

**FOOD STANDARDS
AUSTRALIA NEW ZEALAND**

APPLICATION HANDBOOK

1 March 2016
Prepared by Food Standards Australia New Zealand

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Acronyms and Abbreviations

ACCC	Australian Competition and Consumer Commission
ADI	acceptable daily intake
ALARA	as low as reasonably achievable
AS	Australian Standard
CA	Chemical Abstracts
CCI	confidential commercial information
COAG	Council of Australian Governments
Codex	Codex Alimentarius Commission
DBPCFC	double blind placebo controlled food challenge
ECCB	exclusive capturable commercial benefit
ERL	extraneous residue limit
FAO	Food and Agriculture Organization
Forum	Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMP	good manufacturing practice
HACCP	hazard assessment critical control point
HARVEST	a comprehensive FSANZ database of nutritional information used for dietary modelling
IUPAC	International Union of Pure and Applied Chemists
ISO	International Standards Organization
JECFA	Joint (FAO/WHO) Expert Committee on Food Additives
ME	metabolisable energy
ML	maximum level
MRL	maximum residue limit
NATA	National Association of Testing Authorities
NHMRC	National Health & Medical Research Council
OBPR	Office of Best Practice Regulation
RIS	regulation impact statement
WHO	World Health Organization
WTO	World Trade Organization

Part 1

Overview

1.1 Introduction

Parts 1 and 2 of this Handbook provide information to assist applicants to understand the manner in which FSANZ develops food regulatory measures.

Part 3 contains guideline requirements made under section 23 of the *Food Standards Australia New Zealand Act 1991* (Cth) (FSANZ Act). Section 23 of the FSANZ Act (Application guidelines) provides:

23 Application guidelines

Authority may make guidelines

- (1) The Authority may, by legislative instrument, make guidelines:
 - (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.
- (2) The Authority may only specify information, or kinds of information, under paragraph (1)(b) in relation to an application if the inclusion of that information, or information of those kinds:
 - (a) would enable the Authority to assess the application and develop the relevant food regulatory measure, or the relevant variation of a food regulatory measure; or
 - (b) would enable the Authority to determine whether a charge under section 146 is payable to the Authority in relation to the application.
- (3) The Authority may only specify a thing, or a kind of thing, under paragraph (1)(c) in relation to an application, if the inclusion of that thing, or things of those kinds, would enable the Authority to assess the application and develop the relevant food regulatory measure, or the relevant variation of a food regulatory measure.

Guidelines not subject to disallowance or sunset

- (4) Section 42 and Part 6 of the *Legislative Instruments Act 2003* do not apply to guidelines made under subsection (1).

Subsection 22(2) of the FSANZ Act requires applicants to comply with the guideline requirements.

An application that does not meet the guideline requirements may be rejected, under paragraph 26(2)(a) of the FSANZ Act.

1.2 Navigating the Application Handbook

Part 1 provides general introductory information.

Part 2 provides practical information regarding the lodgement and processing of an application.

Part 3 contains the guideline requirements.

Chapter 3.1 sets out requirements for all applications.

The following Chapters set out requirements for each of the following types of food standards:

- 3.2 Standards related to labelling and other information requirements
- 3.3 Standards related to substances added to food
- 3.4 Standards related to contaminants and natural toxins
- 3.5 Standards related to new foods
- 3.6 Standards related to special purpose foods or standardised foods
- 3.7 Standards related to food production

Each type of standard has different information requirements. Some applications will involve variation of more than one type of standard, in which case each requirement must be met. Applicants should identify all the guidelines that are relevant to their particular application, which could apply to more than one type of standard. The flowchart diagram below may assist applicants.

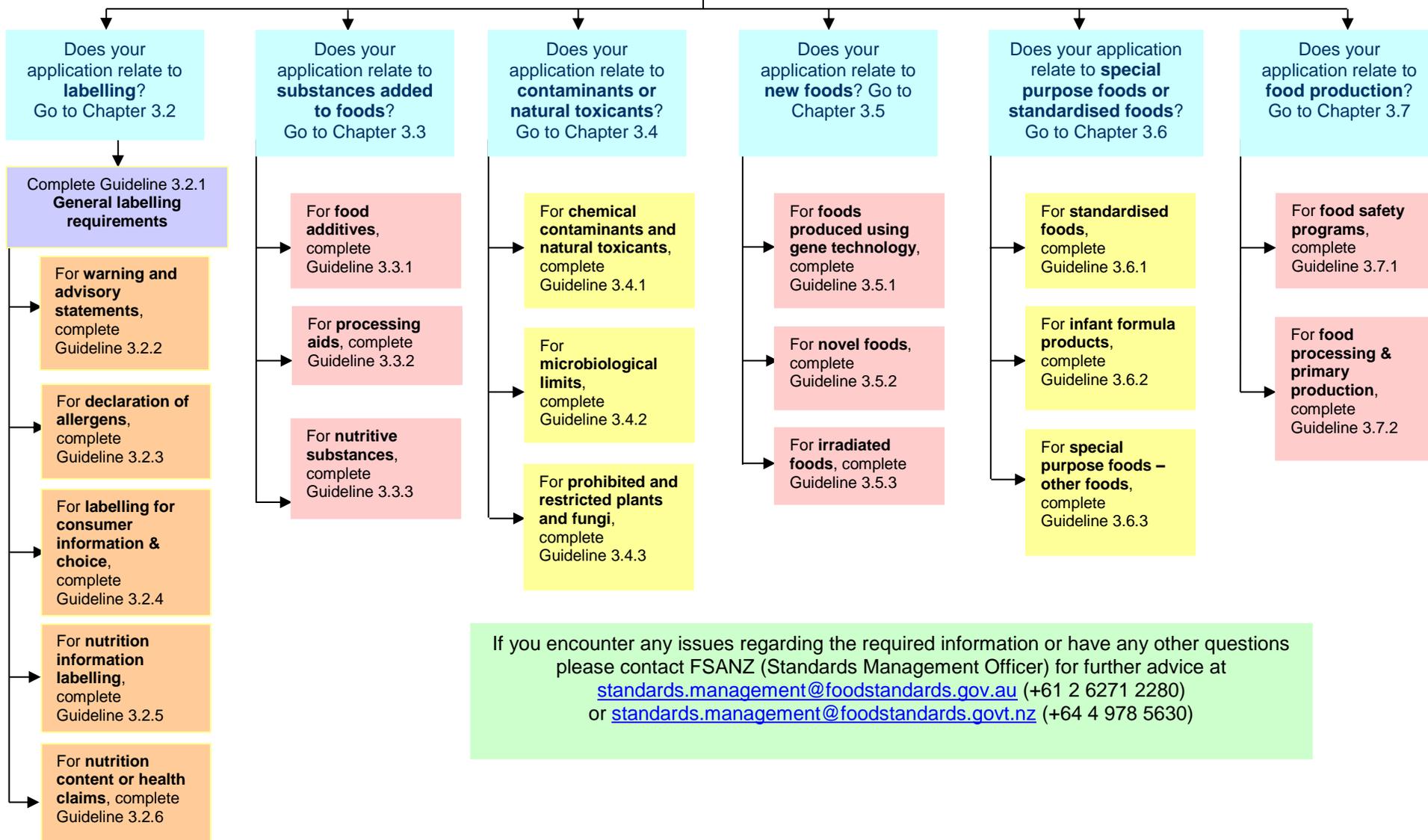
An example of when more than one guideline might apply is where an application involves adding a nutritive substance to infant formula. In this case, the information requirements for Guidelines 3.1.1 – General requirements, 3.3.3 – Substances used for a nutritive purpose and 3.6.2 – Special purpose food – Infant formula Products, would be relevant.

This Handbook does not provide details about the reason why specific information is required or how the information will be used. This is beyond the scope of this Handbook.

Boxed text such as notes or examples in Part 3 provide additional information and are not to be taken to be part of the guidelines.

Read Parts 1 & 2 of the *Application Handbook* which provide essential information for making an application.
 Arrange a meeting with FSANZ to discuss your application prior to submission (strongly recommended)

Begin the application by completing Guideline 3.1.1 – General requirements.
 Proceed to specific chapters listed below



1.3 The Australia New Zealand Food Standards Code

The Code is a collection of food standards. Any agency, body or person can make an application to vary the Code. State, Territory and New Zealand food laws provide that it is an offence to supply food that does not comply with the Code.

The structure of the Code is:

- Chapter 1** *General Food Standards* e.g. definitions, labelling requirements, use of substances added to food, use of new foods, maximum limits for chemical and microbiological contaminants, maximum residue limits for pesticides (Australia only), food processing requirements (Australia only).
- Chapter 2** *Food Product Standards* e.g. composition of cereals, fruits, vegetables, dairy products, beverages and special purpose foods.
- Chapter 3** *Food Safety Standards (Australia only)* e.g. food safety programs, food premises and equipment.
- Chapter 4** *Primary Production Standards (Australia only)* e.g. production and processing of seafood, poultry meat, meat and other commodities.
- Schedules** e.g. permissions for use of substances added to food, permissions for use of new foods, permitted maximum limits for chemical and microbiological contaminants, permitted maximum residue limits for pesticides (Australia only).

The Code is on the FSANZ website at <http://www.foodstandards.gov.au/code/Pages/Food-Standards-Code-from-1-March-2016.aspx>.

1.4 Food Standards Australia New Zealand

1.4.1 Role of FSANZ

FSANZ is an agency of the Australian Government, established by the FSANZ Act. It is an independent standard developing body and its functions are set out in the FSANZ Act. The functions include developing food regulatory measures¹. Food regulatory measures are developed by FSANZ, either by application from any agency, body, or person, or by a proposal prepared by FSANZ on its own initiative.

FSANZ has a range of other functions under the FSANZ Act, including facilitating the harmonisation of State and Territory laws relating to food, coordinating national food surveillance and recall systems, conducting research, working with other national food agencies and international agencies and reviewing existing Standards.

Although FSANZ develops food standards, responsibility for ensuring compliance with food standards for both domestically produced food and imported food rests with local government, States and Territory Governments in Australia and the New Zealand Government. Food imported into Australia is also subject to the *Imported Food Control Act 1992* (Cth).

Contact details for food enforcement agencies are available on the FSANZ website at <http://www.foodstandards.gov.au/about/foodenforcementcontacts/pages/default.aspx>.

¹ Food regulatory measures are food standards or codes of practice.

Role of the Forum

The FSANZ Board's decisions to approve standards, or variations, by the FSANZ Board are considered by the Forum, which has legislative authority and is chaired by the Australian Government. The Forum comprises representatives from all Australian States and Territories and the New Zealand Government.

When the Forum's consideration is completed, standards or variations are gazetted and registered as legislative instruments.

The Forum is also responsible for developing policy guidance to which FSANZ must have regard when developing food regulatory measures.

Current policy guidelines are on the FSANZ website at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

Application of standards

The gazetted standard or variation is adopted by reference by laws of the Commonwealth and the Australian States and Territories.

In New Zealand, the standards are remade as New Zealand standards and have effect 28 days after a relevant food standard has been issued by the New Zealand Minister for Food Safety under the New Zealand *Food Act 2014*.

1.4.2 FSANZ objectives when developing food regulatory measures

Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) when developing food regulatory measures and variations of food regulatory measures as:

- (a) the protection of public health and safety; and
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
- (c) the prevention of misleading or deceptive conduct.

FSANZ must also have regard to:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and
- (e) any written policy guidelines formulated by the Ministerial Council (now known as the Forum).

Part 2

General application information

2.1 Making an application

2.1.1 Application inquiries

Application inquiries must be directed to the Standards Management Officer by email to standards.management@foodstandards.gov.au or standards.management@foodstandards.govt.nz or telephone: +61 2 6271 2280 or +64 4 978 5630.

Applicants must ensure that their applications meet any requirements laid out in the relevant guidelines set out in Part 3 of this Handbook. It is the responsibility of applicants to prepare and finalise their own application for lodgement.

However, prior to formally lodging their application, applicants are strongly advised that it is in their interests to consult with FSANZ to ensure that it contains all the required information. This can be done via a teleconference, a video link or at a face-to-face meeting in FSANZ's offices in Canberra (Australia) or Wellington (New Zealand).

Potential applicants are strongly encouraged to seek their own independent legal advice on proposed amendments to the Code. In addition, when assessing applications or potential applications to amend the Code, the views of FSANZ on proposed amendments may not be the same as the views of food enforcement agencies or the Courts.

Potential applicants are also encouraged to discuss their proposed application with FSANZ prior to submission in order to clarify the nature of the application and to assist in identifying the information required. Many of those applicants whose applications have been rejected after an administrative assessment for failing to meet the mandatory requirements, did not discuss their application with FSANZ prior to formal lodgement.

FSANZ will hold one pre-lodgement meeting only with a potential applicant. Any and all information and comment provided by FSANZ on, or in relation to the meeting, will be provided on the basis that the information and comment:

- are provided on a without prejudice basis
- are not part of any formal statutory process
- are not a substitute for applicants doing their own work in preparing an application that complies with the FSANZ Act
- are not an authoritative or binding statement as to the likely outcome of an application – any information or comment provided by FSANZ in no way constitutes approval in-principle, or otherwise states or implies that FSANZ will accept and approve any application – such a determination can only be made following formal lodgement of an application and completion of the required assessment process in accordance with the FSANZ Act.

Forms requesting a meeting and comments on a draft application are available on the FSANZ website at <http://www.foodstandards.gov.au/code/changes/applying/pages/default.aspx>. Completion of the forms and acceptance of the conditions outlined in the form are a prerequisite for further discussions with FSANZ. Completed forms are to be emailed to standards.management@foodstandards.gov.au.

Additionally, when assessing an application to develop or amend food regulatory measures, FSANZ must have regard to any relevant formal policy guidelines set by the Forum. Applicants should inform themselves of any policy guidelines which may have a bearing on their application and may wish to address these in their application. Applicants should also seek advice from FSANZ on any pending policy guidelines or materials under development which may have a bearing on their application.

2.1.2 Australian Government's Information Publication Scheme

The Australian Government's Information Publication Scheme and the provisions of the FSANZ Act aim to promote transparency and pro-disclosure to inform and facilitate public participation in decision-making. To this end, with the exception of any confidential material, FSANZ publishes all applications to change the Code on our website, as well as submissions on applications and proposals. Issues raised in submissions are also summarised in subsequent assessment reports.

The FSANZ Act also provides that applications, supporting documents and submissions provided to FSANZ become Commonwealth property and, unless they contain confidential commercial information, may be dealt with as FSANZ considers appropriate.

Following completion of the administrative assessment and acceptance of an application, the executive summary of an application will be placed on the website. When the call for submissions occurs, the main application will be placed on the website. However, if a request for access to material, other than that provided confidentially, is made from the public prior to release, it will be provided. Supporting information such as raw studies or references will be available to the public on request at any time. Material that is too large to be placed on the website will be available on request. Submissions will be published as soon as possible after the end of the public comment period.

2.1.3 Information requirements for an application

An application must contain the information and meet the format requirements specified in the guidelines in Part 3 of this Handbook. For further details in relation to data quality, please refer to subsection 3.1.1.5 – Information to support the application.

2.1.4 Cost benefit analysis

As part of the assessment of an application, FSANZ may be required by the OBPR to prepare a RIS. An assessment of costs and benefits under the FSANZ Act is carried out on all applications and can be undertaken using readily available data supplemented by qualitative statements in relation to costs and benefits.

A RIS needs to comply with COAG guidelines and can involve complex economic analysis and may require new economic research. Full details of the RIS process and likely informational requirements are available in the *Best Practice Regulation: A Guide for Ministerial Councils and Standard Setting Bodies (COAG, October 2007)*².

Potential effects of applications to amend the Code are assessed in relation to:

- sectors of the food industry wishing to market the food products subject to the application. In particular, the effect on small business will be studied
- consumers – who may benefit from the outcome of the application (e.g. new products becoming available, provision of more information etc) or be subject to higher costs or savings
- government – there may be an impact on enforcement agencies or one State or Territory may be affected more than others, or there may be a significant impact in New Zealand.

Part 3 of this Handbook indicates what information on any social and economic impacts of a proposed food regulatory measure is required.

2.1.5 Fees

FSANZ's power to recover costs is set out in section 146 of the FSANZ Act which provides that the regulations may fix charges for services provided by FSANZ. The *Food Standards Australia New Zealand Regulations 1994* (FSANZ Regulations) provide for the amount to be paid, payment and refund arrangements.

When do fees apply?

Subsection 146(6) of the FSANZ Act stipulates that a charge may only be fixed by FSANZ in relation to an application to develop or vary a food regulatory measure if:

- (a) the development or variation of the standard would confer an ECCB (see below) on the applicant [payment of charges is mandatory]; or

² https://www.coag.gov.au/coag_councils

- (b) the applicant has elected to have the [commencement of] consideration of the application expedited [payment for this circumstance is voluntary, otherwise the application is put in the 'queue' for assessment].

FSANZ decides as part of the administrative assessment whether or not the development or variation of the standard would confer an ECCB, taking into account the information provided in the application.

Applications with an exclusive capturable commercial benefit

Where an application is likely to result in an amendment to the Code that provides exclusive benefits to the applicant, the application is considered to confer an 'exclusive capturable commercial benefit' (ECCB) and the applicant is required to pay the full cost of processing their application. For example, an application for approval of a novel food that requests an exclusive permission be granted for that particular novel food is likely to be considered to confer an ECCB.

Section 8 of the FSANZ Act provides that:

*An **exclusive, capturable commercial benefit** is conferred upon a person who applies for the development of a food regulatory measure or the variation of a food regulatory measure under section 22 if:*

- (a) *the applicant can be identified as a person or body that may derive a financial gain from the coming into effect of the draft standard or draft variation of the standard that would be prepared in relation to the application; and*
- (b) *any other unrelated persons or bodies, including unrelated commercial entities, would require the agreement of the applicant in order to benefit financially from the approval of the application.*

When are fees payable?

Fees are determined as part of the administrative assessment process. Fees are payable after the applicant has been formally notified of FSANZ's decision in relation to the appropriate assessment procedure pursuant to section 27 of the FSANZ Act.

For applications where an ECCB applies, payment of either the full cost-recovery charge or the 1st instalment (as indicated below) must be paid within 20 business days after the section 27 notification has been issued. The application is rejected if payment is not received by FSANZ within that time.

Where an applicant wishes to expedite the commencement of consideration of the application, there is no deadline for payment of the fees (as indicated below) after the section 27 notification has been issued.

Applications being considered under the minor procedure or level 1 or level 2 of the general procedure or high level health claim variation procedure

FSANZ must receive the full cost recovery fees. Work will not commence on the application until the **full** cost-recovery charge is paid.

Applications being considered under level 3 or level 4 of the general procedure or high level health claim variation procedure

Fees may either be paid in full **OR** in two instalments of the full cost-recovery charge. Work will not commence on the application until either:

- the **full** cost-recovery charge is paid **OR**
- a 1st instalment (**75%** of the full charge) is paid. Payment of the 2nd instalment of the remaining **25%** of the full charge is then due by the date submissions for the round of public comment close. FSANZ will then not continue work on the application until after the 2nd instalment is paid.

Applications being considered under the major procedure

Fees may either be paid in full **OR** in two instalments of the full cost-recovery charge. The fees are exempt from GST. Work will not commence on the application until either:

- the **full** cost-recovery charge is paid **OR**
- a 1st instalment (**25%** of the full charge) is paid. Payment of the 2nd instalment of the remaining **75%** of the full charge is then due by the date submissions for the first round of public comment close. FSANZ will then not continue work on the application until after the 2nd instalment is paid.

Generally, fees must be paid in Australian dollars. However, New Zealand applicants may pay fees in New Zealand currency, the amount of which will be calculated using the official exchange rate on the day the fee is paid. For overseas applicants making deposits, Australian banks may charge a fee on overseas EFT payments – please allow an additional AUD20–25 for this charge, **in addition to** the FSANZ fees. Fees are indicated in the table below:

Procedure	Hours	Hourly Charge	Admin Charge	Total Fees AUD	Indicative Total Fees NZD ¹
Minor Procedure	Maximum of 100 hours	11,500	10,000	21,500	23,650
General procedure	Maximum of 350 hours	40,250	10,000	50,250	55,275
High level health claim variation procedure	Maximum of 650 hours	74,750	10,000	84,750	93,225
	Maximum of 1000 hours	115,000	10,000	125,000	137,500
	More than 1000 hours	115,000+**	10,000	125,000+**	137,500+**
Major Procedure	1200 hours or more	138,000***	10,000	148,000+***	162,000+***

* The figures above are therefore only indicative, calculated on an exchange rate of AUD1 = NZD1.1

** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1000 hours, a surcharge of AUD115 per hour will apply for each completed hour.

*** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1200 hours, a surcharge of AUD115 per hour will apply for each completed hour.

Refunds of the hourly charge and Administrative charge are partially or fully refundable, in accordance with the FSANZ Regulations.

How to pay fees

Payment of fees in Australian Dollars can be made by direct deposit (preferred) or by cheque. **Direct deposits** should be directed to:

Commonwealth Bank of Australia
84 Giles Street
KINGSTON ACT 2604

BSB: 062-910

Account No.: 1000 8279

Account Name: Food Standards Australia New Zealand (AXXX)

SWIFT Code: CTBAU2S

Cheques should be made payable to *Food Standards Australia New Zealand (AXXX)* and sent to:

Finance Department
Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

2.1.6 Confidential commercial information

The FSANZ Act restricts FSANZ's ability to publish or disclose information that is Confidential Commercial Information in relation to food (CCI). Subsection 4(1) of the FSANZ Act provides that CCI means:

- (a) *a trade secret relating to food; or*
- (b) *any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.*

Examples of information that may constitute CCI may include the following where they relate to food:

- trade secrets
- manufacturing processes
- innovative new products
- marketing strategies.

The fact that information must be a trade secret etc makes it very unlikely that a complete application would constitute CCI. It is more likely that only specific, limited sections of an application may be regarded as CCI.

Applicants should notify FSANZ at the outset if they consider that information they intend to provide to FSANZ in their application or other provided material is CCI (that is, meets the above definition). In doing so, they should:

- (a) identify the information that they consider to be CCI; and
- (b) advise FSANZ in writing why and how that information meets the FSANZ Act's definition of CCI.

Guideline 3.1.1 sets out the relevant requirements for claims by applicants that information they provide is CCI.

FSANZ will consider each CCI claim against the criteria set out in the above definition of what constitutes CCI. It remains a question of fact, not opinion, as whether particular information is CCI or not.

Information provided by applicants and which is **not** CCI will generally be published by FSANZ on its website. Supporting information such as raw studies or references will be available to the public on request at any time, but not generally published on the web due to the usual number and size of the documents.

2.1.7 Other confidential information

Applicants may request FSANZ to keep information **that is not CCI** confidential. That is, not publish it or disclose it to third parties. Each request will be considered by FSANZ on its merits.

Such requests should be made before or at the time that the information is provided to FSANZ.

Guideline 3.1.1 sets out the relevant requirements for requests by Applicants for FSANZ to keep non-CCI information confidential.

2.1.8 Food standards development Work Plan

In recognition of the fact that FSANZ has limited resources and it is not possible to process unlimited numbers of applications within a fixed period, FSANZ prioritises its work through the creation of the Food Standards Development Work Plan. The development of a Work Plan is required under section 20 of the FSANZ Act. FSANZ must consult interested persons in developing the Work Plan and FSANZ must review and update the Work Plan at least every three months.

Once the administrative assessment has been carried out and an application is accepted by FSANZ, the application is assigned a number and placed on the Work Plan. Commencement of the formal assessment of unpaid applications depends on the allocation of resources within FSANZ.

Details provided on the Work Plan include:

- the application number and title
- the applicant
- a brief description of the purpose of the application
- date received
- the statutory start and finish dates for the assessment process
- the assessment procedure to be undertaken and the complexity of assessment
- an indication of the anticipated timeframes for the steps in the assessment process.

Following acceptance or preparation, unpaid applications or proposals are not formally included on the Work Plan until after confirmation that resources are available for work to commence (about a month before work is due to commence).

For applications being assessed under the high level health claim variation procedure, minimal information only is included in the Work Plan (no details of the applicant, claim or progress with the assessment will be included), unless an applicant has requested that public submissions be sought.

The Work Plan can be viewed on the FSANZ website at <http://www.foodstandards.gov.au/code/changes/workplan/Pages/default.aspx> or it can be obtained from the FSANZ Information Officer on +61 2 6271 2222. The Work Plan on the website is regularly updated.

2.1.9 FSANZ's obligations to applicants

FSANZ will keep applicants informed of the progress of the application throughout its assessment. FSANZ is obliged to formally notify applicants in writing of its decisions at certain parts of the assessment process including:

- on completion of the administrative assessment of an application where FSANZ has decided whether to accept or reject an application
- on completion of the 'assessment' stage
- on completion of the 'preparation of a draft variation' stage
- after the completion of the 'Approval' stage.

Applicants are also advised of other matters during the assessment process such as:

- receipt of an application
- any decision by the Forum
- when an amendment to the Code resulting from an application is to be gazetted, as well as being included in any public notification of a call for submissions
- information relating to fee refunds.

The project manager for an application will also remain in regular contact with the applicant.

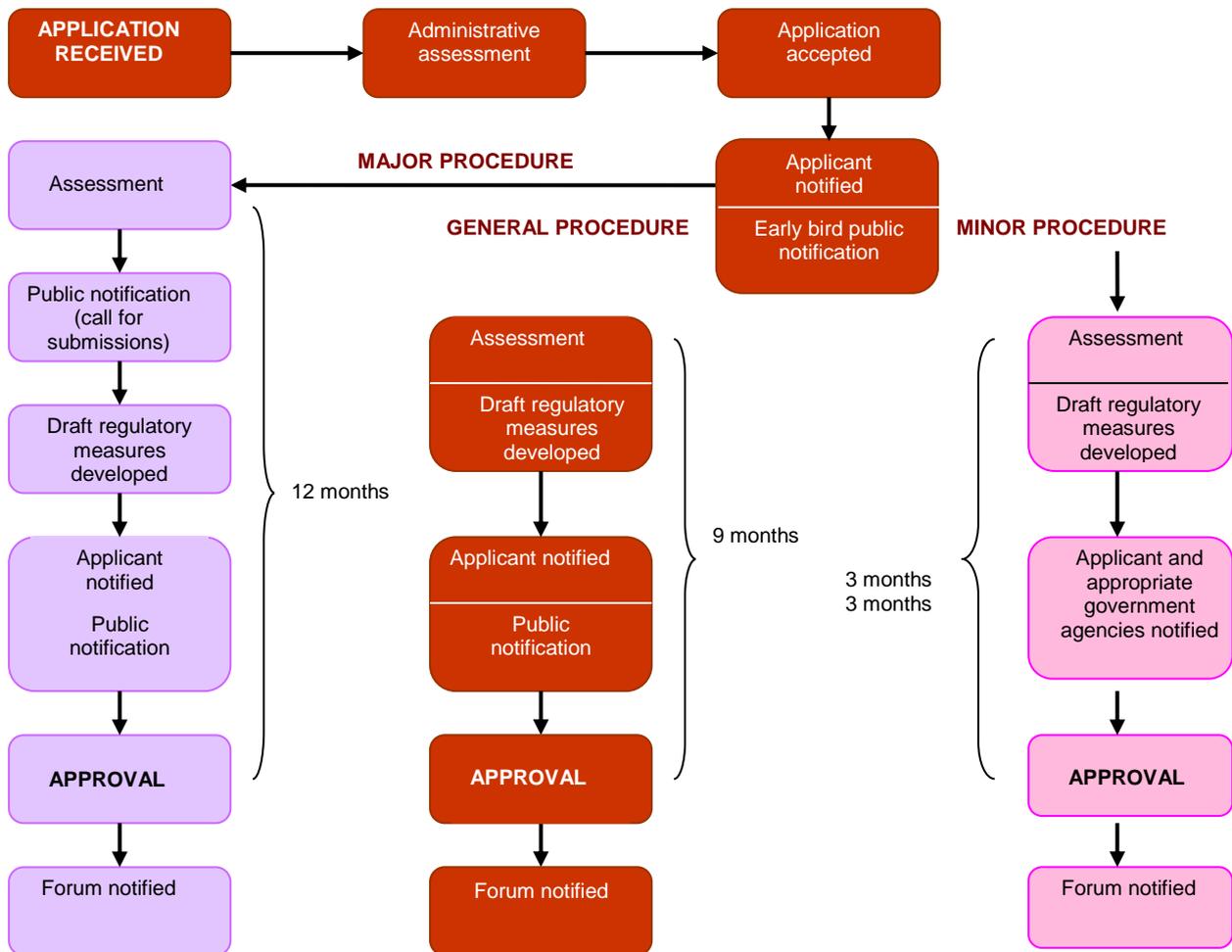
If an application is rejected, FSANZ will notify the applicant in writing outlining the reasons for rejection. An applicant can apply to the Administrative Appeals Tribunal for a review of that decision within 28 days of notification of the rejection.

2.2 Application process

2.2.1 Assessment procedures

All applications are subject to an 'administrative assessment' on receipt by FSANZ. The main purpose of the administrative assessment is to determine whether the application meets the application requirements and the procedure under which it should be assessed.

Applications are then assessed under one of four procedures – general (see Section 2.2.5), minor (see Section 2.2.6), major (see Section 2.2.7) or high level health claim variation (see Section 2.2.8).

