# EXPLANATORY STATEMENT

# AMENDMENTS TO
# FOOD STANDARDS AUSTRALIA NEW ZEALAND
# APPLICATION GUIDELINES

**(known as Part 3 of the FSANZ *Application Handbook*)**

**Amendment No. 2 – 2008**

## 1. Purpose

Section 23 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) empowers Food Standards Australia New Zealand (FSANZ) to make guidelines by legislative instrument:

*(a) specifying the form in which applications for the development of a food regulatory measure, or the variation of a food regulatory measure, are to be made; and*
*(b) specifying the information, or the kinds of information, to be included with such applications; and*
*(c) specifying any thing, or kind of thing, to be included with such applications.*

The guidelines are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, but are not subject to sunsetting or disallowance. For the purposes of section 23, Part 3 of the FSANZ *Application Handbook* (Handbook) which was originally approved by the FSANZ Board in March 2007, fulfils these requirements.

Applications to amend the *Australia New Zealand Food Standards Code* (the Code) need to be supported by all information as determined by FSANZ in writing and in advance – these are contained in Part 3 of the Handbook. If the information requirements are not met, then FSANZ has the power under the FSANZ Act to reject an application at the 'Administrative Assessment' stage.

FSANZ has approved amendments to Part 3 of the Handbook for the following reasons:

- Assessments of applications should generally be able to proceed without past delays where FSANZ seeks further information or data from an applicant to enable assessment of the application to proceed. This will assist in ensuring that statutory timeframes are met.

- Part 3 fulfils the intention of the FSANZ Act amendment that there be clearly defined application requirements, including the requirement to provide supporting material with applications.

The changes in this latest round of amendments relate specifically to nanotechnology.

To date, food regulations globally have not captured and evaluated particle characteristics such as size and shape as part of their regulatory processes. The advent of nanotechnology has created the need (and expectation) for regulators to start capturing the information necessary to more precisely identify and discriminate between particulate substances that may be used in food in the future. The precise identification of particulate substances may be a critical future element in assigning substance specific permissions in the Code and in ensuring the feasibility of compliance and enforcement monitoring or testing.

These amendments ensure clear guidance around the information that may be required to assess the safety of potential applications of nanotechnology in food and to expressly state the requirements for appropriate particle related data to intending applicants.

Details of the amendments are set out in Attachment 1.

### 1.1 Application 'Guidelines'

Under section 22 of the FSANZ Act, an application to amend the Code must:

(a) be in writing; and
(b) if the form in which the application is to be made is specified in the guidelines made under section 23—be in the form specified; and
(c) include all of the information that, under the guidelines made under section 23 is to be included with the application; and
(d) include each thing that, under the guidelines made under section 23, is to be included with the application; and
(e) identify the procedure that, in the applicant's view, applies to the consideration of the application.

If the information requirements are not met, then FSANZ has the power under section 26 of the FSANZ Act to reject the application after a 15-day Administrative Assessment.

## 2. Consultation

Applicants from the food industry are the group potentially affected by these amendments. FSANZ wrote to key industry organisations namely the Australian Food and Grocery Council, the New Zealand Grocery Council and the Australian Beverages Council foreshadowing the proposed amendments. FSANZ staff also met with representatives from these organisations. Industry already understood that FSANZ required some additional information in order to conduct risk assessments of some new substances.

A list of over 550 people with an interest in the Handbook are on a stakeholder mailing list for consultation on amendments. This list was originally compiled for consultation on the initial development of the Handbook in 2006-07 and has been maintained and updated since then as required. This mailing list was sent an email alert calling for submissions on 24 September 2008 with a reminder email on 23 October 2008. An alert was also included in the Food Standards Notification Circulars of 1 October and 28 October 2008. Over 3,800 people are on the mailing list for this alert.

The closing date for comments was 29 October 2008. Comments from nine submitters were received (see Attachment 2).

Many of the comments received are outside the scope of the proposed amendments. However, they may fall within the broader scope of the nanotechnology project being undertaken by FSANZ and will be considered in this context at some stage in the future.

## 3. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory provisions.

Two options are identified in relation to the proposed amendments:

**Option 1** – Not proceed with the amendments to Part 3 of the Handbook.

**Option 2** – Proceed with the amendments to Part 3 of the Handbook.

### 3.1 Affected Parties

Parties affected by the amendments to Part 3 include:

- potential applicants from industry and consumers generally, who may be affected either positively or negatively; and
- FSANZ.

### 3.2 Benefit Cost Analysis

*3.2.1 Option 1 – Not proceed with the amendments to Part 3 of the Handbook*

3.2.1.1 Benefits

- for applicants and FSANZ, this option would not result in any discernable benefits.

