

SUBSTANTIAL EQUIVALENCE OPINION

Isomalto-oligosaccharide (AdvantaFiber™)

The Food Safety Authority of Ireland (FSAI) received an application in February of 2016 from Top Health Ingredients Inc., of Canada for an opinion on the substantial equivalence of its isomalto-oligosaccharide (AdvantaFiber™) to isomalto-oligosaccharide (IMO) produced by BioNeutra Inc. and authorised for the EU market in 2013.

AdvantaFiber™ comprises units of 3-6 monosaccharides connected by α -(1-6) bonds, but also contains low levels of disaccharides (maltose and isomaltose) and longer polysaccharides of up to 9 units. The raw material for the novel ingredient is non-GM corn starch which undergoes a two-stage enzymatic process followed by concentration and purification steps to produce AdvantaFiber™. The starting corn starch is liquefied by α -amylase in the first stage. In the second stage, this liquefied starch is hydrolysed to maltose by β -amylase and further to IMO by the transglucosidase activity of α -glucosidase. The final IMO product is in both syrup and powder form and is packaged following further purification and concentration processes. AdvantaFiber™ is intended for inclusion in beverages, cereal products, confectionary and nutritionally complete and fortified foods at the same levels as the authorised comparator. The syrup and powder forms of AdvantaFiber™ have shelf lives from the date of manufacturing of 12 and 24 months respectively, under appropriate storage conditions.

Composition

Specifications set for AdvantaFiber™ in both powder and syrup forms are almost identical to those for the EU-authorised comparator, and batch analysis demonstrates that AdvantaFiber™ powder and syrup meet those specifications.

Nutritional Value and Metabolism

As the composition of the novel IMO is very similar to the EU-authorised comparator, the nutritional value and metabolism is not expected to differ.

Intended Uses

AdvantaFiber™ is intended for use in the same food categories and at the same maximum use levels as for the authorised comparator. Food categories include beverages, cereal products, confectionary and nutritionally complete and fortified foods.

Level of Undesirable Substances

Analysis of the novel ingredient for the presence of contaminants such as heavy metals (lead, arsenic), total plate counts, yeasts and moulds, *Staphylococcus aureus*, *Escherichia coli* and *Salmonella* demonstrates that AdvantaFiber™ is within the specifications and regulatory limits set for these parameters where they exist.

Conclusions

The FSAI is satisfied from the information provided by Top Health Ingredients Inc. that their IMO (AdvantaFiber™) is substantially equivalent to IMO which was authorised for the EU market to BioNeutra Inc. in 2013. AdvantaFiber™ will be used in the same food categories and at the same maximum use levels as specified for the EU-authorised comparator IMO. Foods containing AdvantaFiber™ will be labelled to inform consumers that they are “unsuitable for diabetics”.