Appendix II

Checklists

Checklist for General requirements

This Checklist will assist you in determining if you have met the mandatory format and information requirements as detailed in Guideline 3.1.1 – General requirements. All applications **must** include this Checklist.

General requirements (3.1.1)		
Check	**Page No.**	**Mandatory requirements**
✓	-	A Form of application ✓ *Application in English* ✓ *Executive Summary (separated from main application electronically)* ✓ *Relevant sections of Part 3 clearly identified* ✓ *Pages sequentially numbered* ✓ *Electronic copy (searchable)* ✓ *All references provided*
✓	4	B Applicant details
✓	4	C Purpose of the application
✓	5	D Justification for the application ✓ *Regulatory impact information* ✓ *Impact on international trade*
✓	6	E Information to support the application ✓ *Data requirements*
✓	7	F Assessment procedure ☐ *General* ✓ *Major* ☐ *Minor* ☐ *High level health claim variation*
✓	7	G Confidential commercial information ✓ *CCI material separated from other application material* ✓ *Formal request including reasons* ✓ *Non-confidential summary provided*
✓	7	H Other confidential information ✓ *Confidential material separated from other application material* ✓ *Formal request including reasons*
✓	8	I Exclusive Capturable Commercial Benefit ✓ *Justification provided*
✓	8	J International and other national standards ✓ *International standards* ✓ *Other national standards*
✓	Appendix I	K Statutory Declaration
✓	Appendix II	L Checklist/s provided with application ✓ *3.1.1 Checklist* ✓ *All page number references from application included* ✓ *Any other relevant checklists for Chapters 3.2–3.7*

Checklist for applications for new foods

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.5.1–3.5.3.

Foods produced using gene technology (3.5.1)		
Check	**Page No.**	**Mandatory requirements**
✓	13	A.1 Nature and identity
✓	16	A.2 History of use of host and donor organisms
✓	17	A.3 Nature of genetic modification
✓	26	B.1 Characterisation and safety assessment
✓	26	B.2 New proteins
✓	26	B.3 Other (non-protein) new substances
N/A	-	B.4 Novel herbicide metabolites in GM herbicide-tolerant plants
✓	21	B.5 Compositional analyses
✓	57	C Nutritional impact of GM food
✓	-	D Other information

Novel foods (3.5.2)		
Check	**Page No.**	**Mandatory requirements**
✓	10	A. Exclusive use
✓	12	B.1 Type of novel food
✓	12	B.2 Information on potential beneficial outcomes
✓	12	B.3 Chemical and physical properties
✓	21	B.4 Impurity profile
✓	13	B.5 Manufacturing process
✓	21	B.6 Specification for identity and purity
✓	25	B.7 Analytical detection method
C.1		***Plant or animal extracts***
☐		C.1.1 Extraction and composition
☐		C.1.2 Effects of food processing or preparation
☐		C.1.3 Current use
☐		C.1.4 Potential adverse effects
C.2		***Plant and animal extracts***
☐		C.2.1 Method or extraction and composition of extract
☐		C.2.2 Use as a food in other countries
☐		C.2.3 Toxicity studies
☐		C.2.4 Safety assessments from other agencies
C.3		***Herbs (both non-culinary and culinary) including extracts***
☐		C.3.1.1 History of use

☐ C.3.2 Composition

☐ C.3.3 Method of extraction and composition of extract

☐ C.3.4 Use in other countries

☐ C.3.5 Potential allergenicity

☐ C.3.6 Toxicity studies

☐ C.3.7 Safety assessments from other agencies

C.4 Single chemical entities & dietary macrocomponents

☐ C.4.1 Toxicokinetics and metabolism

☐ C.4.2 Toxicity studies

☐ C.4.3 Safety assessments from other agencies

C.5 Microorganisms (including probiotics)

☐ C.5.1 Potential pathogenicity

☐ C.5.2 Effects on gut microflora

☐ C.5.3 Use as a food in other countries

☐ C.5.4 Human toleration studies

C.6 Food ingredients derived from a new source

✓ 27 C.6.1 Safety of the source organism, including allergen statement

✓ 27 C.6.2 Composition

✓ 27 C.6.3 Toxicity studies

✓ 46 C.6.4 Overseas safety reports

C.7 Foods produced by a process not previously applied to food

☐ C.7.1 Details of the new process

☐ C.7.2 Toxicity studies

☐ C.7.3 Overseas safety reports

✓ 49 D.1 List of foods likely to contain the novel food or novel food ingredient

✓ 49 D.2 Proposed levels in foods

✓ 49 D.3 Information on levels of consumption

✓ 56 D.4 Percentage of food group or market

✓ 49 D.5 Where consumption has changed, information on likely consumption

✓ 49 D.6 Information to show whether the food or ingredient will replace another food

✓ 46 D.7 Use in other countries

✓ 58 E.1 Nutritional impact information

✓ 60 E.2 Public health impact

✓ 62 F.1 Demonstrated consumer awareness and understanding

✓ 62 F.2 Potential behaviour in response to foods

✓ 63 F.3 Demonstration of no adverse effects on any population groups

Substances used of a nutritive purpose (3.3.3)		
Check	**Page No.**	**Mandatory requirements**
✓	12	A.1 Purpose of the use of the substance
✓	12	A.2 General data requirements for supporting evidence
✓	13	B.1 Identification
✓	12	B.2 Chemical and physical properties
✓	21	B.3 Impurity profile
✓	13	B.4 manufacturing process
✓	21	B.5 Specification for identity and purity
✓	25	B.6 Analytical method for detection
✓	12	B.7 Proposed food label
✓	31	C.1 Toxicokinetics and metabolism, degradation products and major metabolites
✓	27	C.2 Animal or human studies
✓	46	C.3 International safety assessments
✓	49	D.1 List of food groups or foods likely to contain the nutritive substance
✓	49	D.2 Proposed maximum levels in food groups or foods
✓	49	D.3 Likely level of consumption
✓	56	D.4 Percentage of food group to use nutritive substance
✓	46	D.5 Use in other countries (if available)
✓	49	D.6 Where consumption has changed, information on likely consumption
✓	58	E.1 Need to permit addition of vitamin or mineral
✓	58	E.2 Demonstrated potential to address deficit or health benefit
✓	58	F.1 Nutritional purpose (other than vitamins and minerals)
✓	62	G.1 Consumer awareness and understanding
✓	62	G.2 Actual or potential behaviour of consumers
✓	63	H.3 Demonstration of no adverse effects on any population groups
✓	63	H.3 Demonstration of no adverse effects on any population groups