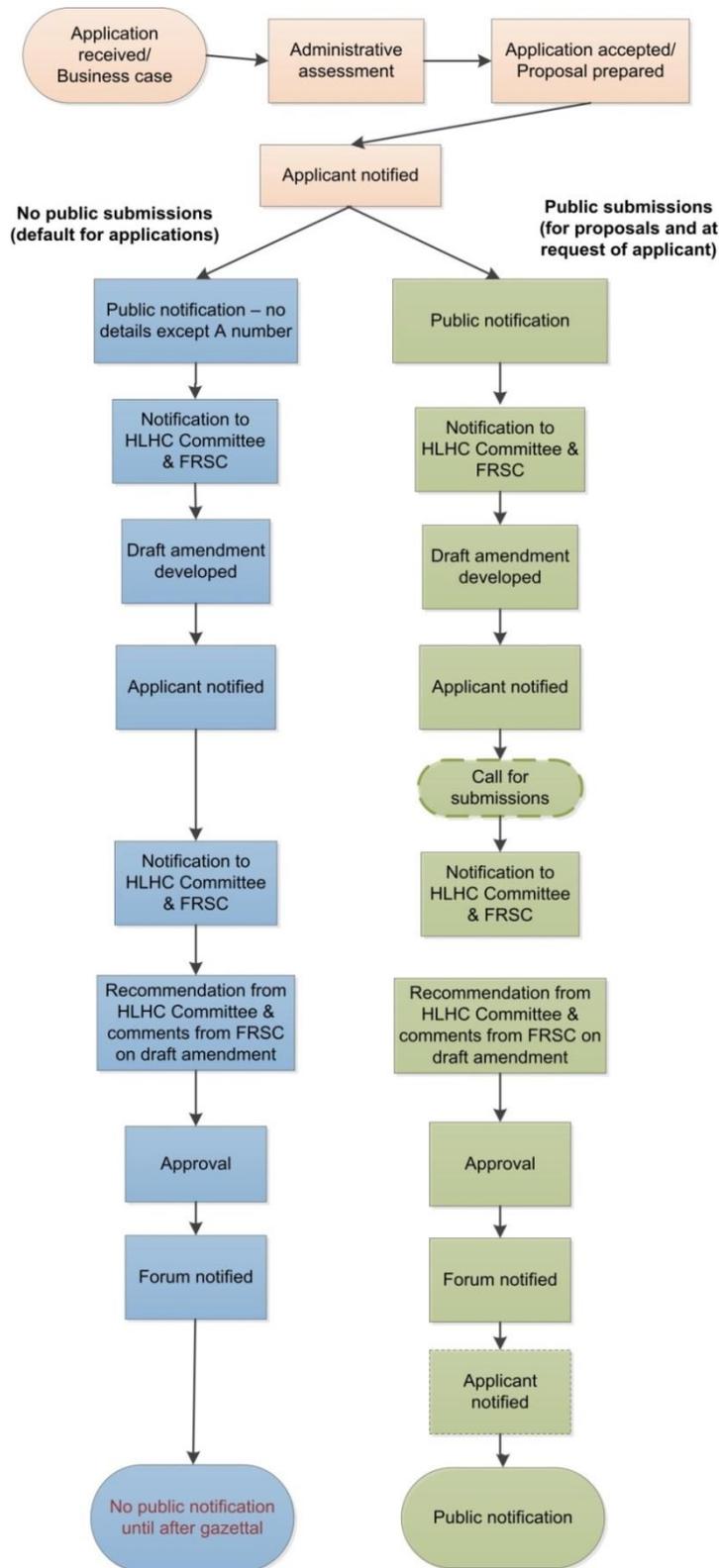


Applications to make a change to the list of high level health claims as permitted in the table to S4—4 or to add a general level health claim to the table to S4—5

Applications seeking a variation whose effect is to make a change to the list of high level health claims in the table to S4—4, or to add a general level health claim to the table to S4—5 (as described in section 1.2.7—17 of Standard 1.2.7) will be assessed as a high level health claims variation using the procedure outlined in subdivision G of Division 1 of Part 3 of the FSANZ Act (see Part 2.2.8). All other applications to amend Standard 1.2.7 or Schedule 4 will be assessed under the general, minor or major procedure.

If an application seeks either a high level or general level health claim variation amongst other variations, then FSANZ will treat the other variations as a separate application and progress them under the relevant general, minor or major procedure. For example, if the claim related to an unapproved novel food, then FSANZ would generate a separate application process seeking approval for the novel food. FSANZ would then progress both applications in parallel. Applicants should seek advice from FSANZ before lodging their application to ensure that they are aware of how FSANZ will apply the different procedures.

The flow chart below is a general outline of the process for high level and general level health claim variations. Applicants should check the FSANZ Act for specific legislative requirements.



2.2.2 Community involvement and consultation

FSANZ has a commitment towards community involvement and recognises that community involvement is a two-way process. Effective consultation begins with FSANZ being very open about food standards under development and informing the community about the processes and issues pertinent to each application and proposal. FSANZ is also very welcoming of comments on each application and proposal, either as formal submissions on assessment reports or through participation at stakeholder forums.

This commitment has its basis in the FSANZ Act and reflects the need to ensure that consultation informs the assessment of applications.

The aim of FSANZ's approach to consultation is to adopt a flexible approach, varying the scope and intensity of community involvement to suit the circumstances and importance of the issues under consideration. A variety of community involvement techniques are used to best suit the diverse needs of those being consulted and people and organisations are encouraged to use a variety of methods to make their views known.

Interest groups and individuals have differing resources and this affects their ability to become involved in the consultation process.

New Zealand has its own statutory obligations under the New Zealand *Food Act 2014* when issuing food standards. Whilst they differ slightly, these requirements are accommodated in FSANZ's stated consultation processes.

The views of Māori and indigenous peoples also have to be addressed in FSANZ's community involvement processes.

The process by which FSANZ considers food standards matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ's assessment reports.

In many cases there may be strong conflicting views expressed by submitters. Some of these views will be subjective. The FSANZ approach has to be consistent and decisions have to be based on the best available scientific evidence.

FSANZ needs to ensure that it has collected sufficient evidence, including from outside experts if necessary, in order to be able to undertake a rigorous analysis of each case. In some situations the best available scientific evidence is irrefutable. In others there might be conflicting scientific views, a lack of evidence or some uncertainty in the science. Where the evidence is in dispute, FSANZ will ensure that it sets out the reasoning and logic used to reach its decision.

2.2.3 Statutory timeframes

The FSANZ Act and the associated Regulations require FSANZ to make its decisions relating to applications within stipulated periods of time, depending on the procedure under which an application will be assessed. The FSANZ Act prescribes a consideration period of 12 months, unless a shorter period is provided for in the FSANZ Regulations:

- administrative assessment –15 business days (from receipt of application to decision to accept or reject application)
- general procedure (Subdivision D of the FSANZ Act – 9 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure)
- minor procedure (Subdivision E of the FSANZ Act – 3 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure)
- major procedure (Subdivision F of the FSANZ Act – 12 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure)
- high level health claim variation procedure (Subdivision D of the FSANZ Act – 9 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure).

The statutory timeframe for applications being considered under the major procedure only can be extended for up to six months by FSANZ. This statutory timeframe does not include time taken for an applicant to provide additional information or fees (where applicable).

FSANZ is required to indicate where it has extended the timeframe for completion of an assessment or where it has failed to meet its statutory timeframes and the reasons why in its Annual Report.

FSANZ also has the discretion to 'stop the clock' if it needs more information in order to complete an assessment of an application (section 108 of the FSANZ Act).

If an applicant fails or refuses to comply with FSANZ's request for further information under section 108 of the FSANZ Act without reasonable excuse, the application is taken to have been withdrawn.

2.2.4 Administrative Assessment

An administrative assessment of an application is made by FSANZ within 15 business days after an application is given to FSANZ. The purpose of this assessment is to determine whether an application is accepted or rejected under section 26 of the FSANZ Act.

In undertaking an administrative assessment, FSANZ must have regard to:

- whether the application meets the requirements (including such information as is specified by FSANZ in the guidelines in Part 3 of the Handbook
- whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants the variation of a food regulatory measure
- whether the application is so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought to be rejected
- any other relevant matter.

After undertaking an administrative assessment FSANZ must either accept or reject an application:

- if the application is rejected, FSANZ notifies the applicant with a statement of reasons; or
- if the application is accepted:
 - determines the assessment procedure to be applied
 - determines whether or not the proposed development or variation of the food regulatory measure would confer an exclusive, capturable commercial benefit on the applicant
 - notifies the applicant that the application has been accepted and the procedure under which the application will be assessed.

If the application is accepted, it will be placed on the Work Plan once fees are paid or when resources become available to commence work (see Section 2.1.6).

2.2.5 General procedure

The general procedure is the default assessment process and involves at least one round of public comment. For the purposes of cost-recovery under the FSANZ Regulations, the general procedure is split into four levels. **The following descriptions are only indicative of what matters may be considered under each level.**

Level 1 (maximum of 350 hours)

For example, an application for a variation of a food regulatory measure involving:

- extending the use of a food or food additive that is permitted under a standard
- a new source organism for an enzyme
- a minor change to a labelling requirement
- a minor change to a compositional requirement for a food
- reducing a maximum residue limit.

This kind of application is likely to:

- involve an assessment of the risk to public health and safety of less than average complexity; or

- have a limited, or no, social or economic impact; or
- require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of less than average complexity; or
- require an assessment of risk management measures of less than average complexity; or
- involve the development of a basic community communications strategy to address public concern.

Level 2 (maximum of 650 hours)

For example, an application for a variation of a food regulatory measure involving:

- extending the use of a substance to a specific food
- a pre-market approval similar to a previous approval
- a new microorganism
- changing a compositional requirement for a food
- inserting or increasing a maximum residue limit.

This kind of application is likely to:

- involve an assessment of the risk to public health and safety of average complexity; or
- have a low social or economic impact; or
- require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of average complexity; or
- require an assessment of risk management measures of average complexity; or
- involve the development of a community communications strategy to address public concern.

Level 3 (maximum of 1000 hours)

For example, an application for a variation of a food regulatory measure involving:

- extending the use of a substance to a range of foods
- changing a labelling requirement for a food
- a pre-market approval
- establishing or increasing a maximum permitted concentration for an environmental contaminant or heavy metal.

This kind of application is likely to:

- involve an assessment of the risk to public health and safety of greater than average complexity; or
- have a broad social or economic impact; or
- require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of greater than average complexity; or
- require an assessment of risk management measures of greater than average complexity; or
- involve the development of a complex community communications strategy to address public concern; or
- require targeted consultation with key stakeholders or special interest groups; or
- require the provision of advice to advisory groups, peak organisations or other stakeholders.

Level 4 (more than 1000 hours)

For example, an application for a variation of a food regulatory measure involving:

- adding a new substance to a limited range of foods
- changing a labelling requirement for a limited range of foods
- a complex pre-market approval.

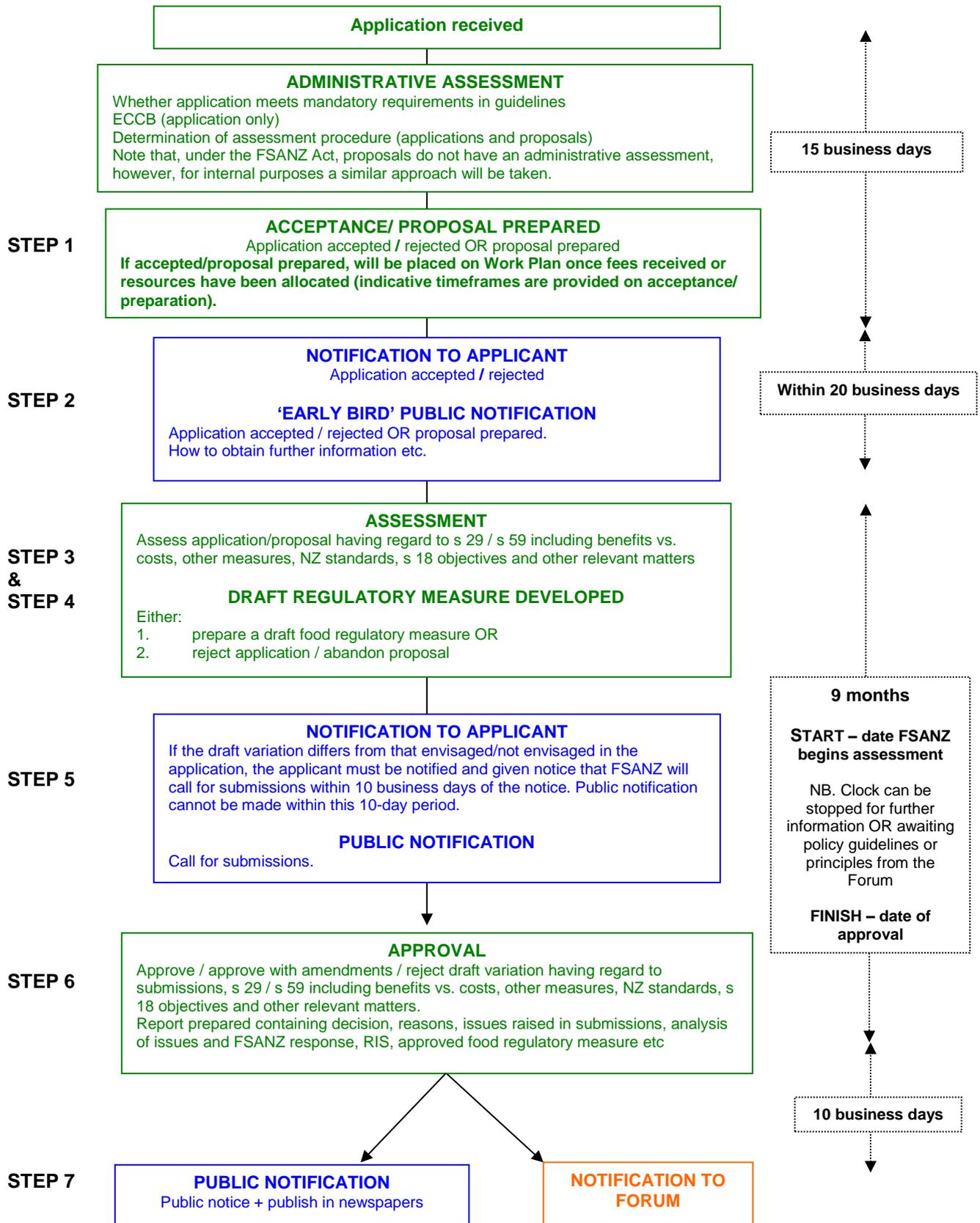
This kind of application is likely to:

- involve an extensive and complex assessment of the risk to public health and safety; or
- have a broad and significant social or economic impact; or
- require an extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- require an extensive and complex assessment of risk management measures; or
- involve the development of an extensive and complex community communications strategy to address public concern; or
- require targeted consultation with key stakeholders or special interest groups; or
- require the development and distribution of community education material; or
- require the establishment of external working groups to discuss and interpret scientific evidence and social perceptions.

Key procedural steps

- Step 1 Acceptance or rejection of application
- Step 2 Notification to applicant and 'early bird' public notice
- Step 3 &
Step 4 Assessment & draft food regulatory measure developed
- Step 5 Notification to applicant and call for public submissions
- Step 6 Approval of draft food regulatory measure
- Step 7 Notification of approval of draft food regulatory measure to Forum
- Step 8 Gazettal following advice from Forum to not review the approval decision

**GENERAL PROCEDURE
(Subdivision D)
Default – Applications or proposals**



2.2.6 Minor procedure

Assessment under the minor procedure applies to an application for the variation of a food regulatory measure that, if made, would not directly or indirectly:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of the measure.

One round of consultation is carried out with government agencies only, although FSANZ as a matter of openness and transparency will consult with affected parties and take into account their views in making a decision on the matter. An application would fall within this procedure if its only effect would be:

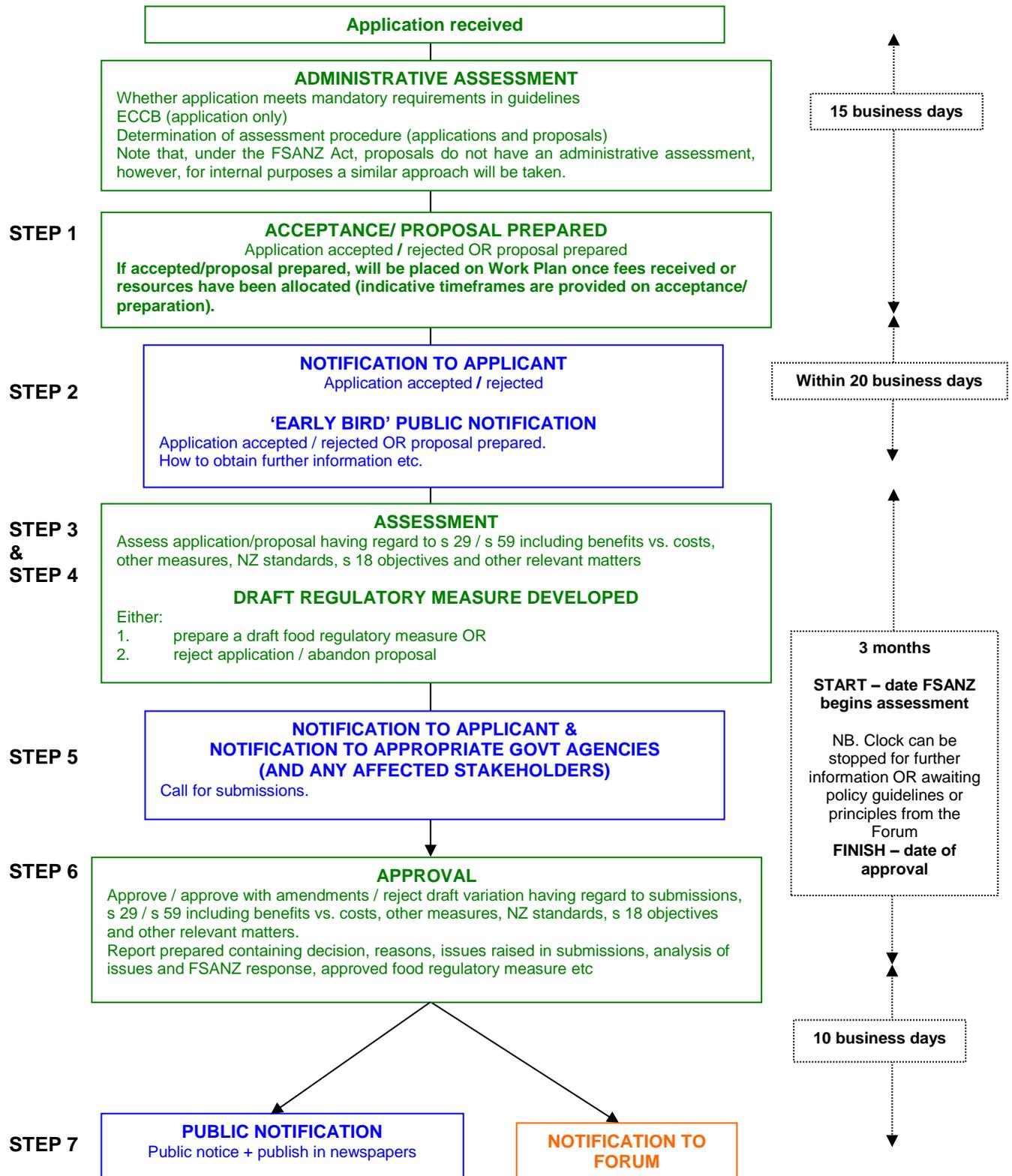
- correcting a typographical error; or
- updating a reference to another document; or
- amending a cross-reference within a food regulatory measure; or
- omitting provisions of a food regulatory measure that has ceased to have effect; or
- any other matter of similar complexity

Key procedural steps

- Step 1 Acceptance of application
- Step 2 Notification to applicant and 'early bird' public notice
- Step 3 &
Step 4 Assessment & draft food regulatory measure developed
- Step 5 Notification to applicant and call for submissions from government agencies
- Step 6 Approval of draft food regulatory measure
- Step 7 Notification of approval of draft food regulatory measure to Forum
- Step 8 Gazettal following advice from Forum to not review the approval decision

**MINOR PROCEDURE
(Subdivision E)**

Applications or proposals – only for minor matters which do not impose, vary or remove a current obligation, right or legal effect



2.2.7 Major procedure

Assessment under the major procedure applies to:

- (a) an application for the development of a new food regulatory measure; and
- (b) an application for the variation of a food regulatory measure that:
 - (i) involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or
 - (ii) involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it.

A minimum of two rounds of public comment is required and consultation might also require the establishment of external working parties or advisory groups to assist with the assessment.

An application for the development of, or a major variation to, a new food regulatory measure involving:

- developing a new standard
- changing a labelling requirement affecting a wide range of foods
- changing a compositional requirement for a wide range of foods
- adding a new substance affecting a wide range of foods
- a pre-market approval, with no similar previous approvals.

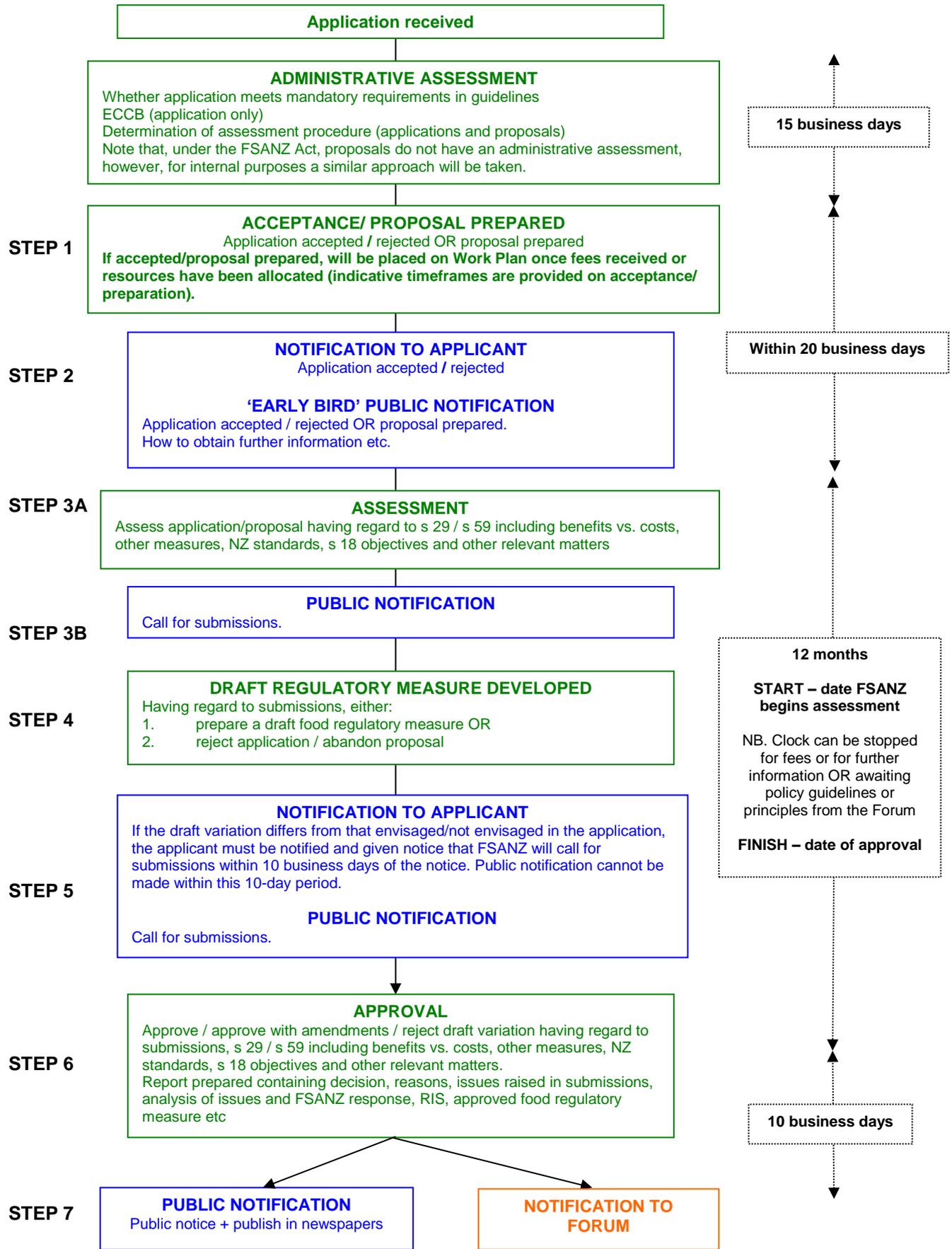
This kind of application is likely to:

- involve a very extensive and complex assessment of the risk to public health and safety; or
- have a very broad and significant social or economic impact; or
- require a very extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- require a very extensive and complex assessment of risk management measures; or
- involve the development of a very extensive and complex community communications strategy to address public concern; or
- require targeted consultation with key stakeholders or special interest groups; or
- require the development and distribution of community education material; or
- require extensive consultation with government agencies, industry, health professionals and consumer groups; or
- require the establishment of high-level advisory groups to discuss and interpret scientific evidence and social perceptions; or
- require community meetings including public hearings.

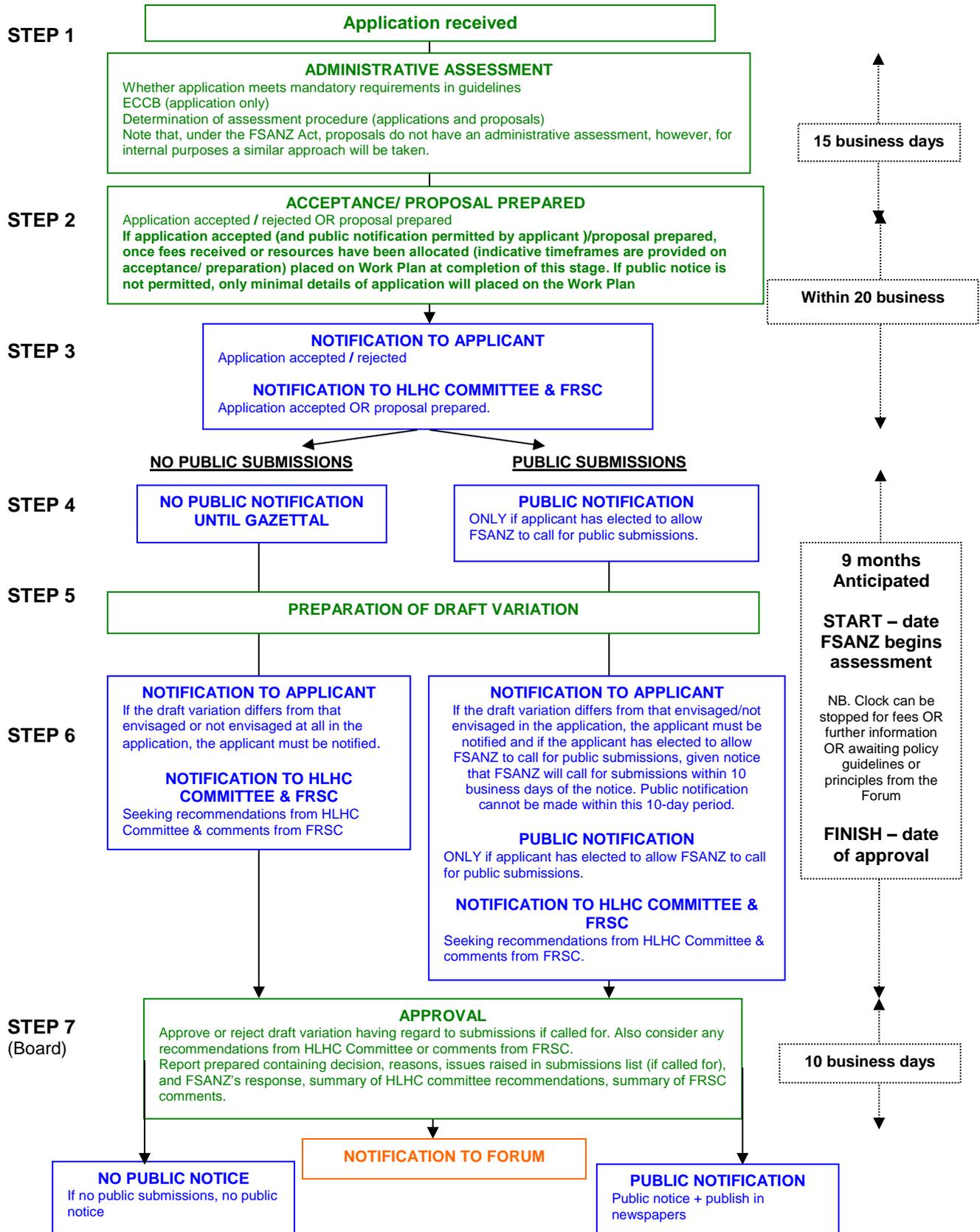
Key procedural steps

- Step 1 Acceptance of application
- Step 2 Notification to applicant and 'early bird' public notice
- Step 3 Assessment, notification to applicant and call for public submissions
- Step 4 Draft food regulatory measure developed
- Step 5 Notification to applicant and call for public submissions
- Step 6 Approval of draft food regulatory measure
- Step 7 Notification of approval of draft food regulatory measure to Forum
- Step 8 Gazettal following advice from Forum to not review the approval decision

**MAJOR PROCEDURE
(Subdivision F)**
Applications or proposals – Development of new food regulatory measures & major variations



HIGH LEVEL HEALTH CLAIM VARIATION PROCEDURE (Subdivision G) Applications or proposals – for a high level health claim variation

