



Nestlé Submission

Application A1253 – Bovine Lactoferrin in Infant Formula Products

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited.

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula products and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code').

Nestlé thanks FSANZ for the A1253 consultation paper and welcomes the opportunity to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Regulation of the voluntary use of bovine lactoferrin in infant formula products. We thank FSANZ for their consideration of the comments, issues and views raised in this submission.

Introduction:

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants. We welcome the consultative effort of FSANZ to determine the best nutrition advice and outcomes for Australian and New Zealand infants.

In situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition. Nestlé advocates a science-based approach to formulating products for the health and well-being of infants and young children. It is important that health recommendations and regulations focus on the best interests of the child and are based on the latest body of scientific evidence.

Discussion:

Nestlé supports approval of the voluntary use of bovine lactoferrin (bLf) in infant formula products (IFP).

Nestlé supports the proposed maximum addition rate of 40mg bLf /100kJ in infant formula products, noting that bLf is approved for use in infant formula and follow-on formula (ready to drink) at 100 mg/100 ml in Europe. Singapore and China also specify a maximum permitted amount of 1000 mg/L of prepared infant formula product. Nestlé supports consistency of the Code with international food regulations.

However, as others including AFGC raise, we wonder whether the application should be approved as a nutritive substance as discussed further below.

Implications for use of bLf in general foods and other special purpose foods

Nestlé is concerned with regard to the potential regulatory uncertainty for bLf in general foods and other special purpose foods in Part 2.9 of the Code. There are dairy-based products currently in the marketplace containing bLf, however the CFS is silent on the status of bLf already incorporated into foods other than infant formula products.

Nestlé notes that bLf is a naturally occurring component of bovine milk and strongly supports the ACNF (Advisory Committee Novel Foods) record of views that bLf is a traditional food when used at 10-100mg/100mL or 100g in dairy products. (See Table 1).

Table 1 – extract from Record of views formed by the FSANZ Novel Foods Reference Group or the Advisory Committee on Novel Foods

Lactoferrin (Bovine) for use in dairy products at 10-100 mg/100mL or 100 g	<ul style="list-style-type: none">• Traditional food• Not novel food	Normal constituent of bovine milk at 20-200 µg/mL (2-20 mg/100 mL). Proposed use in yoghurt is within the normal range of dietary intake of lactoferrin from dairy foods in the diet. Traditional food when used in this way.
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FSANZ has previously considered the inclusion of bLf in processed foods in the 1st CFS for P1024. In SD3 Section 3 (3) Summary 'Eligible Food Criteria', FSANZ specifically considers and supports the inclusion, without further pre-market clearance being required, of extracts from animal and plant commodities where they are added to 'any processed food' and where the total concentration of the naturally occurring and added components in the target food is no higher than that present as if the source food were used as an ingredient. Table A3 of the same document gives specific examples of addition of bLf extract to any processed food.

Nestlé supports FSANZ views on this issue noting that this position is also consistent with ACNF views.

Nestlé seeks clarity on these issues, firstly to avoid unwarranted consumer concern, and secondly to avoid a 'flurry' of unnecessary and costly Applications which could 'gridlock' FSANZ's already busy work program.

Exclusivity

Nestlé supports the intent of exclusive use permissions for novel foods as described in *Proposal P305 – Permission for Exclusivity of Use of Novel Foods* (2007) and extended to nutritive substances as part of *Application A1155 – 2'-FL and LNnT in infant formula and other products* (2020). Exclusivity supports innovation by providing a commercial benefit to applicants who have invested considerable resources into the research and development of a novel food or a new nutritive substance.

Nestlé understands that a period of exclusive use for a specific brand or class of food can be requested by applicants requesting approval of a novel food or a new nutritive substance.

However, we note that A1253 is not an application requesting approval of a novel food or new nutritive substance. Bovine lactoferrin has been widely manufactured in Australia and New Zealand for many years.

Considering publicly available information, Nestlé is concerned that there is insufficient justification to support the potential precedent set in this application regarding exclusivity.

As previously stated in our response to A1251, we are concerned that a precedent regarding exclusivity for use is being set for all foods, through individual applications. The topic may have broader stakeholder relevance for future consideration.

Conclusion

Nestlé supports approval of the voluntary use of bovine lactoferrin (bLf) with a proposed maximum addition rate of 40mg bLf /100kJ in infant formula products.

However, due to our concerns detailed above, we would like to seek regulatory clarity for:

- the use of bLf in general foods and other special purpose foods
- exclusivity of use period to novel foods or nutritive substances which already have an extensive history in Australia and New Zealand