3.2.1.2 Costs

- Applicants will be disadvantaged if their completion of the assessment of their applications is delayed due to insufficient information.

- Part 3 of the *Application Handbook* would not accurately reflect the Code.

*3.2.2 Option 2 – Proceed with the amendments to Part 3 of the Handbook*

3.2.2.1 Benefits

- Applicants will be able to release products into the market in a timely manner.

- FSANZ will not have to assess applications which are deficient in relevant data thus freeing-up resources for other work.

3.2.2.2 Costs

- for applicants and FSANZ, this option would not result in any discernable costs.

### 3.3 Comparison of Options

FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community. There was no other option other than to proceed with the amendments.

## 4. Commencement

These variations commence on the date of the registration of the instrument.

## ATTACHMENTS

1. Details of the Amendments to Part 3 of the FSANZ *Application Handbook*
2. Consultation on amendments to the FSANZ *Application Handbook*

# ATTACHMENT 1

**Details of the Amendments to Part 3 of the FSANZ *Application Handbook***

**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). These amendments also reinforce 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.

# ATTACHMENT 2

**Stakeholder comments on amendments to *Application Handbook* – October 2008**

**Submitters:**

Rob Richards (Food Technology Assoc of Australia)
Elaine Attwood (Private)
Bill Leonard (Private)
Beth Nathan (Private)
Arnold Ward (Private)
Kim Leighton (Australian Food & Grocery Council)
Georgia Miller (Friends of the Earth)
Jo Immig (National Toxics Network)
Scott Kinnear (Biological Farmers of Australia)

