

CHECKLIST FOR STANDARDS RELATED TO NEW FOODS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.5.1-3.5.3 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Form of application
<input checked="" type="checkbox"/> Applicant details
<input checked="" type="checkbox"/> Purpose of the application
<input checked="" type="checkbox"/> Justification for the application
<input checked="" type="checkbox"/> Information to support the application | <input checked="" type="checkbox"/> Assessment procedure
<input checked="" type="checkbox"/> Confidential Commercial Information
<input checked="" type="checkbox"/> Exclusive Capturable Commercial Benefit
<input checked="" type="checkbox"/> International standards
<input checked="" type="checkbox"/> Statutory Declaration |
|---|--|

Foods Produced using Gene Technology (3.5.1)

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|---|--|
| <input type="checkbox"/> Nature and identity of GM food
<input type="checkbox"/> History of use of host and donor organisms
<input type="checkbox"/> Nature of genetic modification
<input type="checkbox"/> Labelling information on GM food
<input type="checkbox"/> Antibiotic resistance marker genes (if used)
<input type="checkbox"/> Characterisation of novel protein(s)/substances | <input type="checkbox"/> Toxicity of novel protein(s)/substances
<input type="checkbox"/> Potential allergenicity of novel protein(s)
<input type="checkbox"/> Compositional analysis of GM food
<input type="checkbox"/> Nutritional impact of GM food
<input type="checkbox"/> Animal feeding studies (if available) |
|---|--|

Novel Foods (3.5.2)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Support for the application
<input checked="" type="checkbox"/> Exclusive use
<input checked="" type="checkbox"/> Type of novel food
<input checked="" type="checkbox"/> Chemical and physical properties
<input checked="" type="checkbox"/> Impurity profile
<input checked="" type="checkbox"/> Manufacturing process

<input checked="" type="checkbox"/> Specification and identity
<input checked="" type="checkbox"/> Analytical detection method
<input checked="" type="checkbox"/> Safety information for specified section I-VIII
*(see below)
<input checked="" type="checkbox"/> List of foods likely to contain the novel food or
novel food ingredient | <input checked="" type="checkbox"/> Percentage of food group anticipated to
contain novel food or novel food ingredient
<input checked="" type="checkbox"/> Predicted consumption (replacement)
<input checked="" type="checkbox"/> Details of target or at risk population groups
<input checked="" type="checkbox"/> Use in other countries
<input checked="" type="checkbox"/> Nutritional impact information
<input checked="" type="checkbox"/> Demonstrated consumer awareness and
understanding
<input checked="" type="checkbox"/> Potential behaviour in response to foods
<input checked="" type="checkbox"/> Demonstration of no adverse affects to any
population groups
<input checked="" type="checkbox"/> Impact on food industry

<input checked="" type="checkbox"/> Impact on trade |
|---|--|

- ☒ Proposed levels in foods

***Novel foods - safety information**

(I) Plants and animals (or their components)

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|--|--|
| <input type="checkbox"/> Composition | <input type="checkbox"/> Current use |
| <input type="checkbox"/> Effects of food processing or preparation | <input type="checkbox"/> Potential adverse effects |

(II) Plant and animal extracts

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|---|--|
| <input checked="" type="checkbox"/> Method or extraction and composition of extract | <input checked="" type="checkbox"/> Toxicity studies |
| <input checked="" type="checkbox"/> Use as a food in other countries | |

(III) Herbs (including extracts)

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|--|--|
| <input type="checkbox"/> History of use | <input type="checkbox"/> Potential allergenicity |
| <input type="checkbox"/> Composition | <input type="checkbox"/> Toxicity studies |
| <input type="checkbox"/> Method of extraction and composition of extract | <input type="checkbox"/> Overseas safety reports |
| <input type="checkbox"/> Use in other countries | |

(IV & V) Single chemical entities & dietary macrocomponents

- | | |
|--|--|
| <input type="checkbox"/> Toxicokinetics and metabolism | <input type="checkbox"/> Overseas safety reports |
| <input type="checkbox"/> Toxicity studies | |

(VI) Micro-organism

- | | |
|--|---|
| <input type="checkbox"/> Potential pathogenicity | <input type="checkbox"/> Use as a food in other countries |
| <input type="checkbox"/> Effects on gut microflora | <input type="checkbox"/> Human toleration studies |

(VII) Food ingredients derived from a new source

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|--|--|
| <input type="checkbox"/> Safety of the source organism | <input type="checkbox"/> Toxicity studies |
| <input type="checkbox"/> Composition | <input type="checkbox"/> Overseas safety reports |

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

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|---|--|
| <input type="checkbox"/> Details of the new process | <input type="checkbox"/> Overseas safety reports |
| <input type="checkbox"/> Toxicity studies | |

Irradiated Foods (3.5.3)

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|---|---|
| <input type="checkbox"/> Support for the application | <input type="checkbox"/> Analytical detection method |
| <input type="checkbox"/> Nature of the food or food ingredient to be irradiated | <input type="checkbox"/> Composition of irradiated food |
| <input type="checkbox"/> Technological need for irradiation | <input type="checkbox"/> Dietary intake |
| <input type="checkbox"/> Food products likely to contain irradiated food | <input type="checkbox"/> Data on potential nutritional impact |
| <input type="checkbox"/> Packaging for irradiated food | <input type="checkbox"/> Irradiation facilities information |
| <input type="checkbox"/> Food labelling information | <input type="checkbox"/> Dosimetry and record keeping |
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