

SUBSTANTIAL EQUIVALENCE OPINION

Galacto-oligosaccharide (GOS)

The Food Safety Authority of Ireland (FSAI) received an application in January of 2017 from Dairy Crest Limited in the UK for an opinion on the substantial equivalence of its galacto-oligosaccharide (GOS) to a similar ingredient already on the EU market (Vivinal[®] GOS).

Galacto-oligosaccharides, also called transgalactosylated oligosaccharides, transgalacto-oligosaccharides and oligogalactosyl-lactose, are medium length non-digestible oligosaccharides. Vivinal[®] GOS, produced by Friesland Foods/Campina Domo was on the EU market prior to May 15, 1997 and is therefore outside the scope of the novel food Regulation. The applicant considers that Dairy Crest GOS is substantially equivalent to Vivinal[®] GOS and intends to market it in infant and follow-on formula in accordance with Directive 2006/141/EC, and in growing up milks in accordance with general food law.

The production process for the novel ingredient is very similar to that of the comparator, beginning with the aqueous dissolution of the raw material, pure lactose or sweet whey permeate. This is followed by the enzymatic action of β -galactosidase, derived from *Aspergillus oryzae*, which breaks down the lactose and reassembles the sugar constituents into non-digestible saccharides, typically comprising one glucose and one to seven galactose moieties. A secondary reaction is initiated by the addition of the β -galactosidase from *Kluyveromyces lactis* which hydrolyses residual lactose. Enzyme deactivation is achieved by high temperature and low pH treatment, after which the novel ingredient is subjected to standard purification processes. The novel GOS is stable across a range of temperatures and pH conditions, and is stable for up to 12 months at ambient temperatures.

Composition

The novel ingredient is a clear to light yellow syrup with a dry matter content of 75%. The raw material used for production is pure lactose (similar to the Vivinal[®] GOS comparator) or sweet whey permeate (a lactose-rich derivative of cow's milk). The applicant demonstrates that the levels of the primary constituents (GOS, Glucose Lactose and Galactose) are very similar in both the novel and comparator GOS.

Typical Analysis	Dairy Crest GOS	Vivinal [®] GOS
Dry matter (DM)	75% (W/W)	75% (W/W)
GOS	59% of DM (W/W)	59% of DM (W/W)
Glucose	18% of DM (W/W)	19% of DM (W/W)
Lactose	15% of DM (W/W)	21% of DM (W/W)
Galactose	8% of DM (W/W)	1% of DM (W/W)
Sulphated ash	≤0.3% of DM (W/W)	≤0.3% of DM (W/W)
Nitrogen	≤0.016% of DM (W/W)	≤0.032% of DM (W/W)

Nutritional Value and Metabolism

Galacto-oligosaccharides pass through the human gastrointestinal tract largely undigested and therefore are not of direct significant nutritional consequence. GOS is termed a “Prebiotic” which is generally interpreted to mean that on reaching the colon it is fermented by commensal gut bacteria. The high level of similarity in terms of macro- and micro-constituents between the novel GOS and the comparator means that there should not be any discernible differences in terms of nutritional value and metabolism.

Nutritional Measure	Dairy Crest GOS	Vivinal [®] GOS
Energy (Kcal/100g)	239	240
(KJ/100g)	1,005	1,007
Total fat (g/100g)	0.0	0.0
Total Carbohydrate (g/100g)	74	75
Fibre (g/100g)	28.4	30.6
Sugars (g/100g)	45.6	44.6
Protein (g/100g)	≤0.2	0.0

Intended Uses

The applicant intends to use the novel GOS for the same purposes and at the same levels as the comparator, which includes infant and follow-on formulae and “Growing up” milks. The addition of GOS to infant and follow-on formulae in the EU is controlled at up to 0.8 g/100mL (Directive 2006/141/EC, as amended). In growing up milks, the applicant intends to incorporate the novel GOS at a level of 1.08g/100mL which is in line with similar uses of the comparator.

Level of Undesirable Substances

The novel GOS is produced to GMP standards in line with HACCP principles in a BRC accredited facility with a Food Safety Management System (FSSC 22000: version 3 2013). The applicant has provided analytical results for microbiological contaminants (enterobacteriaceae, *Escherichia. coli*, yeasts, moulds and *Salmonella*) as well as heavy metals (aluminium, copper, iron, tin, zinc, arsenic, cadmium, lead and mercury), pesticide residues and other environmental contaminants including dioxins and PAHs, with no cause for concern identified

Conclusions

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