

SUBSTANTIAL EQUIVALENCE OPINION

Nestlé's Galacto-oligosaccharide (GOS)

The Food Safety Authority of Ireland (FSAI) received an application in October of 2015 from Nestec Ltd. of Switzerland for an opinion on the substantial equivalence of Nestlé's galacto-oligosaccharide (GOS) to a similar food ingredient already on the EU market. Nestlé's GOS is considered novel in the EU and falls within *Article 1.2(e)* of the novel food Regulation (EC) No 258/97 "*foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*".

Nestec Ltd. has not yet trademarked their GOS and so it will be referred to as "Nestlé's GOS" in this opinion. Galacto-oligosaccharide (GOS) is also known as oligogalactose, transgalactosylated oligosaccharide and transgalacto-oligosaccharide and is produced from lactose (glucose-galactose disaccharide). GOS produced from milk lactose has been on the EU market for many years and its use in infant and follow-on formulae specifically is regulated by Commission Directive 2006/141/EC. Vivinal[®] GOS, produced by Friesland Foods/Campina Domo is outside the scope of the novel food Regulation as it was on the EU market before May 15 1997. Nestlé's GOS is compared to Vivinal[®] GOS as the existing comparator in this application to establish its substantial equivalence.

GOS consists of one molecule of glucose with one to seven molecules of galactose, and is produced by an enzymatic process involving β -galactosidase. The enzyme initially breaks lactose down to its constituent monosaccharides (glucose & galactose) and then reassembles galactose into galacto-oligosaccharides, leaving an excess of glucose along with some mono- and di-saccharides.

The applicant intends adding Nestlé's GOS to infant and follow-on formulae in accordance with Directive 2006/141/EC and in growing up milks in line with general food law.

Composition

The raw material for the production of Nestlé's GOS is sweet whey permeate (lactose-rich derivative of cow's milk) while the raw material for Vivinal GOS can be pure lactose or sweet whey permeate. The production processes are very similar, with Nestlé's GOS being produced using β -galactosidase from *Aspergillus oryzae* compared to β -galactosidase from *Bacillus circulans* for Vivinal® GOS. Analytical results and specification ranges are generally similar with respect to dry matter, moisture, protein and ash, while the level of total oligosaccharides and the proportions of lactose, glucose and galactose are also similar. The applicant demonstrates through HPLC analysis that GOS products on the EU market have slightly different oligosaccharide profiles which originate in the starting material and the enzymes used. Nestlé's GOS is stable at ambient temperature for 12 months, with longer term stability studies ongoing.

Nutritional Value and Metabolism

Galacto-oligosaccharide (GOS) is not digested by endogenous enzymes as it contains predominantly β -linkages (rather than α -linkages) and so passes through the human gastrointestinal tract largely undigested. For this reason, GOS is termed a "Prebiotic" which is understood as a nutrient that on reaching the colon is fermented by commensal gut bacteria. GOS is broken down by bacterial β -glycosidases to yield CO₂ which is then expired, with any residual non-fermented GOS excreted. The minor proportional differences in the content of GOS, lactose, glucose and galactose and other micronutrients will not have a significant impact on the nutritional equivalence of Nestlé's GOS compared to the existing GOS.

Intended Uses

The applicant intends to use Nestlé's GOS for the same purposes and at the same levels as Vivinal® GOS which includes infant and follow-on formulae and "Growing up" milks. Its use in infant and follow-on formulae in the EU is controlled at up to 0.8 g/100mL by Directive 2006/141/EC, as amended. The applicant intends using Nestlé's GOS at levels of approximately 0.78 g of total oligosaccharides per 100mL.

Level of Undesirable Substances

Nestlé's GOS is produced according to GMP and in accordance with HACCP principles. Like Vivinal[®] GOS, it is highly purified with specifications relating to levels of undesirable substances including microorganisms and heavy metals.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Nestlé's GOS manufactured by Nestec Ltd. is substantially equivalent to Vivinal[®] GOS that is already on the EU market. This opinion relates only to the substantial equivalence of Nestlé's GOS in accordance with the novel food Regulation (EC) No 258/97 and is without prejudice to the requirements of any other EU or national food legislation.