

Call for submission A1253 – Bovine lactoferrin in infant formula products

Prepared by Dairy Australia on behalf of the Australian dairy industry

Dairy Australia and the Australian dairy industry

Dairy Australia is the dairy industry-owned service company, limited by guarantee, whose members are farmers and industry bodies, including the Australian Dairy Farmers, and the Australian Dairy Products Federation.

The Australian dairy industry:

- Is the third largest regional industry in Australia, after grains and beef, and makes a significant economic contribution to regional economies.
- Is present in every state across Australia, with dairy farming activity close to major metropolitan areas to ensure reliable, year-round fresh drinking milk for local consumption.
- As of 2022, the industry directly employed almost 34,700 people across Australia both in farming and processing, predominantly in regional areas.
- In 2022, produced some 8,554 million litres of milk with a farmgate value of approximately A\$4.9 billion, much of which is returned directly into local regional economies.
- This production was processed into some 2.4 billion litres of drinking milk, and with some further processing made 408,246 tonnes of cheese, 79,436 tonnes of butter and 192,623 tonnes of various milk powders.

Underpinning Dairy Australia's policy and regulatory, public health and nutrition science expertise is a commitment to evidence-based public health policy and food regulation. Our role is to provide expertise and evaluate proposals considering the most current relevant evidence, in the context of sound regulatory and policy development principles.

Dairy Australia welcomes the opportunity to present this submission in response to A1253 – Bovine lactoferrin in infant formula products

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Key issues to address

1. Support

Dairy Australia support's the voluntary addition of bovine Lactoferrin (bLF) up to max 40mg/100kJ in infant formula products and supports amendment to Standard 2.9.1 of the Australia New Zealand Food Standards Code (FSC) for this purpose. bLF has been widely used globally and has demonstrated a long history of safe use in infant formula internationally at these levels. Such levels of bLF will be consistent with the maximum levels for infant formula products in the legislation of the European Union (EU), China and Singapore. Infants in many other countries and regions have for considerable time benefited from the voluntary addition of bLF to infant formula products.

Dairy Australia support's the voluntary addition of bovine Lactoferrin (bLF) up to max 40mg/100kJ in infant formula products

2. Classification of bovine Lactoferrin as a 'nutritive substance'

We wish to raise concerns regarding the categorisation of bLF as a "nutritive substance" . We note that bLf has important immune properties and has a long and safe history of use here in Australia and around the world. Categorisation of bLF as a "nutritive substance" potentially has broader implications for the current use of bLf in general foods. With the absences of *a completed P1024 Novel foods and nutritive substances and a long history of and safe use of bLF around the world*, Dairy Australia considers that the definition of nutritive substance in the Code is vague, difficult to interpret, enforce and furthermore is misaligned with other regulatory jurisdictions such as the EU where focus is on safety of an ingredient.

Dairy Australia recommends that A1253 recognise bLF in infant formula products as a general food ingredient.

3. Alignment with international regulation, standards and specifications – facilitates trade and harmonisation

Bovine Lactoferrin is widely available and has a long history of use and sale in infant formula in international markets. The proposed specifications for A1253 are very specific and not risk-based or proportionate. The proposed parameters in the regulatory specification are misaligned with earlier precedence set by FSANZ in Schedule 3- Identity and Purity and mis- aligned with International regulatory standards in both the European Union and China.

The bLF specification included in A1253 is more akin to a customer product specification which outlines many varied elements which categorise product quality as opposed to directing regulation whose purpose is to manage food safety risk. Inclusion of elements such as heavy metal residue levels is not required for bLF, a dairy based ingredient, where this is essentially covered else where in the FSC with respect to dairy powders.

Dairy Australia recommends that the FSC align the bLF specification with that currently published in China and EU regulations .This will support a risk-based approach to permitting the voluntary addition of bLF to infant formula products, whilst also aligning with existing regulations with key trading partners

4. Iron

Dairy Australia recommends that the iron content limit suggested in A1253 should be increased from 15mg/100g to 35mg/100g.

The proposed 15 mg/100g is unnecessarily restrictive and does not allow for seasonal variation which may occur in the composition of bovine milk, or the use of currently available production technologies. The reduced iron limit (15 mg/100g) does not impact on

the safety of the product, nor is it aligned to either the EU (35mg/100g), or China (35mg/100g). Furthermore, US GRAS notices demonstrate that levels above 15 mg/100g can be considered safe

The limit of 15mg/100g is reflective of product quality and purity and whilst this may be appealing to some customers, should be reflected in a customer buying specification and discussed in a commercial arrangement. Expanding the limit to 35mg/100g will not pose any food safety risk, however, will facilitate trade and access to use this ingredient in infant formula products for a broader range of infants.

5. Exclusivity

Dairy Australia supports the principle of exclusivity, being available for companies submitting applications to change the code. The principle of exclusivity helps to foster innovation while managing and protecting the significant investment required to bring new innovations to market. Considering these principles and recognising that bovine Lactoferrin has been manufactured and available on the market for greater than 20 years by manufactures in Australia, New Zealand and around the world. Bovine Lactoferrin offered in application A 1253 is not unique and as such an exclusivity period would unnecessarily prohibit competition.

Dairy Australia does not support nor do we believe that the exclusivity clause is justified or warranted for A1253.