



Dairy for life

19/08/2022

Dear FSANZ,

A1251 - 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products

Fonterra is a global dairy nutrition company owned by 10,000 farmers and their families. With a can-do attitude and collaborative spirit, we are a world leading dairy exporter. We draw on generations of dairy expertise and are one of the world's largest investors in dairy research and innovation, to produce more than two million tonnes annually of value-added advanced dairy ingredients, foodservice and consumer products for over 140 markets.

Fonterra has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant formula and young child formulas globally. Fonterra produces formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

Fonterra welcomes the opportunity to provide comments and information to FSANZ on **A1251**. We thank FSANZ for the consideration of the comments outlined in this submission.

Fonterra supports the continued protection of breastfeeding noting the many benefits this has for both mothers and infants. For non-breast-fed infants that are fed infant formula, Fonterra supports a regulatory approach that ensures the best possible nutrition for such infants. This includes measures to ensure appropriate food safety and protection of public health, while allowing for continued innovation including scientific and technical development of infant formula. Fonterra supports alignment with relevant international standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.

Fonterra supports the content and views of the Infant Nutrition Council (INC) A1251 submission.

We thank FSANZ for the consideration of the comments outlined in our submission. If there are any queries relating to this submission, please contact [REDACTED]

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General Comments

- Fonterra support and welcome the application to permit the addition of 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans (2'-FL and GOS and/or ITF) to infant formula products.
- Fonterra had previously outlined our concerns to FSANZ around the prohibition to use 2'-FL and GOS and/or ITF in combination, including the lack of harmonisation with other markets that permit these substances in combination globally and knock-on impacts on viability, costs and innovation for products targeting infants and young children in Australia and New Zealand.
- We agree with the safety assessments undertaken by FSANZ that the combination of 2'-FL and GOS and/or ITF is safe and well tolerated by infants.
- This application enables alignment with international permissions in markets such as the EU, US, Hong Kong and Vietnam which similarly permit addition in combination.

Exclusivity

- In this section Fonterra makes a number of general comments on broader principles of exclusivity;; We do support clear exclusivity principles being available for companies submitting applications to change the code in future. This helps protect the substantial investment that goes into bringing new innovations to market.
- We understand originally P305 (2007) permitted the specific provision for exclusivity of novel foods and that this was extended to nutritive substances following endorsement from the Food Ministers Meeting in 2020 in relation to A1155. This indicates that the scope of exclusivity continues to creep beyond what was agreed in 2007. The challenge for industry is that this is being managed through applications rather than a clear consultation to determine and agree on minimum requirements for exclusivity.
- Precedence set through applications for exclusivity by FSANZ demonstrates that we've seen exclusivity apply to new ingredients launched to market (novel foods and nutritive substances) and this is now being proposed to be extended to 'how you use ingredients.'
- The extension of existing exclusive use permissions needs to be carefully considered to its impact not only to infant formula products but more broadly to the food supply. As such we recommend broader stakeholder consultation on the scope of exclusivity and the threshold for evidence that must be met. P305 provided the opportunity for broad stakeholder engagement on establishing requirements and since then we've observed scope creep in how exclusivity may be applied.
- Not all applications are reviewed by all industry stakeholders as they are prioritised based on business impact. It is therefore difficult to understand the scope of exclusivity being applied more broadly. A standard guideline outlining requirements and scope would be beneficial in providing clarity for future applications.

Use as a nutritive substance

- Fonterra notes FSANZ regards 2'FL as being *used as a nutritive substance. Fonterra continues to welcome the consideration being given by P1024 to the revision of the regime for Nutritive Substances and Novel Foods. Fonterra continues to consider that any regime for pre-market assessment for new ingredients should focus on safety, thereby removing the ambiguity in the existing framework whilst achieving a balance between protecting the integrity of the food supply and supporting industry innovation.

Exclusion of FSFYC

- Fonterra reinforce previous views that continued exclusion of HMO use in FSFYC is leading to not only inconsistency against international regulations in terms of permissions for young children (>12 months), but also, now within Australia where the Therapeutic Good Administration has approved its use as a supplement for young children from age one through to senior adults, inconsistency across product categories within Australia and New Zealand.