

## **Appendix II**

### **Checklists**

General requirements (3.1)		
Check	Page No.	Mandatory requirements
		A Form of application
<input checked="" type="checkbox"/>	n/a	<input checked="" type="checkbox"/> <i>Application in English</i> <input checked="" type="checkbox"/> <i>Executive Summary (separated from main application electronically)</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>All references provided (in electronic copy)</i>
<input checked="" type="checkbox"/>	8	B Applicant details
<input checked="" type="checkbox"/>	9	C Purpose of the application
		D Justification for the application
<input checked="" type="checkbox"/>	9	<input checked="" type="checkbox"/> <i>Regulatory impact information</i>
	10	<input checked="" type="checkbox"/> <i>Impact on international trade</i>
<input checked="" type="checkbox"/>	11	E Information to support the application
		<input checked="" type="checkbox"/> <i>Data requirements</i>
		F Assessment procedure
<input checked="" type="checkbox"/>	11	<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>
		G Confidential commercial information
<input checked="" type="checkbox"/>	13	<input checked="" type="checkbox"/> <i>CCI material separated from other application material</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"/>	14	H Other confidential information
		<input checked="" type="checkbox"/> <i>Confidential material separated from other application material</i>
		<input checked="" type="checkbox"/> <i>Formal request including reasons</i>
<input checked="" type="checkbox"/>	14	I Exclusive Capturable Commercial Benefit
		<input checked="" type="checkbox"/> <i>Justification provided</i>
<input checked="" type="checkbox"/>	15	J International and other national standards
		<input checked="" type="checkbox"/> <i>International standards</i>
		<input checked="" type="checkbox"/> <i>Other national standards</i>
<input checked="" type="checkbox"/>	16	K Statutory Declaration
		L Checklist/s provided with application
<input checked="" type="checkbox"/>	16	<input checked="" type="checkbox"/> <i>3.1 Checklist</i> <input checked="" type="checkbox"/> <i>All page number references from application included</i> <input checked="" type="checkbox"/> <i>Any other relevant checklists for Parts 3.2—3.7</i>

Processing aids (3.3.2)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>	*	A.1 Type of processing aid
<input type="checkbox"/>	*	A.2 Identification information
<input type="checkbox"/>	*	A.3 Chemical and physical properties
<input type="checkbox"/>	*	A.4 Manufacturing process
<input type="checkbox"/>	*	A.5 Specification information
<input type="checkbox"/>	*	A.6 Analytical method for detection
<input type="checkbox"/>	*	B.1 Industrial use information (chemical only)
<input type="checkbox"/>	*	B.2 Information on use in other countries (chemical only)
<input type="checkbox"/>	*	B.3 Toxicokinetics and metabolism information (chemical only)
<input type="checkbox"/>	*	B.4 Toxicity information (chemical only)
<input type="checkbox"/>	*	B.5 Safety assessments from international agencies (chemical only)
<input type="checkbox"/>	*	C.1 Information on enzyme use on other countries (enzyme only)
<input type="checkbox"/>	*	C.2 Toxicity information of enzyme (enzyme only)
<input type="checkbox"/>	*	C.3. Allergenicity information of enzyme (enzyme only)
<input type="checkbox"/>	*	C.4. Overseas safety Assessment Reports
<input checked="" type="checkbox"/>	27	D.1 Information on source organism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	30	D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	30	D.3 Genetic stability of source organism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	28	E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)
<input type="checkbox"/>	*	F.1 List of foods likely to contain the processing aid
<input type="checkbox"/>	*	F.2 Anticipated residue levels in foods
<input type="checkbox"/>	*	F.3 Information on likely level of consumption
<input type="checkbox"/>	*	F.4 Percentage of food group to use processing aid
<input type="checkbox"/>	*	F.5 Information on residues in foods in other countries (if available)
<input type="checkbox"/>	*	F.6 Where consumption has changed, information on likely consumption

\* Sections A, B, C, and F are not applicable to this application.

Novel Foods (3.5.2)		
Check	Page No.	Mandatory requirements

- |                                     |    |  |
|-------------------------------------|----|--|
| <input checked="" type="checkbox"/> | 17 | A. Exclusive use                                 |
| <input checked="" type="checkbox"/> | 19 | B.1 Type of novel food                           |
| <input checked="" type="checkbox"/> | 19 | B.2 Information on potential beneficial outcomes |
| <input checked="" type="checkbox"/> | 20 | B.3 Chemical and physical properties             |
| <input checked="" type="checkbox"/> | 31 | B.4 Impurity profile                             |
| <input checked="" type="checkbox"/> | 21 | B.5 Manufacturing process                        |
| <input checked="" type="checkbox"/> | 36 | B.6 Specification for identity and purity        |
| <input checked="" type="checkbox"/> | 47 | B.7 Analytical detection method                  |