| **Issue** | **Submitter** | **FSANZ Comment / Action** |
|---|---|---|
| An overarching amendment is required which states that FSANZ will not recognise vivisection as acceptable research toward the safety assessment of edibles intended for human consumption. The text should indicate acceptance only of results of clinical trials and non-invasive microbiology as proof of efficacy or safety. | Bill Leonard (Private) | Clarification of the physical particle characteristics (size, size distribution, morphology) required in an application to amend the Code does not relate to vivisection. |
| Need to use precautionary principle. | Arnold Ward (Private)<br><br>Georgia Miller (Friends of the Earth) | Consistent with the precautionary principle, FSANZ undertakes a comprehensive (safety) assessment as part of the pre market approval process. Satisfactory scientific evidence establishing the safety of foods must be provided or approval will not be granted. |
| Supports proposed amendments | Rob Richards (FTAA)<br><br>Kim Leighton (AFGC) | Noted |
| FSANZ's proposed amendments are a start – and are supported, BUT they do not go far enough to ensure a safe and suitable food supply | Elaine Attwood (Private) | Noted |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| Definition of 'nano' required – FSANZ needs to include the definition for the guidance of industry. At present most people accept that a particle up to 100 nm qualifies, but there is evidence that particles up to 300 nm may be of concern. | Elaine Attwood (Private) | The term nanometre is an internationally recognised (SI) unit of length. The proposed amendments will ensure any particle size related properties are part of the safety assessment. Particle size alone, or the arbitrary figure of 100 nm or 300 nm, is not a useful parameter for risk characterisation as diminishing particle size often does not equate to increased toxicity (risk can diminish with size). |
| Define manufactured nanoparticles and nanoscale food components as all ingredients and additives that are added to food or packaging, including as processing aids, which:<br>• measure <0.3-300 nm in one or more dimension, or that have a structure that exists at this scale, or<br>• in which particle size is important to achieving the technological function or may relate to a difference in toxicity | Georgia Miller (Friends of the Earth) | All nanometre scale substances are covered by existing definitions in the Code depending on what they are e.g. additives, processing aids, novel foods, nutritive substances. FSANZ will assess the safety of each unique particulate material. Particle size alone, or the arbitrary figure of 300 nm, is not a useful parameter for risk characterisation as diminishing particle size often does not equate to increased toxicity (risk can diminish with size). |
| There is no agreed single definition of 'nanotechnology' but it can be broadly described as the engineering of functional systems and control of matter on the atomic and molecular scale, normally 1-100 nm. | Kim Leighton (AFGC) | Noted |
| FSANZ should carry out research to find out how many nano products are being used in the Australian and New Zealand food supply. | Elaine Attwood (Private) | Outside scope of proposed amendments, however, FSANZ is doing this. |
| FSANZ must determine from manufacturers which nano products are being used in Australia and New Zealand, both in food and packaging. | Elaine Attwood (Private) | Outside scope of proposed amendments, however, FSANZ is doing this. |
| Proposed amendments should include provision for discerning where nano packaging is used and what nano material is used in that packaging | Elaine Attwood (Private) | Noted. FSANZ is separately looking at the regulatory approach to migration of packaging chemicals (including nanometre particles) into food and any associated food safety issues. |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| There must be recognition of the new toxicities and risks associated with materials that have previously been used at the macro level with no, or manageable safety issue | Elaine Attwood (Private) | The proposed amendments will help ensure the data necessary to assess potential risks are provided with applications. |
| Acceptance that, because of weight-related toxicity tests, some nano materials may slip through present regulatory agency requirements. | Elaine Attwood (Private) | The proposed amendments will help ensure the data necessary to assess potential risks are provided. |
| Until specific testing for nano materials is developed, remove any nano product (including packaging ), presently on supermarket shelves. | Elaine Attwood (Private) | These changes relate to information required in applications. While FSANZ actively monitors significant developments in the area of food, along with our regulatory partners, enforcement is outside the scope of these proposed amendments. Satisfactory scientific evidence establishing the safety of new specific substances must be provided with applications or approval will not be granted. |
| Address the issue of labelling of all products and packaging produced using nanotechnology<br><br>Manufacturers should have to disclose the use of nanotechnology in food processing, manufacture and packaging<br><br>All nano ingredients, and foods produced using nanotechnology, should be clearly labelled to give people the right to make an informed choice, as well as for public health reasons (to trace adverse effects) | Elaine Attwood (Private)<br><br>Beth Nathan (Private)<br><br>Georgia Miller (Friends of the Earth)<br><br>Jo Immig (NTN)<br><br>Scott Kinnear (Biological Farmers) | The proposed amendments to the Handbook deal with clarification of the data required with applications. Labelling policy is outside the scope of these proposed amendments. |
| Engage the public and ensure transparency in dealing with nanotechnology | Elaine Attwood (Private) | Noted. FSANZ is committed to public engagement and consults on food regulatory measures in accordance with the FSANZ Act. |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| Recognise that nano materials will need assessment from 'cradle to grave' as their impact on the environment needs to be part of the equation | Elaine Attwood (Private) | Environmental considerations fall outside of the FSANZ statutory objectives, but are covered by other Government agencies. FSANZ does regulate contaminates in food and these may be from environmental sources. Amendments to the information required for applications to amend the standard for contaminants are proposed. |
| Nanoparticles should be identified as new substances. New safety assessment should be required that is specific to the particular nanoparticle (e.g. of given size, shape, surface characteristics etc) | Beth Nathan (Private)<br>Jo Immig (NTN) | Nanometre scale particles exist naturally in food and are not all new substances. The proposed amendments will help ensure the data necessary to assess potential risks are provided. All nanometre scale substances are covered by existing definitions in the Code depending on what they are e.g. additives, processing aids, novel foods, nutritive substances. FSANZ will assess the safety of each unique particulate material. |
| Nanofoods should be assessed as novel foods | Beth Nathan (Private)<br><br>Jo Immig (NTN)<br><br>Scott Kinnear (Biological Farmers)<br><br>Georgia Miller (Friends of the Earth) | FSANZ will require applications and undertake premarket (safety) assessments under the most appropriate standard according to the definitions. It could be the food additive, processing aid or nutritive substance standard, depending on its function. The novel food standard will be used where it applies. |
| Nanofoods and packaging must be subject to new, nanoparticle appropriate testing | Beth Nathan (Private)<br><br>Jo Immig (NTN)<br><br>Scott Kinnear (Biological Farmers) | The proposed amendments will help ensure the data necessary to assess potential risks are provided. FSANZ is separately looking at the regulatory approach to migration of packaging chemicals (including nanometre particles) into food and any associated food safety issues. |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| Manufacturers should have to disclose to FSANZ the addition of all additives, nutritive substances, processing aids and contaminants where these are added to food or food packaging in nanoparticle form | Beth Nathan (Private)<br><br>Jo Immig (NTN) | Noted. This is the intent of the proposed amendments. |
| Contends the term particulate can include sub-atomic particles and recommends FSANZ develop an alternative wording to the clause 'particulate in nature' to better capture the intent of the amendments to ensure that material with nanoscale particles are appropriate assessed in FSANZ applications. | Kim Leighton (AFGC) | FSANZ will provide explanation in the Guidelines and is applying common usage of the term 'particulate' as it applies to particulate matter, rather than the specialised use in the field of nuclear physics as with sub-atomic particles. Common use of the term refers to tiny particles of solid, or liquid suspended in a gas. Particulates may be anthropogenic or natural in origin and comprise a gathering of a few molecules, with an overall size of less than 10 nm, to a collection of many thousands of molecules (like or unlike) at a size of more than 100 micrometres. |
| Apply a moratorium to the sale of all nanofoods until new nanoparticle risk assessment and detection methodologies are developed as recommended by the Austrian Ministry of Health. | Georgia Miller (Friends of the Earth) | Noted. Outside scope of proposed amendments. |
| Require disclosure and safety testing for all manufactured nanoparticles and nanoscale food components that are used as food processing aids. | Georgia Miller (Friends of the Earth) | Processing aids require premarket approval. Satisfactory scientific evidence establishing the safety of processing aids for food use must be provided with applications or approval will not be granted. |
| Soluble manufactured nanoparticles and nanoscale food components to be included in nanoparticle definitions, disclosure and safety testing requirements. | Georgia Miller (Friends of the Earth) | Readily soluble substances will be unlikely to remain as particles in the final food. New food substances are still assessed for safety and require specifications however, detailed particle characteristics are not required as dissolution in food alters the form ingested. Satisfactory scientific evidence establishing the safety of foods must be provided with applications or approval will not be granted. |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| Define as nanoparticles agglomerates and aggregates whose primary particles are nanoscale or which possess nanostructures and subject them to nanoparticle-appropriate risk assessment and exposure metrics. | Georgia Miller (Friends of the Earth) | The behaviour of particles in food and the body (tendency to agglomerate, aggregate or disassociate) will be a consideration in the risk assessment. |
| Define manufactured nanoparticles and nanoscale food components as a new class of chemicals. Each nanoparticle or nanoscale food component, irrespective of its solubility, must be subject to case by case safety testing that is tailored to the unique risks of nanoparticles, with pharmacological endpoint testing. | Georgia Miller (Friends of the Earth)<br><br>Scott Kinnear (Biological Farmers) | FSANZ does not need to create a new regulatory class in order to conduct a premarket safety assessment. Existing standards for additives, processing aids, novel foods, nutritive substances apply. Satisfactory scientific evidence establishing the safety of specific substances must be provided with applications or approval will not be granted. |
| Testing requirements must be clearly stated by FSANZ in the Handbook, rather than being left to the discretion of FSANZ or the applicant. | Georgia Miller (Friends of the Earth)<br><br>Scott Kinnear (Biological Farmers) | Handbook has general requirements relating to the quality of scientific studies, use of good laboratory practice etc but does not prescribe exact study methodology as this will vary for different substances and uses. Guidance documents do provide further explanation about the types and rigour of studies to be provided in support of an application. Flawed or poor quality studies will not carry weight in demonstrating safety. |
| Identify foods to which manufactured nanoparticles or nanoscale food components have been added or which are wrapped in packaging to which manufactured nanoparticles have been added as novel foods and require them to face pharmacological endpoint safety testing. | Georgia Miller (Friends of the Earth) | These changes relate to information required in applications. While FSANZ actively monitors significant developments in the area of food, along with our regulatory partners, enforcement is outside the scope of these proposed amendments. The most applicable Standard will be applied and satisfactory scientific evidence establishing the safety of new specific substances must be provided with applications or approval will not be granted. |

