

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)

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|---|-------------------------------------|--|
| 3.1.1 Form of application | <input checked="" type="checkbox"/> | 3.1.7 Confidential Commercial Information |
| <input checked="" type="checkbox"/> <i>Executive Summary</i> | | <input type="checkbox"/> <i>Confidential material separated in both</i> |
| <input checked="" type="checkbox"/> <i>Relevant sections of Part 3 identified</i> | | <i>electronic and hard copy</i> |
| <input checked="" type="checkbox"/> <i>Pages sequentially numbered</i> | | <input type="checkbox"/> <i>Justification provided</i> |
| <input checked="" type="checkbox"/> <i>Electronic + 2 hard copies</i> | | |
| <input checked="" type="checkbox"/> <i>Electronic and hard copies identical</i> | | |
| <input checked="" type="checkbox"/> <i>Hard copies capable of being laid flat</i> | | |
| <input checked="" type="checkbox"/> <i>All references provided</i> | | |
| 3.1.2 Applicant details | <input checked="" type="checkbox"/> | 3.1.8 Exclusive Capturable Commercial Benefit |
| 3.1.3 Purpose of the application | <input checked="" type="checkbox"/> | 3.1.9 International and Other National standards |
| 3.1.4 Justification for the application | <input checked="" type="checkbox"/> | 3.1.10 Statutory Declaration |
| 3.2.5 Information to support the application | <input checked="" type="checkbox"/> | 3.1.11 Checklist/s provided with Application |
| | | <input type="checkbox"/> <i>3.1 Checklist</i> |
| | | <input type="checkbox"/> <i>Any other relevant checklists for Sections 3.2-3.7</i> |
| 3.1.6 Assessment procedure | | |
| <input checked="" type="checkbox"/> <i>General</i> | | |
| <input type="checkbox"/> <i>Major</i> | | |
| <input type="checkbox"/> <i>Minor</i> | | |
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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.

Food Additives (3.3.1)

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|--|---|
| <input type="checkbox"/> A.1 Nature and technological function information | <input type="checkbox"/> B.1 Toxicokinetics and metabolism information |
| <input type="checkbox"/> A.2 Identification information | <input type="checkbox"/> B.2 Toxicity information |
| <input type="checkbox"/> A.3 Chemical and physical properties | <input type="checkbox"/> B.3 Safety assessments from international agencies |
| <input type="checkbox"/> A.4 Impurity profile | <input type="checkbox"/> C.1 List of foods likely to contain the food additive |
| <input type="checkbox"/> A.5 Manufacturing process | <input type="checkbox"/> C.2 Proposed levels in foods |
| <input type="checkbox"/> A.6 Specifications | <input type="checkbox"/> C.3 Likely level of consumption |
| <input type="checkbox"/> A.7 Food labelling | <input type="checkbox"/> C.4 Percentage of food group to contain the food additive |
| <input type="checkbox"/> A.8 Analytical detection method | <input type="checkbox"/> C.5 Use in other countries (if applicable) |
| <input type="checkbox"/> A.9 Additional functions | <input type="checkbox"/> C.6 Where consumption has changed, information on likely consumption |

Processing Aids (3.3.2)

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|---|--|
| <input checked="" type="checkbox"/> A.1 Type of processing aid | <input type="checkbox"/> C.3. Allergenicity information of enzyme (enzyme only) |
| <input checked="" type="checkbox"/> A.2 Identification information | <input checked="" type="checkbox"/> C.4. Overseas safety Assessment Reports |
| <input checked="" type="checkbox"/> A.3 Chemical and physical properties | <input type="checkbox"/> D.1 Information on source organism (enzyme from microorganism only) |
| <input checked="" type="checkbox"/> A.4 Manufacturing process | <input type="checkbox"/> D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only) |
| <input type="checkbox"/> A.5 Specification information | <input type="checkbox"/> D.3 Genetic stability of source organism (enzyme from microorganism only) |
| <input type="checkbox"/> A.6 Analytical method for detection | <input type="checkbox"/> E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism) |
| <input checked="" type="checkbox"/> B.1 Industrial use information (chemical only) | <input checked="" type="checkbox"/> F.1 List of foods likely to contain the processing aid |
| <input checked="" type="checkbox"/> B.2 Information on use in other countries (chemical only) | <input type="checkbox"/> F.2 Anticipated residue levels in foods |

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|--|--|
| <input checked="" type="checkbox"/> B.3 Toxicokinetics and metabolism information (chemical only) | <input checked="" type="checkbox"/> F.3 Information on likely level of consumption |
| <input checked="" type="checkbox"/> B.4 Toxicity information (chemical only) | <input type="checkbox"/> F.4 Percentage of food group to use processing aid |
| <input checked="" type="checkbox"/> B.5 Safety assessments from international agencies (chemical only) | <input checked="" type="checkbox"/> F.5 Information on residues in foods in other countries (if available) |
| <input type="checkbox"/> C.1 Information on enzyme use on other countries (enzyme only) | <input checked="" type="checkbox"/> F.6 Where consumption has changed, information on likely consumption |
| <input type="checkbox"/> C.2 Toxicity information of enzyme (enzyme only) | |

Nutritive Substances (3.3.3)

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|---|---|
| <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 |
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