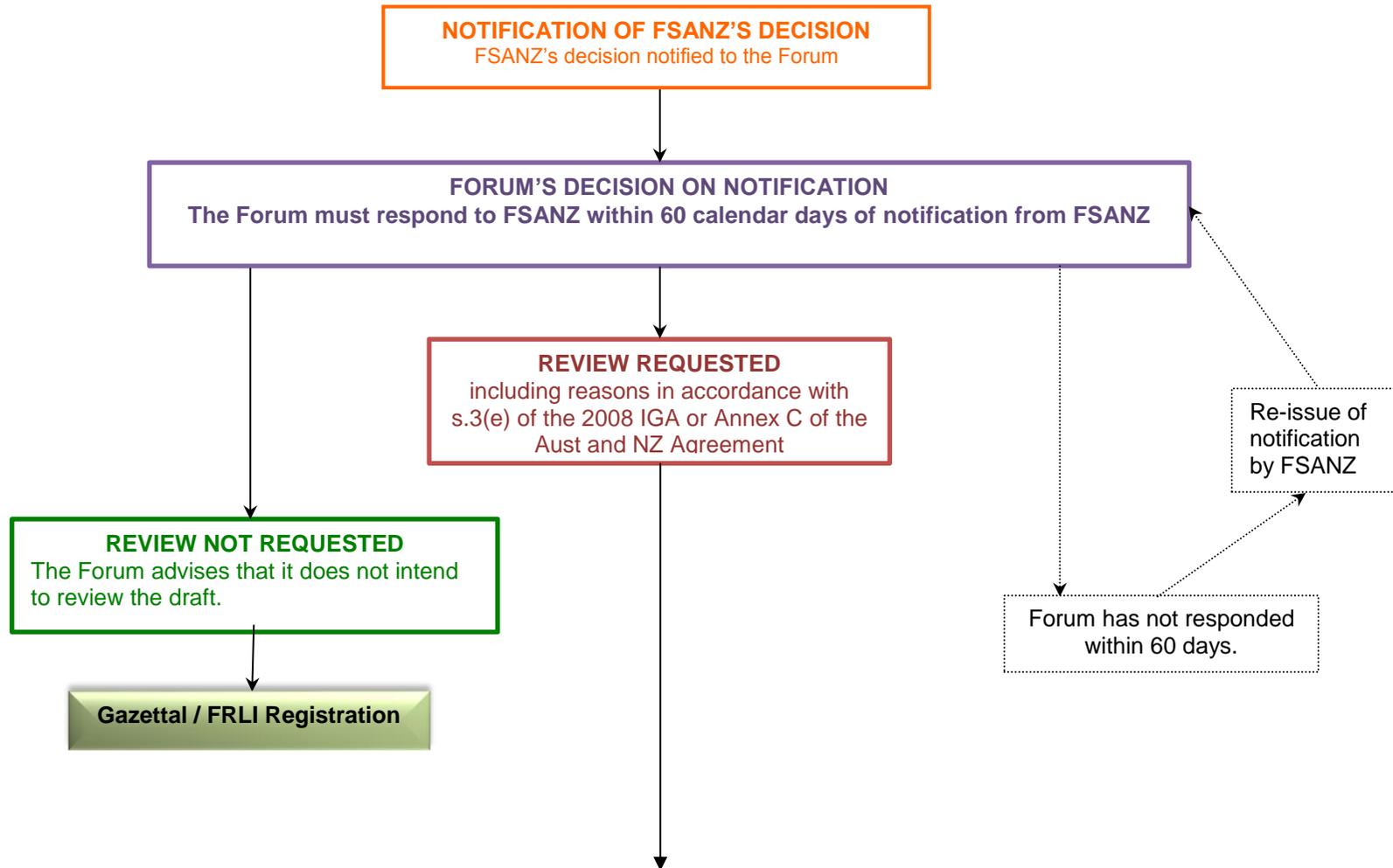


2.2.8 Forum review

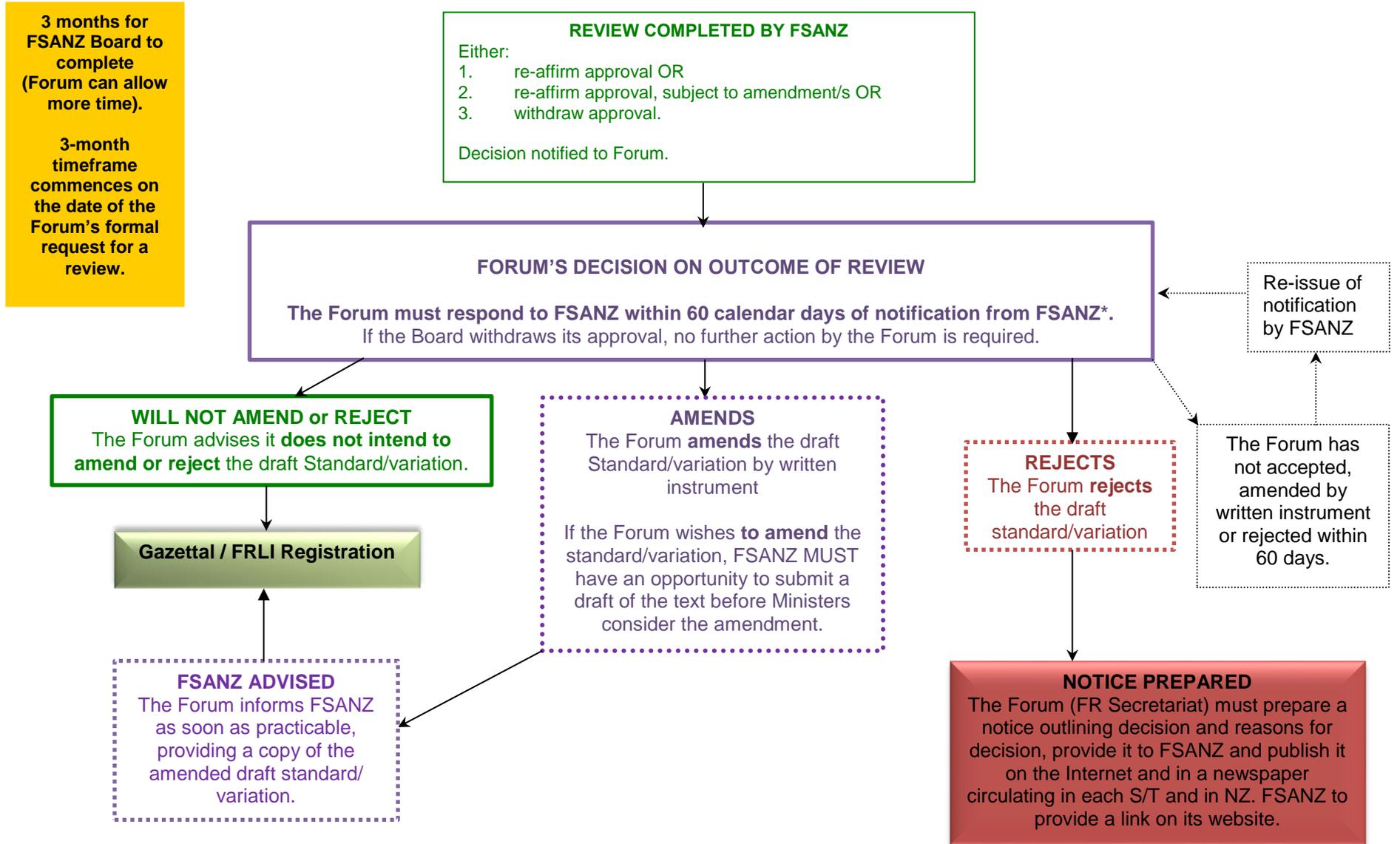
The Forum has one opportunity, by majority decision, to request a review of a decision made by FSANZ. Following the review by FSANZ, the Forum must make one of the following decisions:

- inform FSANZ that it does not intend to amend or reject the draft
- amend the draft
- reject the draft.

FORUM PROCESS



REVIEW



2.2.9 Withdrawal of an application

Withdrawal of an application can occur in one of two ways:

1. An applicant can withdraw their application at any time after it has been formally lodged with FSANZ under section 22 of the FSANZ Act, but before the approval of a food regulatory measure or notification that FSANZ has rejected an application. The notice to FSANZ of withdrawal must be in writing (to the Standards Management Officer).
2. An application can be taken to have been withdrawn by FSANZ if an applicant fails or refuses to comply with FSANZ's request for further information under section 108 of the FSANZ Act without reasonable excuse.

If the application is a paid application, fees will be partially refundable, in accordance with the FSANZ Regulations.

2.2.10 Rejection of an application

Rejection of an application can occur at a number of stages in the assessment process:

1. **By FSANZ** – at the conclusion of the administrative assessment when a decision is taken to accept an application or not. The grounds for rejection are:
 - whether the application complies with the requirements set down in the guidelines in Part 3
 - whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants the variation of a food regulatory measure
 - whether the application is so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought to be rejected
 - any other relevant matter.

If the application is a paid application and is rejected, fees may be partially refundable, in accordance with the FSANZ Regulations.

2. **By FSANZ** – when fees due for an application with an ECCB have not been received. The grounds for rejection are:
 - if the charge is not paid within 20 business days of the notification of the acceptance of an application.

Rejection in this case does not preclude the application from being re-submitted to FSANZ.

3. **By FSANZ** – at the completion of the assessment or approval stages. The grounds for rejection are:
 - whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
 - whether other measures would be more cost-effective than a food regulatory measure developed or varied as a result of the application
 - any relevant New Zealand standards
 - submissions made to FSANZ
 - any other relevant matters, including the objectives of the FSANZ in developing food regulatory measures and variations of those measures (section 18 of the FSANZ Act).

If the application is a paid application and is rejected, fees may be partially refundable, in accordance with the FSANZ Regulations.

4. **By the Forum** – after a request to FSANZ for a review of a decision. The grounds for rejection of a draft variation or standard (from the Inter-Governmental Agreement and the Treaty between Australia and New Zealand on the joint food standards system) are:
- it is not consistent with existing Forum policy guidelines
 - it is not consistent with the objectives of the FSANZ Act
 - it does not protect public health and safety
 - it does not promote consistency between domestic and international standards where these are at variance
 - it does not provide adequate information to enable informed choice
 - it is difficult to enforce or comply with in both practical or resource terms
 - it places an unreasonable cost burden on industry or consumers.
 - it is not consistent with the principles for the establishment of food standards set down in this Agreement, including consistency with both countries' World Trade Organization obligations and consistency with the domestic laws and regulations of both countries (Treaty only)
 - it is inappropriate on the grounds of exceptional environmental or cultural factors (Treaty only).

2.3 GM applications – additional information

This information replaces the FSANZ document *Safety assessment of genetically modified foods* (FSANZ 2007) and reflects recent scientific developments and changes to GM food safety assessment practices within FSANZ.

In undertaking GM food safety assessments, FSANZ applies the approach outlined in *Foods derived from modern biotechnology* (Codex 2009). This publication is a compilation of internationally agreed principles and guidelines for GM food safety assessment:

- Principles for the risk analysis of foods derived from modern biotechnology (CAC/GL 44-2003)
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003)
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms (CAC/GL 46-2003)
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals (CAC/GL 68-2008).

This approach differs from the traditional risk assessment approach which was elaborated specifically to investigate chemical hazards and was not intended to apply to whole foods, such as GM foods. The traditional approach relies extensively on animal toxicity testing and is mainly used for the assessment of single substances of known purity such as food additives, pesticides and contaminants. This approach cannot easily be applied to whole foods. In fact, few conventional foods safely consumed today have been assessed scientifically in a manner that would fully characterise all potential risks associated with the food. It is also the case that many foods contain substances (e.g. natural toxicants) that would likely be found harmful if subjected to conventional approaches to safety testing.

Consequently, the Codex (Codex 2009) multidisciplinary approach to GM food safety assessment uses the concept of a scientific comparison of the GM food to a conventional counterpart having a history of safe use. The basic principles behind this comparative approach³ were first discussed internationally through a Joint FAO/WHO Consultation in 1991 (FAO/WHO 1991) and were further elaborated by the Organisation for Economic Cooperation and Development (OECD 1993).

³ Also referred to as 'substantial equivalence'

A Joint FAO/WHO Expert Consultation on Safety Aspects of Genetically Modified Foods of Plant Origin re-evaluated the usefulness of the comparative approach and concluded that “there were presently no alternative strategies that would provide a better assurance of safety of GM foods” (FAO/WHO 2000). This approach was subsequently endorsed for use with foods derived from GM microorganisms (FAO/WHO 2001a) and GM animals (FAO/WHO 2004).

The main purpose of the GM food safety assessment is to identify new or altered hazards associated with the food as a result of the genetic modification. If a new or altered hazard, nutritional or other food safety concern is identified, further investigation is undertaken to determine its relevance to human health.

The assessment itself is characterised by:

1. Case-by-case consideration

The key issues requiring consideration in a safety assessment will depend on the nature of the food being evaluated and the particular genetic modification. Application of the safety assessment guidelines therefore needs to remain flexible so the specific and unique issues that can arise as a result of different genetic modifications can be addressed. This means the data requirements can be adjusted (e.g. either expanded or contracted) to suit the case being assessed.

2. Consideration of the intended and unintended effects of the genetic modification.

Intended effects are the changes introduced as a direct consequence of the genetic modification e.g. herbicide tolerance. There might also be other changes associated with the genetic modification that were unintended (see subsection 2.3.2). The human health impact of both types of changes is considered in the safety assessment.

3. Comparisons with other foods having an acceptable standard of safety.

These comparisons aid in the identification of similarities and differences between the GM food and an appropriate comparator (see subsection 2.3.1). Any identified differences become the focus of further scrutiny to determine if they raise potential safety and nutritional issues. The extent of this further scrutiny will depend on the nature of the identified differences, and could include relevant comparisons with other foods or additional testing of the nutritional or toxicological properties of the GM food. This will need to be decided on a case by case basis.

Use of the comparative approach relies on: (i) consideration of the molecular characterisation of the genetic modification; (ii) phenotypic characterisation of the new organism, compared with an appropriate comparator; (iii) consideration of the safety of new substances produced in the food by the introduction of new genetic material; and (iv) compositional analysis of the food.

It is important to note that the key focus of the assessment is ultimately on whether the GM food is safe rather than how different/similar it is to the chosen comparator(s). If the identified differences do not raise any safety or nutritional concerns then it can be concluded the GM food is comparable to other foods already in the food supply in terms of its safety for human consumption.

2.3.1 Selection and use of comparators

The comparative approach requires identifying a suitable comparator(s) against which the GM product will be compared throughout the safety assessment. It is acceptable for more than one comparator to be used across different studies, or within a single study. Comparators are particularly important for informing the molecular characterisation (see subsection 2.3.3), compositional analyses (see Section 6), and any corresponding nutritional assessment (see subsection 2.3.6).

In the first instance, the relevant comparison should be between the GM organism and its nearest non-GM genetic relative, otherwise known as the near-isogenic line. Use of a close genetic relative as an experimental control optimises the sensitivity of the comparison because it minimises differences due to germplasm alone. Ideally, the near-isogenic line will be the original transformed (parental) line. However in practice, it may be more relevant to use a line with a similar genetic background to the GM line undergoing assessment. This is particularly true for GM crops in which complex conventional breeding steps have occurred to arrive at the GM line of greatest commercial value.

For the molecular characterisation, usually only one comparator, the parental line, is relevant for assessment. For compositional analyses it is necessary to establish the extent of natural variation already present in the food supply; in addition to the near-isogenic line, a number of commercial varieties (often referred to as reference lines) are almost always included in field trials and analysed in the same way as the GM and near-isogenic lines. It is also acceptable to use published data to establish a literature range representative of variability in commercial crop composition. Comparing data from a GM plant against the range of natural variability already present in the food supply assists in interpreting whether any identified differences between the GM line and its near-isogenic comparator are biologically significant.

While it has generally been accepted the comparators should all be non-GM, in certain circumstances this may be impractical or unsound from a scientific perspective. For example where:

- The parental line itself is already a GM line. This situation would most likely require a three-way comparison between the original non-GM line, the GM parental line and the new re-transformed line.
- GM lines make up the bulk of commercial plantings. In these situations it may be appropriate to include approved commercial GM lines to determine a reference range that more accurately reflects the existing food supply.
- The breeding tree is complex. It can sometimes be difficult to identify a non-GM comparator that has both a history of safe use as food, and which is also closely related to the line from which the GM food is derived. This would occur if the breeding programme had been so complex that the final food-producing line may no longer be closely related to the original transformed line. The food-producing line may be a hybrid that has been crossed then backcrossed to elite lines. In this case it would be acceptable for the comparator used for the compositional analyses to be a null (or negative) segregant⁴ with an equivalent breeding history.

A number of other issues may also be relevant when selecting an appropriate comparator or comparators:

- If it is not possible to maintain a genetically “pure” line because of a high frequency of inbreeding depression, the comparator used for the compositional analyses could consist of a population of genetically similar but not identical (isogenic) individuals.
- For logistical reasons, the comparator(s) for GM animals may be more appropriately sourced from traditionally-bred animals of the same species not necessarily closely related. However, the comparator should ideally be matched in housing and husbandry conditions, breed, age, sex, parity, lactation, or laying cycle (where appropriate), although this will be species specific and may not be feasible in all cases.
- In the case of a food produced from a GM microorganism, it is likely the food will be highly purified (e.g. a protein) and, except in the case of proteins that are protein-engineered, will be identical to that produced in its natural source (nature identical). Any comparator would either have to be the same purified substance (from any source) as used already in the food industry (recognising that the amino acid sequence of the protein may exhibit natural variation), or the same substance produced using a near-isogenic strain of microorganism.

Because of the complexity of the technology, it is not possible to envisage all potential scenarios for the selection and use of comparators. Ultimately, the comparators that are used should be those best suited to the particular GM food in question. FSANZ will assess the appropriateness and acceptability of the selected comparators on a case-by-case basis.

⁴ A null or negative segregant is an individual selected from the progeny that has not inherited the introduced gene.

2.3.2 Unintended effects

One of the objectives of the safety assessment is to consider the unintended effects of the genetic modification (Section 1), and in particular whether these raise any food safety concerns.

Gene technology is frequently used to introduce new DNA expressing one or more genes into genomes to produce a novel trait or phenotype. The insertion of such sequences can often be accompanied by other genetic changes, such as the insertion of additional DNA, deletions and/or rearrangements. These changes are collectively referred to as insertional effects and are an unavoidable consequence of genetic engineering (Schnell et al. 2015). While such changes have the potential to give rise to unintended effects, experience to date with GM plants indicates very few in fact give rise to discernible changes to plant phenotype. In cases where unintended changes to plant phenotype have occurred these have not led to any safety concerns. For any single GM line that is commercialised, it is likely that during the course of development more than 1,000 individual lines would have been screened (Phillips McDougall 2011) and any exhibiting unintended effects discarded from further review. This is consistent with the common practice of discarding lines of conventionally bred plants exhibiting undesirable properties during the course of a commercial selection programme. The phenotypic and other comparisons that are routinely required for the GM food safety assessment therefore primarily serve as confirmation that the selection process has been effective and that any potentially hazardous unintended changes are absent from the food being assessed.

A variety of data can be used to derive information about the occurrence of unintended effects in the new GM food. A thorough characterisation of the genetic modification, and any newly expressed substances, along with a comprehensive analysis of the composition of the food is essential to ensure that any important differences between the GM food and the non-GM counterpart are identified. Where unintended differences are observed that are not consistent with normal biological variation, further assessment should be done to determine if they raise any food safety concerns. The type of further assessment required will depend on the differences identified and is therefore decided on a case-by-case basis.

Notwithstanding the above, it is important to note that the occurrence of genetic changes as a result of the insertion of new DNA, and any consequent unintended effects, is not restricted to the insertion of new DNA using gene technology but may also occur spontaneously or when conventional breeding techniques are used (Schnell et al. 2015). Gene technology therefore presents a similar level of risk, in terms of the occurrence of unintended effects, to other genetic changes that can occur in plants as a result of natural processes or conventional breeding practices.

2.3.3 Molecular characterisation

The characterisation provides an understanding of the DNA introduced into the host genome and helps to inform the safety assessment in relation to both the intended and possible unintended effects resulting from the transformation (OECD 2010).

Molecular characterisation typically addresses the following:

- The transformation method together with a detailed description of any DNA sequences that could potentially transfer to the host genome. A breeding pedigree for the various generations produced during selection of the lead event is also important.

This information is essential for analysing and interpreting the data from the characterisation of the inserted DNA and insertion site (below).

- A characterisation of the inserted DNA and the insertion site.

This information is used to describe the configuration of genetic elements introduced into the host organism. The characterisation includes information about the nature and number of expression cassettes and the number of insertion sites, including a description of any rearrangements or deletions that may have occurred as a result of the transformation. It also includes the identification and analysis of any unintended open reading frames of significant length created as a result of the insertion event.

- Inheritance and genetic stability of the inserted DNA.

Analysis of inheritance includes consideration of whether the inserted DNA has been stably integrated into the host genome and inherited from one generation to the next and provides assurance that the safety assessment is applicable to future generations. The stability of the genetic modification may be analysed at the genotypic and/or phenotypic level.

In cases where RNA interference (RNAi) has been used, the molecular characterisation can also include consideration of any transcripts that are produced, and/or evidence of silencing (where an endogenous gene has been targeted).

2.3.4 Characterisation of new substances

This part of the assessment provides an understanding of any newly expressed substances that are produced in the food as a consequence of the genetic modification and assists in the identification of any potential hazards. Typically, the main focus of the characterisation will be on newly expressed proteins, however, other (non-protein) substances may also be included on a case-by-case basis.

The main purpose of the characterisation is to describe the nature of any new substances and their phenotypic and biochemical effects on the organism in which they are expressed, particularly in the parts of the organism consumed as food. The level and site of expression of any new substances is useful information for determining potential exposure, should a particular hazard be identified. Where appropriate, the level of expression of new substances in processed food fractions can also provide useful information on potential exposure. It is also important to determine if any new substances are expressed as expected, including, in the case of proteins, whether any post-translational modifications have occurred.

Safety assessment of newly expressed proteins

One of the key considerations in relation to proteins that are expressed as a result of the genetic modification will be to determine if the expressed protein is new to the organism. Proteins expressed from genes derived from unrelated organisms may require greater assessment than those derived from related organisms, especially those that already have a history of safe use as food.

This issue was discussed at a workshop hosted by FSANZ to discuss new plant breeding techniques (FSANZ 2012). It was concluded that the source of the gene (i.e. whether it is from the same or a different species) could potentially influence the type of safety assessment that would be required. Where the transferred gene is derived from either the same or a cross-compatible species (i.e. a species that is able to be crossed with the host organism by traditional plant breeding to obtain fertile offspring), as would be the case where either cisgenesis⁵ or intragenesis⁶ had been used, and the gene donor belongs to a species that is commonly used as food and has a history of safe use, it can be reasonably assumed that the expressed protein is safe. Subjecting the expressed protein to the full battery of safety studies would therefore serve no legitimate safety assessment purpose. In this situation, evidence would need to be provided to demonstrate the equivalence of the newly expressed protein to one that has already previously been safely consumed.

The issue of exposure to the expressed protein was also discussed at the workshop on new plant breeding techniques. If the expressed protein is absent from the parts of the organism consumed as food consideration could be given to waiving the assessment of potential toxicity and allergenicity. This could occur for example in the case of a grafted plant where a transgenic rootstock has been used in combination with a non-transgenic scion. If food is only derived from the scion, and it can be shown that the newly expressed protein does not translocate to the scion, then there will be no need to consider the safety of the expressed protein.

⁵ Cisgenesis involves transferring DNA to a plant where that DNA has been derived from the same species or a cross-compatible species. To qualify as cisgenic, the introduced DNA must comprise a natural genomic fragment containing the gene of interest with its own introns as well as regulatory sequences (promoter, terminator).

⁶ Intragenesis involves the use of donor DNA from the same or a cross-compatible species, however, new combinations of DNA fragments are acceptable, for example using non-native promoters

When assessing the safety of any new proteins, it is important to acknowledge that a large and diverse range of proteins are ingested as part of the normal human diet without any adverse effects. Only a relatively small number of proteins have the potential to impair health. As proteins perform a wide variety of functions in organisms, different possible effects have to be considered during the safety assessment including potential toxic, anti-nutritional and allergenic effects.

Where specific safety studies are undertaken using isolated protein, this protein should ideally be the same as the protein expressed in the new GM organism. If it is not possible to obtain sufficient quantities of protein from the new GM organism for testing, then an equivalent protein produced in a microbial expression system may be used as a substitute. In these circumstances, a range of studies should be undertaken to demonstrate that the microbially expressed protein is structurally, functionally and biochemically equivalent to that expressed in the new GM organism. Collectively, these are referred to as equivalence studies, and they serve to fully characterise the newly expressed protein in the GM organism.

Assessment of potential toxicity

All ingested proteins are subject to the same digestive processes, irrespective of their source or function, including any new proteins expressed in GM foods. Most proteins that are ingested have a predictable metabolic fate. They are typically broken down by proteolytic enzymes in the stomach and small intestine to amino acids and small peptides (di-peptides and tri-peptides), which are readily absorbed.

While the vast majority of dietary proteins are innocuous, a small number may be harmful. Of these, the bacterial toxins (e.g. botulinum toxin) are the best described. A number of toxic or anti-nutritional proteins are also produced by plants, an example being ricin, a highly toxic plant lectin found in the seeds of *Ricinus communis*, commonly known as the castor oil plant.

If the GM food differs from the conventional counterpart food by the presence of one or more new proteins, these proteins should be fully characterised and assessed for their potential toxicity. The main purpose of an assessment of potential toxicity is to establish, using a weight of evidence approach, that the new protein will behave like any other innocuous dietary protein once ingested. If questions remain following this assessment, additional investigation should be undertaken.

An assessment of potential toxicity of a new protein should consider the following:

1. *History of safe use (HOSU)*. This part of the assessment considers whether the new protein has a prior history of safe human consumption. This can be assumed if the protein is identical to proteins present in foods that have a long HOSU. Where amino acid changes have been introduced into the protein but it retains the same biological function as related proteins with a HOSU in food, and the exposure level is similar to functionally related proteins, then the modified protein could also be considered to be sufficiently similar to proteins with a HOSU.
2. *Amino acid sequence similarity between the new protein and known protein toxins and anti-nutrients*. This assessment is typically undertaken using bioinformatic analysis where the amino acid sequence of the new protein is compared to the amino acid sequence of known protein toxins and anti-nutrients in public domain databases. This analysis can demonstrate whether the new protein shares any sequence or structural similarity with proteins already identified as toxins and known to pose toxicological hazards.
3. *Resistance to digestion of the new protein*. This is typically assessed through the use of *in vitro* digestibility studies, particularly pepsin digestion. Evidence of slow or limited protein digestibility does not necessarily indicate a safety concern, however proteins that are resistant to proteolysis may be more likely to be absorbed in a biologically intact form or exert effects directly on the GI tract.

If a new protein is found to have no significant sequence similarity to known protein toxins, is readily digested in validated *in vitro* digestibility tests, is sufficiently similar to proteins that have been safely consumed in food, and its biological function does not raise any safety concerns, it can be reasonably concluded that the protein is non-toxic to humans and no further investigations would be required.

Where results from the protein characterisation and assessment of potential toxicity indicate the need for further investigation, appropriate acute oral toxicity studies in animals might also be considered. The need for, and nature of, such studies should be discussed with FSANZ prior to submitting an application.

Assessment of potential allergenicity

Food allergies are abnormal immunological responses mostly to particular proteins in foods, and are a significant public health concern. Virtually all food allergies are caused by a small number of common allergenic foods including peanuts, soybeans, milk, eggs, fish, crustacea, cereals and tree nuts. These eight foods account for over 90% of all moderate to severe allergic reactions to foods in susceptible individuals.

Although food allergens are generally proteins, the human diet contains many thousands of proteins that are not allergenic. Dietary proteins come from a diverse array of plant, animal and microbial food sources; some of these are staple foods consumed widely around the world, while others are more exotic (e.g. insects) with consumption limited to certain geographical regions. It should be noted that additional protein diversity is sometimes introduced into the food supply through conventional plant breeding techniques. For example, since commercialisation, the conventionally bred kiwi fruit has proven to be an additional source of food allergens.

The consumption of food produced using gene technology can contribute in a defined way to the diversity of proteins in the diet. Consequently, the possible allergenicity of any new protein should be part of the safety evaluation. This should include whether the new protein:

- is one to which certain individuals are already known to be sensitive
- is considered likely to cause an allergic reaction in some individuals.

There are presently no reliable animal models for the assessment of allergenicity, and no single test that can be applied to a protein to predict whether it is likely to be allergenic in humans. The evaluation of new proteins for potential allergenicity was the subject of a Joint FAO/WHO Expert Consultation in 2001 (FAO/WHO 2001b) The outcome of this consultation was subsequently used by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology to develop guidance on the best possible scientific approach to assess protein allergenicity (see e.g. Annex 1 in Codex 2003a). As a result, there is general agreement that a step-wise, weight-of-evidence approach can be used to indicate whether a newly expressed protein is a possible allergen.

The weight of evidence approach takes into account data and information derived from several types of analysis and includes consideration of the following⁷:

1. *Source of the newly expressed protein.* It is important to determine if the source of the protein (i.e. the donor organism) is associated with allergic reactions in humans. Genes derived from sources known to be allergenic would in particular be a focus of investigation.
2. *Amino acid sequence similarity between the newly expressed protein and known allergens.* The amino acid sequences of many allergenic proteins are readily available through public domain databases, which are updated and expanded on a regular basis.

In silico bioinformatic analyses are done to determine the overall level of similarity. The possibility of IgE cross-reactivity between the new protein and a known allergen should be considered when there is greater than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001b; Codex 2009).

⁷ Previously, the level of expression of a novel protein was thought to be an important factor to consider in assessing potential allergenicity (Metcalfe et al. 1996), however very little information currently exists on threshold levels of proteins required for sensitisation and subsequent elicitation of an allergic response. As a consequence, it is currently not possible to consider the level of expression of a novel protein as a relevant factor in the assessment of potential allergenicity. This may change in the future as knowledge improves.

3. *Physicochemical properties of the newly expressed protein.* This includes, but is not limited to, its susceptibility to digestion, heat stability and/or acid and enzymatic treatment.

Resistance to hydrolysis by digestive proteases has been observed in several food allergens (Astwood et al. 1996). The standard test that has been advocated to determine susceptibility to digestion is pepsin hydrolysis (Codex 2003a; Codex 2003b; Thomas et al. 2004). Recent evidence however indicates there may not be a strong association between stability to digestion and allergenicity (Herman et al. 2007) therefore the results of the digestibility assay by itself should not be relied upon as an indicator of allergenicity.

