

# **APPENDIX 1**

## **Checklists**

## Checklist for General requirements

This Checklist will assist you in determining if you have met the information requirements as detailed in Section 3.1 – General Requirements. All applications must include this Checklist.

General requirements (3.1)			
<input checked="" type="checkbox"/>	3.1.1 Form of application	<input checked="" type="checkbox"/>	3.1.6 Assessment procedure
	<input checked="" type="checkbox"/> Application, abstracts and other key documents in English		<input checked="" type="checkbox"/> General
	<input checked="" type="checkbox"/> Executive Summary (separated from main application electronically and in hard copy)		<input type="checkbox"/> Major
	<input checked="" type="checkbox"/> Relevant sections of Part 3 clearly identified		<input type="checkbox"/> Minor
	<input checked="" type="checkbox"/> Pages sequentially numbered	<input type="checkbox"/>	<input type="checkbox"/> High level health claim variation
	<input checked="" type="checkbox"/> Electronic copy (searchable)	<input type="checkbox"/>	
	<input checked="" type="checkbox"/> 1 hard copy	<input type="checkbox"/>	
	<input checked="" type="checkbox"/> Electronic and hard copy identical	<input type="checkbox"/>	
	<input checked="" type="checkbox"/> Hard copy capable of being laid flat	<input type="checkbox"/>	
	<input checked="" type="checkbox"/> All references provided (in electronic and hard copy)	<input type="checkbox"/>	
		N/A	3.1.7 Confidential Commercial Information
			<input type="checkbox"/> Confidential material separated in both electronic and hard copy
			<input type="checkbox"/> Formal request including reasons
			<input type="checkbox"/> Non-confidential summary provided
<input checked="" type="checkbox"/>	3.1.2 Applicant details	<input type="checkbox"/>	3.1.8 Exclusive Capturable Commercial Benefit
		N/A	<input type="checkbox"/> Justification provided
<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"/> International standards
			<input checked="" type="checkbox"/> Other national standards
<input checked="" type="checkbox"/>	3.1.4 Justification for the application	<input checked="" type="checkbox"/>	3.1.10 Statutory Declaration
	<input checked="" type="checkbox"/> Regulatory impact information		
	<input checked="" type="checkbox"/> Impact on international trade		
<input checked="" type="checkbox"/>	3.1.5 Information to support the application	<input checked="" type="checkbox"/>	3.1.11 Checklist/s provided with application
	<input checked="" type="checkbox"/> Data requirements		<input checked="" type="checkbox"/> 3.1 Checklist
			<input checked="" type="checkbox"/> Any other relevant checklists for Parts 3.2-3.7

## Checklist for Standards related to substances added to food

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.3.1-3.3.3.

<b>Nutritive Substances (3.3.3)</b>			
<input type="checkbox"/>	A.1 Identification information	<input type="checkbox"/>	C.2 Proposed maximum levels in food groups or foods
<input type="checkbox"/>	A.2 Chemical and physical properties	<input type="checkbox"/>	C.3 Likely level of consumption
<input type="checkbox"/>	A.3 Impurity profile information	<input type="checkbox"/>	C.4 Percentage of food group to use nutritive substance
<input type="checkbox"/>	A.4 Manufacturing process	<input type="checkbox"/>	C.5 Use in other countries (if available)
<input type="checkbox"/>	A.5 Specification information	<input type="checkbox"/>	C.6 Where consumption has changed, information on likely consumption
<input type="checkbox"/>	A.6 Analytical detection method	<input type="checkbox"/>	D.1 Nutritional purpose
<input type="checkbox"/>	A.7 Proposed food label	<input type="checkbox"/>	E.1 Need for nutritive substance
<input type="checkbox"/>	B.1 Toxicokinetics and metabolism information	<input type="checkbox"/>	E.2 Demonstrated potential deficit or health benefit
<input type="checkbox"/>	B.2 Animal or human toxicity studies	<input type="checkbox"/>	F.1 Consumer awareness and understanding
<input type="checkbox"/>	B.3 Safety assessments from international agencies	<input type="checkbox"/>	F.2 Actual or potential behaviour of consumers
<input type="checkbox"/>	C.1 List of food groups or foods likely to contain the nutritive substance	<input type="checkbox"/>	F.3 Demonstration of no adverse effects on any population groups

## Checklist for Standards related to special purpose foods and standardised foods

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.6.1-3.6.3.

### Special purpose foods – Infant formula products (3.6.2)

- |  |  |
|--|--|
| <input type="checkbox"/> A.1 Purpose of compositional change   | <input type="checkbox"/> B.3 Information relating to the substance                                   |
| <input type="checkbox"/> A.2 Data for supporting evidence  | <input type="checkbox"/> C.1 Safety or nutritional impact of labelling change                        |
| <input type="checkbox"/> A.3 Specific information requirements<br><input type="checkbox"/> <i>Characterisation of proposed substance in breast milk</i><br><input type="checkbox"/> <i>Nutritional safety and tolerance</i><br><input type="checkbox"/> <i>Efficacy of proposed compositional change</i><br><input type="checkbox"/> <i>Tolerance of proposed compositional change</i> | <input type="checkbox"/> C.2 Demonstrated consumer understanding of labelling change                 |
| <input type="checkbox"/> B.1 Dietary intake or exposure of target population   | <input type="checkbox"/> D. Internationally recognised codes of practice and guidelines on labelling |
| <input type="checkbox"/> N/A B.2 Level of consumption  |  |