### C – Information on the safety of the novel food

#### (I) *Plant or animal extracts*

- ☐ 1 Extraction and composition
- ☐ 2 Effects of food processing or preparation
- ☐ 3 Current use
- ☐ 4 Potential adverse effects

#### (II) *Plant and animal extracts*

- ☐ 1 Method or extraction and composition of extract
- ☐ 2 Use as a food in other countries
- ☐ 3. Toxicity studies
- ☐ 4 Safety assessments from other agencies

#### (III) *Herbs (both non-culinary and culinary) including extracts*

- ☐ 1 History of use
- ☐ 2 Composition
- ☐ 3 Method of extraction and composition of extract
- ☐ 4 Use in other countries
- ☐ 5 Potential allergenicity
- ☐ 6 Toxicity studies
- ☐ 7 Safety assessments from other agencies

#### (IV & V) *Single chemical entities & Dietary macrocomponents*

- ☒ 52 1 Toxicokinetics and metabolism
- ☒ 49, 53-72 2 Toxicity studies
- ☒ 73 3 Safety assessments from other agencies

#### (VI) *Microorganisms (including probiotics)*

- ☐ 1. Potential pathogenicity
- ☐ 2 Effects on gut microflora
- ☐ 3 Use as a food in other countries
- ☐ 4 Human toleration studies

**(VII) Food ingredients derived from a new source**

- ☐ 1 Safety of the source organism, including allergen statement
- ☐ 2 Composition
- ☐ 3 Toxicity studies
- ☐ 4 Overseas safety reports

**(VIII) Foods produced by a process not previously applied to food**

- ☐ 1 Details of the new process
- ☐ 2 Toxicity studies
- ☐ 3 Overseas safety reports

- ☒ 80 D.1 List of foods likely to contain the novel food or novel food ingredient
  - ☒ 80 D.2 Proposed levels in foods
  - ☒ 80 D.3 Information on levels of consumption
  - ☒ 80 D.4 Percentage of food group or market
  - ☒ 80 D.5 Where consumption has changed, information on likely consumption
  - ☒ 80 D.6 Information to show whether the food or ingredient will replace another food
  - ☒ 81-85, 87 D.7 Use in other countries
  - ☒ 100 E.1 Nutritional impact information
  - ☒ 101 E.2 Public health impact
  - ☒ 103 F.1 Demonstrated consumer awareness and understanding
  - ☒ 103 F.2 Potential behaviour in response to foods
  - ☒ 103 F.3 Demonstration of no adverse effects on any population groups
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Special purpose foods – Infant formula products (3.6.2)		
Check	Page No.	Mandatory requirements
<input checked="" type="checkbox"/>	91	A.1 Purpose of compositional change
<input checked="" type="checkbox"/>	92, 48	A.2 Data for supporting evidence
		A.3 Specific information requirements
<input checked="" type="checkbox"/>	92, 49	<input checked="" type="checkbox"/> <i>Characterisation of proposed substance in breast milk</i>
	48	<input checked="" type="checkbox"/> <i>Nutritional safety and tolerance</i>
	92	<input checked="" type="checkbox"/> <i>Efficacy of proposed compositional change</i>
		<input type="checkbox"/> <i>Tolerance of proposed compositional change</i>
<input checked="" type="checkbox"/>	80	B.1 Dietary intake or exposure of target population
<input checked="" type="checkbox"/>	86	B.2 Level of consumption
<input checked="" type="checkbox"/>	80	B.3 Information relating to the substance
<input checked="" type="checkbox"/>	103	C.1 Safety or nutritional impact of labelling change
<input checked="" type="checkbox"/>	103	C.2 Demonstrated consumer understanding of labelling change
<input checked="" type="checkbox"/>	103	D Internationally recognised codes of practice and guidelines on labelling

**Special purpose foods – Other foods (3.6.3)**

<b>Check</b>	<b>Page No.</b>	<b>Mandatory requirements</b>
<input checked="" type="checkbox"/>	91	A.1 Identity and need of target population
<input checked="" type="checkbox"/>	91	A.2 Purpose of compositional change
<input checked="" type="checkbox"/>	48	A.3 Safety of proposed compositional change
<input checked="" type="checkbox"/>	92	A.4 Nutritional or performance impact
<input checked="" type="checkbox"/>	80	B.1 Dietary exposure data
<input checked="" type="checkbox"/>	86	B.2 Level of consumption
<input checked="" type="checkbox"/>	103	C.1 Safety and nutritional impact of labelling change
<input checked="" type="checkbox"/>	103	C.2 Demonstrated consumer understanding of labelling change
<input checked="" type="checkbox"/>	103	D Internationally recognised codes of practice and guidelines