Comments from Victorian Departments of Economic Development, Jobs, Transport and Resources, and Health and Human Services

Due date of submission – 3 February 2017

The Victorian Departments of Economic Development, Jobs, Transport and Resources, and Health and Human Services (the departments) welcome the opportunity to provide comments on Application A1123 isomalto-oligosaccharide as a novel food.

Application A1123 seeks approval of isomalto-oligosaccharide (IMO) as a novel food for use as an alternative (lower calorie) sweetener and as a bulk filler.

From the FSANZ assessment report it is understood that:

- The application seeks to amend Schedule 25 of the Australian and New Zealand Food Standards Code (the Code) to permit the sale and use of IMO as a food ingredient in Australia and New Zealand up to 15 g IMO per serving in a number of food categories including carbonated beverages, sports and energy drinks, soy drinks, milk-based drinks, milk-based and non-milk based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionary.
- Commercial IMO preparations are mixtures of sugar units (saccharides) linked together to form a blend of various oligosaccharides with the majority of the oligosaccharides having chain lengths of three to seven monosaccharides. Therefore, the energy contribution of IMO will depend on the proportion of oligosaccharides in the blend considered to be available or unavailable carbohydrates. As such, food ingredient companies will be required to provide food manufacturers with information on the kilojoule content of the IMO preparation/blend.
- Standard 1.2.4 (Information requirements) requires food manufacturers to list IMO in the statement of ingredients using a name by which the ingredient is commonly known (or a name that describes its true nature e.g. isomalto-oligosaccharide). This will be particularly important for individuals with congenital or acquired sucrose-isomaltase deficiency. The departments note the prevalence of congenital sucrose-isomaltase deficiency is about 0.2% in North Americans of European ancestry.[1] FSANZ's planned communication strategy to health professions who may clinically manage patients with sucrose-isomaltase deficiency is acknowledged.
- IMO is permitted as a food ingredient in a number of overseas jurisdictions including the US, UK and Canada.
- FSANZ's risk and technical assessment report (Supporting Document 1) indicates that IMO shows no evidence of genotoxicity and no evidence of adverse effects in healthy humans up to a 40 g IMO per day.
- FSANZ considers that broadening the list of foods permitted to contain IMO, with the exception of infant formula products (Standard 2.9.1), food for infants (Standard 2.9.2) and formulated supplementary foods for young children (Standard 2.9.3, Division 4), does not pose a risk to population health and safety.

The departments note that FSANZ is seeking responses to specific questions provided on page 11 of the Call for Submissions and has no further comment. The departments consider that FSANZ has addressed the costs and benefits in permitting the use of IMO as a novel food in all foods except those identified and thus supports Option 1:

[1] Peterson ML, Herber R. (1967) Intestinal sucrose deficiency. Trans Assoc Am Physicians, 80: 275-83.

Prepare a draft variation to the Code to permit the use of IMO as a novel food in all foods except infant formula products, infant foods, and formulated supplementary food for young children.

However, the departments query the assumption made in the dietary exposure assessment (page 23 of Supporting Document 1), where IMO replaced added sugars on a gram for gram basis to predict the dietary intake of IMO for the Australian population. The applicant provided an example (page 9 of SD1 - the butter cake recipe) where added sugar was replaced with IMO using a conversion factor of 1.67 given that the relative sweetness of IMO is approximately 60% that of sucrose. This suggests that, in estimating dietary exposure of the Australian population to IMO, one gram of added sugar should be replaced with 1.67 g IMO to more closely reflect predicted exposure. Using this conversion factor, the daily dose for some population groups is likely to be higher than 40 g IMO per day, at which level, evidence for adverse effects in healthy humans is lacking.

The unknown effects of IMO at levels above 40 g per day, the reported gastro intestinal effects in haemodialysis patients[2] (noted in the Supporting Document page 19), and the limits set for the addition of IMO in foods in the US, UK and EU suggests that further consideration of the conditions of use is required.

There are existing provisions in the Code for advisory statements on foods containing sugar alcohols (Standard 1.2.3-2). Moreover, it is noted that BioNeutra proposed two possible advisory statements[3] in their application to add IMO to foods to the US Food and Drug Administration (FDA).[4] The FDA approved the use of IMO without any advisory statements, however has set an upper limit of 15 g per serving.

The departments recommend that further engagement and consultation with industry is necessary to determine whether an advisory statement or a limit on the amount of IMO that can be added per serving is appropriate.

Subject to this final comment being addressed, the departments support the progression of Application A1123.

[2] Wang H-F et al., (2001) Use of isomalto-oligosaccharide in the treatment of lipid profiles and constipation in hemodialysis patients. Journal of Renal Nutrition. 2: 73-79.

[3] Cautions: In case of gastrointestinal discomfort or abdominal bloating, IMO use should be discontinued
Warnings: Very high dosages (> 40 g/day) may develop gastro-intestinal discomfort

[4] http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm268863.pdf