

# APPLICATION – EXECUTIVE SUMMARY

**NOVEMBER 2015**

**TO:**

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

**IN RELATION TO:**

APPLICATION FOR APPROVAL OF ISOMALTO-  
OLIGOSACCHARIDE (IMO) AS A NOVEL FOOD

## EXECUTIVE SUMMARY

*(As per section 3.1.1B of the Application Handbook 1 September 2013)*

Essence Group is making this application to amend Schedule 25 – Permitted Novel Foods of the Australia New Zealand Food Standards Code (hereafter the Code).

The amendment will permit the sale and use of isomalto-oligosaccharide (hereafter IMO) as a food ingredient in Australia and New Zealand.

Essence Group intends to market IMO as a food ingredient in Australia and New Zealand for use as an alternative (lower calorie) sweetener and bulk filler in a number of food categories including carbonated beverages, sports and energy drinks, soy milks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionary at levels up to 15g IMO/serving.

The Applicant advises that while it is proposed that foods intended for particular dietary uses are included in the proposed list of foods (formulated meal replacement and formulated supplementary food), there is no intention for formulated supplementary food for young children or foods for infants to contain IMO.

IMO can be used as an alternative to, and at similar levels to, other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups. IMO is also an alternative bulk filler for ingredients such as fructose oligosaccharides (FOS), inulin, polydextrose and dextrin.

The FSANZ Advisory Committee on Novel Foods determined that IMO is a 'non-traditional food', as it does not have a history of human consumption as a food in Australia or New Zealand which requires an assessment of public health and safety considerations, making it a novel food.

Isomalto-oligosaccharides (IMOs) are glucose oligomers with  $\alpha$ -D-(1,6) linkages, including among others, isomaltose, panose, isomaltotetraose, isomaltopentaose, nigerose, kojibiose and higher branched oligosaccharides.

Overall, the applicant considers there is a substantial body of evidence to support the safety of IMO. On the basis of the available toxicology data, nutritional evaluations, and appropriate food-grade specifications and manufacturing protocols in accordance with GMP, it is concluded that IMO does not present a significant risk for human health at the intake which would result from its intended uses in food. The use of IMO in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects.

Essence Group propose the IMO is approved as a novel food for the following reasons:

- opportunity for companies to import IMO for use in food manufacturing or to import products containing IMO;
- opportunity for manufacturers to produce foods containing IMO;
- increase choice for consumers who will have access to foods containing IMO; and
- International alignment of regulations which will reduce the potential for creation of regulatory trade barriers.

In conclusion, the available scientific evidence presented in this application document indicates that IMO, meeting appropriate food grade specifications and manufactured in accordance with GMP, would not produce adverse effects on human health when consumed at the intended levels in the foods described within the application.

To: Food Standards Australia New Zealand

In relation to: Application for approval of isomalto-oligosaccharide (IMO) as a Novel Food

November 2015