

SUBSTANTIAL EQUIVALENCE OPINION

Isomalto-oligosaccharide (ImoSweet™)

The Food Safety Authority of Ireland (FSAI) received an application in January of 2016 from Aquapharm Health & Nutrition GmbH of Germany for an opinion on the substantial equivalence of its isomalto-oligosaccharide (ImoSweet™) to isomalto-oligosaccharide (IMO) authorised for the EU market to BioNeutra Inc. in 2013.

ImoSweet™ is composed of a mixture of glucose oligomers (up to 9 units) that are characterised by a terminal glucose linked by an α -(1-6) bond to a glucose, or to oligosaccharides that are connected by α -1,4-linkages. ImoSweet™ contains relatively low levels of mono- or disaccharides. The raw material used for the production of the novel ingredient is non-GM corn and tapioca starch. In the production process, starch is first liquefied by the enzymatic action of α -amylase to yield mono-, di- and oligosaccharides. Glucose is then enzymatically attached to these saccharides by α -glucosidase, resulting in a crude IMO syrup. Monosaccharides and other hydrolysis-susceptible carbohydrates are subsequently reduced in the crude syrup by yeast fermentation. Following further purification steps, the ImoSweet™ syrup is either packaged directly or else dried to produce the powder form, and then packaged. ImoSweet™ has a shelf life of one year under appropriate storage conditions and is intended for use in beverages, cereal products, confectionary and nutritionally complete and fortified foods at the same levels set for the EU-authorised comparator.

Composition

The specifications for ImoSweet™ in both powder and syrup forms are almost identical to those for the authorised IMO, with batch analysis results provided in support.

Nutritional Value and Metabolism

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

Intended Uses

ImoSweet™ is intended for use in the same food categories and at the same maximum use levels as stipulated for the EU-authorised IMO. Food categories include

beverages, cereal products, confectionary and nutritionally complete and fortified foods.

Level of Undesirable Substances

Analytical results for contaminants are provided and include heavy metals (lead, arsenic), total plate counts, yeasts and moulds, *Staphylococcus aureus*, *Escherichia coli* and *Salmonella*. The levels of these potential contaminants are within specifications and regulatory limits, where such limits exist.

Conclusions

The FSAI is satisfied from the information provided by Aquapharm Health & Nutrition GmbH that ImoSweet™ is substantially equivalent to IMO authorised to BioNeutra Inc. as a novel food ingredient for the EU market in 2013. ImoSweet™ will be used in the food categories and at the maximum use levels specified for the EU-authorized IMO. Foods containing ImoSweet™ will be labelled to indicate that they are “unsuitable for diabetics”.