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

Submission by Public Health Services, Department of Health, Tasmania

Contact details:

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Thank you for the opportunity to comment on the call for submissions for Application *A1251- 2'FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products.*

Application A1251 seeks to permit the voluntary combination of 2'-fucosyllactose (2'-FL) with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products. Currently the Code prohibits the use of GOS and/or ITF in infant formula products with 2'FL.

The Applicant (Nutricia and Chr.Hansen A/S) also requested exclusive use permission for a period of 15 months for this combination.

Public Health Services in the Department of Health, Tasmania has the following comments on this application.

Evidence of benefit

Public Health Services acknowledges that the beneficial health effects for the individual addition of 2'FL and GOS and ITF to infant formula products has previously been assessed. The addition on 2'FL (A1155) was based on 'plausible' evidence (that was considered weak), on its beneficial role in normal growth and development. As a result, it was agreed at the Food Ministers Meeting on Food Regulation (27 November 2020) that within five years of gazettal (26 March 2021) a review of the permission to allow 2'FL is required to determine whether there is sufficient evidence for a *'substantiated beneficial role in the normal growth and development of infants, or a technological role'* (Ministerial Policy Guideline on the Regulation of Infant Formula Products 2011).

FSANZ indicated that the current application identified no additional studies on human interventions on the anti-pathogenic effect of this combination. They also concluded that the applicability of in vivo studies to human infant immune development is unclear as well as the

bifidogenic effect of this combination. Public Health Services considers direct evidence of the beneficial role of the *combination* of these ingredients is required, not just the beneficial role of each ingredient alone. Public Health Services also recommends that FSANZ ensures the applicant is aware that the use of 2'FL (under A1155 and A1190) is to be reviewed in five years.

Evidence of safety and tolerance

FSANZs review of the safety of the combination of 2'FL and GOS and/or ITF found there were no safety concerns when 2'FL was added up to 1g/L when GOS and/or ITF is added. Whilst the safety of 2'FL alone has previously been assessed up to 2.4g/L, FSANZ has not assessed the safety at this higher level with the combination proposed. Public Health Services does not support the conclusions drawn by FSANZ on the safety of this combination at the proposed levels, based on the rationale that the proposed levels are lower than human milk oligosaccharides (HMOs) from human milk. Human milk has over 200 oligosaccharides which cannot be extrapolated to the current proposed combinations to determine the maximum level. Infants are a vulnerable population group and as such the regulation should be commensurate with this level of risk. Public Health Services considers direct evidence showing the safety and tolerance of these ingredients at the proposed levels is required.

Exclusivity

As outlined in the FSANZ paper an applicant may request exclusive permission to use and sell a food or ingredient for a certain period of time to recognise the investment made in developing the ingredient. Public Health Services question whether this should be granted in this application. The mixture of GOS and ITF have been added to infant formula products for approximately 20 years and were approved by FSANZ during Proposal P306 (FSANZ 2008). The original application for 2'FL (A1190) already has exclusivity as a novel food due to a different GM source and specifications and therefore this investment has already been accounted for. The research relied on to demonstrate safety of the combination of these two ingredients has been funded by other bodies and companies and therefore the justification for exclusivity of this combination is unwarranted.

Summary

Public Health Services is concerned about extending permissions for the addition of HMOs or the combination of HMOs with other ingredients to infant formula products. Adding substances to infant formula that provide no benefit (and presumably add to the cost) is misleading to caregivers of formula fed infants. FSANZ noted from their literature review to inform P1028 that caregivers preferred longer ingredient lists, as they were perceived to be more nutritionally complete (FSANZ 2022). FSANZ also noted that domestic consumers may benefit from increased variety of infant formula products for sale. Public Health

Services does not support the addition of ingredients for 'perceived' benefits or greater variety.

In agreeing to the addition of HMOs in application A1155 and A1190 we were not convinced 'plausible' evidence of benefit to infants was sufficient and requested, along with several other jurisdictions, that the evidence be reviewed in five-years. If the five year review fails to find more convincing evidence of the health benefit of infant formula with added HMOs compared to infant formula without HMOs, our expectation is that permissions granted under A1155 and A1190 should be revoked. It would make sense to withhold further permissions until the five-year review is completed.