The presence of any post-translational modifications, e.g. glycosylation, and their impact on the allergenic potential of the novel protein would also be a relevant consideration. Glycosylation may affect the susceptibility of a protein to processing and proteolysis and may introduce glycan peptides, which are known to be highly cross-reactive epitopes (FAO/WHO 2001b)

4. *Specific serum screening.* This should be undertaken when a newly expressed protein is derived from a source known to be allergenic or has amino acid sequence similarity with a known allergen.

Specific serum screening involves testing the immunoreactivity of the newly expressed protein against IgE antibodies in sera obtained from individuals with an allergy to the source of the protein, or a known allergen identified in the bioinformatics analysis. Such tests are contingent on the availability of sera from well characterised patients. Additional testing, for example using skin prick tests, may be necessary to confirm a negative result from the serum screening.

The potential exposure to the new protein and the effects of relevant food processing will contribute to an overall conclusion about any human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration to determine whether normal processing would have an effect on the integrity of the protein or remove it altogether from the final food product.

This assessment strategy is not applicable to assessing whether a new protein is capable of inducing gluten-sensitive or other enteropathies. In cases where the introduced gene is obtained from wheat, rye, barley, oats or related cereal grains, newly expressed proteins should be evaluated for any possible role in the elicitation of gluten-sensitive enteropathy.

If the assessment of allergenicity risk results in a conclusion that the newly expressed protein is a potential allergen, FSANZ would take appropriate regulatory action to manage the risk to susceptible population groups. On a case-by-case basis, management could involve mandatory labelling to inform consumers of an identified risk, other measures to limit exposure in vulnerable groups, or could mean the GM food would not be approved.

Other (non-protein) substances

The safety of other (non-protein) substances should be assessed on a case-by-case basis taking into account the identity and biological function of the substance, whether it has previously been safely consumed in food or has a HOSU, and potential dietary exposure. The types of studies or information that might be relevant to the assessment will depend on the substance in question and should be discussed with FSANZ prior to submitting an application.

In cases where RNAi has been used, considerations may include a discussion of the role of any target gene, the expression level of the transcript in various plant parts, and the specificity of the RNAi effect.

Novel herbicide metabolites

In the case of herbicide-tolerant plants, where tolerance is achieved by metabolism of the herbicide, it is possible that one or more novel metabolites may accumulate in the GM plant following the application of herbicide. In these situations, the assessment should consider whether these are present in food products and whether their presence raises any toxicological concerns.

In particular, the assessment should consider if appropriate health-based guidance values (i.e. an Acceptable Daily Intake⁸ or Acute Reference Dose⁹) need to be established.

The assessment will also need to consider residue data in order to confirm the concentration of the novel metabolite relative to the parent herbicide in the final food. The amount of herbicide residue that is allowed to be present on the food however is addressed under a process that is separate from the GM food safety assessment and involves a separate standard (Schedule 20). Residues can only legally be present on food if they comply with specific MRLs. The MRLs apply equally to foods regardless of their source i.e. whether they were produced from non-GM or GM crops. Where necessary, an MRL pertaining to a particular herbicide on a crop may have to be set.¹⁰

Mechanisms of herbicide tolerance that do not rely upon the conversion of the herbicide into herbicidally inactive forms (e.g. where a gene encoding an herbicide insensitive form of an endogenous enzyme has been introduced into the plant), would not be expected to result in the accumulation of novel metabolites.

2.3.5 Compositional analysis

The main purpose of the compositional analysis is to determine if any unintended changes in composition have occurred in the food. Compositional analysis is also used for evaluating deliberate changes to food composition, since it can confirm whether the introduced trait is being expressed appropriately, and quantify the magnitude of the change.

Compositional analysis of food is often limited by available analytical methodologies. It is therefore important that appropriate validated analytical methods are used and referenced and that the sensitivity (e.g. limit of detection and limit of quantitation) is documented (Rogers 2013).

The classic approach to the compositional analysis of GM food is targeted. Rather than analysing every single constituent, which would be impractical, the aim is to analyse only those constituents (analytes) most relevant to the nutritional profile of the food in question. The focus is therefore on key nutrients, natural toxicants and anti-nutrients – components in a particular food that have been identified as important in the context of the diet. They may be major constituents (fats, proteins, carbohydrates or enzyme inhibitors such as anti-nutrients) or quantitatively more minor constituents (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be inherently present in an organism, such as compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes). It is recognised that animals, unlike plants, do not generally contain pathways involved in producing toxins or anti-nutrients and animal metabolites are therefore not considered to raise human health or food safety concerns. There are, however exceptions, particularly with aquatic organisms.

The OECD has developed a series of Consensus Documents¹¹ to aid in the compositional analysis of foods derived from GM plants. These documents provide information on the key constituents for particular crops and also provide baseline data on the concentration range for each constituent. The International Life Sciences Institute (ILSI) has developed a Crop Composition Database¹² that is regularly updated and provides high quality data that can be used to inform the range of levels for important crop analytes in corn, cotton and soybean varieties already in commercial production. To date this database has not included information from commercialised GM lines.

⁸ An estimate of an amount of a chemical substance in food that can be ingested daily over a lifetime without appreciable health risk to the consumer

⁹ The amount of a chemical substance that can be ingested in one day without appreciable health risk to the consumer.

¹⁰ A fact sheet explaining the process for establishing MRLs in Australia and New Zealand can be found on the FSANZ website at <http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx>.

¹¹ <http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonthesafetyofnovelfoodsandfeedsplants.htm>

¹² <https://www.cropcomposition.org/query/index.html>

Depending on the nature of the genetic modification, or the characteristics of a new protein, additional constituents may need to be analysed. This will need to be determined on a case-by-case basis. For example, if a gene is transferred which results in increased production of a particular nutrient (e.g. the amino acid lysine), the levels of other constituents resulting from metabolism of that nutrient should also be determined for comparison with an appropriate comparator.

Analyses of concentrations of key components of the GM food should be compared with an equivalent analysis of food derived from an appropriate comparator (typically this would be the conventional counterpart) produced under the same conditions (see subsection 2.3.1). This may not be feasible in all cases, however a line as close as possible should be chosen. The relevance of any observed differences should be assessed in the context of the range of natural variation for that parameter to determine its biological significance (see subsection 2.3.1).

When the genetic modification results in a food with significant compositional changes, it may be appropriate to select relevant comparator products that are more closely matched in terms of the key nutrient composition in order to assess the nutritional impact of the food (e.g. in the case of high oleic acid soybean oil, olive oil may provide a more suitable comparison than standard soybean oil). Such comparator products should have a history of safe use as food, but they do not need to come from close genetic relatives.

It is important to recognise that food composition is not due entirely to the genes of an organism (germplasm) but is also known to be influenced by numerous environmental factors (Privalle et al. 2013). For example, the mineral composition of many plant-derived foods is heavily influenced by soil type and fertiliser practices. In the case of animals, diet is known to influence the composition of food products. For example, supplementation of the diet of chickens with omega-3 fatty acids has been used to increase the omega-3 content of eggs. Studies for the collection of compositional data should be designed and conducted in such a way as to minimise differences that could be attributed to these external factors.

For GM plants, field trial sites should be generally representative of the range of environmental conditions under which the crop would be grown commercially. Standard agronomic practices should be employed but in addition, a comparison with the GM plant grown under its expected agronomic conditions may need to be considered. The number of trial sites should be sufficient to allow accurate assessment of phenotypic/agronomic characteristics over this range and an adequate number of plants should be sampled. Where the number of trial sites is limited, consideration should be given to repeating the trials over more than one season. Each trial site should include replicates and the treatments should be randomised (e.g. randomised complete block design).

For GM animals, it is recognised that a compositional analysis is likely to require sacrifice of the whole animal in cases where the meat/organ is the food product. In cases where the animal is not sacrificed, the available number of samples for compositional analysis may be limited. A number of different foods may also need to be sampled (e.g. meat, milk, eggs) which adds complexity to the overall compositional analysis. There is likely to be larger variation between individual samples derived from animals, even those bred and raised under the same husbandry conditions and, to date, there are no compositional databases available, as there are for plants, which may provide information on the normal ranges of analytes.

Statistical analysis of the GM line and the comparator should be appropriate to the experimental design and be documented. In addition to supplying raw data, summary descriptive statistics (e.g. mean, standard error) for each analyte in each treatment should be provided. It is also appropriate, but not essential, to provide 95% tolerance intervals. Comparisons to reference and/or literature ranges are made to determine the range of natural variation and to establish the biological significance of any identified statistical differences. Through this process it is then possible to determine whether any statistically significant differences require further investigation.

2.3.6 Nutritional considerations

GM foods that have altered nutritional characteristics should be subjected to additional nutritional assessment in order to investigate the consequences of the introduced changes and determine whether nutrient intakes are likely to be altered by the introduction of such foods into the food supply (Codex 2009).

If necessary, FSANZ will undertake a dietary exposure assessment of the nutrients in the GM food by combining food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food nutrient composition data.

When the modification results in a food product, such as vegetable oil, with a composition that is significantly different from its conventional counterpart, it will be appropriate to use additional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the GM food) as comparators to assess the nutritional impact of the food (see also subsection 2.3.5).

Further assessment of nutritional impact, using information gained from volunteer human studies, will be necessary if changes in the bioavailability of nutrients are expected or if the composition is not comparable to other foods in the food supply. If the assessment indicates the available data are insufficient for a thorough safety assessment, FSANZ will consider the need for additional studies, including whether whole food animal feeding studies are likely to be informative.

2.3.7 Whole food animal feeding studies

Animal toxicity studies with whole GM foods are not routinely required to complete a safety assessment. There is clear evidence that, in a majority of circumstances, a scientifically-informed comparative assessment using a relevant comparator can generally identify any potential adverse health effects or differences in the GM food requiring specific evaluation (Bartholomaeus et al. 2013; Herman and Ekmya 2014). The evidence now accumulated confirms the conclusions of an expert panel convened by FSANZ in June 2007 to develop guidance and recommendations on the possible role of animal feeding studies in assessing the safety of GM foods. A report is published on the FSANZ website¹³.

Notwithstanding this decision, there may be some GM foods, particularly those involving intentional modifications to nutrient composition, where the results of well-designed feeding studies in appropriate animal species may be informative. This would be likely to apply for example to a GM crop developed specifically to improve the nutritional quality of feed for the production of livestock for human consumption, or for use in aquaculture.

The need for whole food studies will therefore continue to be determined on a case-by-case basis, taking into account the nature and purpose of the genetic modification and the results of the compositional analyses and overall comparative assessment. Discussion with FSANZ prior to submission of a data package in support of an application is therefore indicated. It should be noted that studies of any duration in rodents using whole foods would rarely be warranted.

2.3.8 GM microorganisms

Microorganisms can be consumed as foods (e.g. edible cultures) or used for the production of substances added to foods to achieve a technological function. Predominantly, such substances derived from GM microorganisms are subject to regulation as food additives (Standard 1.3.1 and Schedules 14 and 15) or processing aids (Standard 1.3.3 and Schedule 18). Food additives and processing aids undergo a pre-market safety assessment and their use in foods is usually restricted according to their technological function. Unless specifically modified (e.g. by protein engineering), the substance may be indistinguishable from the equivalent, naturally-occurring (nature identical) product. In these instances, the safety assessment of the substance produced from a GM microorganism may therefore be essentially the same as that from a non-GM source, or one that is chemically synthesised.

The GM microorganisms that are typically used to produce food additives and processing aids (e.g. enzymes used in the manufacture of cheese) are generally strains that have a history of safe use in food production. Where the recipient strains do not have a history of safe use, particular attention to the integrity of the consumed substance needs to be applied. This entails a detailed characterisation of the substance and its degree of compliance with established specifications for purity, including consideration of any possible contaminants carried over from the GM production organism.

¹³ <http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx>

The requirement for assessment of a GM microorganism under Standard 1.5.2, is applicable to those microorganisms that are present in foods or constitute the final food e.g. probiotic bacteria, fermentation cultures, etc. The food may contain either viable or non-viable GM microorganisms (e.g. heat-inactivated), or both forms may be present in the food.

Where GM microorganisms remain in or constitute the final food (e.g. lactic acid bacteria in yoghurt) the safety assessment considers:

- *The possibility of gene transfer, including bacterial antibiotic resistance genes, between organisms*
Molecular characterisation of the inserted genetic elements in the GM microorganism allows an assessment of the possible consequences of a transfer of functional DNA to commensal organisms in the human gastrointestinal tract. It is important to establish that strains carrying antibiotic resistance genes are not used, particularly where viable microorganisms are present in the final food. Any indication of the presence of transmissible elements such as plasmids, transposons and integrons containing such resistance genes should be specifically investigated.
- *The possibility of a change in pathogenicity as a result of the genetic modification*
In most cases, the recipient microorganism will have a history of safe use as food. The assessment considers whether the genetic changes could cause a change in the viability of the organism or produce a toxin. A detailed characterisation of the introduced gene/s and gene product/s, together with studies demonstrating the biological effects in the organism address these safety issues.

Permanent, life-long colonisation of the digestive tract by ingested microorganisms is rare, however the possibility remains that an ingested GM microorganism could influence the gastrointestinal microflora of the human host (FAO/WHO 2001a). For this reason, the viability and residence of the GM microorganism may need to be examined. If processing (such as baking) of the final food eliminates viable microorganisms, or if accumulation of end-products toxic to the microorganism (such as alcohol or acids) extinguishes viability, then this scenario need not be examined in any detail.

2.3.9 GM animals

The safety assessment of foods derived from GM animals can largely be performed along the lines that have already been established for food from GM plants, using a comparative safety assessment approach (FAO/WHO 2004).

Given the diverse range of animals used as food (e.g. mammals, birds, finfish and shellfish) and the combined impacts of their genetic diversity, husbandry and conditions under which they are raised or harvested, the assessment framework that has been developed is intended to address the general safety issues that are common to all types of GM animals (Codex 2009). Additional issues that may relate only to one type of animal or species would need to be considered on a case-by-case basis.

In assessing the safety of food from GM animals, the approach takes into account the nature of the DNA construct and its expression products (if any), the health status of the GM animal, and the composition of the food.

In contrast to plants, an evaluation of the health of the animal is one of the essential steps in ensuring the safety of food derived from GM animals. This is because, unlike plants, animals that have a history of safe use as sources of food generally do not contain genes encoding toxic substances. The health of an animal is therefore a useful indicator of food safety and the practice of only allowing animals with an acceptable health status to enter the human food supply is an essential step in ensuring safe food.

In undertaking the health assessment, it is important to compare the health status of the GM animal with the health status of an appropriate counterpart (Section 2.3.1), taking into account developmental stage. The assessment includes consideration of general health and performance indicators, including behaviour, growth and development, general anatomy, and reproductive function (if appropriate), physiological measures, including clinical and analytical parameters and species-specific considerations, where appropriate.

2.3.10 Review of safety assessments

FSANZ routinely monitors and reviews the scientific literature and other information about GM foods to determine if there is any new scientific information that might alter the conclusions of previous safety assessments. This analysis also extends to any new scientific developments in relation to the technology in general which may be relevant to the safety assessment approach. These reviews are available from the FSANZ website¹⁴.

FSANZ also liaises with other Australian and New Zealand food agencies to maintain a watching brief on any potential safety issues with internationally traded foods whether GM or not. This ensures that appropriate action can be initiated by relevant agencies if necessary to prevent unsafe or non-compliant food from entering the food supply or, if already present, to have the food removed.

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2.4 Maximum residue limits for agricultural and veterinary chemicals

The table to section S20—3 in Schedule 20 lists the maximum permissible levels of agricultural and veterinary chemical residues in food. These are known as maximum residue limits or MRLs. The Schedule applies in Australia only. Australia and New Zealand independently and separately develop limits for agricultural and veterinary chemicals in food.

Where required for trade, FSANZ's processes currently allow consideration of harmonising with an MRL established by Codex or in some cases by a regulatory authority in a recognised jurisdiction. FSANZ recognises that agricultural chemicals are used differently among production regions as product use patterns, pests and diseases and environmental factors differ internationally. Where residues do not pose health or safety concerns, MRLs in the Code may be varied in line with international standards or trading partners' standards to reflect requirements for foods containing legitimate residues to be imported.

FSANZ has two mechanisms available to advocate specific limits for inclusion in the Code: the MRL proposal route and the MRL application route. For both processes, key issues for FSANZ are the safety, legitimacy and justification for the presence of the residues in food in accordance with good agricultural practice. The assessment considers whether residues may occur in food as a result of legitimate use of chemical products. That is, whether the active/s are permitted to be used in producing the relevant food in the source country or countries; whether residues are expected to occur as a result of this use; whether the source country and importing countries have determined MRLs or equivalent standards; and whether the food is imported to Australia. FSANZ's assessment also considers other relevant MRLs internationally and whether in the context of the Australian diet, consuming residues of the chemical that may occur in the food is within health-based guidance values (HBGVs). The relevant details should be provided to FSANZ.

The MRL proposal route is the usual process where FSANZ considers harmonisation requests. Each request must meet specific criteria in order for it to be included, such as HBGVs being available by the Office of Chemical Safety of the Australian Government Department of Health or the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues (JMPR). Data requirements for the dietary exposure assessment may include 'Highest Residue' and 'Supervised Trial Median Residue' data accepted by JMPR. Another requirement is that the requested commodity must be produced in the country/region in which the MRL is set. FSANZ generally considers one MRL proposal each year. A guide for submitting requests for MRL proposals is provided on the FSANZ website at <http://www.foodstandards.gov.au/publications/Pages/Guide-for-Submitting-Requests-for-MRL-Proposals.aspx>.

MRL applications provide an alternate route for the assessment of MRL requests, and may be prepared when the information requirements for a proposal are unable to be met in a timely manner, or to expedite consideration of a harmonisation request. The information that is required includes that specified in the guide for MRL proposals, and additional information requirements are considered on a case-by-case basis. This may include: data to support how MRLs or HBGVs have been established in other countries, details of the significance of the market and the cost impacts of the lack of adequate MRLs in the Code for the food. FSANZ will discuss the specific requirements with applicants where this approach is appropriate.

Please contact MRL.Contact@foodstandards.gov.au if you have any questions relating the MRL proposal process, or standards.management@foodstandards.gov.au if you have any questions relating to MRL applications.

Part 3

Application guidelines

Subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (Cth) (FSANZ Act) provides that an application for the development or variation of a food regulatory measure **must**, amongst other things:

- be in the form specified in the application guidelines; and
- include all the information specified by the Application guidelines.

The application guidelines set out at this Part 3 of the *Application Handbook* are guidelines made by legislative instrument in accordance with subsection 23(1) of the FSANZ Act.

For the purposes of these guidelines, an **application** includes all documents provided to FSANZ in support of the development or variation of a food regulatory measure.

The guidelines outline requirements related to each of the groups of standards in the following list. Applications to vary the Code will generally, but not exclusively, relate to one or more of the following groups of standards. In many cases, an application may seek a change that means the information requirements of several guidelines must be met:

- standards related to labelling and other information requirements
- standards related to substances added to food
- standards related to contaminants and natural toxins
- standards related to new foods
- standards related to special purpose foods or standardised foods
- standards related to food production

Each of these broad groups of standards contains a number of individual food standards which relates to specific food matters. For each, there will be different information requirements. Applicants should identify the guidelines that are relevant to their particular application.

An example of when more than one guideline might apply is where an application involves adding a nutritive substance to infant formula. In this case, the information requirements for Guidelines 3.1.1 – General requirements, 3.3.3 – Substances used for a nutritive purpose and 3.6.2 – Special purpose food – Infant formula products, would be relevant.

In the case of Chapter 3.2, Applicants should begin with the Guideline on general food labelling, which contains general requirements for an application related to labelling. The other guidelines relate to particular aspects of labelling, which may or may not be relevant to a particular application.

Boxed text such as notes or examples in these application guidelines provide additional information or clarification of requirements outlined in the guidelines only. They do not form part of the guidelines.

Chapter 3.1

General requirements for applications

3.1.1 General requirements

The application **must** contain the information specified in this Guideline (3.1.1) and as appropriate, the information indicated in Chapters 3.2–3.7.

Note:

Consultation with FSANZ

Applicants are strongly advised to consult with FSANZ prior to submitting an application to ensure that the application contains all the necessary information relevant to the proposed food regulatory measure or variation to a food regulatory measure. On-going consultation with FSANZ throughout the application process is also encouraged.

Industry and consumer groups are also encouraged to bring to the attention of FSANZ food standards issues which may require attention through means other than via an application.

Mandatory information requirements

The word '**must**' is used in these guidelines to identify information must be included in an application. Applicants should note that if this information is not provided, the application may be rejected at the administrative assessment stage. Rejection will not preclude an applicant from re-lodging the application at a later date.

Non-mandatory information requirements

The word '**should**' is used in these Application guidelines to identify information which, though not required to be included in an application, may assist FSANZ in its assessment. Failure to provide this information will not result in rejection of an application at the administrative assessment stage. However, the information may be requested during assessment of the application.

There may be occasions where the information required or recommended for inclusion in an application by these Application guidelines is not sufficient to allow FSANZ to properly assess an application. In such situations, pursuant to section 108 of the FSANZ Act, FSANZ may request additional information from an applicant.

Drafting

It is recommended that applicants not include proposed drafting in their application. It is FSANZ's responsibility to determine what the appropriate drafting should be for the food regulatory measure in response to an application. To enable FSANZ to prepare appropriate drafting, applicants are expected to outline in general terms the change(s) to the Code that they consider are required to secure the outcomes they want. This can include mentioning the relevant sections of the Code and the matters that any amended or new provisions need to cover or address. Providing explicit drafting in an application may limit that application's scope and make its assessment more difficult. If proposed drafting is included in an application, in the absence of an express request in the application to include that drafting in the Code, FSANZ will proceed on the basis that that drafting is not being sought by the applicant, but is provided only as an example of how the Code might be amended.

A Form of the application

A.1 Language

The application **must** be in English.

Note:

FSANZ will accept supporting information of high relevance to the application in a language other than English that is accompanied by a full English translation.

A.2 Format

The application should contain a table of contents. The table of contents should use the heading titles for the guidelines that are relevant to the application.

The application **must** contain an executive summary of the application. The executive summary **must** be provided as an electronic file separate from other parts of the application.

Information contained within the application must clearly identify all parts of the relevant guideline(s) to which they relate.

The application **must** be numbered sequentially on each page.

A.3 Copies

The application **must** be submitted electronically. The application **must** not be sent by facsimile.

The application should be provided on a thumb drive, CD or other device, as an attachment to an email or through the FSANZ website.

Unless these Application guidelines state otherwise, the application **must** include full electronic copies of all references referred to in the application.

The application should be searchable by word and phrase.

Note:

Before any application is formally lodged, ensure all documents are able to be opened by checking on a different computer to the one which was used to create or burn them on CD. This will help ensure that documents that are corrupted or have other problems which prevent FSANZ access, are not provided.

If under 20 MB, or via a compressed file if larger than 20 MB, the application can be emailed to the Standards Management Officer at applications@foodstandards.gov.au or sent by post or courier to either of the following addresses:

Standards Management Officer
Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Standards Management Officer
Food Standards Australia New Zealand
Ground Floor
Boeing House
55 Blackall Street
BARTON ACT 2600
AUSTRALIA

B Applicant details

The application **must** contain the following contact details:

- (a) applicant (individual or organisation's) name
- (b) name of contact person
- (c) address (street and postal)
- (d) telephone number
- (e) email address
- (f) nature of applicant's business

- (g) details of other individuals, companies or organisations associated with the application.

C Purpose of the application

The application **must** contain a statement regarding the purpose of the application. To the extent possible, the application should identify existing food regulatory measure(s) that need to be varied to achieve the intended purpose of the application. For applications that relate to a matter dealt with under Chapters 3.2–3.7, the purpose of the application relevant to any particular guidelines **must** be provided.

D Justification for the application

The application **must** provide information to indicate why a food regulatory measure is proposed. Such information may, depending on the purpose of the application as outlined according to requirements in section C of this Guideline (3.1.1), include:

- (a) the need for the proposed change
- (b) the advantages of the proposed change over the status quo, taking into account any disadvantages.

Note:

The following general issues should be considered:

- (a) any public health and safety issues related to the proposed change including details of target groups and population groups that may be adversely affected
- (b) any consumer choice issues related to the proposed change
- (c) any evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change.

The application **must** also contain details of the status of similar applications made in other countries by the applicant, if applicable.

D.1 Regulatory impact information

The application **must** include current information and data on the following costs and benefits:

D.1.1 Costs and benefits of the application

This may include:

- (a) the cost and benefits to the consumer e.g. health benefits
- (b) the costs and benefits to industry and business in general, noting any specific effects on small businesses e.g. savings in production costs
- (c) the costs and benefits to government e.g. increased regulatory costs.

Costs and benefits **must** be quantified in monetary terms wherever possible, or where this is not possible, other quantitative measures and qualitative evidence **must** be provided.

Reference must be made to other sections of the application that contain detailed supporting information, where necessary.

Note:

If the OBPR makes a decision that a RIS is required, FSANZ must meet the OBPR's information requirements. In such a case, FSANZ may need to request further information from an applicant before the assessment of the application can continue.

D.1.2 *Impact on international trade*

This may include information on the impact of the proposed change on international trade.

E Information to support the application

The application **must** contain sufficient supporting information or data to enable the objectives specified in section 18 of the FSANZ Act to be addressed. This includes all information relevant to the consideration of the safety of a substance.

Note:

Where the application relates to matters referred to in Chapters 3.2–3.7, please refer to the relevant guideline for specific information requirements. In some instances more than one guideline may apply.

E.1 Data requirements

Note:

The term '**data**' in this document refers, among other things, to units of information; facts; observations; or results of an experiment, study or survey.

FSANZ will assess all the available data presented in support of an application.

Wherever the data requirements are mandatory but cannot be met, a reason should be provided.

When a literature search is undertaken, the application **must**:

- (a) list the databases and journals searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, CINAHL, Cochrane Library, or the Australian Medical Index etc)
- (b) provide the criteria used to specify the search, such as the key words, the time period of the search, and any other limiting criteria
- (c) list all of the papers identified in the search
- (d) list and provide in full all of the papers included as the basis of the evidence in the application. Summaries of study findings and papers are not adequate.

Note:

Useful guidelines on undertaking literature searches can be found at <http://www.nhmrc.gov.au/publications/synopses/cp65syn.htm>.

The data underpinning the evidence to support the Application should also:

- (a) identify the source, author(s) and year the data was produced
- (b) be obtained using validated or standardised methods, where these are available. Standardised methods should be validated for accuracy and reproducibility, and declare the sensitivity and specificity of the method where appropriate
- (c) be representative of the Australian and New Zealand populations
- (d) be analysed using appropriate statistical techniques.

E.1.1 Data related to safety studies

- (a) Studies submitted for safety assessment purposes should be designed and conducted in accordance with the principles and intent of good laboratory practice (GLP). For safety assessments of chemicals, reference should be made to the following:
- (i) OECD Principles on Good Laboratory Practice
<http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm>
 - (ii) relevant OECD Guidelines for the Testing of Chemicals
<http://www.oecd.org/env/ehs/testing/>
 - (iii) other recognised test guidelines such as:

US Food and Drug Administration Redbook 2000 *Toxicological Principles for the Safety Assessment of Food Ingredients*
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm>.
- (b) All studies conducted for a regulatory purpose should be accompanied by evidence of a quality control/assurance program or evidence of independent auditing of the conduct and reporting of the study.
- (c) Studies should contain full details of the conduct of the study and its results, including raw data where appropriate.

E.1.2 Data related to surveys on chemicals or other substances in food

- (a) The survey design and method should be clearly enunciated along with the findings and the conclusions. Where surveys are designed to be targeted or selective, the basis for doing so should be clearly stated.
- (b) The survey should use a design that avoids biasing the results. The target population should be identified, and the sample frame described in terms of the target population. The survey should have a sample size that provides sufficient power to detect an effect. The sampling method used (e.g. simple random sampling, cluster sampling) should be described, and the reason for the method provided. Any deviations from the sampling method should be identified and the reasons for deviation provided. Data analysis and reporting should be consistent with the sampling method. If any observation/case is excluded from data analysis, the reason for exclusion should be defined and reported.
- (c) Surveys should include evidence of quality control/assurance systems. Information on limits of reporting should also be included.

E.1.3 Data related to epidemiological/intervention studies in humans

- (a) Epidemiological/intervention studies should include comprehensive detail about:
- (i) **the study design** e.g. randomised controlled trial, cohort study, nested case-control study
 - (ii) **the objectives or hypothesis**
 - (iii) **the sample size in the study groups** including the numbers in each group that were recruited, randomised, completed the study, and included in the analyses, and any power calculations
 - (iv) **the participants' characteristics** including age, sex, setting, health status
 - (v) **the methodology** including duration of intervention (or study) and period of follow-up, measurement of outcomes and confounders, statistical analysis
 - (vi) **the study results** including effect size and statistical significance, any adverse effects.

- (b) The studies should have a sample size that provides sufficient power to detect an intended effect.