| Issue | Submitter | FSANZ Comment / Action |
|---|---|---|
| FoEA would like to note its unhappiness with the poor public notification of this consultation. The call for comment was not noted in emails alerting FSANZ subscribers, nor was it mentioned in the media release issued that day, nor listed on the webpage advertising the commencement of the consultation period. The consultation was not noted on the nanotechnology webpage. Given the ongoing efforts of FSANZ to communicate with industry stakeholders, it is also hard to understand why FSANZ did not notify any of the community groups that it knows are interested in the use of nanotechnology and other new technologies in food that the consultation was under way. | Georgia Miller (Friends of the Earth) | Noted. The call for public comment was included in 2 Notification Circulars, alerts for which are sent to nearly 4000 subscribers) – noting that the alert only highlights applications and proposals and provides a link to the Circular, but advises that other significant matters are in the Circular. Subscribers are encouraged to pass on the alert to other interested people.<br><br>FSANZ also manages a permanent group of stakeholders with a direct interest in the Handbook (over 550) who were directly contacted on 2 occasions about the proposed amendments.<br><br>FSANZ acknowledges the call for comment should have been listed on the Documents for Public Comment webpage, in addition to the location on the Handbook consultation Opportunities webpage, and this extra link was included as soon as this oversight was drawn to our attention. |