SUBSTANTIAL EQUIVALENCE OPINION

Oligomate Galacto-oligosaccharide (GOS)

The Food Safety Authority of Ireland (FSAI) received an application in April of 2013 from Yakult Pharmaceutical Industry Co., Ltd. for an opinion on the substantial equivalence of its galacto-oligosaccharide (GOS) to a similar ingredient already on the EU market (Vivinal® GOS). Oligomate is the trade name for GOS that is the subject of this opinion, with Oligomate 55N being the syrup form and Oligomate 55P the powder form. Galacto-oligosaccharide (GOS) is also known as transgalactosylated oligosaccharide, transgalacto-oligosaccharide and oligogalactosyl-lactose.

Oligomate GOS is produced by San-ei Sucrochemical Co., Ltd. in Japan from refined edible lactose, a disaccharide milk sugar comprising glucose and galactose monomers. Like the existing Vivinal® comparator, Oligomate GOS is the product of an enzymatic conversion of lactose into galacto-oligosaccharides and consists primarily of tri-, di- and tetra-saccharides, along with trace levels of higher oligosaccharides. The production of Oligomate GOS begins with the trans-glycosylation of lactose by the activity of a β-Galactosidase enzyme derived from the yeast *Sporobolomyces singularis*. After this process is complete and the enzyme inactivated, a second yeast β-Galactosidase enzyme from *Kluyveromyces lactis* is used to hydrolyse residual lactose. β-Galactosidase is a dual-function enzyme with transgalactosylic activity which converts lactose into galacto-oligosaccharides and a hydrolytic activity which breaks the galactose-β-1-4-glucose bond in lactose to release glucose and galactose. The β-Galactosidase enzyme from *Sporobolomyces singularis* possesses relatively high transgalactosylic activity compared to that from *Kluyveromyces lactis* which is primarily a hydrolytic lactase.

Following the enzymatic process, the saccharide mixture is purified by standard procedures to yield a final product with a minimum of 55% GOS (dry matter) and lower proportions of lactose, glucose and galactose. The product is intended for use in foods including infant and follow-on formulae and will be limited to the range of foods in which Vivinal® GOS is currently used.

Composition

The applicant provides data on the product specifications for Oligomate 55N and Oligomate 55NP and compares them directly with the comparator GOS (Vivinal®). Oligomate 55N comprises 75% - 76% dry matter (74% - 76% for Vivinal®) while the powder form (Oligomate 55NP) has a minimum of 97% dry matter. The specified maximum or minimum levels of GOS, lactose, glucose and galactose in both products are equivalent, while protein and undesirable substances (microorganisms and heavy metals) specifications are identical or equivalent where established.

Nutritional Value and Metabolism

The minor differences in the proportional content of GOS, lactose, glucose and galactose will not have a significant impact on the nutritional equivalence of the Oligomate and Vivinal® GOS products. Because it only contains β-linkages (rather than α-linkages), galacto-oligosaccharide is not digested by endogenous enzymes and therefore passes through the human gastrointestinal tract largely undigested. When it reaches the colon, GOS is fermented by specific gut bacteria and broken down by bacterial β-glycosidases, primarily yielding CO_2 which is then expired.

Nutrients such as galacto-oligosaccharides that reach the colon relatively undigested and are metabolised by certain gut bacteria are termed prebiotics and are reported to favour the growth of so-called beneficial bacteria. The applicant maintains that a review of the literature does not suggest that the slight differences in the proportions of di-, tri-, tetra- and higher oligosaccharides between Oligomate and Vivinal® GOS would favour one bacterial species over another, for example Bifidobacteria over *Lactobacillus spp*.

Intended Uses

The applicant intends to use Oligomate GOS for the same purposes and at the same levels as Vivinal® GOS which includes infant and follow-on formulae. The use of Oligomate GOS in general foodstuffs with respect to hygiene and labelling will adhere to general EU food law. However, the addition of GOS to infant and follow-on formulae in the EU is controlled by legislation governing foods for particular nutritional uses (PARNUTS), in particular Annexes I and II of Directive 2006/141/EC as amended.

Level of Undesirable Substances

Oligomate GOS, like Vivinal® GOS is highly purified with specifications relating to levels of undesirable substances including microorganisms and heavy metals. Levels of protein, ash and nitrite are identical or equivalent for both products. The heavy metal specifications for both products are identical, as are those for microorganisms, with the exception of coliforms which is not established for the Vivinal® GOS.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Oligomate GOS manufactured by San-ei Sucrochemical Co., Ltd. and marketed by Yakult Pharmaceutical Industry Co., Ltd. is substantially equivalent to Vivinal® GOS that is already on the EU market. This opinion relates only to the substantial equivalence of Oligomate 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.