Note:

Examples of the main types of intervention and epidemiological study designs include:

Intervention (experimental) studies:

- clinical trials
- field trials
- individual level
- aggregated level (community trials)

Observational (non-experimental) studies:

- cohort studies
- case-control studies
- cross-sectional surveys
- routine data-based studies:
 - individual level data
 - aggregated level data (ecological studies)

Note:

A number of resources exist which provide guidance on how to report research methods and findings. These resources specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular, issues that might introduce bias into the research. Most widely recognised guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field, including research methodologists and journal editors. These resources are all available online. A list of links to useful resources is provided below:

- (i) [Equator Network](http://www.equator-network.org/index.aspx?o=1032): overview of reporting guidelines
<http://www.equator-network.org/index.aspx?o=1032>
- (ii) [GRADE](http://www.jclinepi.com/content/jce-GRADE-Series): Grades of Recommendation, Assessment, Development, and Evaluation
<http://www.jclinepi.com/content/jce-GRADE-Series>
- (iii) [CONSORT Statement](http://www.consort-statement.org/): Consolidated Standards Of Reporting Trials
<http://www.consort-statement.org/>
- (iv) [PRISMA Statement](http://www.prisma-statement.org/) (formerly QUOROM): Preferred Reporting Items for Systematic Reviews and Meta-Analyses
<http://www.prisma-statement.org/>
- (v) [STARD Statement](http://www.consort-statement.org/resources/downloads/other-instruments/): Standards for Reporting Studies of Diagnostic Accuracy
<http://www.consort-statement.org/resources/downloads/other-instruments/>
- (vi) [MOOSE Statement](http://www.consort-statement.org/index.aspx?o=1347): proposal for reporting meta analyses of observational studies in epidemiology
<http://www.consort-statement.org/index.aspx?o=1347>
- (vii) [STARLITE Statement](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1629442/pdf/i1536-5050-094-04-0421.pdf): Standards for Reporting Literature searches
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1629442/pdf/i1536-5050-094-04-0421.pdf>
- (viii) [STROBE Statement \(& STREGA\)](http://www.strobe-statement.org/): STrengthening the Reporting of OBservational studies in Epidemiology.
<http://www.strobe-statement.org/>

F Assessment procedure

If related to a variation to the Code, the application **must** provide details as to what an applicant considers is the appropriate procedure to be adopted in assessing the application i.e. general, minor, major or high level health claim variation. This is a requirement under paragraph 22(2)(e) of the FSANZ Act. As a matter of practice, FSANZ has regard to the applicant's suggestion, but makes its own determination on the process to be adopted. The process to be adopted by FSANZ will be communicated to FSANZ in accordance with section 27(c) of the FSANZ Act.

Note:

FSANZ makes the final determination on the appropriate procedure and cost recovery level (based on the number of hours estimated for the assessment) during the administrative assessment, taking account of the purpose and complexity of the application.

G Confidential commercial information (CCI)

Any information that the applicant considers to be CCI **must** be identified as CCI. This information **must** be separated from the other parts of the application (both electronically and in hard copy).

The application **must** be accompanied by a written explanation of why and how that identified information is CCI. That is, how that information satisfies the definition of CCI in section 4 of the FSANZ Act.

The application **must** be accompanied by provide a non-confidential general summary of any information that they consider to CCI. That summary **must** be sufficiently detailed for it to be useful for assessment. This allows FSANZ to address the information in general terms as part of the assessment.

Note:

FSANZ may not accept an applicant's claim that information is CCI. In such a case, if FSANZ is satisfied that the information is not CCI, FSANZ will advise the applicant that it does not consider that the material is protected by section 114 of the FSANZ Act.

FSANZ will deal with CCI in accordance with section 114 of the FSANZ Act. Applicants should note that section 114 allows CCI to be disclosed to third parties in certain circumstances.

FSANZ will provide CCI to advisory committees or groups established by FSANZ to provide it with expert advice and analysis on an as needs basis, for example, information relating to analytical methods. The members of such advisory committees and groups are subject to the same confidentiality requirements of the FSANZ Act as FSANZ staff.

H Other confidential information

Applications **must** identify all non-CCI information that the applicant wishes to be treated as confidential.

That information **must** be separated from other material provided to FSANZ and be marked 'Confidential'. It **must** be accompanied by a written statement detailing the reasons as to why the applicant wishes that information to be treated as confidential. For example, disclosure of the information would be detrimental to the applicant or the information is not publicly available and known only to a limited number of people.

Applicants who provide unpublished manuscripts **must** indicate whether or not the author is aware that the manuscript has been provided to FSANZ.

Note:

The fact that FSANZ agrees to accept information on a confidential basis does not mean that that information cannot be made public or disclosed to others. FSANZ can be required by law, Parliament and the courts to disclose information provided to it on a confidential basis.

If applicants have concerns about personal information contained in an application being published by FSANZ on its website, they may wish to provide a redacted version of the application, in addition to the required complete electronic version of that application. FSANZ will then decide whether to publish the redacted version instead of the complete version.

I Exclusive capturable commercial benefit (ECCB)

The applicant should indicate whether or not the application is expected to confer an exclusive capturable commercial benefit. The applicant should provide a justification for their assertion to assist FSANZ in making a decision.

Note:

Consideration of the circumstances surrounding the application, including the following factors, may help in determining whether or not an ECCB is conferred:

- Why are you making this application? What are you hoping to get out its approval?
- How will you benefit from the approval of your application?
- Who besides you, will benefit from the approval of your application? How and why will they benefit?
- If your application is approved, whose permission will be required before anyone can derive a benefit from that approval?
- Who holds the intellectual property in the subject matter of your application?

J International and other national standards**J.1 International Standards**

The application **must** contain details of any Codex Alimentarius Commission (Codex) Standards relevant to the application.

Note:

This information is required since one of the five additional objectives to which FSANZ must have regard is *the promotion of consistency between domestic and international standards*.

Codex standards are regarded as the international standards related to food by the World Trade Organization (WTO). Information on Codex Alimentarius can be found at <http://www.fao.org/docrep/w9114e/w9114e00.htm>.

A list of current official Codex standards can be found at http://www.codexalimentarius.net/web/standard_list.do?lang=en.

Both Australia and New Zealand, as members of the WTO, must comply with the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary (SPS) Agreements of the WTO.

J.2 Other national standards or regulations

The application should contain details of relevant standards or regulations in other countries with comparable regulatory processes, where available.

K Statutory declaration

The application **must** contain a signed statutory declaration that includes the following statements:

1. *The information provided in this application fully sets out the matters required.*
2. *The information provided in this application is true to the best of my knowledge and belief.*
3. *No information has been withheld that might prejudice this application, to the best of my knowledge and belief.*

A statutory declaration provided on behalf of a body corporate **must** be made by a senior officer of that body corporate who is authorised to make the declaration on its behalf. The senior officer **must** state their name and source of knowledge and authority in making the statutory declaration and include a sufficient explanation of who they are (name, address, organisation/employer, position).

Templates for Australian and New Zealand statutory declarations are provided on the FSANZ website at <http://www.foodstandards.gov.au/code/changes/applying/Pages/Statutory-declaration.aspx>.

Note:

For overseas applicants, FSANZ will accept signed equivalent documents from other countries (in English).

L Checklist

More than one guideline may apply to an application. The application **must** contain completed checklists for all relevant guidelines with regard to format and information requirements relevant to the application (*see Appendix 1*).

Page numbers **must** be included with the checklist as indicated in the Appendix.

Note:

An example of when more than one guideline might apply is where an application involves adding a nutritive substance to infant formula. In this case, the checklists for Guidelines 3.1.1 – General requirements, 3.3.3 – Substances used for a nutritive purpose and 3.6.3 – Special purpose foods – Other foods, would be relevant.

Chapter 3.2

Guidelines for applications for labelling and other information requirements

3.2.1 General food labelling

An application to vary the Code is required to change the many aspects of food labelling that are detailed in Part 1.2 – Labelling and other information requirements. This includes both the information contained on the label and the way in which this information is presented on the food product, including the conditions that govern such information.

The following information is required to support an application related to food labelling. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

Additional information may be required if the application relates to one or more of the following:

- (a) warning and advisory statements
- (b) declaration of allergens
- (c) labelling for consumer information and choice
- (d) nutrition information labelling
- (e) nutrition content and health claims.

The additional information requirements relating to the above matters are outlined in Guidelines 3.2.2–3.2.6.

A General information to support the proposed labelling change

The application **must** contain the following information:

A.1 A description of the proposed labelling change

This includes detailed information on the proposed labelling change, and should indicate the Standards and clauses which will be affected.

A.2 A list of the foods or food groups likely to be affected by the proposed change

This includes details of the specific foods or food categories affected by the proposed change.

Note:

Specific food categories include packaged or unpackaged food, food intended for restaurants, food intended for catering purposes, food intended for retail sale and food not intended for retail sale. Additional information on likely foods to be exempted from proposed labelling would also be useful.

B Information related to the potential impact on consumer understanding and behaviour

The application **must** contain the following information:

B.1 Information to demonstrate consumer support of the proposed labelling change

This includes information (possibly consumer research data) to show that the issue(s) underlying the proposed labelling change are significant to consumers. This also includes information on which consumer groups will be affected and the number of consumers affected.

B.2 Information to demonstrate that the proposed labelling change will be understood and will assist consumers

This includes consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

B.3 *Information to demonstrate that the proposed labelling change will not have any adverse health or diet impacts on any population groups (e.g. age or cultural groups)*

Note:

The extent of the impact of a food labelling change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the labelling change
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

Also, there may be situations where consumer impact from the proposed labelling is not required e.g. where there is an identified public health benefit associated with the labelling change, or where the impact is on industry rather than consumers.

3.2.2 Warning and advisory statements

An application to vary the Code is required to include or change the mandatory warning and advisory requirements that are listed in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations or Schedule 9 – Mandatory advisory statements.

Note:

Warning statements are generally reserved for well-characterised, potentially life-threatening public health and safety risks where the target population is unaware of the potential risk and a prescribed labelling statement is needed to alert consumers. Advisory statements may be used to advise the general population or a specific target population of potential public health and safety risks associated with a food.

The following additional information is required to support an application to include or change a mandatory warning or advisory statement in relation to a food or food ingredient.

This information is in addition to that specified in Guideline 3.1.1 – General requirements and 3.2.1 – General food labelling. Declaration of allergens is considered under Guideline 3.2.3.

A Additional information related to the safety of the food or food ingredient

The application **must** contain the following information:

A.1 Data to indicate that the food or food ingredient presents a potential health concern to one or more population groups

This includes one or more of the following types of information:

- (a) epidemiology studies on the target population group(s)
- (b) clinical studies on individuals from the target population group(s)
- (c) case studies of affected individuals
- (d) reports adverse food-medicine interactions in individuals
- (e) reports of safety studies in experimental animals

Note:

The nature of the target population will vary with the particular potential health concern. Examples of mandatory advisory statements can be found in the Code in the table to section S9—2. Examples of mandatory warning statements and declarations can be found in sections 1.2.3—3, 4 and 5 in the Code.

B Additional information related to consumers' awareness of a potential public health and safety risk associated with the food

The application **must** contain the following information:

B.1 Data to indicate that one or more consumer groups are unaware of the public health and safety risk

This includes one or more of the following types of information:

- (a) currently available information regarding use and consumption of the food
- (b) reports of epidemiology studies or case studies of consumers being at risk through consumption of the food or food ingredient
- (c) data from consumer surveys indicating a potential risk associated with the use of the food or food ingredient.

3.2.3 Declaration of allergens

An application is required to vary the Code to include or change the requirements for mandatory declaration of certain foods or food ingredients, which are listed in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations.

A Additional information to support addition of an allergen to the list of declared foods

The following additional information is required to support an application to add an allergenic food on the list of foods in the Standard which are required to be declared on the label. This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

The application **must** contain the following information:

A.1 Information to demonstrate the food causes an IgE-mediated allergy

This includes clinical data associating IgE-mediated allergic reactions with the specific food including one or more of the following:

- (a) patient history
- (b) skin testing
- (c) double-blind placebo-controlled food challenges (DBPCFC).

A.2 Information on the incidence in the population of allergic reactions to the food

This includes published data or data derived from allergy clinics on the incidence of allergic reactions to the food in the population.

A.3 Information on the severity of the allergic reaction to the food in relation to the amount of food consumed

This includes clinical reports on the range of symptoms associated with the allergic reaction and an estimate of the amount of food that may provoke these symptoms.

A.4 Information on the extent of use in the food supply and the range of food containing the allergen

This includes information on the quantity of the allergen in the food supply and an indication of the range of foods where it is used. As much as possible, projections for extended use in the immediate and near future should also be included.

B Additional information to support removal of a food derivative from the list of declared foods

The following additional information is required to support an application to exclude a derivative of an allergenic food from the list of foods in the Standard which are required to be declared on the label. This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

The application **must** contain the information in sections B.1–4 of this Guideline (3.2.3). Data **must** also be provided in accordance with subsection B.5 if the information derived from sections B.1–4 is insufficient to conclude that the food derivative should be exempted from declaration on the label.

B.1 Information on the nature of the food derivative

This includes a specification for identity and purity for the food derivative, including data on the level of protein in the derivative.

B.2 Information on the use of the food derivative and its presence in the final food

This includes information on how the food derivative is used in foods and the range of foods in which it is used.

B.3 Information on the level of dietary intake of the food derivative

This includes information on dietary intake for different population groups.

B.4 Information on the history of safe use of foods containing the food derivative

This includes information on the range of foods containing the food derivative and reports of any allergic reactions to these foods.

B.5 Clinical information on the safety of the food derivative, if applicable

This includes clinical challenge studies where the food derivative is tested in individuals who are sensitised to the source of the food derivative.

3.2.4 Labelling for consumer information and choice

An application is required to vary the Code to include or change the labelling requirements which are in place to provide adequate information and allow consumer choice.

Note:

Certain food labelling is directed towards:

- (i) providing adequate information in order to allow consumers to make to an informed choice; or
- (ii) preventing misleading and deceptive conduct by food manufacturers. Such labelling could be in relation to a public health and safety matter or the need for additional information to give consumers confidence in the food regulatory system. This is sometimes referred to as a 'market failure'.

In the case of deceptive conduct to mislead the consumer, this would be dealt with under Australian Consumer Law, rather than through a variation to the Code.

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of GM, irradiated or novel foods, or other foods using new technologies, the relevant Policy Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take the Policy Guideline into consideration.

The following additional information is required to support an application related to food labelling for consumer information and choice.

This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

A Additional information related to assisting consumers to make an informed choice

The application **must** contain the following information:

A.1 Information to show that the current labelling, or lack of labelling, or information from alternative sources does not allow consumers to make an informed choice

This includes information to show that consumers have a limited ability to make an informed choice based on the information provided on the label and that consumers are unable to source the necessary information from alternative sources.

A.2 Information to show that there are no, or a limited number of, suitable substitute products in all food categories currently available to consumers

A.3 Information to show that the proposed specific labelling change will assist consumers to make an informed choice or will provide alternative labelling that will not hinder consumers from making an informed choice

This includes information on the proposed specific labelling change and consumer research data to demonstrate the appropriate consumer response to the proposed change, or data from an overseas market where the proposed labelling is currently used.

A.4 Information to demonstrate that, in the absence of the proposed labelling, alternative measures to address the issue would not be effective

This includes information on one or more of the following alternative measures:

- (a) voluntary labelling (e.g. endorsement or product approval programs)
- (b) self-regulation (e.g. codes of practice)
- (c) other legislative measures (e.g. trade practices)
- (d) national manufacturing standards (including those developed by Standards Australia)

Note:

The Code should be read in conjunction with other applicable laws, such as the Australian Consumer Law (Commonwealth legislation) and the New Zealand and State and Territory Fair Trading Acts. The provisions in these Acts, particularly relating to conduct which is false, misleading or deceptive, apply to the supply of food in trade and commerce.

The prevention of misleading or deceptive conduct is one of the primary subsection 18(1) objectives in the FSANZ Act that must be satisfied by FSANZ in developing or varying a food standard.

The ACCC is responsible for ensuring compliance with the Australian Consumer Law. The substantive provisions of the Australian Consumer Law are expressly limited to activities undertaken by corporations, subject to certain exceptions and qualifications. State and Territory fair trading laws are not subject to these constitutional limitations, and so fill the gaps left by the limited application of the Australian Consumer Law. The Code is usually given legal force through State legislation and is enforced by the States and Territories and by the Australian Government at the border.

3.2.5 Nutrition information labelling

An application is required to vary the Code to change the labelling requirements which are in place to provide nutrition information.

The following additional information is required to support an application related to food labelling for nutrition information.

This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

A Additional information to support a change to the nutrition information labelling of a food

The following additional information is required to support an application to include or remove nutrition information on a food label or to change the way in which the label currently displays the nutrition information.

The application **must** contain the following information:

A.1 A description of how the proposed labelling will change the nutrition information labelling of the food

This includes detailed information on the nature and intent of the proposed labelling change, and should indicate the foods or food categories which will be affected.

If applicable, this also includes information on how the proposed labelling of a specific nutrient or energy will affect the declaration of related nutrients.

A.2 Data to demonstrate that the proposed labelling change will assist consumers to make an informed choice and will not mislead them

This includes consumer research data or data obtained from an overseas market where the proposed labelling is in place, to demonstrate the anticipated consumer response to the proposed change.

If applicable, this also includes information to show that alternative measures to provide the nutrition information are not, or would not, be effective.

B Additional information to establish or vary an energy factor of a food ingredient

The application **must** contain the following information to support the establishment of an energy factor for a new food ingredient or to vary an energy factor for an existing food ingredient.

B.1 Information on the nature and composition of the food ingredient

This includes information related to the identity and purity of the food ingredient. If it is a mixture of ingredients, this should identify the relative proportions of each, together with information related to the variability between commercial batches and the batch tested for the various energy measurements.

B.2 Details on the calculation of the energy factor

This includes details on the calculation of the proposed energy factor for a food ingredient. This calculation **must** follow the following equation. Energy factors based on other calculation methods will not be considered.

$$ME = GE - FE - UE - GaE - SE$$

where

ME means **metabolisable energy**

GE means **gross energy** (as measured by bomb calorimetry).

FE means energy lost in **faeces**.

UE means energy lost in **urine**.

GaE means the energy lost in **gases** produced by fermentation in the large intestine.

SE means the energy content of waste products lost from **surface areas**.

The application **must** include the following information set out in (a)–(e) relating to the calculation of the food ingredient's energy factor.

- (a) The components and result of the equation (**ME, GE, UE, FE, GaE and SE**) expressed in kilojoules per gram of food ingredient.
- (b) The proportion (as a percentage) of gross energy per gram of original food ingredient lost through each of **FE, UE, GaE and SE**.

For example: 30% of the food ingredient is lost in faeces, and the GE of the food ingredient is 16 kJ/g, therefore FE = 4.8 kJ/g (0.3 x 16 kJ/g).

- (c) A calculation of either the total **FE** or a sum of its individual components such that $FE = uFE + mFE + oFE$. The individual FE components are the energy lost from:

uFE: the proportion of the food ingredient that is excreted unchanged in the faeces

mFE: the excretion of microbial mass in faeces that is produced from the proportion of the food ingredient that reaches the large intestine and is fermented

oFE: the excretion into the faeces of other produced substances from the proportion of the food ingredient that escapes absorption, such as short chain fatty acids or other metabolites.

- (d) The proportion of the food ingredient that reaches the large intestine and is fermented, for use in calculations of **mFE, oFE or GaE**. This amount should be calculated either by:
- (i) a direct measurement of the percentage of the food ingredient that reaches the large intestine and is fermented; or
- (ii) subtracting measured amounts of the food ingredient that are excreted unchanged in the faeces (uFE) from amounts that are *not* absorbed in the upper intestine (jejunum and duodenum).
- (e) The use or otherwise of default values for one or more of **mFE, oFE, GaE or SE**. Default values are listed in the following table:

	For ingredients fermented or partly fermented in the large intestine	For ingredients not fermented in the large intestine
mFE (as a % of the ingested food ingredient that is fermented in the large intestine)	30	Not applicable
oFE (as a % of the ingested food ingredient that is fermented in the large intestine)	0	Not applicable
GaE (as a % of the ingested food ingredient that is fermented in the large intestine)	5	Not applicable
SE (as a % of the ingested food ingredient)	0	0

If default values are not used for mFE, oFE, GaE of fermented food ingredients, or for SE, then the value for that respective component of the energy factor equation **must** be substantiated.

B.3 Substantiation of the proposed energy factor of the food ingredient

The application **must** include specific details on how each of the individual components (GE, UE, FE, GaE, and SE) of ME has been determined, and the scientific evidence and methods used to substantiate these individual values.

Note:

It is acceptable to use multiple scientific methods to substantiate the individual components of the energy factor calculation. The following is a list of methods (not exhaustive) that are acceptable for estimating the individual components of ME:

- (a) **bomb calorimetry – GE**
The GE of food ingredients, metabolites and excreta is determined as the heat of combustion, as measured by adiabatic bomb calorimetry. This is the only acceptable method for determining GE.
- (b) **classical dietary energy balance – FE and UE**
This method measures the energy excreted in faeces (FE) and urine (UE) following the ingestion of a known amount (and GE) of the food ingredient. The method involves careful measurement and control of intake for at least several days, preceded by a period of habituation, together with collection of urine and faeces for the equivalent period. It is acceptable for this method to use animal or human subjects, although coprophagy must have been eliminated during rat studies. This method is best suited to measurements of food ingredients that are not fermented in the large intestine and which do not produce gas. However, it is acceptable to use this method for food ingredients that are fermented in the large intestine if it is combined with other methods that measure the percentage of the food ingredient that is fermented (or gas production directly).
- (c) **isotopic tracer methods – FE, UE, upper intestinal absorption, large intestinal fermentation**
These methods involve the use of isotopically labelled substrates (e.g. ^{13}C or ^{14}C) and measure the percentage of the given dose that is recovered in metabolised form (e.g. in CO_2 in breath), in unmetabolised (urine) form, or undigested (faeces) form. It is acceptable to combine this method with other techniques to provide adjunct information on intestinal absorption (e.g. analysis of blood glucose fluctuations or other metabolites) and fermentation (breath hydrogen). It is also acceptable to use studies in germ free animals to provide comparative data that calculates the amount of the food ingredient fermented in the large intestine.
- (d) **breath hydrogen test – GaE, large intestinal fermentation**
The breath hydrogen response is a reflection of the nutrients fermented in the large intestine, and is also suitable for use in estimating GaE. A common form of the test is to measure basal breath H_2 obtained after a dose of lactulose compared with the breath H_2 after a dose of the test food ingredient.
- (e) **ileal intubation and ileostomy effluent – small intestinal absorption, large intestinal fermentation**
Ileal intubation involves the insertion of a nasogastric tube and sampling the digestive matter in the terminal ileum. Ileostomy studies involve subjects who have had their large bowel surgically removed and in whom digestive excreta (from the end of the small bowel) is collected in a plastic bag. The results of these studies may not be quantitatively representative of normal physiologic status, but they are able to provide a direct estimate of upper intestine absorption by measuring small bowel content at the terminal end of the ileum. Combined with faecal excretion, ileal intubation is also able to provide an indirect measure of the proportion of the food ingredient that reaches the large intestine and is fermented.

B.4 Information on other factors that affect the calculation of the energy factor

The application **must** include information on the following matters where relevant:

- (a) justification for and limitations of the evidence and methods used to substantiate the individual components of the energy factor equation
- (b) whether the GE of the food ingredient is constant or varies with different proportions of constituent compounds
- (c) any variation in the digestion and absorption related to the variation in the composition of the food ingredient
- (d) effects of habituation/adaptation to consumption of the food ingredient
- (e) dose dependency
- (f) the nature of the background diet (e.g. high or low in one or more of fat, fibre or protein)
- (g) individual variability.

3.2.6 Nutrition content and health claims

The following information is required to amend Standard 1.2.7 – Nutrition, health and related claims, Schedule 4 – Nutrition, health and related claims, or Schedule 6 – Required elements of a systematic review. This information is required in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

This Guideline (3.2.6) is divided into two parts. Section A addresses the application requirements for amendments to Standard 1.2.7. Section B is for applications to add a new food-health relationship to the table to section S4—4 (high level health claims) or to the table to section S4—5 (general level health claims) in the Code.

Note:

Applications to make a change in Schedule 4 to the list of high level health claims in section S4—4 and to add a general level health claim to section S4—5 are required to be considered using the high level health claim variation procedure. Other applications seeking to amend Standard 1.2.7 will be assessed using the general, minor or major procedure as applicable. If a single application seeks a high level or general level health claim variation as well another variation, then FSANZ will automatically progress the different variations under separate applications, each using the relevant procedure.

A Amendments to Standard 1.2.7 or Schedule 4, other than adding new food-health relationships to the tables to sections S4—4 and 5

A.1 Information related to nutrition content claims in the table to section S4—3

If the application relates to nutrition content claims in the table to section S4—3, the following information **must** be provided:

- (a) consideration of the following in relation to any proposed changes to the claim conditions related to the property of food and each descriptor:
 - (i) the nutrient composition of foods likely to carry the nutrition content claim as described in response to subsection A.2 in Guideline 3.2.1
 - (ii) any relevant reference values pertaining to the property of food
 - (iii) whether the conditions are achievable in the Australian and New Zealand food supply.

If the application is for new claim conditions for a property of food not already mentioned in Schedule 4, the application must include a robust analytical method suitable for analytical laboratories to use for detecting and quantifying the property of food in a food.

A.2 Information related to the amendment of an existing high level or general level health claim in the table to S4—4 or the table to S4—5

If the application seeks to vary the food, property of food or the health effect of an existing high level or general level health claim, the application **must** meet the requirements in Section 2 of this Guideline. If the application seeks to delete an existing high level or general level health claim from the tables to S4—4 or S4—5, then it **must** contain sufficient detail to justify why the relationship should not be regarded as causal.

If the application seeks to vary the conditions in Column 5 of the tables to sections S4—4 or S4—5 relating to the food or property of food that is the subject of the food-health relationship, then it **must** contain sufficient detail about the relationship to allow an effective amount of the food or property of food to be determined. Information about the likely dietary intake of the food or property of food by the target group (if there is one) or by the whole population **must** also be provided.

A.3 Information related to the amendment of the nutrient profiling scoring criterion or method in Schedules 4 or 5 of Standard 1.2.7

If the application seeks to vary the nutrient profiling scoring criterion or method in Schedules 4 or 5, the following information **must** be provided:

- (a) a description of the variation(s) to Schedules 4 or 5, including any food category and other definitions that are to be introduced
- (b) a detailed analysis of the impact of the proposed variation on the food eligibility that would occur if the proposed variation was implemented. The analysis **must** include a range of different types of foods illustrative of those in the market in Australia and New Zealand, not solely the foods of interest to the applicant. It **must** include:
 - (i) a description of how the applicant selected the range of foods examined, including how their nutrient and other relevant compositional characteristics were determined
 - (ii) a description of how the eligibility status of the range of foods tested was affected when evaluated under the current requirements and under the proposed variation.

FSANZ may request the applicant to supply the dataset containing the range of foods analysed in a form that enables FSANZ to review the data referred to in paragraph A.3(b) of this Guideline (3.2.6).

A.4 Information related to variation of the required elements of a systematic review in Schedule 6

If the application seeks to vary any of the required elements of a systematic review as described in Schedule 6, the application **must** provide sufficient information to support the proposed variation, including an indication about how the proposed variation will deliver an equivalent level of rigour in evaluating the scientific information.

B Amendments to add food-health relationships to the tables to sections S4—4 or S4—5

If the application seeks to add a new food-health-relationship to either the tables to sections S4—4 or S4—5, the application **must** include suitable data, as described below, to assess the nominated food-health relationship and to permit determination of appropriate conditions for a claim based on the relationship.

If the application seeks to vary a food-health relationship already listed in the Code (Columns 1 and 2 in the tables to sections S4—4 or S4—5), then this is equivalent to a new relationship and appropriately suitable data **must** be provided, as outlined below.

B.1 The scope of the food-health relationship

B.1.1 A clear description of the food or property of food in the food-health relationship

The application **must** clearly characterise the food group, the food (e.g. genus, species, variety) or property of food that is the subject of the proposed health effect.

Note:

The food or property of food (see for example, Column 1 in the tables to sections S4—4 or S4—5) may include:

- a food group (e.g. fruit)
- a single ingredient food (e.g. banana)
- a food with more than one ingredient (e.g. chewing gum, bread)
- a property of food that may either be added or inherent (e.g. a nutrient, ingredient, a component of an ingredient, such as dietary fibre, or other substance or feature of food).

If the food or property of food is a substance or a novel food, a permission to add the substance to food or introduce a novel food must be present in the Code. If there is no permission in the Code for the substance or novel food, a simultaneous application may be required because the processes to amend the relevant standards are different.

There can be concurrent, but separate, applications for both a new substance or novel food and a new food-health relationship.

If a property of food is the subject of the food-health relationship, the application **must** also include:

- (a) a summary of the source and specifications of the property of food
- (b) if permission to add the property of food to food is already in the Code, evidence to confirm that the property of food under consideration is the same as already in the Code
- (c) a description of the relative bioequivalence of the property of food when consumed in different food matrices, or of a relevant aspect of bioequivalence such as bioavailability or bioconversion
- (d) a robust analytical method suitable for analytical laboratories to use for detecting and quantifying the property of food in the foods in which it is present.

B.1.2 A clear description of the health effect in the food-health relationship

The application **must** detail the health effect of the food or property of food and how it is measured.

B.1.3 A clear description of the proposed food-health relationship

The application **must** contain a summary of the food-health relationship including the amount of food or property of food required to achieve the health effect, the nature and extent of the health effect, including its direction, and the target population group.

B.2 Identifying and filtering literature for the proposed food-health relationship

The application **must** contain the information in either subsections B.2.1 or B.2.2 of this Guideline (3.2.6), whichever applies. Only original literature involving humans can be used as a basis to establish a food-health relationship or update an existing systematic review.

B.2.1 A clear description of the search strategy used for food-health relationships examined using original literature only

If the proposed food-health relationship is being examined using the original literature, the application **must** contain a clear description of the search strategy used to capture the scientific evidence. This includes:

- (a) identification of the electronic databases (e.g. Medline, CINAHL, Cochrane Library, Embase and PsycINFO etc.) used for the search
- (b) the search parameters including search terms, time period and languages
- (c) justification for excluding the use of any closely related and search terms
- (d) reasons for choosing a specified time period
- (e) other restrictions placed on the search (e.g. language and study design)
- (f) a description of any manual (non-electronic) search techniques employed, including hand-searching, and the strategy used to identify any unpublished studies
- (g) a list of inclusion and exclusion criteria used to filter the literature
- (h) the number of studies identified from the search strategy, and number of studies excluded at each stage (Title filter, abstract filter and full-text filter) of filtering
- (i) a list of the publications (includes author, reference and publication details) excluded at the full text screening stage, and for each excluded publication, the reason(s) why it was considered not relevant (e.g. the inclusion criteria that were not met).

Note:

If a completed literature search yields a very large number of articles (e.g. 500) it is suggested using the inclusion and exclusion criteria to filter studies by reading the titles, then read the abstracts to screen those left, and then finally screen with full-text reading.

