SUBSTANTIAL EQUIVALENCE OPINION

Galacto-oligosaccharide (GOS)

The Food Safety Authority of Ireland (FSAI) received an application in June of 2017 from FrieslandCampina Domo of the Netherlands for an opinion on the substantial equivalence of galacto-oligosaccharide (Vivinal® GOS B) to a similar GOS product (Vivinal® GOS) already on the EU market before 1997 and thus outside the scope of the novel food Regulation. Galacto-oligosaccharide (GOS) is also known as oligogalactose, transgalactosylated oligosaccharide and transgalacto-oligosaccharide and is produced from lactose. It consists of one molecule of glucose with one to seven molecules of galactose, and is produced by an enzymatic process.

The novel Vivinal® GOS B and existing comparator Vivinal® GOS are both produced by FrieslandCampina Domo in the Netherlands using a similar process. The applicant intends adding the novel Vivinal® GOS B to infant and follow-on formulae, in accordance with Directive 2006/141/EC and to growing up milks in line with general food law.

Vivinal® GOS B 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*".

Composition

The raw material used in the production of the novel and comparator GOS is milk-derived lactose. The production and purification processes are very similar, except that the source of the *β*-galactosidase enzyme which produces the novel GOS is the yeast *Pichia pastoris* expressing the *β*-galactosidase gene from *Sporobolomyces singularis*. In contrast, the *β*-galactosidase enzyme used to produce the existing Vivinal® GOS comes from *Bacillus circulans*. The specifications for the novel and existing GOS products are the same, with the only difference between them being the relative content of tri-, tetra, penta- and hexa- oligosaccharides, which may be a result of the different enzymes sources.

Parameter	Vivinal® GOS B	Vivinal® GOS
Dry matter (DM)	74.0 – 76.0 (%)	74.0 – 76.0 (%)
Galacto-oligosaccharides (%DM)	>57.0	>57.0
Lactose anhydrous (%DM)	<23.0	<23.0
Glucose anhydrous (%DM)	<22.0	<22.0
Galactose (%DM)	>0.8	>0.8
Nitrogen (%DM)	<0.03	<0.03

Nutritional Value and Metabolism

Galacto-oligosaccharide (GOS) is not digested by human endogenous enzymes as it contains predominantly β-linkages (rather than α-linkages) and so passes through the human gastrointestinal tract largely undigested. On reaching the large intestine, GOS is fermented by commensal gut bacteria to yield CO_2 which is expired, while short chain fatty acids and any residual non-fermented GOS are excreted. The minor differences in the relative content of tri-, tetra, penta- and hexa- oligosaccharides in the novel GOS will not have a significant impact on its nutritional or metabolic equivalence.

Intended Uses

The applicant intends to use the novel GOS for the same purposes and at the same levels as the comparator 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 by Directive 2006/141/EC while its use in "growing up milks" will be regulated under general food law.

Level of Undesirable Substances

The applicant is certified to FSSC 22000 standards relating to the manufacturing of dairy products. The novel GOS is highly purified with specifications governing the levels of undesirable substances including microorganisms (*E. coli*, *Salmonellae* and *S. aureus*) and heavy metals (arsenic, cadmium, lead, mercury and aluminium).

Conclusions

The FSAI is satisfied from the information provided that the novel Vivinal® GOS B manufactured by FrieslandCampina Domo is substantially equivalent to the existing Vivinal® GOS in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.