferred approach is to retain the existing permission, however clarify that L(+) lactic acid producing microorganisms may only be added for acidification purposes. FSANZ also proposes to clarify the permission that only non-pathogenic or nontoxigenic microorganisms may be used.

FSANZ also notes that microorganisms added to infant formula products for a probiotic purpose require pre-market assessment as a novel food prior to use.

Additive Solutions' stance is that this proposed change to restrict the use of probiotics in infant formula will not meet some of the stated objectives of the proposal:

- consistency with advances in scientific knowledge
- industry innovation and/or trade is not hindered

The above proposed change states that L(+) lactic acid producing microorganisms “may only be added for acidification purposes” - with no exceptions listed.

It then states that adding any lactic acid producing bacteria for any purposes other than for acidification requires a pre-market assessment contradicts the first point, it implies that lactic acid producing bacteria may be added pending the pre-market assessment.

The proposal states that one reason for preparing the proposal is to “clarify some standards” however the proposed changes mentioned above are conflicting and therefore confusing.

We seek to retain the current permission for L(+) lactic acid producing microorganisms without any further amendments to restrict the permission to only acidification purposes.

To restrict the adding of probiotics to infant formula would be to disregard the lengthy history (20+ years), extensive research, and proven safety and efficacy of these ingredients. Probiotics are well established and already embedded in the infant formula industry.

Additive Solutions acknowledges that pre-market assessment of any new ingredients would be appropriate to ensure continued safety for the consumer.

History of use of Probiotics in Infant Formula

Bifidobacterium longum BB536 strain is an example of a probiotic strain that has been widely used in the market since 2006.

This is the naturally occurring and predominant strain in infants' intestinal flora. It is compatible with breast milk and is suitable for cofeeding.

Extensive studies and data are available, as provided by our manufacturer (Morinaga Milk Industry Co):

Approved as safe:

- Morinaga BB536 was approved its safety by FDA GRAS (GRN877)

- There were fourteen studies involving the administration of BB536 to infants or toddlers. Findings from the studies provide support for the safe and well-tolerated use of B. longum BB536 in infants and toddlers under the test conditions.

https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=877&sort=GRN_No&order=DESC&startrow=1&type=basic&search=bifidobacterium%20longum

Benefits of BB536 in infants:

- Reported by clinical studies: development of healthy intestinal microflora, protection against diarrhea, reduction of skin allergies ie eczema, reduction in upper respiratory symptoms.
- BB536 used in Australian NICU since 2017

<https://www.nature.com/articles/s41390-021-01884-x.pdf>

Widespread Use of BB536:

- BB536 has been used as a functional food ingredient in various products such as milk-based drink, yogurt, infant formula, and nutritional supplements and has been marketed in over 30 countries for more than 40 years.

Probiotics as Novel Foods

Ref: Standard 1.5.1: Novel Foods:

novel food means a non-traditional food that requires an assessment of the public health and safety considerations having regard to:

- (a) *the potential for adverse effects in humans; or*
- (b) *the composition or structure of the food; or*
- (c) *the process by which the food has been prepared; or*
- (d) *the source from which it is derived; or*
- (e) *patterns and levels of consumption of the food; or*
- (f) *any other relevant matters.*

non-traditional food means:

- (a) *a food that does not have a history of human consumption in Australia or New Zealand; or*
- (b) *a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or*
- (c) *any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.*

BB536 meets the definition of non-novel and traditional:

- Non-novel: has been used as an ingredient in infant formula since ~2006
- Traditional: is an ingredient that does have a history of human consumption in Australia and New Zealand, used currently by some major infant formula suppliers

As an example, it should be noted that *Bifidobacterium Longum* (different strain RO175) was assessed in 2020 by the ACNF as “not novel”.

In addition, European food safety authority (EFSA) approved the safety of *Bifidobacterium longum*, included in Qualified presumption of safety (QPS) list.

<https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps>

International Alignment

Ref: 1.2 Reason for Preparing the Proposal (page 7)

FSANZ states as one outcome to be “to align with relevant international and overseas regulations, as appropriate in the Australian and New Zealand context.”

However, the proposed FSANZ approach will differ to Codex which recognises L(+) lactic acid producing cultures as permitted ingredients.

- the Codex Infant Formula (CXS72-1981) standard provides “*Only L(+)lactic acid producing cultures may be used*” as optional ingredients.