The following data sources are not suitable:

- articles published in newspapers, magazines, or newsletters
- books or book chapters for consumers or the general public
- information intended for the general public on the internet, such as Wikipedia.

A relationship between a food or property of food and a health effect cannot be established from animal and *in vitro* studies alone. However, animal and *in vitro* studies may be provided in support of a relationship.

B.2.2 Food-health relationships based on updating existing systematic reviews

Where the proposed food-health relationship is based on an existing systematic review, the application **must**:

- (a) demonstrate that the food-health relationship described in the existing systematic review is based on the same, or is within the scope of, the proposed food-health relationship
- (b) demonstrate that the existing review includes all relevant data from human studies (i.e. evidence in favour, equivocal evidence and evidence that is not in favour of the food-health relationship) given the time period and search criteria that it used
- (c) include a full copy of the existing systematic review
- (d) describe how the existing systematic review was updated.

Note:

The comparability with the methods of the existing systematic review could be demonstrated by showing that the updating search was done using the same criteria (i.e. points in paragraphs B.2.1 (a)–(f) and B.2.2(a)–(b) above) that were described by the authors of an existing review. It is important to include the time period covered by an existing review and show how the updated review complements the existing review.

B.3 Summarising literature for the proposed food-health relationship

The application **must** summarise the studies in humans for the proposed food-health relationship in tabular form, including objectives, sample size, participant characteristics, measurement methods, control for confounding, results and any adverse effects. If an existing systematic review is being updated, the tabulation **must** include studies from the existing systematic review as well as additional literature identified in the update. If the tabulation in the existing review covers all the items, then it is acceptable to reproduce the table(s) from the existing review, or to expand them if one or more items are missing.

Each study **must** be assessed for quality. A description of the quality assessment method used **must** be provided.

Note:

Presentation of data from human studies

Relevant data from each of the included studies should be presented in tabulated form. Original studies (i.e. not reviews or pooled/meta-analyses) should be organised according to study design (e.g. intervention/experimental studies, observational studies) into one or more tables. Tables should include the following information for each study:

- (a) the study reference: reference by author/date for each study
- (b) the study design: e.g. randomised controlled trial, cohort study, nested case-control study
- (c) the objectives or hypothesis
- (d) the sample size in the study groups: including the numbers in each group who were recruited, randomised, completed the study, and included in the analyses, and any power calculations. Include loss to follow up or non-response
- (e) the participants characteristics: including age, sex, setting, health status, background diets (including use of supplements if relevant) and other relevant aspects of lifestyle
- (f) the method used to measure the food or property of food including amount consumed: including additional dietary intake (including methodology for this), method and frequency of consumption, form of substance including the food matrix (where applicable), amount consumed per day, duration of intervention (or study) and period of follow-up
- (g) confounders measured and method used to control for confounding
- (h) the method used to measure the health effect
- (i) the study results, including effect size and statistical significance
- (j) any adverse effects.

Where an application is based on an existing systematic review, data from the studies included in the existing review and the additional studies that update the review should be organised in one or more tables and provide the information listed under a-j above.

Updates of existing reviews should include commentary about how the update affects the conclusions drawn by the authors of the existing reviews.

Empirical analysis of the data

A meta-analysis of the data can be undertaken. This may add to the weight of evidence in support of the food-health relationship.

B.4 Assessment of the data from human studies

The application **must** include a scientific assessment about how the studies reviewed demonstrate, with a high degree of certainty, that a causal relationship exists between the food or property of food and the health effect.

Note:

Whether a causal relationship is likely to be established depends on the totality and weight of evidence that supports the proposed food-health relationship under investigation. The evidence would include consideration of a consistent association across all high quality studies that are independent of other factors, inclusion of well-conducted trials temporality and biological plausibility. It may be useful to consider if the relationship could be reversed by at least one additional high quality study.

B.5 Information for setting conditions

The application **must** contain sufficient detail about the relationship to allow the amount of the food or property of food that is necessary to achieve the health effect, to be determined. Information about the likely dietary intake by the target population group (if there is one) or the whole population of the food or property of food **must** also be provided.

If the proposed food-health relationship covers a wider target population group than the groups studied (for example, a wider age-sex range than covered by the included studies), the application **must** include justification of the validity of the extrapolation."

Chapter 3.3

Guidelines for applications for substances added to food

3.3.1 Food additives

An application to vary the Code is required to approve the use of a new food additive in the food supply or to change the permissions for a currently used food additive. Permissions for use of food additives are specified in Schedule 15 – Substances that may be used as food additives.

The substance or preparation assessed should be representative of the commercial product for which approval is sought. A statement to that effect must be made in the application. If this situation is not the case for any of the relevant studies then a justification and explanation is required.

The following information is required to support an application for a new permissions to use a food additive or to change the permissions for a currently used food additive. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Technical information on the food additive

The application **must** contain the following technical information:

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For food additives, the relevant Guideline is the Addition to Food of Substances other than Vitamins and Minerals. Since food additives perform a technological purpose in food the specific order policy principles relevant for food additives are the five listed under Technological Function within this Guideline.

FSANZ will have regard to these policy principles during the assessment of the application. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take the Policy Guideline into consideration.

A.1 Nature and technological purpose of the additive

This includes information related to the technological purpose of the food additive and includes the following specific information:

- (a) each of the technological purposes listed in Schedule 14 – Technological purposes performed by substances used as food additives that the additive fulfils
- (b) the reason why the food additive is needed to fulfil these purposes in each of the foods in which it is proposed to be used
- (c) evidence that the amounts proposed to be added are consistent with achieving the technological purpose
- (d) if the food additive is a preservative, data to demonstrate its effectiveness in each of the food groups in which it is proposed to be used
- (e) information is required on how the food additive is incorporated homogeneously and stably into the different food matrices to which it is proposed to be added.

Data should also be provided to address losses of the substance from the foods during normal shelf life conditions.

A.2 Information to enable identification of the additive

This includes the chemical name (according to both Chemical Abstracts (CA) and the International Union of Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and Chemical Abstract Service (CAS) registry number. For new food additives, a common name should be proposed.

For additives that are not single chemicals, the name should describe the additive as completely as possible. The sources of the additive should be provided, together with either sufficient compositional data to accurately identify the additive, or reference to its common name in other publications used by regulatory agencies. For additives that are derived from animals, plants or microorganisms, the source should be provided.

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

This 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 purpose or may relate to a difference in toxicity, the application **must** include information on particle size, size distribution, and morphology, as well as any size-dependent properties.

A.4 Information on the impurity profile

This includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the additive preparation. Where possible, impurities should be identified by their CA or IUPAC names.

A.5 Manufacturing process

This includes a description of the method of manufacture of the food additive.

A.6 Specification for identity and purity

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If there is no published specification in one of the identified sources, a detailed specification **must** be provided. Specifications should include information on the name of the food additive, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods of determining purity.

Information is also required for the presence of known allergens (see section 1.2.3—4 in the Code) in the commercial product.

A.7 Information for food labelling

This includes information on the class of the food additive and, if available, the code number for the additive.

A.8 Analytical method for detection

An analytical method **must** be provided for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used.

This includes information on available methodology for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used. The application **must** include a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

A.9 Potential additional purposes of the food additive when added to food

This includes a brief description about any additional purposes, such as a nutritive or health-related purpose, of the food additive at the levels proposed to be added.

B Information related to the safety of the food additive

Note:

FSANZ will undertake a safety assessment using the detailed study reports, where possible, of all animal and human toxicity studies related to the food additive and, if applicable, establish an acceptable daily intake (ADI) for the food additive, if the studies are suitable for this purpose.

An application for a food additive **must** contain the following information:

B.1 Information on the toxicokinetics and metabolism of the food additive and, if necessary, its degradation products or major metabolites

- (a) For an application for a new food additive, this includes detailed reports of all studies conducted in animals or humans to examine the metabolic fate of the food additive and, if necessary, its degradation products or major metabolites.
- (b) For an application to extend the use of a currently permitted food additive, reports of the studies conducted since the last safety evaluation by FSANZ should be included. If no previous evaluation by FSANZ is available, published papers or a comprehensive review article on this matter should be included.

B.2 Information on the toxicity of the food additive and, if necessary, its degradation products and major metabolites

- (a) For an application for a new food additive, this includes reports of all *in vitro* and *in vivo* studies conducted in animals or humans to examine the toxicity of the food additive and, if necessary, its metabolites or degradation products.

The application should address the following categories of studies:

- (a) acute toxicity
- (b) short-term toxicity
- (c) long-term toxicity and carcinogenicity
- (d) reproductive toxicity
- (e) developmental toxicity
- (f) genotoxicity
- (g) special studies, such as neurotoxicity or immunotoxicity

Where data are not available or are not considered relevant to the safety assessment of the additive, an explanatory statement **must** be provided.

- (b) For an application to extend the use of a currently permitted food additive, this need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ.

B.3 Safety assessment reports prepared by international agencies or other national government agencies, if available

This includes safety assessment reports prepared by JECFA (unless provided under subsection B.2 of this Guideline (3.3.1)) or by other national or supranational agencies responsible for food safety.

C Information related to the dietary exposure to the food additive

Note:

FSANZ may undertake a dietary exposure assessment for all food additive applications requesting changes to permissions in Schedule 15 using a custom-made computer program, HARVEST, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys, together with food chemical concentration data derived from either the proposed levels of use, the current permissions for use specified in the Code, analytical data derived from surveys or data on use provided by the manufacturers. The information required to undertake this assessment will be derived from different sources, including the application.

The application **must** contain the following information:

C.1 *A list of the food groups or foods proposed to contain the food additive, or changes to currently permitted foods*

The food list should be based on the food group descriptions in the table to S15—5.

C.2 *The maximum proposed level or the concentration range of the food additive for each food group or food, or the proposed changes to the currently permitted levels*

C.3 *For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption*

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children's NNS (5–14 years).

The application should contain the following information:

C.4 *The percentage of the food group in which the food additive is proposed to be used or the percentage of the market likely to use the food additive*

This includes information based on projected uptake or market share data for foods likely to contain the food additive. This can be based on a similar market in another country.

C.5 *Information relating to the use of the food additive in other countries, if applicable*

This includes information on the foods or food groups in which it is used and the use levels.

C.6 *For foods where consumption has changed in recent years, information on likely current food consumption*

This includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data, or sales data, or on a similar market in another country.

3.3.2 Processing aids

An application to vary the Code is required to approve the use of a new processing aid or to change the permissions for a currently used processing aid. Permissions for use of processing aids are specified in Schedule 18 – Processing aids.

The substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect must be made in the application. If this situation is not the case for any of the relevant studies then a justification and explanation is required.

The following information is required to support an application for a new processing aid or to change the permissions for a currently used processing aid. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For processing aids, the relevant Guideline is the Addition to Food of Substances other than Vitamins and Minerals. Since processing aids perform a technological function during the manufacture of food the specific order policy principles relevant for processing aids are the five listed under Technological Function within this Guideline.

FSANZ will have regard to these policy principles during the assessment of the application. The Policy Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined in this section take the Policy Guideline into consideration.

A Technical information on the processing aid

The application **must** contain the following information:

A.1 Information on the type of processing aid

This includes a brief description of the processing aid, the category (if any) in Schedule 18 into which it falls and evidence that the form and the amount of the processing aid performs the intended purpose.

The various functions performed by processing aids are listed in the relevant sections in Schedule 18.

A.2 Information on the identity of the processing aid

This includes the chemical name (according to both Chemical Abstracts (CA) and the International Union for Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and CAS registry number. For enzymes, this includes the name and source of the enzyme together with the Enzyme Commission (EC) number. If the enzyme is from a genetically modified microbial source, this includes both the host and donor organism, including alternative names for the microbial source, if applicable, and a statement as to whether or not the enzyme has been protein-engineered.

For new processing aids, a common name should be proposed. Where relevant, this information should support the evidence that the amounts proposed to be added are consistent with achieving the technological purpose.

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

This includes details of the chemical and physical properties that make it suitable as a food processing aid.

Information on how the food additive is incorporated homogeneously and stably into the different food matrices to which it is proposed to be added should be provided. Data should also be provided to address losses of the substance from the foods during normal shelf life conditions.

The application **must** include information on possible interactions of the processing aid with different foods. If the processing aid is an enzyme, the application **must** include information on its technological purpose, including enzymatic properties.

Where the substance, in the form in which it will be present in food, is particulate in nature, the application **must** include information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

A.4 ***Manufacturing process***

This includes a description of the method of manufacture of the processing aid.

Information is required to address whether the manufacture of the processing aid results in carry-over of allergens or gives rise to any food safety issues. This should cover both the processing aid and, if relevant, other substances that are inherently part of the commercial product (for example, preservatives in a processing aid preparation).

For enzymes, detailed information on the manufacturing process **must** be provided, including any recombinant DNA techniques used to prepare genetically modified organisms used as an enzyme source.

A.5 ***Specification for identity and purity***

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If a published specification is not available, a detailed specification **must** be provided. Specifications should include information on the name of the processing aid, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods for determining purity.

The presence of known allergens (see section 1.2.3—4 in the Code) in processing aid preparations **must** be identified

A.6 ***Analytical method for detection***

Where a processing aid or breakdown or by-products of a processing aid are likely to be present in the final food, an analytical method **must** be provided to detect and quantify the amount(s). Such an analytical method should be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code. This information is not required in the case of an enzymatic processing aid.

B **Information related to the safety of a chemical processing aid**

The application **must** contain the following information:

B.1 ***General information on the industrial use of the chemical***

This includes any information on non-food industrial uses for the chemical, particularly where the information is relevant to human safety.

B.2 ***General information on the use of the chemical as a food processing aid in other countries***

This includes any information on the use of the chemical as a processing aid in other countries, particularly where the information is relevant to human safety.

B.3 Data on the toxicokinetics and metabolism of the chemical processing aid and, if necessary, its metabolites

- (a) For an application for a new chemical processing aid, this includes detailed reports of all studies conducted in animals or humans to examine the metabolic fate of the processing aid and, if necessary, its major metabolites; particularly when a residue of the chemical processing aid or its metabolites is expected in the final food.
- (b) For an application to extend the use of a currently permitted processing aid, this includes only the reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, published papers and /or a comprehensive review article on this matter should be included.

B.4 Information on the toxicity of the chemical processing aid and, if necessary, its major metabolites

- (a) For an application for a new chemical processing aid, this includes detailed reports of all *in vitro* and *in vivo* studies conducted in animals or humans to examine the toxicity of the chemical processing aid and, if necessary, its metabolites; particularly when a residue of the chemical processing aid or its metabolite is expected in the final food.

The application should address, as a minimum, the following categories of studies:

- (a) acute toxicity
- (b) short-term toxicity.

The application should also address the following categories of studies, if data are available:

- (a) long-term toxicity and carcinogenicity
- (b) reproductive toxicity
- (c) developmental toxicity
- (d) genotoxicity
- (e) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are not considered relevant to the safety assessment of the additive, an explanatory statement **must** be provided.

- (b) For an application to extend the use of a currently permitted chemical processing aid, this need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this should include reports of any evaluation by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) or equivalent expert group.

B.5 Safety assessment reports prepared by international agencies or other national government agencies, if available

This includes safety assessment reports prepared by JECFA (unless provided under subsection B.4 of this Guideline (3.3.2)) or by other national or supranational agencies responsible for food safety.

C Information related to the safety of an enzyme processing aid

The application **must** contain the following information:

C.1 General information on the use of the enzyme as a food processing aid in other countries

This includes any information on the use of the enzyme as a processing aid in other countries, particularly where the information is relevant to human safety.

C.2 Information on the potential toxicity of the enzyme processing aid

This includes the following for all enzymatic processing aids:

- (a) information on the enzyme's prior history of human consumption and its similarity to proteins with a history of safe human consumption
- (b) information on any significant similarity between the amino acid sequence of the enzyme and that of known protein toxins.

In the case of an enzyme which does not have a history of safe human consumption, or where there is significant similarity between the amino acid sequence of the enzyme and that of a known protein toxin, the following additional information **must** be provided:

- (c) information on the stability of the enzyme to degradation in appropriate gastric and, if applicable, intestinal model digestion systems.

In the case that the enzyme is tested for stability and found to be stable, the following data **must** be provided:

- (d) Acute or short term oral toxicity studies in a rodent species.

Where data are not considered relevant to the safety assessment of the enzyme, an explanatory statement **must** be provided.

There is no requirement to routinely conduct acute or short term oral toxicity studies or genotoxicity studies on enzyme processing aids. However, if such data already exists, it should also be provided.

C.3 Information on the potential allergenicity of the enzyme processing aid

Note:

The information provided in this subsection will enable FSANZ to consider whether:

- (a) the enzyme is one to which certain individuals may already be sensitive; and
- (b) an enzyme new to the food supply is likely to elicit allergic reactions in some individuals.

This includes the following for all enzymatic processing aids:

- (a) the source of the enzyme processing aid
- (b) an analysis of similarity between the amino acid sequence of the enzyme and that of known allergens.

In the case of an enzyme derived from an allergenic source, or where there is significant similarity between the amino acid sequence of the enzyme and that of a known allergen, the following additional information **must** be provided:

- (c) information on the stability of the enzyme to degradation in appropriate gastric and, if applicable, intestinal model digestion systems.

In the case that the enzyme is tested for stability and found to be stable, the following data **must** be provided:

- (d) specific serum screening.

Information on whether the enzyme has a role in the elicitation of gluten-sensitive enteropathy **must** also be provided if the enzyme has been obtained from wheat, rye, barley, oats, or related cereal grains.

Where data are not considered relevant to the assessment of potential allergenicity of the enzyme, an explanatory statement **must** be provided.

C.4 *Safety assessment reports prepared by international agencies or other national government agencies, if available*

This includes safety assessment reports prepared by JECFA or by other national or supranational agencies responsible for food safety.

D **Additional information related to the safety of an enzyme processing aid derived from a microorganism**

The application **must** contain the following additional information:

D.1 *Information on the source microorganism*

The information provided should include the production strain and the strains from which it was originally derived. Information should also be provided on where the wild-type strain is normally found. Any other information on the taxonomy of this strain which would help its characterisation should be provided. It should be stated if the production strain is currently used in food enzyme production.

The information provided should also contain the production method used.

D.2 *Information on the pathogenicity and toxicity of the source microorganism*

This includes information to demonstrate that the strain of the source microorganism is non-pathogenic and non-toxicogenic. If the enzyme is from a fungal source, the application **must** include information to demonstrate that the strain does not produce toxicologically significant amounts of mycotoxins.

D.3 *Information on the genetic stability of the source organism*

This includes information to demonstrate that the strain of the source microorganism does not undergo strain drift and that the culture conditions can be applied consistently between batches. The steps which are taken to ensure strain stability should be provided, such as tests for morphological, growth and production characteristics of the strain.

E **Additional information related to the safety of an enzyme processing aid derived from a genetically-modified microorganism**

The application **must** contain the following additional information:

E.1 *Information on the methods used in the genetic modification of the source organism*

This includes information on the nature of the genetic modification and the steps used to construct the final production strain.

The application should provide, as a minimum, the following information:

- (a) a full description of the gene construct, including information on the size, source and function of all genetic components, including marker genes
- (b) full details of any modifications to the DNA or amino acid sequence of the enzyme
- (c) a full description of the final production strain, including the steps and methods used to construct it, the integration site (plasmid or chromosome) of the introduced gene and organisation of all inserted genetic material
- (d) information on the stability of the inserted gene.

F Information related to the dietary exposure to the processing aid

Note:

FSANZ may undertake a dietary exposure assessment for processing aid applications when a residue of the processing aid or its metabolites is expected in the final food. This assessment will be undertaken using a custom-made computer program, HARVEST, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys, together with food chemical concentration derived from analytical data on the level of the processing aid or its metabolite in the final foods. The information required to undertake this assessment will be derived from different sources, including the application.

The application **must** contain the following information:

F.1 A list of foods or food groups likely to contain the processing aid or its metabolites

The food list should be based on the food group descriptions in the table to S15—5.

F.2 The levels of residues of the processing aid or its metabolites for each food or food group

The chemical identity of the residue **must** be stated.

F.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children's NNS (5–14 years).

The application should contain the following information:

F.4 The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid

This includes information based on projected uptake or market share data for foods likely to contain the processing aid or its metabolites.

F.5 Information relating to the levels of residues in foods in other countries

This includes information on the food groups or foods in which the processing aid is used and any relevant concentration data for its metabolites.

F.6 For foods where consumption has changed in recent years, information on likely current food consumption

This includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data or sales data or on a similar market in another country.

3.3.3 Substances used for a nutritive purpose

An application to vary the Code is required to approve the use of a new nutritive substance or to change the permissions for use of a nutritive substance. The use of a nutritive substance in food is achieved by the addition of that substance to food.

Note:

If the substance or ingredient intended to be added to food is not to be used as a nutritive substance, it may be regarded as a novel food substance and considered under Guideline 3.5.2 – Novel foods. A nutritive substance may also be regarded as a novel food, in which case both guidelines will apply.

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written Policy Guidelines formulated by the Forum.

In the case of an application to add vitamins or minerals to food, either through voluntary or mandatory fortification, the relevant Policy Guideline is the Fortification of Food with Vitamins and Minerals.

For applications relating to substances other than vitamins or minerals, the relevant Policy Guideline is the Addition to Food of Substances other than Vitamins and Minerals.

The Policy Guidelines are available at
<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined in this section take each Policy Guideline into consideration.

The following information is required to support an application for use of a new nutritive substance or to change the permissions for a use of a nutritive substance. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Information on the use of the nutritive substance

A.1 Information on the purpose of the use of a nutritive substance in food

The application **must** state all of the purpose(s) of the use of the nutritive substance in food. If such a substance has multiple purposes or functions then these must all be briefly described.

When the purpose for using a nutritive substance in food (including special purpose foods) relates to a nutritional purpose to deliver a potential beneficial physiological or health-related outcome, the application **must**:

- (a) include a brief description of all of the physiological or health-related function(s) of the substance at the proposed level
- (b) be stated in a way that can be measured i.e. as an outcome in clinical studies

A.2 General data requirements for supporting evidence

The nutritive substance assessed should be representative of the commercial product on which approval is sought. A statement to that effect **must** be made in the application. If this situation is not the case for any of the relevant studies, then a justification and explanation **must** be provided.

Studies provided as evidence to support an application **must** contain sufficient detail to enable an independent assessment of the methods and results to confirm the study conclusions. The scientific evidence for a potential beneficial physiological or health-related-outcome **must**:

- (a) be based on studies conducted on human subjects
- (b) be based on foods or food groups which contain the nutritive substance rather than the use of the substance alone
- (c) relate to normal use by the target population group and the foods must contribute to the demonstrated nutritional role relevant to that target population.

Note:

Refer to section E in Guideline 3.1.1 for further information regarding data quality.

B Technical information on the use of the nutritive substance

For an application to extend the use of a nutritive substance, this **must** indicate that the technical information required in subsections B.1–B.7 in this Guideline (3.3.3) meets the current identity and purity specifications.

The application **must** contain the following technical information:

B.1 Information to enable identification of the nutritive substance

This includes the chemical name (according to both Chemical Abstracts (CA) and the International Union for Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and CAS registry number. For biologically-derived nutritive substances, the source should be provided.

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

This includes detailed chemical and physical properties of the nutritive substance that are important for understanding how the substance is incorporated into the requested food matrices. Specifically, information and data **must** be provided on how the substance is incorporated in a uniform manner into the food matrices. Studies on the stability of the incorporated substance in particular detailing losses during food processing and storage to the end of shelf life **must** be provided for the different food matrices.

In cases where particle size is important to achieving the nutritive purpose or may relate to a difference in nutritional status or toxicity, the application **must** include information on particle size, size distribution, and morphology, as well as any size-dependent properties.

B.3 Information on the impurity profile

This includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the nutritive substance preparation. Where possible, impurities should be identified by their CA or IUPAC names.

B.4 Manufacturing process

This includes a description of the method of manufacture of the nutritive substance.

B.5 Specification for identity and purity

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If a published specification is not available, a detailed specification should be provided.

B.6 Analytical method for detection

This includes a method for detection and quantification of the nutritive substance or its degradation products in the foods in which it is proposed to be used. The application **must** include a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

B.7 Information on the proposed food label

This includes details of the proposed labelling statements relating to the presence of the nutritive substance in the food.

C Information related to the safety of the nutritive substance

Note:

FSANZ will undertake an assessment of all available reports of animal and human toxicity studies related to the nutritive substance, where appropriate, and, if possible, establish a safe level of intake, or assess the safety of the use of the nutritive substance at the levels proposed in the food. Where an upper level of safety (UL) has been established, this will be considered. The NHMRC publication *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes* contains ULs for a range of vitamins and minerals. This publication can be found at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>.

The application **must** contain the following information:

C.1 Information on the toxicokinetics and metabolism of the nutritive substance and, if necessary, its degradation products and major metabolites

For an application for use of a new nutritive substance, this includes published reviews or individual study reports on the metabolic fate of the nutritive substance and, if necessary, its degradation products and major metabolites.

For an application to extend the use of a currently permitted form of a nutritive substance, this need only include the studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this should include published papers or a comprehensive review article on this matter.

C.2 Information from studies in animals or humans that is relevant to the toxicity of the nutritive substance and, if necessary, its degradation products and major metabolites

- (a) For an application for the use of a new nutritive substance, this includes published reviews or detailed reports of all *in vitro* and *in vivo* studies conducted in animals or humans to examine the toxicity of the nutritive substance and, where necessary, its metabolites or degradation products.

The following categories of studies need to be considered:

- (a) acute toxicity
- (b) short-term toxicity
- (c) long-term toxicity and carcinogenicity
- (d) reproductive toxicity
- (e) developmental toxicity
- (f) genotoxicity
- (g) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are not considered relevant to the safety assessment of the nutritive substance, an explanatory statement should be provided.

- (b) For an application to extend the use of a currently permitted form of a nutritive substance, this need only include the original reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, published papers or a comprehensive review article on this matter should be included.

C.3 Safety assessment reports prepared by international agencies or other national government agencies, if available

This includes safety assessment reports prepared by the WHO or by other national or supranational agencies responsible for food safety or public health.

D Information on dietary intake of the nutritive substance

Note:

FSANZ may undertake a dietary exposure assessment for all nutritive substance applications using a custom-made computer program, HARVEST, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys, together with food nutrient concentration data derived from naturally-occurring concentrations, proposed levels of use, the current permissions for use specified in the Code, analytical data derived from surveys or data on use provided by the manufacturers. The information required to undertake this assessment will be derived from different sources, including the application.

The application **must** contain the following information:

D.1 A detailed list of the food groups or foods in which the use of a nutritive substance is proposed, or changes to currently permitted foods in which a nutritive substance is used

This includes information about the nutrient content of foods to which the use of the nutritive substance is proposed such as total fat and saturated fat, total sugars, sodium, and energy content.

D.2 The maximum proposed level of the use of the nutritive substance for each food group or food, or the proposed changes to the currently permitted use levels

This includes information on the proposed levels of the use in food, as well as naturally-occurring levels in foods.

D.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children's NNS (5–14 years).

The application should include the following information:

D.4 The percentage of the food group to which the use of the nutritive substance is proposed or the percentage of the market likely to use the nutritive substance

This includes information based on projected uptake of the use of the nutritive substance in foods or market share data for foods to which the use of the nutritive substance is likely. This could be based on a similar market in another country.

D.5 Information relating to the use of the nutritive substance in other countries

This includes information on the foods or food groups in which the nutritive substance is used, the use levels and consumption amounts in other countries.

This information provides an indication of the range of foods in Australia and New Zealand that might contain the used nutritive substance.

D.6 *For foods where consumption has changed in recent years, information on likely current food consumption*

This includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data or sales data or on a similar market in another country.

E **Information related to the nutritional impact of a vitamin or mineral**

The application **must** contain the following information:

E.1 *Information to demonstrate a need to permit the addition of a vitamin or mineral to food*

This includes information addressing at least one of the following:

- (a) data to demonstrate clinical or sub-clinical evidence of deficiency or data to demonstrate low levels of intake in one or more population groups
- (b) data to demonstrate that deficiencies are likely to develop in one or more population groups because of changing food habits
- (c) generally accepted scientific evidence that an increase in the intake of a vitamin or mineral can deliver a health benefit
- (d) evidence that the reduced nutritional profile of a processed food can be substantially restored
- (e) evidence that the nutritional profile of the specified substitute food can be aligned with the primary food.

E.2 *Information to demonstrate the permitted addition of the vitamin or mineral has the potential to address the deficit or deliver a health benefit to the population or a population subgroup*

This includes:

- (a) data on the level of absorption of the particular form of the vitamin or mineral from the specified food at normal levels of consumption
- (b) data on the metabolic fate of the vitamin or mineral under the conditions above
- (c) information on the food vehicle, including the presence of substances that will have an inhibitory or enhancing effect on absorption.

F **Information related to the nutritional impact of a nutritive substance other than vitamins and minerals**

The application **must** contain the following information:

F.1 *Information related to the nutritional purpose of the use of the substance in each food*

This includes data to demonstrate the nutritive substance is consistent with its proposed purpose as described in subsection A.1 in this Guideline (3.3.3) and **must** include:

- (a) the target population(s) be clearly stated
- (b) data to demonstrate that specific food(s) containing the form and amount of the nutritive substance can contribute to the nutritional purpose in the target population(s) at the anticipated level of intake. The total amount should include naturally-occurring and added amounts.
- (c) data to demonstrate that the nutritional composition of the specified substitute food can be aligned with the reference food.

G Information related to potential impact on consumer understanding and behaviour

Note:

In addition to the information specified in this section, some of the information derived from section D in this Guideline (3.3.3) will be used also to assess the impact on consumers of the nutritive substance.

The application **must** contain the following information:

G.1 Information to demonstrate the level of consumer awareness and understanding of the nutritive substances in the food(s)

G.2 Information on the actual or potential behaviour of consumers in response to proposed food(s)

This includes information such as changes in consumption behaviour and changes in health and diet behaviour.

