

SUBSTANTIAL EQUIVALENCE OPINION

Galacto-oligosaccharide (GOS)

The Food Safety Authority of Ireland (FSAI) received an application in May of 2017 from Dairy Crest Ltd. in the UK for an opinion on the substantial equivalence of its galacto-oligosaccharide (GOS - 2nd gen.) to a similar ingredient already on the EU market (Vivinal[®] GOS). Galacto-oligosaccharides (GOS), also known as oligogalactosyl-lactose, transgalactosylated oligosaccharides and transgalacto-oligosaccharides are oligosaccharides of medium chain length. They are made up of one molecule of glucose at the reducing end, along with one to seven galactose moieties. The human digestive system has a limited ability to break down GOS and so they pass through the gastrointestinal tract largely undigested, and are fermented in the colon by commensal microorganisms. Dairy Crest GOS - 2nd gen. is produced in a standard process beginning with the enzymatic action of β -galactosidase from *Bifidobacterium bifidum* on milk-derived lactose. The novel GOS has a shelf life of 12 months at ambient temperature and is produced in a UK facility that has a certified Food Safety Management System (FSSC 22000: version 3 2013) and is approved as BRC audited grade A.

The applicant intends to market Dairy Crest GOS - 2nd gen. in infant formulae, follow-on formulae and growing up formulae. The novel GOS 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 Dairy Crest GOS - 2nd gen. is pure lactose or sweet whey permeate. The specifications for the novel and existing GOS products are the same, with the only notable differences being the slightly higher GOS content and lower level of free lactose in the novel ingredient. Protein levels are negligible while fat is not present.

| Parameter | Dairy Crest GOS - 2nd gen. | Vivinal [®] GOS |
|-----------------|----------------------------|--------------------------|
| Dry Matter (DM) | 75 %(w/w) | 75 %(w/w) |
| GOS | 66 %(w/w DM) | 59 %(w/w DM) |
| Nitrogen | ≤ 0.016 %(w/w DM) | ≤ 0.032 %(w/w DM) |
| Sulphated ash | ≤ 0.3 %(w/w DM) | ≤ 0.3 %(w/w DM) |
| Lactose | 11 %(w/w DM) | 21 %(w/w DM) |
| Glucose | 21 %(w/w DM) | 19 %(w/w DM) |
| Galactose | 2 %(w/w DM) | 1 %(w/w DM) |

Nutritional Value and Metabolism

Galacto-oligosaccharides (GOS) predominantly contain β -linkages which are more difficult to break down in the human digestive tract compared to α -linkages. As a result they pass through the human gastrointestinal tract largely undigested and are fermented by commensal microorganisms in the colon. The composition of Dairy Crest GOS – 2nd gen. is similar to the existing comparator, with slightly more GOS present and about half the level of free lactose. As the composition is similar, it follows that the nutritional value and metabolism would also be similar.

Intended Uses

The applicant intends to use the novel GOS for the same purposes and at the same use levels as the existing comparator which includes infant and follow-on formulae in accordance with the requirements of Directive 2006/141/EC, and “Growing up formulae” (1.08 g/100ml) in accordance with general food law.

Level of Undesirable Substances

Batch analyses demonstrate that the levels of microorganisms (yeasts, moulds, *E. coli*, *Salmonellae* and coagulase +ve *Staphylococcus*) and heavy metals (arsenic, cadmium, lead and mercury) are not a specific concern.

Conclusions

The FSAI is satisfied from the information provided that GOS - 2nd gen. manufactured by Dairy Crest Ltd. in the UK is substantially equivalent to the existing Vivinal[®] GOS in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.