

# Application to amend the Australia New Zealand Food Standards Code to permit a combination of GOS/ITF and 2'-FL in infant formula products

Nutricia Australia Pty Ltd (Nutricia) & Chr. Hansen A/S

## EXECUTIVE SUMMARY

Nutricia Australia Pty Ltd (Nutricia) and Chr. Hansen A/S (Chr. Hansen) have submitted a joint application to Food Standards Australia New Zealand (FSANZ) requesting an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition to infant formula products of a combination of two ingredients that are currently permitted to be added separately, but not in combination.

Nutricia's short chain galacto-oligosaccharide (scGOS)/long chain fructo-oligosaccharide derived from inulin (lcFOS) ingredient is currently added to infant formula products in Australia and New Zealand at 8 grams per litre (g/L) at a patented ratio of scGOS/lcFOS of 9:1 (7.2 g/L GOS and 0.8 g/L FOS). Chr. Hansen's 2'-fucosyllactose (2'-FL) ingredient was recently permitted by FSANZ to be added to infant formula products at up to 2.4 g/L. However, while both Nutricia's scGOS/lcFOS and Chr. Hansen's 2'-FL ingredients are individually permitted to be added to infant formula products, section 2.9.1—7(2) of the Code does not permit a combination of these ingredients to be added.

Nutricia and Chr. Hansen have established that the addition of both scGOS/lcFOS and 2'-FL to infant formula products is safe, well tolerated and provides nutritional and developmental benefits for infants approaching the benefits of infants fed breast milk. Although breast feeding is preferred and recommended for infants internationally, infant formula products provide the only alternative source of nutrition for infants that are not breast fed. Infant formula products are therefore formulated to, as closely as possible, resemble the composition of human milk and the normal growth and development outcomes that human milk provides.

Human milk contains a variety of prebiotic oligosaccharide ingredients (human milk oligosaccharides (HMO)) that are not absorbed in the small intestine but are fermented in the large intestine. Nutricia's scGOS/lcFOS is added to infant formula products as a prebiotic that mimics the prebiotic effects and functional benefits of human milk prebiotics, providing a more favourable gut microbiota composition and activity than products that do not contain the ingredient. Chr. Hansen's 2'-FL is a HMO identical ingredient. 2'-FL is the most abundant HMO present in human milk and is added to infant formula products to provide a more compositionally similar profile to human milk and to provide bifidogenic effects and limit infection, including by pathogenic strains of *Campylobacter jejuni* in infants.

The combination of GOS/ITF and Chr. Hansen's 2'-FL is intended to be added to infant formula products to produce these independent effects but also to provide combined support to the immune system (through antipathogenic and direct effects), and bifidogenic effects.

This application requests permission to add both GOS/ITF at up to 8 g/L and Chr. Hansen's 2'-FL at up to 2.4 g/L in combination to infant formula products in Standard 2.9.1 including infant formula, follow-on formula and infant formula products for special dietary use. For clarity, the application does not relate to products for young children aged over 12 months (Standard 2.9.3 - formulated supplementary foods for young children), nor to the ingredient lacto-N-neotetraose, which is also permitted to be added to infant formula products.