G.3 Information to demonstrate that the consumption of food(s) containing the nutritive substance will not adversely affect any population groups (e.g. particular age or cultural groups).

Note:

Consumption behaviour changes include substitution, addition or avoidance. Health and diet behaviour changes relate to the potential impacts of the food in the context of not promoting patterns inconsistent with nutrition and physical activity policies or guidelines for Australia and New Zealand.

The extent of the impact of the use of a nutritive substance to food on consumer behaviour will vary depending on:

- (a) the nature of the nutritive substance and the food(s) to which it will be added
- (b) the projected consumption levels for the food(s) containing the nutritive substance including amount consumed and how often it will be consumed
- (c) whether currently used foods may be substituted for food(s) containing the nutritive substance
- (d) whether there is a claim.

Thus, the amount of information necessary to address the impact on consumer behaviour will depend on the level of the impact. This will need to be considered in addressing the points above.

Information to support subsections G.1–3 in this Guideline (3.3.3) could include:

- (a) a literature review of the available evidence from Australia and New Zealand, or internationally (where appropriate)
- (b) robust quantitative or qualitative empirical research (where appropriate) assessing consumer responses to the proposed change e.g. studies assessing the Australian and New Zealand general population; findings broken down by population subgroups, including target and non-target population groups.

Where there is insufficient information on Australian and New Zealand consumer responses (or potential responses), as specified in Section F in this Guideline (3.3.3), FSANZ may request the applicant to conduct empirical research to address these points. FSANZ can provide guidance here.

Chapter 3.4

Guidelines for applications for contaminants and natural toxicants

3.4.1 Chemical contaminant and natural toxicant maximum levels

An application to vary the Code is required to approve a new maximum level for a contaminant in food or to change the current maximum levels which are specified in Schedule 19 – Maximum levels of contaminants and natural toxicants.

The following information is required to support an application for a new maximum level for a contaminant or to change the current maximum level. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A General information on the contaminant or natural toxicant

The application **must** contain the following:

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

This 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 and their effectiveness.

In cases where particle characteristics may relate to the toxicity of the food contaminant, the application **must** include information on particle size and morphology.

A.2 Analytical method for detection

This includes a method for detection and quantitation of the contaminant or natural toxicant in the foods in which it is found.

B Information on the safety of the contaminant or natural toxicant

The application **must** contain the following:

B.1 Information on the toxicokinetics and metabolism of the contaminant or natural toxicant and, if necessary, its degradation products

This includes published reviews or individual study reports on the metabolic fate of the contaminant or natural toxicant and, if necessary, its degradation products.

B.2 Information from studies in animals that is relevant to the toxicity of the contaminant or natural toxicant and, if necessary, its degradation products

This includes published reviews or detailed reports of all *in vitro* and *in vivo* studies conducted in animals to examine the toxicity of the contaminant or natural toxicant.

The following categories of studies need to be considered:

- (a) acute toxicity
- (b) short-term toxicity
- (c) long-term toxicity and carcinogenicity
- (d) reproductive toxicity
- (e) developmental toxicity
- (f) genotoxicity
- (g) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are not considered relevant to the safety assessment of the contaminant, an explanatory statement should be provided.

B.3 *Information from human studies that is relevant to the toxicity of the contaminant or natural toxicant and, if applicable, its degradation products*

This includes reviews or reports on human epidemiology studies or individual case studies related to the contaminant or natural toxicant, particularly reports of potential adverse effects on population sub-groups at the levels found in food.

C **Information on dietary exposure to the contaminant or natural toxicant**

The application **must** contain the following information:

C.1 *The foods or food groups) where a maximum level is proposed, or where a change to the maximum level is proposed*

This includes information on the full range of foods likely to contain the contaminant or natural toxicant.

C.2 *Surveys on the levels of the contaminant or natural toxicant in foods*

This includes the details of any surveys which have been conducted in Australia or New Zealand on the levels found in foods.

If data derived from an analytical survey are used, details of how the survey was conducted and the analytical methods used **must** be provided. These details should include the sampling plan, the number of samples, where the samples were collected, whether the analysis was conducted on composite or individual samples, the method of analysis, the limits of detection/quantification/reporting (LOD, LOQ, LOR) for the analytical method used, whether the foods were prepared/cooked before analysis, whether the samples were from the edible portion only, and whether the sampling was targeted or randomly sampled.

If applicable, details of any surveys conducted in other countries **must** be included.

C.3 *For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption*

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children's NNS (5–14 years).

The application should include the following information:

C.4 *For foods where consumption has changed in recent years, information on likely current food consumption*

This includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This may be based on market share data or sales data or on a similar market in another country.

3.4.2 Microbiological limits

An Application to vary the Code is required to change the permissible limits for a microorganism in food or to change the sampling provisions, including the sampling plans, the prescribed methods of analysis or other requirements which are specified in Standard 1.6.1 – Microbiological limits in food or Schedule 27 – Microbiological limits in food.

The following information is required to support an Application for a new maximum permissible limit or to change the current maximum permissible limits, or to change other aspects of this standard. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Technical information on food production methods

The Application **must** contain the following information:

A.1 Information relating to raw inputs, production and manufacturing process for the food(s)

This includes:

- (a) details of the raw ingredients, production process and methods of manufacture, including key properties that may impact on microbial growth, survival or inactivation (e.g. pH, water properties etc)
- (b) full details of the analytical controls and quality assurance procedures used during the various stages of these manufacturing, processing and packaging operations through to storage conditions of retailer (if applicable).

A.2 Information on the use of new or amended food technology, if applicable

This includes details of any new or amended food technology to be used to support the proposed changes to the microbiological limits.

B Information related to food safety

The application **must** contain the following information:

B.1 Nature of the microbiological hazard

This includes information on the nature of the microbiological hazard and any dose-response data or available epidemiological data.

B.2 Data on the source and prevalence of the microbiological contamination

This includes:

- (a) survey results on the prevalence and levels of the pathogen along the entire food production chain, including raw materials
- (b) microbiological validation studies and challenge test data (in either/or both laboratory and pilot-scale studies, if appropriate).

B.3 Information on consumer handling and use of foods, if applicable

This includes information on consumer use of the product including storage, product shelf life and handling instructions.

C Information on the nutritional impact

The application **must** contain the following information:

C.1 Evidence of the nutritional benefit of the proposed amendment, if applicable

This includes any information on the nutritional composition of food which indicates a nutritional benefit from the proposed amendment to the Standard.

D Information related to dietary exposure

The application **must** contain the following information:

D.1 Food consumption data, if applicable

This includes data on food consumption levels for the foods affected by the proposed amendment, as either proposed serves per day (gram amount) or per capita. For new foods (foods not included in the most recent Australian and New Zealand NNSs, the application **must** include projected consumption data, which can include information from international markets.

Note:

The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children’s NNS (5–14 years).

3.4.3 Prohibited and restricted plants and fungi

An application to vary the Code is required to add, modify or delete an entry in relation to a plant or fungi in Schedule 23 – Prohibited plants and fungi or Schedule 24 – Restricted plants and fungi.

The following information is required to support an application to add, modify or delete an entry in relation to a plant or fungi in Schedules 23 or 24. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A General information on the plant or fungi (or a part or derivative thereof)

The application **must** contain the following:

A.1 Nature of the plant or fungi

This includes information on the nature and identity of the plant or fungi, and its potential for use in food.

A.2 Information on identity and levels of natural toxicants in the plant or fungi

This includes information on the natural toxicants in the food and the factors which influence the levels found in food.

B Information on the safety of the plant or fungi (or a part or derivative thereof)

The application **must** contain the following:

B.1 Reviews or reports of toxicity studies on the plant or fungi

This includes a literature survey of relevant toxicity literature.

B.2 Reviews or reports of human cases of toxicity associated with the plant or fungi

This includes any reports of potential adverse effects on population sub-groups, particularly at the levels found in food.

B.3 Use of the plant or fungi in other countries, if applicable

This includes information on the use of the plant or fungi in food products in other countries.

Chapter 3.5

Guidelines for applications for new foods

3.5.1 Foods produced using gene technology

Applications to vary the Code are required to approve the use of new foods produced using gene technology. Approved genetically modified (GM) foods are specified in Schedule 26 – Food produced using gene technology.

The following information is required to support an application for a new genetically modified food. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

Note:

Further explanatory information regarding some of the data requirements for this Guideline (3.5.1) is available in Part 2.3 of this Handbook (GM applications – additional information).

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of GM foods, the relevant Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take this Policy Guideline into consideration.

A Technical information on the food produced using gene technology

The application **must** contain the following information:

A.1 Nature and identity of the genetically modified food

This **must** include all of the following:

- (a) a description of the GM organism from which the new GM food is derived. The description **must** include the nature and purpose of the genetic modification
- (b) the name, line number and OECD Unique identifier of each of the new lines or strains of GM organism from which the food is derived
- (c) the name the food will be marketed under (if known).

A.2 History of use of the host and donor organisms

The common and scientific names of host and donor organisms **must** be stated. Where information relating to an organism has been included in previous safety assessments prepared by FSANZ, it is not necessary to provide any further information. Where an organism has not been considered previously by FSANZ, the following information **must** be provided.

- (a) For the donor organism(s) from which the genetic elements are derived:
 - (i) any known pathogenicity, toxicity or allergenicity of relevance to the food;
 - (ii) history of use of the organism in the food supply or history of human exposure to the organism through other than intended food use (e.g. as a normal contaminant).
- (b) For the host organism into which the genes were transferred:
 - (i) its history of safe use for food
 - (ii) the part of the organism typically used as food
 - (iii) the types of products likely to include the food or food ingredient
 - (iv) whether special processing is required to render food derived from the organism safe to eat.

A.3 *The nature of the genetic modification*

This **must** include all of the following:

- (a) a description of the method used to transform the host organism
- (b) a description of the construct and the transformation vectors used, including:
 - (i) the size, source and function of all the genetic components including marker genes, regulatory and other elements
 - (ii) a detailed map of the location and orientation of all the genetic components contained within the construct and vector, including the location of relevant restriction sites.
- (c) A full molecular characterisation of the genetic modification in the new organism, including:
 - (i) identification of all transferred genetic material and whether it has undergone any rearrangements
 - (ii) a determination of the number of insertion sites, and the number of copies at each insertion site
 - (iii) full DNA sequence of each insertion site, including junction regions with the host DNA
 - (iv) a map depicting the organisation of the inserted genetic material at each insertion site
 - (v) details of an analysis of the insert and junction regions for the occurrence of any open reading frames (ORFs).
- (d) A description of how the line or strain from which food is derived was obtained from the original transformant (i.e. provide a family tree or describe the breeding process) including which generations have been used for each study.
- (e) Evidence of the stability of the genetic changes, including:
 - (i) the pattern of inheritance of the transferred gene(s) and the number of generations over which this has been monitored
 - (ii) the pattern of inheritance and expression of the phenotype over several generations and, where appropriate, across different environments.
- (g) an analysis of the expressed RNA transcripts, where RNA interference has been used.

B **Characterisation and safety assessment of new substances**

The application **must** address the following sections:

B.1 *Characterisation and safety assessment of new substances*

This **must** include all of the following:

- (a) a full description of the biochemical function and phenotypic effects of all new substances (e.g. a protein or an untranslated RNA) that are expressed in the new GM organism, including their levels and site of accumulation, particularly in edible portions
- (b) information about prior history of human consumption of the new substances, if any, or their similarity to substances previously consumed in food.
- (c) information on whether any new protein has undergone any unexpected post-translational modification in the new host
- (d) where any ORFs have been identified (in subparagraph A.3(c)(v) of this Guideline (3.5.1)), bioinformatics analyses to indicate the potential for allergenicity and toxicity of the ORFs.

B.2 *New proteins*

If it can be shown the new protein(s) is identical to one previously assessed by FSANZ, the only other safety information that must be provided is an updated bioinformatics comparison of the amino acid sequence to known protein toxins, anti-nutrients and allergens.

Where the new protein is not identical to one previously assessed by FSANZ, the following **must** be provided:

- (a) information on the potential toxicity of any new proteins, including:
 - (i) a bioinformatic comparison of the amino acid sequence of each of the new proteins to known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins)
 - (ii) information on the stability of the protein to proteolysis in appropriate gastrointestinal model systems
 - (iii) an animal toxicity study if the bioinformatic comparison and biochemical studies indicate either a relationship with known protein toxins/anti-nutrients or resistance to proteolysis.
- (b) information on the potential allergenicity of any new proteins, including:
 - (i) source of the new protein
 - (ii) a bioinformatics comparison of the amino acid sequence of the novel protein to known allergens
 - (iii) the new protein's structural properties, including, but not limited to, its susceptibility to enzymatic degradation (e.g. proteolysis), heat and/or acid stability
 - (iv) specific serum screening where a new protein is derived from a source known to be allergenic or has sequence homology with a known allergen
 - (v) information on whether the new protein(s) have a role in the elicitation of gluten-sensitive enteropathy, in cases where the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.

Where the new protein has been produced from an alternative source (e.g. microbial expression system) in order to obtain sufficient quantities for analysis, information **must** be provided to demonstrate that the protein tested is biochemically, structurally and functionally equivalent to that expressed in the food produced using gene technology.

Information on the potential toxicity and potential allergenicity of a newly expressed protein is also not required if:

- (a) the protein is expressed from a transferred gene that is derived from the same species as the host or a species that is cross-compatible with the host, provided evidence is provided to demonstrate the following:
 - (i) the gene donor belongs to a species that is commonly used as food and has a history of safe use
 - (ii) the protein is expressed at levels in the new food produced using gene technology that are consistent with the levels in the gene donor.
- (b) evidence is provided to demonstrate the absence of the newly expressed protein from the parts of the host organism consumed as food.

B.3. Other (non-protein) new substances

If other (non-protein) substances are produced as a result of the introduced DNA, information must be provided on the following:

- (a) the identity and biological function of the substance
- (b) whether the substance has previously been safely consumed in food
- (c) potential dietary exposure to the substance
- (d) where RNA interference has been used:
 - (i) the role of any endogenous target gene and any changes to the food as a result of silencing that gene
 - (ii) the expression levels of the RNA transcript
 - (iii) the specificity of the RNA interference

B.4 Novel herbicide metabolites in GM herbicide-tolerant plants

Note:

Novel metabolites are those not normally found in non-GM crops sprayed with the same herbicide.

Data **must** be provided on the identity and levels of herbicide and any novel metabolites that may be present in the food produced using gene technology.

If novel metabolites are present then the application should address the following, where appropriate:

- (a) toxicokinetics and metabolism
- (b) acute toxicity
- (c) short-term toxicity
- (d) long-term toxicity and carcinogenicity
- (e) reproductive and developmental toxicity
- (f) genotoxicity.

B.5 Compositional analyses of the food produced using gene technology

This **must** include all of the following:

- (a) the levels of relevant key nutrients, toxicants and anti-nutrients in the food produced using gene technology compared with the levels in an appropriate comparator (usually the non-GM counterpart). A statistical analysis of the data must be provided.
- (b) information on the range of natural variation for each constituent measured to allow for assessment of biological significance should any statistically significant differences be identified
- (c) the levels of any other constituents that may potentially be influenced by the genetic modification, as a result, for example, of downstream metabolic effects, compared with the levels in an appropriate comparator as well as the range of natural variation.

In the case of herbicide-tolerant plants, the levels of each constituent in the food produced using gene technology **must** be determined using plants sprayed with the herbicide.

C Information related to the nutritional impact of the food produced using gene technology

The application **must** contain the following information if the compositional analysis indicates biologically significant changes to the levels of certain nutrients in the food produced gene technology compared to the non-GM counterpart food:

- (a) data are required on the anticipated dietary intake of the GM food in relation to the overall diet, together with any information which may indicate a change to the bioavailability of the nutrients from the GM food
- (b) where the GM food contains an intended nutritional change, information, such as clinical trial data, **must** be provided to determine the nutritional impact of the GM food.

D Other information

There is no requirement to conduct animal feeding or whole food toxicity studies on the food produced using gene technology. However, if a 90-day (or longer) whole food toxicity study in rodents has been provided to satisfy the data and information requirements of another jurisdiction, this should also be provided to FSANZ as additional supporting information.

3.5.2 Novel foods

An application to vary the Code is required to approve the use of a new novel food or novel food ingredient. Permissions for use of novel foods or novel food ingredients are specified in Schedule 25 – Permitted novel foods.

Note:

For further information relating to the operation of Standard 1.5.1 – Novel foods, particularly in relation to whether a particular food would be regarded as novel, refer to the FSANZ website at <http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx>.

The term **novel food** includes both whole foods and food ingredients – these terms are used either together or separately in this document, depending on the circumstances. When the novel food is clearly a food ingredient, only novel food ingredient is used.

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

In the case of an application seeking approval of a novel food or ingredient, the relevant Guidelines are Novel Foods, the Addition to Food of Substances other than Vitamins and Minerals and the Labelling of Foods produced or processed using New Technologies.

The Guidelines are available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take each Policy Guideline into consideration.

The following information is required to support an application for a novel food. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Exclusive use of novel foods

This includes a statement as to whether the application is seeking exclusive permission for the novel food. If exclusive permission is sought, the application **must** include details of the following:

- (a) the specific class of food
- (b) the brand of the food, including the name the food will be marketed under (if known).

Exclusive permission can only be sought if requested by the applicant at the time the application is received by FSANZ.

B Technical information on the novel food

The substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect **must** be made in the application. If this situation is not the case for any of the relevant studies, then a justification and explanation **must** be provided.

The application **must** contain the following information:

B.1 Information on the type of novel food

This includes a brief description of the novel food, including the name the food will be marketed under (if known), and whether it falls within one of the following major identified categories:

- plants or animals and their components
- plant or animal extracts
- herbs (both non-culinary and culinary) including extracts
- single chemical entities

- dietary macro-components
- microorganisms (including probiotics)
- food ingredients derived from new sources
- foods produced by a process not previously applied to food.

Note:

These categories are provided as a guide based on previous experience and knowledge of the nature of products from enquiries received by FSANZ. It is anticipated that most novel foods will fall under one of these categories, however, this may not always be the case and the categories listed are not intended to be exhaustive.

The term **dietary macro-component** generally refers to those dietary components which constitute a significant proportion of the food, such as fats, sugars, proteins and polysaccharides. Novel macro-components are used to replace the naturally-occurring components, either for a functional purpose or to reduce the energy value of the food. Examples include tagatose, cyclodextrin, diacylglycerol oil, trehalose, resistant starches.

The term 'single chemical entity' generally refers to a substance, however derived, that is added to food but not consumed as food in its own right. It is intended for addition to food at levels consistent with use as a food ingredient. For the purposes of Standard 1.5.1, a single chemical entity does not include a substance used for a technological purpose.

A novel food may fit under more than one category above. In this case, all applicable requirements for each category should be addressed.

B.2 Information on the purpose of adding a novel food ingredient to food

The application must state the purpose(s) of the addition of the novel food ingredient to food. If an added substance has multiple purposes or functions then these **must** all be specified.

If the purpose for adding a novel food ingredient to food (including special purpose foods) relates to a potential beneficial physiological or health-related outcome, the purpose **must**:

- include a brief description of any physiological or health-related function(s) of the substance at the proposed level
- be stated in a way that can be measured i.e. as an outcome in clinical studies
- provide supporting evidence that the form and total amount of the novel food ingredient added to the food vehicle(s) delivers the stated purpose in the target population group. The total amount should include naturally-occurring amounts. The target population **must** be clearly stated.

B.3 Information on the physical and chemical properties of the novel food or novel food ingredient

This 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 application **must** include information on particle size, size distribution, and morphology, as well as any size-dependent properties.

B.4 Information on the impurity profile for a typical preparation

This includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the novel food ingredient preparation. Impurities should be identified by their Chemical Abstract (CA) or International Union of Pure and Applied Chemists (IUPAC) names.

B.5 *Manufacturing process for a novel food ingredient*

This includes a comprehensive outline of the method of manufacture of the novel food ingredient.

B.6 *Specification for identity and purity for a novel food ingredient*

This includes a specification from one of the published sources identified in Schedule 3 – 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 application **must** include information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

B.7 *Analytical method for detection of a novel food ingredient*

The application **must** contain the following information:

This includes a method for detection and quantification of the novel food ingredient or its degradation products (where relevant) in the foods in which it will be used. Such analytical methods need to be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code.

C **Information on the safety of the novel food**

Note:

FSANZ will undertake an assessment of all available reports of animal and human studies which provide information related to the toxicity of the novel food or novel food ingredient. The safety of the novel food will be assessed at the proposed levels of use, using both the technical information provided in section A of this Guideline (3.5.2) and the information specified in this section.

For a novel food ingredient, a safe level of intake will be established, if possible, from the available studies.

There are a number of categories of novel foods. The data required for a safety assessment will therefore vary depending on the nature of the novel foods. Factors to consider in a safety assessment will include:

- (a) the history of use as a food in other countries
- (b) the composition of the novel food, particularly the levels of anti-nutrients and naturally-occurring toxins
- (c) the method of preparation and specifications of a novel food ingredient
- (d) potential for allergenicity of the novel food
- (e) metabolism/toxicokinetic studies on the novel food ingredient
- (f) animal toxicity studies on the novel food ingredient
- (g) human toleration studies on the novel food ingredient

The nature of the information on the safety of the novel food to be submitted will depend on the category of the novel food as identified in subsection B.1 of this Guideline (3.5.3).

C.1 *Plants or animals (or their components)*

An application for a novel food which is a plant or animal (or their components) **must** contain the following information:

C.1.1 *Information on the composition of the novel food*

This includes information on the levels of anti-nutrients and naturally-occurring toxins in the plant or animal (or their components).

C.1.2 Information on the effects of food processing or preparation

This includes information on methods of reducing the levels of anti-nutrients or naturally-occurring toxins during food processing or food preparation, if relevant.

C.1.3 Information on the current use of this food or food component in population sub-groups or in other countries

This includes information on the extent and history of use of the food in other countries; any particular preparation, processing or cooking practices normally used; and the level and purpose of consumption (e.g. staple food, ceremonial use). This evidence of safe use should include the frequency of consumption, the extent of the population using the food, and the period of use.

C.1.4 Information regarding the potential adverse effects associated with the food or its ingredients

This includes published or unpublished reports of allergenicity or other adverse effects in humans associated with the food. If available, this also includes any reports of toxicity studies conducted in animals or toleration studies conducted in humans.

C.2 Plant or animal extracts

An application for a novel food which is a plant or animal extract **must** contain all of the information in subsection C.1 Plants or animals (or their components) above, as well the following additional information:

C.2.1 Information on the method of extraction and the composition of the concentrated extract

This includes the methodology used to prepare the extract and the composition of the extract. This **must** include information on the levels of potential contaminants from the extraction process.

C.2.2 Information on the use of this plant or animal extract as a food in other countries

This includes information on the extent and history of use of the extract in other countries, together with reports of any adverse health effects.

Use of the plant or animal extract as a dietary supplement, natural medicine or complementary medicine in other countries should be provided. In some countries, this is regarded as food use, rather than medicinal use. If adverse effects are reported, the nature of the adverse event reporting scheme should be provided, if known.

C.2.3 Information on the toxicity of the extract obtained from studies conducted in animals or humans

This includes reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

C.2.4 Safety assessment reports prepared by international agencies or other national government agencies

This includes published safety assessment reports prepared by other agencies.

C.3 Herbs (both non-culinary and culinary) including extracts

An application for a novel food which is a herb (both non-culinary and culinary) including extracts **must** contain the following information:

C.3.1.1 Information on the history of use of the herb

This includes information on the use of the herb as a complementary medicine in Australia or as a dietary supplement in New Zealand, or as a food or medicine in other countries. The plant part(s) used **must** also be specified.

C.3.2 *Information on the composition of the herb*

This includes information on the levels of active constituents in the herbs or herbal extracts, and information on their potential adverse effects.

C.3.3 *For a herbal extract, information on the method of extraction and the composition of the concentrated extract*

This includes detailed information on the plant part(s) used to prepare the extract, the method used to prepare the extract and the composition of the extract. The application **must** include information on the levels of potential contaminants from the extraction process.

C.3.4 *Information on the use of this herbal extract as a food in other countries*

This includes information on the extent and history of use of the herbal extract in other countries, together with reports of any adverse health effects. The nature of the adverse event reporting scheme in that country should be detailed, if available.

C.3.5 *Information regarding the potential allergenicity of the herb or herbal extract*

This includes reports of allergenicity associated with the herb or herbal extract.

C.3.6 *Information on the toxicity of the herb, or herbal extract, or any key constituents obtained from studies conducted in animals or humans*

This includes reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

C.3.7 *Safety assessment reports prepared by international agencies or other national government agencies*

This includes published safety assessment reports prepared by other agencies.

C.4 **Single chemical entities and Dietary macro-components**

An application for a novel food which is a single chemical entity or a dietary macro-component **must** contain the following information:

C.4.1 *Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites*

This includes reports of all studies conducted in animals or humans to examine the metabolic fate of the single chemical entity or dietary macrocomponent and, where necessary, its degradation products and major metabolites.

C.4.2 *Information from studies in animals or humans that is relevant to the toxicity of the single chemical entity and, where appropriate, its degradation products and major metabolites*

This includes detailed reports of all *in vitro* and *in vivo* toxicity studies conducted in animals or humans to examine the toxicity of the single chemical entity or dietary macro-component and, where necessary, its metabolites or degradation products.

The application should address the following categories of studies:

- (a) acute toxicity studies
- (b) short-term toxicity
- (c) long-term toxicity studies and carcinogenicity studies
- (d) reproductive toxicity studies
- (e) developmental toxicity studies
- (f) genotoxicity studies

- (g) special studies such as neurotoxicity or immunotoxicity

Where data are not available or is not considered relevant to the safety assessment of the single chemical entity, an explanatory statement should be provided.

C.4.3 Safety assessment reports prepared by international agencies or other national government agencies

This includes safety assessment reports prepared by the WHO or by other national or supranational agencies responsible for food safety or public health.

C.5 Microorganisms (including probiotics)

An application for a novel food which is a microorganism (including probiotics) **must** contain the following information:

C.5.1 Information on potential pathogenicity

This includes information related to the potential pathogenicity of the microorganism and related microorganisms.

C.5.2 Information on the effects of the microorganism on gut microflora

This includes studies to demonstrate that the microorganism does not have adverse effects on the gut microflora.

C.5.3 Information on the use of this microorganism in food or as a food in other countries

This includes information on the extent and history of use of this microorganism or related microorganisms in other countries, together with reports of any adverse health effects. The nature of any adverse event reporting system in that country should be detailed, if available.

C.5.4 Information on human toleration studies

This includes any published or unpublished reports of toleration studies conducted in humans. Clinical evaluation of potential probiotics **must** use double-blind, placebo-controlled human trials, with detailed reporting of adverse side effects, which can be used to confirm the results observed in animal tests or *in vitro* studies.

C.6 Food ingredients derived from a new source

An application for a novel food which is a food ingredient derived from a new source **must** contain the following information:

C.6.1 Information on the safety of the source organism

This includes information on whether the source organism of the novel ingredient has a history of safe use as a food. If the source organism is microbial, the application **must** include information on any potential pathogenicity and toxicity. The application **must** also include information on potential naturally-occurring toxins, if applicable.

The application **must** include details on the presence of known allergens (see section 1.2.3—4 in the Code).

C.6.2 Information on the composition of the novel food ingredient derived from a new source

This includes information on the levels of major components and nutrients in the final food.

C.6.3 *Information on the toxicity of the novel food ingredient derived from the new source*

This includes any published or unpublished reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

C.6.4 *Safety assessment reports prepared by international agencies or other national government agencies*

This includes safety assessment reports prepared by the WHO or by other national or supranational agencies responsible for food safety or public health.

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

An application for a novel food which is produced by a process not previously applied to food **must** contain the following information:

C.7.1 *Details of the process not previously applied to food*

This includes details of the new food processing technology and its impact on the composition of the food.

C.7.2 *Information on the toxicity of the novel food produced by a process not previously applied to food*

This includes any published or unpublished reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans. The nature of the toxicity or toleration studies to be submitted will depend on the category of the novel food as set out in B.1.

The application **must** include details on the presence of known allergens (see section 1.2.3—4 in the Code).

C.7.3 *Safety assessment reports prepared by international agencies or other national government agencies*

This includes safety assessment reports prepared by the WHO or by other national or supranational agencies responsible for food safety or public health.

D **Information on dietary exposure to the novel food**

Note:

FSANZ may undertake a dietary exposure assessment for all novel foods applications. The type of dietary exposure assessment will vary depending on the nature of the novel food.

This may depend on whether the novel food is the final food, a major component of the final food or a minor component of the final food.

The dietary exposure assessment will use a custom-made computer program, HARVEST, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys, together with food chemical concentration data derived from the proposed levels of use provided by the applicant or other concentration data where relevant, for example data from analytical surveys.

The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children's NNS (5–14 years).

The dietary exposure assessment may be based on the projected market share data, or data from markets in other countries.

The application **must** contain the following information:

D.1 *A list of the foods or food groups proposed to or which might contain the novel food ingredient or substance*

D.2 *The proposed level of the novel food ingredient or substance for each food or food group*

Data **must** be provided about the proposed concentration (or levels of addition) of the novel food ingredient in each of the foods or food groups identified in subsection D.1 of this Guideline (3.5.2) (i.e. proposed to contain the substance). Any information on naturally-occurring levels of the substance **must** also be provided. The application should indicate whether these are maximum or actual use levels.

D.3 *For foods or food groups not currently listed in the most recent Australian or New Zealand (NNSs), information on the likely level of consumption*

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should contain the following information:

D.4 *The percentage of the food group in which the novel food ingredient is proposed to be used or the percentage of the market likely to use the novel food ingredient*

This includes information based on projected uptake or market share data for foods likely to contain the novel food or novel food ingredient. This can be based on a similar market in another country.

D.5 *For foods where consumption has changed in recent years, information on likely current food consumption*

This includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data or sales data or on a similar market in another country.

