

# APPLICATION – CHECKLIST

NOVEMBER 2015

**TO:**

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

**IN RELATION TO:**

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

General requirements (3.1)			
<input checked="" type="checkbox"/>	3.1.1 Form of application  <input checked="" type="checkbox"/> <i>Application, abstracts and other key documents in English</i>  <input checked="" type="checkbox"/> <i>Executive Summary (separated from main application electronically and in hard copy)</i>  <input checked="" type="checkbox"/> <i>Relevant sections of Part 3 clearly identified</i>  <input checked="" type="checkbox"/> <i>Pages sequentially numbered</i>  <input checked="" type="checkbox"/> <i>Electronic copy (searchable)</i>  <input checked="" type="checkbox"/> <i>1 hard copy</i>  <input checked="" type="checkbox"/> <i>Electronic and hard copy identical</i>  <input checked="" type="checkbox"/> <i>Hard copy capable of being laid flat</i>  <input checked="" type="checkbox"/> <i>All references provided (in electronic and hard copy)</i>	<input checked="" type="checkbox"/>	3.1.6 Assessment procedure  <input checked="" type="checkbox"/> <i>General</i>  <input type="checkbox"/> <i>Major</i>  <input type="checkbox"/> <i>Minor</i>  <input type="checkbox"/> <i>High level health claim variation</i>
		<input checked="" type="checkbox"/>	3.1.7 Confidential Commercial Information  <input checked="" type="checkbox"/> <i>Confidential material separated in both electronic and hard copy</i>  <input checked="" type="checkbox"/> <i>Formal request including reasons</i>  <input checked="" type="checkbox"/> <i>Non-confidential summary provided</i>
<input checked="" type="checkbox"/>	3.1.2 Applicant details  Note change of Company name since the application was originally submitted in 2014.	<input type="checkbox"/>	3.1.8 Exclusive Capturable Commercial Benefit  <input type="checkbox"/> <i>Justification provided</i>  N/A
<input checked="" type="checkbox"/>	3.1.3 Purpose of the application	<input checked="" type="checkbox"/>	3.1.9 International and other national standards <input checked="" type="checkbox"/> <i>International standards</i>  <input checked="" type="checkbox"/> <i>Other national standards</i>

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<input checked="" type="checkbox"/>	3.1.4 Justification for the application <input checked="" type="checkbox"/> <i>Regulatory impact information</i> <input checked="" type="checkbox"/> <i>Impact on international trade</i>	<input checked="" type="checkbox"/>	3.1.10 Statutory Declaration
<input checked="" type="checkbox"/>	3.1.5 Information to support the application <input checked="" type="checkbox"/> <i>Data requirements</i>	<input checked="" type="checkbox"/>	3.1.11 Checklist/s provided with application <input checked="" type="checkbox"/> <i>3.1 Checklist</i> <input checked="" type="checkbox"/> <i>Any other relevant checklists for Parts 3.5.2</i>

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Novel Foods (3.5.2)			
<input type="checkbox"/>	A. Exclusive use No	<input checked="" type="checkbox"/>	B.4 Impurity profile
<input checked="" type="checkbox"/>	B.1 Type of novel food	<input checked="" type="checkbox"/>	B.5 Manufacturing process
<input checked="" type="checkbox"/>	B.2 Information on potential beneficial outcomes	<input checked="" type="checkbox"/>	B.6 Specification for identity and purity
<input checked="" type="checkbox"/>	B.3 Chemical and physical properties	<input checked="" type="checkbox"/>	B.7 Analytical detection method
C – Information on the safety of the novel food			
(IV & V) <i>Single chemical entities &amp; Dietary macrocomponents</i>			
<input checked="" type="checkbox"/>	1. Toxicokinetics and metabolism	<input checked="" type="checkbox"/>	3. Safety assessments from other agencies
<input checked="" type="checkbox"/>	2. Toxicity studies		
<input checked="" type="checkbox"/>	D.1 List of foods likely to contain the novel food or novel food ingredient	<input checked="" type="checkbox"/>	D.7 Use in other countries
<input checked="" type="checkbox"/>	D.2 Proposed levels in foods	<input checked="" type="checkbox"/>	E.1 Nutritional impact information
<input checked="" type="checkbox"/>	D.3 Information on levels of consumption	<input checked="" type="checkbox"/>	E.2 Public health impact

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Novel Foods (3.5.2)			
<input checked="" type="checkbox"/>	D.4 Percentage of food group or market		F.1 Demonstrated consumer awareness and understanding
	D.5 Where consumption has changed, information on likely consumption		F.2 Potential behaviour in response to foods
<input checked="" type="checkbox"/>	D.6 Information to show whether the food or ingredient will replace another food	<input checked="" type="checkbox"/>	F.3 Demonstration of no adverse effects on any population groups

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