

16 May 2017
[13–17]

Supporting document 2

Assessment against the Policy Guidelines (at Approval) – Application A1123

Isomalto-oligosaccharide as a Novel Food

Under Section 18 of the FSANZ Act, FSANZ must have regard to any written policy guidelines formulated by the [Australia and New Zealand Ministerial Forum on Food Regulation](#)¹ (the Forum). There are two policies relevant to A1123:

- Policy Guidelines on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals

FSANZ has had regard to these Ministerial Policy Guidelines and our assessment is summarised in the table below. The ‘high order’ principles in these guidelines reflect FSANZ’s statutory objectives which are described in section 2.5.1 and 2.5.2 of the assessment summary, and are therefore not covered in the tables below.

¹ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

1 Novel foods

The table below summarises how FSANZ has had regard to the Ministerial Policy Guideline on Novel foods.

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles
To ensure that public and industry confidence in the food system is maintained.	The risk assessment, labelling requirements and information for health professionals will provide confidence for the food industry and consumers. Input from stakeholders including the public and industry (through the call for submissions) will also build confidence.	Yes
To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.	FSANZ has a specific assessment process in place to ensure access to confidential material provided by the Applicant is limited and protected to the maximum extent possible.	Yes
To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.	Novel foods or ingredients labelling requirements ensure any declarations and/or claims made on labels are truthful and appropriate for consumers.	Yes

2 Substances other than Vitamins and Minerals

The table below summarises how FSANZ has had regard to the Ministerial to the Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

'Specific order' policy principles are provided for substances added for a technological function as well as for 'Any Other Purpose'. This Application falls under 'Any Other Purpose' and therefore regard has been given to the following policy principles in the assessment of this Application.

Specific Order Policy Principles – Any Other Purpose

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
The purpose for adding IMO to food (the stated purpose) has been articulated clearly by the manufacturer i.e. the stated purpose as a food sweetener and bulk filler	The purpose for adding IMO to food (the stated purpose) has been articulated by the manufacturer as a food sweetener and bulk filler The food technology assessment has determined that when IMO is used as an ingredient to replace sugars, mainly sucrose in a food, it meets the stated purposes of a bulk filler. Also, according to the Applicant's reported composition of IMO (i.e. lower levels of mono- and di-saccharides than sucrose) and FSANZ's proposed specification for IMO, it could be used as a sweetener with approximately 60% sweetness compared to sucrose. (SD1 Food Technology).	Yes
The addition of IMO to food is safe for human consumption	The risk assessment has determined that IMO is safe and suitable for addition to nearly all foods i.e. the Applicant notes that it is not intended that IMO would be added to formulated supplementary foods for young children or in foods (and formulas) for infants (SD1).	Yes
The substance is added in a quantity and a form which is consistent with delivering the stated purpose	IMO would be added in a quantity and form that would deliver the stated purpose (of sweetening food and providing bulk). The Applicant has provided expected levels of use and an example is also provided (SD1).	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
<p>The addition of the substance is not likely to create a significant negative public health impact to the general population or sub population</p>	<p>The risk assessment indicates the addition of IMO as proposed would not create a significant public health impact. Also, this would be a voluntary permission; its presence in a food product would be declared on a label; and it is in line with national nutrition advice as it could potentially reduce the level of sugars added to a product.</p> <p>However, IMO is likely to be poorly tolerated by certain individuals with congenital or acquired sucrase-isomaltase deficiency. Generic labelling requirements will enable such individuals to identify food with IMO to avoid. FSANZ will also provide information to relevant health professional bodies to assist their members in advising patients who have this deficiency.</p>	<p>Yes</p>
<p>The presence of the substance does not mislead the consumer as to the nutritional quality of the food</p>	<p>The mandatory labelling requirements to provide information in the NIP (including the sugar content), and to declare IMO's presence in the ingredient list, plus the Code claims requirements, would ensure the consumer is not misled as to the nutritional quality of the food.</p>	<p>Yes</p>