

**Proposed Amendments to Part 3 of the
FSANZ *Application Handbook*
October 2008**

Schedule Amendments

Items [1.2], [2.2], [3.2], [5.2]

These amendments are to ensure that information on the identity and purity of substances in applications for food additives, processing aids, nutritive substances and novel foods is adequate to properly define and assess the chemical entity for which approval is sought. Information on particle size, size distribution and morphology will ensure that the safety studies, risk assessments and approvals all relate to the same specific substance(s). This will support the possible future use of Standard 1.3.4 – Identity and Purity to define and limit specific forms of some particulate substances.

Items [1.1], [2.1], [3.1], [5.1]

These amendments are to ensure that information on the chemical and physical properties of substances in applications for food additives, processing aids, nutritive substances and novel foods is adequate to properly define and assess the application. Information on the functional relationship between particle size, size distribution and morphology and insight into the physico-chemical properties of function will ensure that the safety studies, risk assessments and approvals all relate to the same specific substance(s). This amendment also reinforces the provision of this information under the specifications for identity and purity.

Items [4.1]

These amendments make clear that an applicant must provide information on particle size and morphology in cases where these characteristics may relate to the toxicity of a food contaminant. The industrial application of nanotechnology in the future could result in more nanometre scale particles entering the food chain as contaminants. In future, it may be necessary to specify different physical forms of some particulate food contaminants in order to properly assess, define, and set safe limits.

FSANZ *Application Handbook* – Part 3 – Amendment No. 2 – 2008

Food Standards Australia New Zealand Act 1991

Preamble

The amendments set forth in the Schedule below are **proposed** variations to guidelines in Part 3 of the *FSANZ Application Handbook* which was originally registered as a legislative instrument on 1 August 2007.

These amendments are published pursuant to section 23 of the *Food Standards Australia New Zealand Act 1991*.

Citation

These amendments may be collectively known as the *FSANZ Application Handbook – Amendment No. 2 – 2008*.

Commencement

These variations **will commence** on the date of the registration of this instrument.

SCHEDULE

[1] ***Part 3.3.1 is varied by –***

[1.1] *omitting –*

B.3. Information on the chemical and physical properties of the additive

This part includes sufficiently detailed information to enable the technological properties of the additive in a food matrix to be characterised, such as how it may interact with different foods, as well as providing general information on the likely metabolic fate of the additive following consumption.

substituting –

B.3. Information on the chemical and physical properties of the additive

This part includes sufficiently detailed information to enable the technological properties of the additive in a food matrix to be characterised, such as how it may interact with different foods, as well as providing general information on the likely metabolic fate of the additive following consumption. In cases where particle size is important to achieving the technological function or may relate to a difference in toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.

[1.2] *omitting –*

B.6. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If there is no published specification in one of the identified sources, a detailed specification must be provided.

substituting –

B.6. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If there is no published specification in one of the identified sources, a detailed specification must be provided. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

[2] **Part 3.3.2** is varied by –

[2.1] *omitting –*

B.3. Information on the chemical and physical properties of the processing aid

This part includes details of the chemical and physical properties that make it suitable as a food processing aid. This must include information on possible interactions of the processing aid with different foods. If the processing aid is an enzyme, this must include information on its enzymatic properties.

substituting –

B.3. Information on the chemical and physical properties of the processing aid

This part includes details of the chemical and physical properties that make it suitable as a food processing aid. This must include information on possible interactions of the processing aid with different foods. If the processing aid is an enzyme, this must include information on its enzymatic properties. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

[2.2] *omitting –*

B.5. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity will be available. If a published specification is not available, a detailed specification must be provided.

substituting –

B.5. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity will be available. If a published specification is not available, a detailed specification must be provided. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

[3] **Part 3.3.3** is varied by –

[3.1] *omitting* –

B.2. Information on the chemical and physical properties of the nutritive substance

This part includes detailed information on the food technology aspects of using the nutritive substance in each of the foods or food categories proposed. It should contain sufficient detail to support the use of the nutritive substance in each food and provide a rationale for how the nutritional purpose will be achieved in each food. It should also provide information on the likely metabolic fate of the nutritive substance.

substituting –

B.2. Information on the chemical and physical properties of the nutritive substance

This part includes detailed information on the food technology aspects of using the nutritive substance in each of the foods or food categories proposed. It should contain sufficient detail to support the use of the nutritive substance in each food and provide a rationale for how the nutritional purpose will be achieved in each food. It should also provide information on the likely metabolic fate of the nutritive substance. In cases where particle size is important to achieving the nutritive purpose or may relate to a difference in nutritional status or toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.

[3.2] *omitting* –

B.5. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification should be provided.

substituting –

B.5. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification should be provided. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

[4] **Part 3.4.1** is varied by –

[4.1] *omitting* –

B.1. Nature of the contaminant or natural toxicant, including chemical and physical properties

This part includes information on the nature of the contaminant or natural toxicant, its chemical and physical properties, the source of the contaminant or natural toxicant, the factors that influence the level of contamination of food, the interaction of the contaminant or natural toxicant with the food, and current control measures.

substituting –

B.1. Nature of the contaminant or natural toxicant, including chemical and physical properties

This part includes information on the nature of the contaminant or natural toxicant, its chemical and physical properties, the source of the contaminant or natural toxicant, the factors that influence the level of contamination of food, the interaction of the contaminant or natural toxicant with the food, and current control measures. In cases where particle characteristics may relate to the toxicity of the food contaminant, the applicant must provide information on particle size and morphology.

[5] **Part 3.5.2** is varied by –

[5.1] *omitting –*

B.2. Information on the physical and chemical properties of the novel food or novel food ingredient

This part includes detailed information on the physical and chemical properties of the novel food or novel food ingredient including, where relevant, chemical name, CAS registry number, empirical and structural formula, molecular weight, chemical stability, thermal stability, solubility in water and melting point.

substituting –

B2. Information on the physical and chemical properties of the novel food or novel food ingredient

This part includes detailed information on the physical and chemical properties of the novel food or novel food ingredient including, where relevant, chemical name, CAS registry number, empirical and structural formula, molecular weight, chemical stability, thermal stability, solubility in water and melting point. In cases where particle size is important to achieving the functionality or may relate to a difference in nutritional status or toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.

[5.2] *omitting –*

B.5. Specification for identity and purity for a novel food ingredient

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification must be provided.

substituting –

B.5. Specification for identity and purity for a novel food ingredient

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification must be provided. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.