Note:

The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey (2 years and above), the 2008–09 New Zealand NNS (15 years and above) and the 2002 New Zealand Children’s NNS (5–14 years).

D.6 *Data to show whether the food, or the food in which the novel food ingredient is used, is likely to replace another food from the diet, if applicable*

This includes information on projected consumption levels for the novel food or food(s) containing the novel food ingredient, and frequency of consumption. This could include market research data or data from other international markets.

D.7 *Information relating to the use of the novel food or novel food ingredient in other countries, if applicable*

This includes information on the food groups or foods in which it is used and the use levels.

E **Information on the nutritional and health impact of the novel food**

Note:

Some of the information derived from section C in this Guideline (3.5.2) will be used also to assess the nutritional impact of the novel food. The information in this section E is in addition to the information set out in section C of this Guideline (3.5.2). Information in relation to the safety, dietary exposure and nutritional impact will be considered by FSANZ in characterising the risk of the novel food or novel food ingredient.

The application **must** contain the following information:

E.1 *Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet*

This includes information relating to the effect of the novel food, ingredient or substance on the bioavailability of other nutrients.

This also includes consideration of the effect on the intake of other components of the overall diet (particularly macronutrients) which may arise from the novel food, ingredient or substance.

E.2 *Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact*

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, this will include information from scientific studies on any potential adverse effect(s) on the physiological status of the target or non-target population, including long term impact on health. This information is in addition to that outlined in section F of this Guideline (3.5.2).

F **Information related to potential impact on consumer understanding and behaviour**

Note:

Some of the information derived from section D in this Guideline (3.5.2) will be used also to assess the impact on consumers of the novel food. The information below is in addition to this information.

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, the application **must** contain the following information:

F.1 *Information to demonstrate the level of consumer awareness and understanding of the novel food or novel food ingredient*

F.2 *Information on the actual or potential behaviour of consumers in response to the novel food or novel food ingredient*

This includes information such as changes in consumption behaviour and changes in health and diet behaviour.

F.3 Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)

Note:

Consumption behaviour changes include substitution, addition or avoidance. Health and diet behaviour changes relate to the potential impacts of the food in the context of not promoting patterns inconsistent with nutrition and physical activity policies and guidelines for Australia and New Zealand. The extent of the impact of the addition of a novel food ingredient to food on consumer behaviour will vary depending on:

- (a) the nature of the novel food ingredient and the food(s) to which it will be added
- (b) the projected consumption levels for the food(s) containing the novel food ingredient including amount consumed and how often it will be consumed
- (c) whether currently used foods may be substituted for food(s) containing the novel food ingredient
- (d) whether there is a claim.

Thus, the amount of information necessary to address the impact on consumer behaviour will depend on the level of the impact. This will need to be considered in addressing the points above.

Information to support subsections F.1–3 of this Guideline (3.5.2) could include:

- (a) a literature review of the available evidence from Australia and New Zealand, or internationally (where appropriate)
- (b) robust quantitative or qualitative empirical research (where appropriate) assessing consumer responses to the proposed change e.g. studies assessing the Australian and New Zealand general population; findings broken down by population subgroups, including target and non-target population groups.

Where there is insufficient information on Australian and New Zealand consumer responses (or potential responses), as specified in section F, FSANZ may request an applicant to conduct empirical research to address these points. FSANZ can provide guidance here.

3.5.3 Irradiated foods

An application to vary the Code is required to approve the irradiation of food. Permissions for irradiation of foods are specified in Standard 1.5.3 – Irradiation of food.

In support of an application for irradiation of a particular food and to demonstrate that there is a technological need to irradiate a food, the following information must be provided.

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of irradiated foods, the relevant Policy Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take this Policy Guideline into consideration.

A Technical information on the irradiated food

The application **must** contain the following information:

A.1 Information on the nature of the food or food ingredient to be irradiated

This includes a description of the primary foods, food ingredients or mixed foods to be irradiated.

A.2 Information on the technological need to use irradiation compared to other available technologies

This includes the following data or information to support that irradiation if used appropriately and at the correct doses can reduce bacterial contamination or increase shelf-life or reduce/eliminate pest infestation:

- (a) data on the reduction in microbiological load to demonstrate the effectiveness of the irradiation procedure in each of the foods on which it is proposed to be used
- (b) data on the expected increase in shelf-life of a food post-irradiation, compared to its pre-irradiated shelf-life
- (c) data or support from an appropriate quarantine agency (e.g. the Australian Government Department of Agriculture and Water Resources or the New Zealand Ministry for Primary Industries) that the use of irradiation is justified at the dose range requested (including a minimum and maximum value) to achieve the technological function of pest disinfection.

A.3 The food products likely to contain the irradiated food or food ingredient

This includes information on use of the irradiated food or food ingredient in food products.

B Information on the safety of irradiation

The application **must** include studies that demonstrate the toxicological safety of the food that is the subject of the application or of closely related foods. Any studies performed to demonstrate the toxicological safety of the food following irradiation **must** be submitted. In particular, this should include the identity of any new components in the food formed as a result of the irradiation process.

C Information on the nutritional impact of irradiation

You **must** contact FSANZ regarding information required to determine the nutritional impact of irradiation.

Chapter 3.6

Guidelines for applications for special purpose foods and standardised foods

3.6.1 Standardised foods

An application to vary the Code is required to change the compositional requirements for standardised foods.

The following information is required to support an application related to the composition of standardised foods. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

If the compositional change involves a change to the current permissions for a food additive, processing aid, novel food or novel food ingredient, or a nutritive substance, the information requirements to change these permissions are provided in other guidelines in Part 3.

Additional information may be required if the application relates to a special purpose food. Additional information requirements relating to special purpose foods are in Guidelines 3.6.2 – Special purpose foods – Infant formula products and 3.6.3 – Special purpose foods – Other foods.

A General information to support the proposed compositional change

The application **must** contain the following information:

A.1 A description of the nature of the proposed compositional change

This includes detailed information on the proposed compositional change, and should indicate the Standards which will be affected.

A.2 A list of the foods likely to be affected by the proposed compositional change

This includes details of the foods affected by the proposed compositional change.

B Information related to nutritional impact

The application **must** contain the following information:

B.1 Information on the nutritional content of the standardised food

This includes details of any anticipated change in the overall nutrient content of the standardised food which may affect the overall diet for the affected population groups.

C Information related to potential impact on consumer understanding and behaviour

The application **must** contain the following information:

C.1 Information to demonstrate consumer understanding of the proposed compositional change

C.2 Information to demonstrate that the proposed compositional change will not have any adverse health or diet impacts on any population groups (e.g. age or cultural groups).

Note:

The extent of the impact of a food compositional change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the compositional change; and
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

3.6.2 Special purpose food – Infant formula products

Infant formula products comprise infant formula (0–12 months), follow-on formula (6–12 months) and infant formula for special dietary use (for infants aged 0–12 months).

An application to vary the Code is required to change the compositional or labelling requirements for infant formula products.

Compositional changes include: addition of a new substance not currently approved for use in infant formula products; an increase or decrease in the amount of a substance required for, or voluntarily added to, infant formula products. For the purposes of the Handbook, an increase or decrease in energy content or a macronutrient amount is considered to be a change to a nutritive substance.

The information requirements outlined below are in addition to those specified in Guideline 3.1.1 – General requirements and in other relevant guidelines in Part 3. The relevance of other guidelines is dependent on the proposed variation to the Code. Possible Guidelines include:

- 3.3.1 for a food additive
- 3.3.2 for a processing aid
- 3.3.3 for a nutritive substance
- 3.5.2. for a novel food or novel food ingredient
- 3.2.1 for general food labelling
- 3.2.3 for food allergens
- 3.2.4 for labelling for consumer information and choice
- 3.2.5 for nutrition information labelling

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum. The relevant Policy Guidelines for infant formula products are: the Regulation of Infant Formula Products, and Intent of Part 2.9 – Special Purpose Foods. These Policy Guidelines provide guidance on the composition, labelling, advertising and promotion of infant formula products.

Part 3 sets out the information requirements to enable FSANZ to have regard to these Policy Guidelines during the assessment of an application.

The Policy Guidelines are available on the FSANZ website at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

A Information related to composition

A.1 Purpose of the compositional change

The application **must** state the purpose of the compositional change to infant formula products.

This includes a brief description of all of the technological, nutritive or health-related function(s) of the substance at the proposed level in the relevant infant formula product(s). Where an added substance or compositional change has multiple purposes or functions, then these **must** be specified. This includes information on the target infant population(s) e.g. healthy term infants aged 0–12 months, or infants older than 6 months.

A.2 General data requirements for supporting evidence

This includes the general evidential requirements whereas A.3 includes the specific information required for the assessment of nutritional safety and efficacy.

Studies provided as evidence to support an application **must** contain sufficient detail to enable an independent assessment of the methods and results to confirm the study conclusions.

An application **must** include human studies as supporting evidence for nutritional safety, tolerance and the efficacy of the proposed compositional change. This can include published studies, detailed reports of unpublished studies and systematic reviews (with underlying studies also provided). It may be acceptable in certain cases not to include human studies. In this situation, safety and efficacy must be demonstrated by relevant data (as specified elsewhere in this Handbook); and the application **must** include an explanation of why human studies are not applicable.

Note:

Further information on design and reporting of data and data quality is found in subsection E of Guideline 3.1.1.

Discussion and guidance on data requirements for changes to infant formula products is available from the following:

- (a) The US Institute of Medicine, Food and Nutrition Board guidelines that clarify the types and extent of safety testing necessary for new formula ingredients, particularly unconventional substances derived from novel sources or technologies.
<http://www.iom.edu/Reports/2004/Infant-Formula-Evaluating-the-Safety-of-New-Ingredients.aspx>.
- (b) The US Food and Drug Administration discussion paper prepared by the US Academy of Pediatrics on the clinical testing of infant formulas which can be found at
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm170649.htm>.

A.3 Specific information requirements for the nutritional safety, tolerance and efficacy of the proposed compositional change

This describes evidential requirements that **must** be addressed for a proposed change to the composition of infant formula products and it is divided into two components depending on the category of compositional change.

An application that relates to addition or changing the level of a nutritive substance (including energy or macronutrient), novel food or novel food ingredient **must** address the requirements listed in subsection A.3.1 of this Guideline (3.6.2).

An application that relates to a food additive or processing aid **must** address the requirements listed in component in subsection A.3.2 of this Guideline (3.6.2).

A.3.1 Nutritive substance (including energy or macronutrient), novel food, or novel food ingredient

- (a) Characterisation of proposed substance or the comparable substances in breast milk

An application **must** include information about the presence of the proposed or comparable substance in breast milk. This supporting evidence includes:

- (i) The mean amount and range of the proposed or comparable substance in breast milk. Where possible, include reference to breast milk composition from Australian or New Zealand mothers, or if not available, from mothers in countries with similar dietary patterns to Australia and New Zealand. The breast milk reference values must be relevant to the type of infant formula product under consideration, for example levels found in colostrum may not be a relevant basis for levels in follow-on formula.
- (ii) The variability of the levels of the proposed or comparable substance and consideration of the influence of maternal diet or other physiological factors e.g. hormones, biochemical processes.
- (iii) Comparison of relevant biochemical, physiological and functional endpoints between breastfed infants and infants fed the infant formula product containing the proposed composition change.

Where a proposed or comparable substance is not present in breast milk or no information is available on the presence or function of this substance in breast milk, the application **must** include an explanation of the reason(s) why the information is not provided.

(b) Nutritional safety and tolerance of the proposed compositional change

A composition change involving a nutritive substance (including energy or macronutrient) or a novel food or novel food ingredient **must** meet the respective safety requirements of Guidelines 3.3.3 and 3.5.2.

Note:

The requirement for human studies is primarily intended to establish infant tolerance of the formula and to ensure that the formula is able to support normal infant growth and development (see (i) below) and, in certain circumstances, to ensure no adverse effects on the absorption of essential nutrients.

The application **must** include evidence to support the nutritional safety and tolerance of the proposed composition change. This evidence includes:

- (i) Human infant studies demonstrating that the infant formula products containing the substance at the proposed level, will support normal infant growth and development over a minimum interval of 3–4 months, beginning no later than 1 month of age. Reported growth measures **must** include at least infant length and weight. If studies for infant formula products demonstrating normal growth and development have been conducted for 3–4 months for infants aged from 1 month, additional studies for the same substance at the same level in follow-on formula are not required.
- (ii) The exception to (b)(i) is an application for follow-on formula only (intended for use from 6 months). Studies **must** monitor and report growth measures for a minimum period of 2 months within the relevant age range.
- (iii) Human infant studies **must** include a control group (i.e. an infant formula-fed group that is not exposed to the proposed compositional change), an exposure group (i.e. a formula-fed group that is exposed to the proposed compositional change, plus a breastfed reference group. If a breastfed reference group is not included, a rationale for its omission is required.
- (iv) Information on the quality and strength of the evidence **must** include descriptions of the study design, methodology and characteristics of the study population and study limitations (refer to subsection 3.1.5.A of Guideline 3.1.1) for guidance).
- (v) Evidence to demonstrate there is no risk of nutrient imbalances as a result of infants fed the infant formula product containing the proposed compositional change **must** be provided. If this evidence is not applicable, a rationale for its omission is required.

(c) Efficacy of the proposed compositional change

Any nutritive substance (including energy or macronutrient), novel food or novel food ingredient **must** meet the respective requirements of Guideline 3.3.3 (sections D or E) or Guideline 3.5.2 (section E). In addition, for a compositional change to infant formula products, efficacy and potential beneficial effect(s) of consumption of the substance at the proposed level **must** be described and supported by evidence as outlined below:

- (i) Description and measures of the physiological, biochemical or functional effect(s) of the substance.
- (ii) Description and measures of a health outcome. If no health outcome is specified, a rationale **must** be provided for its omission.

- (iii) Study designs **must** align with the requirements for nutritional safety and tolerance outlined in paragraph A.3.1(b) of this Guideline (3.6.2).

Note:

The beneficial role of substances in infant formula products may be determined by the measurement of physiological, biochemical or functional effects and health outcome. Examples of these effects include enzyme pathways, blood levels, microbiological composition and counts, liver, kidney, gastrointestinal or other organ functions. An example of a possible health outcome may be reduced incidence of diarrhoea or ear infection.

Evidence from non-human studies will add weight to the determination of a substance's role, particularly in understanding the mode of action.

A.3.2 For a food additive or processing aid

Compositional changes involving a food additive or processing aid **must** meet the respective safety requirements of Guidelines 3.3.1 and 3.3.2. In addition, the following **must** be provided:

- (a) Tolerance of the proposed compositional change

Evidence to support tolerance **must** include appropriate human studies. This includes an explanation of the way in which this evidence relates to infants.

- (b) Efficacy of the proposed compositional change

If the food additive also provides a nutritive or health-related function, the information requirements listed in component (I) for efficacy of proposed change **must** be met. If the function is purely technological, there are no further requirements in this section.

B Information related to the dietary intake or dietary exposure

B.1 Data to enable the dietary intake or exposure of the target population to be estimated

The application **must** meet the information requirements for the dietary exposure of a food additive, processing aid, novel food or novel food ingredient, or dietary intake of a nutritive substance (including energy or macronutrient), as outlined in these application guidelines. The information provided must have a focus on infants.

B.2 Data on the recommended level of formula consumption for the target population

The application **must** contain the following information:

- (i) the capacity of the product scoop (in grams of product)
- (ii) the number of scoops required per feed
- (iii) the volume of water required per feed
- (iv) total volume of the made-up feed
- (v) recommended number of feeds per day relevant to each age group in the relevant target population.

B.3 Information relating to the substance

The application should also contain information or references on the levels (naturally occurring or naturally occurring and added) of the proposed substance in other foods that infants are likely to consume.

C Information related to labelling requirements under Part 2.9 of the Code

C.1 Information related to safety or nutritional impact of the proposed labelling change

The application **must** include information to support the proposed labelling change. For example, the inclusion of (or change to) a warning or advisory statement, directions for use, or conditions.

C.2 Information to demonstrate that the proposed labelling change will be understood and will assist consumers

This should include consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is already in place.

Note:

The extent of the impact of a labelling change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the labelling change; and
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

D Information related to internationally recognised standards, codes of practice, recommendations AND guidelines

The application **must** include information demonstrating the level of consistency with internationally recognised standards, codes of practices, recommendations or guidelines such as Codex and the WHO, relating to the manufacture and labelling of infant formula products.

Note:

Examples of relevant standards, codes of practice, recommendations and guidelines are:

- (a) Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants at http://www.codexalimentarius.org/download/standards/288/CXS_072e.pdf.
- (b) Codex Standard for Follow-up Formula at http://www.codexalimentarius.org/download/standards/293/CXS_156e.pdf.
- (c) Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at http://www.codexalimentarius.org/download/standards/11026/CXP_066e.pdf.
- (d) Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 at http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-document-brfeed-maif_agreement.htm.
- (e) The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand at <http://www.infantnutritioncouncil.com/marketing-codes/code-in-new-zealand/>.
- (f) the WHO International Code of Marketing of Breast-milk Substitutes at <http://www.who.int/nutrition/publications/infantfeeding/9241541601/en/index.html>.

3.6.3 Special purpose foods – Other foods

An application to vary the Code is required to change the compositional or labelling requirements for Special Purpose Foods contained in Part 2.9 of the Code and the Schedules. Currently, these are:

- Standard 2.9.2 – Foods for infants
- Standard 2.9.3 – Formulated meal replacements and formulated supplementary foods
- Standard 2.9.4 – Formulated supplementary sports foods.
- Standard 2.9.5 – Food for special medical purposes.
- Standard 2.9.6 – Transitional Standard for special purpose foods (including amino acid modified foods)
- Schedule 29 – Special purpose foods (sections S29—11 to S29—21 and parts of section S29—7 (as determined by Standard 2.9.2

Note:

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum. The relevant Policy Guideline for special purpose foods is the Intent of Part 2.9 – Special Purpose Foods (approved in 2009).

The Policy Guideline is available at

<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The following information is required to change the compositional or labelling requirements of a special purpose food under Part 2.9 of the Code. The information requirements outlined below are in addition to that specified in Guideline 3.1.1 – General requirements and in other relevant Guidelines in this Handbook.

The relevance of other guidelines is dependent on the proposed variation to the Code; possible Guidelines include:

- 3.3.1.1 for a food additive
- 3.3.2 for a processing aid
- 3.3.3 for a nutritive substance (including an increase or decrease in energy content or macronutrient amount)
- 3.4.2 microbiological limits
- 3.5.2. for a novel food or novel food ingredient
- 3.2.1 for general food labelling
- 3.2.3 for food allergens
- 3.2.4 for labelling for consumer information and choice
- 3.2.5 for nutrition information labelling.

A Information related to general compositional requirements

The application **must** contain the following information if it relates to a change to the general compositional requirements:

A.1 Information on the identity and physical and physiological need of the target population

The application **must** include a description of the target population for the special purpose food. It **must** also include a description of the physical and physiological need of specific life stages e.g. infancy, physical disease, disorder and disability of the target population; or physical and physiological need of the target population that require altered energy or nutrient intake.

A.2 *Purpose of the compositional change*

The application **must** include a brief description of all of the nutritive or health-related function(s) of the substance at the proposed level in the relevant food product(s). Where an added substance or compositional change has multiple purposes or functions, then these **must** be specified.

A.3 *Information related to the safety of the proposed compositional change*

The application **must** include information related to the safety of a food additive, processing aid, novel food or novel food ingredient, or nutritive substance for the target population (Information to demonstrate safety is also requested elsewhere in Part 3).

A.4 *Information related to the nutritional impact or performance impact of the proposed compositional change*

This demonstrates how the compositional change would contribute to achieving the intended purpose of the special purpose food.

The application **must** include clinical studies that examine the nutritional suitability of the food, for the target population.

This also includes information on the performance goals of sports people, if it relates to the addition of a nutritive substance or novel food ingredient to foods regulated under Standard 2.9.4 – Formulated Supplementary Sports Foods and Schedule 29 (sections S29—16 to S29—19).

Note:

With regard to performance goals of sports people, this should include, as a minimum, the results of a literature search on the potential for the nutritive substance or novel food ingredient to achieve specific nutritional or performance goals.

B *Information related to the dietary intake or dietary exposure*

The application **must** contain the following information if it relates to a change to the general compositional requirements:

B.1 *Data to enable the dietary exposure of the target population to be estimated*

This includes information on the dietary exposure of a food additive, processing aid, novel food or novel food ingredient, or dietary intake of a nutritive substance (as indicated elsewhere in these Applications guidelines for the target population).

B.2 *Data on the recommended level of consumption of the special purpose food for the target population*

Information relating to the recommended number of serves per day and the size of each recommended serve should be provided for relevant special purpose foods for the target population.

C *Information related to labelling requirements under Part 2.9 of the Code*

The application **must** contain the following information if it relates to a change to labelling requirements:

C.1 *Information related to safety or nutritional impact of the proposed labelling change*

This includes information to support the proposed labelling change e.g. the inclusion of (or change to) a warning or advisory statement, directions for use, or claim conditions.

C.2 Information to demonstrate that the proposed labelling change will be understood and will assist consumers, if applicable

This includes consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

For example, information to demonstrate how the proposed label change will assist consumer understanding of the specific nature of the food, the intended population group or the intended special purpose of the food;

Note:

A proposed labelling change will only be relevant to consumers for those special purpose foods which are available for retail sale.

D Information related to internationally recognised codes of practice and guidelines

The application **must** contain information demonstrating the extent to which the application is consistent with internationally recognised standards and codes of practices. These include Codex and the WHO recommendations and guidelines, relating to the composition and labelling of special purpose foods.

Note:

Examples of relevant standards, codes of practice, recommendations and guidelines are:

Codex Guidelines for Formulated Supplementary Foods for Older Infants and Young Children at http://www.codexalimentarius.org/download/standards/298/CXG_008e.pdf.

Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children
http://www.codexalimentarius.org/download/standards/300/CXG_010e.pdf.

Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children
http://www.codexalimentarius.org/download/standards/11026/CXP_066e.pdf.

Codex Standard for Processed Cereal-Based Foods for Infants and Young Children
http://www.codexalimentarius.org/download/standards/290/cxs_074e.pdf.

Codex Standard for Formula Foods for Use in Weight Control Diets
http://www.codexalimentarius.org/download/standards/295/CXS_181e.pdf.

Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes at
http://www.codexalimentarius.org/download/standards/294/CXS_180e.pdf.

Codex Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses
http://www.codexalimentarius.org/download/standards/292/CXS_146e.pdf.

Chapter 3.7

Guidelines for applications for food production

3.7.1 Food safety standards

An application to vary the Code is required to change the requirements for standards in Chapter 3 of the Code. The Chapter 3 standards apply in Australia only. Currently, these are:

- Standard 3.1.1 – Interpretation and Application
- Standard 3.2.1 – Food Safety Programs
- Standard 3.2.2 – Food Safety Practices and General Requirements
- Standard 3.2.3 – Food Premises and Equipment
- Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons.

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Information related to food safety

The application **must** contain the following information:

A.1 Data to show that the proposed change will protect public health and safety

This includes:

- (a) survey data, if applicable, to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard
- (b) information from other countries on current practices that relate to the proposed change.

3.7.2 Food processing and primary production

An application to vary the Code is required to change the food processing requirements specified in Standard 1.6.2 – Processing requirements for meat, or the primary production requirements specified in Chapter 4 – Primary Production Standards. These Standards apply in Australia only.

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

A Information related to food safety

The application **must** contain the following information:

A.1 Data to show that the proposed change will protect public health and safety

This includes:

- (a) data to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard
- (b) information from other countries on current practices that relate to the proposed change.

Appendix 1

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
<input type="checkbox"/>		A Form of application <input type="checkbox"/> <i>Application in English</i> <input type="checkbox"/> <i>Executive Summary (separated from main application electronically)</i> <input type="checkbox"/> <i>Relevant sections of Part 3 clearly identified</i> <input type="checkbox"/> <i>Pages sequentially numbered</i> <input type="checkbox"/> <i>Electronic copy (searchable)</i> <input type="checkbox"/> <i>All references provided</i>
<input type="checkbox"/>		B Applicant details
<input type="checkbox"/>		C Purpose of the application
<input type="checkbox"/>		D Justification for the application <input type="checkbox"/> <i>Regulatory impact information</i> <input type="checkbox"/> <i>Impact on international trade</i>
<input type="checkbox"/>		E Information to support the application <input type="checkbox"/> <i>Data requirements</i>
<input type="checkbox"/>		F Assessment procedure <input type="checkbox"/> <i>General</i> <input type="checkbox"/> <i>Major</i> <input type="checkbox"/> <i>Minor</i> <input type="checkbox"/> <i>High level health claim variation</i>
<input type="checkbox"/>		G Confidential commercial information <input type="checkbox"/> <i>CCI material separated from other application material</i> <input type="checkbox"/> <i>Formal request including reasons</i> <input type="checkbox"/> <i>Non-confidential summary provided</i>
<input type="checkbox"/>		H Other confidential information <input type="checkbox"/> <i>Confidential material separated from other application material</i> <input type="checkbox"/> <i>Formal request including reasons</i>
<input type="checkbox"/>		I Exclusive Capturable Commercial Benefit <input type="checkbox"/> <i>Justification provided</i>
<input type="checkbox"/>		J International and other national standards <input type="checkbox"/> <i>International standards</i> <input type="checkbox"/> <i>Other national standards</i>
<input type="checkbox"/>		K Statutory Declaration
<input type="checkbox"/>		L Checklist/s provided with application <input type="checkbox"/> <i>3.1.1 Checklist</i> <input type="checkbox"/> <i>All page number references from application included</i> <input type="checkbox"/> <i>Any other relevant checklists for Chapters 3.2–3.7</i>

Checklist for applications for labelling and other information requirements

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 Guideline 3.2.1 – General food labelling which is mandatory for all labelling applications. If your application relates to Guidelines 3.2.2–3.2.6, then the information required is in addition to 3.2.1.

General food labelling (3.2.1)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Proposed labelling change
<input type="checkbox"/>		A.2 Foods or food groups potentially affected
<input type="checkbox"/>		B.1 Demonstrated consumer support for change
<input type="checkbox"/>		B.2 Proposed labelling to be understood and assist consumers
<input type="checkbox"/>		B.3 Any adverse health or diet impacts

Warning and advisory statements (3.2.2)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Data on potential health concern
<input type="checkbox"/>		B.1 Data on lack of consumer awareness of health and safety risk

Declaration of allergens (3.2.3)

Check	Page No.	Mandatory requirements
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A Addition of allergen to list of declared foods

<input type="checkbox"/>		A.1 Demonstration that the food causes IgE-mediated allergy
<input type="checkbox"/>		A.2 Incidence of allergic reaction
<input type="checkbox"/>		A.3 Severity of allergic reaction
<input type="checkbox"/>		A.4 Extent of use of allergen in foods

B Removal of food derivative from the list of declared foods

<input type="checkbox"/>		B.1 Nature of food derivative
<input type="checkbox"/>		B.2 Use of food derivative and presence in final food
<input type="checkbox"/>		B.3 Dietary intake information
<input type="checkbox"/>		B.4 History of safe use
<input type="checkbox"/>		B.5 Clinical information on safety of food derivative

Labelling for consumer information and choice (3.2.4)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Current labelling or alternative information inadequacies
<input type="checkbox"/>		A.2 Information on lack of suitable alternatives available to consumers
<input type="checkbox"/>		A.3 How proposed labelling change will assist consumers

- A.4 Information to demonstrate alternate measures in absence of labelling would not be effective

Nutrition information labelling (3.2.5)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Proposed change and how it will change nutrition information labelling
<input type="checkbox"/>		A.2 Data to demonstrate labelling will assist consumers
<input type="checkbox"/>		B.1 Nature and composition of the ingredient
<input type="checkbox"/>		B.2 Calculation of energy factor
<input type="checkbox"/>		B.3.1 Substantiation of energy factor – Bomb calorimetry
<input type="checkbox"/>		B.3.2 Substantiation of energy factor – Classical dietary energy balance
<input type="checkbox"/>		B.3.3 Substantiation of energy factor – Isometric tracer methods
<input type="checkbox"/>		B.3.4 Substantiation of energy factor – Breath hydrogen test
<input type="checkbox"/>		B.3.5 Substantiation of energy factor – Ileal intubation and ileostomy effluent
<input type="checkbox"/>		B.4 Other factors

Nutrition content and health claims (3.2.6)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Nutrition content claims
<input type="checkbox"/>		A.2 Amendment to existing high level or general level claim
<input type="checkbox"/>		A.3 Amendment to nutrient profiling scoring criterion or method
<input type="checkbox"/>		A.4 Variation of required elements of systematic review in Schedule 6
<input type="checkbox"/>		B.1.1 Description of food or property of food in food-health relationship
<input type="checkbox"/>		B.1.2 Description of health effect in food-health relationship
<input type="checkbox"/>		B.1.3 Description of food-health relationship
<input type="checkbox"/>		B.2.1 Description of search strategy for relationships (original literature only)
<input type="checkbox"/>		B.2.2 Food-health relationship based on updating systematic reviews
<input type="checkbox"/>		B.3 Summarising literature for proposed food-health relationship
<input type="checkbox"/>		B.4 Assessment of data from human studies
<input type="checkbox"/>		B.5 Information for setting conditions

Checklist for applications for substances added to food

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 3.3.1–3.3.3.

Food additives (3.3.1)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Nature and technological purpose information
<input type="checkbox"/>		A.2 Identification information
<input type="checkbox"/>		A.3 Chemical and physical properties
<input type="checkbox"/>		A.4 Impurity profile
<input type="checkbox"/>		A.5 Manufacturing process
<input type="checkbox"/>		A.6 Specifications
<input type="checkbox"/>		A.7 Food labelling
<input type="checkbox"/>		A.8 Analytical detection method
<input type="checkbox"/>		A.9 Additional functions
<input type="checkbox"/>		B.1 Toxicokinetics and metabolism information
<input type="checkbox"/>		B.2 Toxicity information
<input type="checkbox"/>		B.3 Safety assessments from international agencies
<input type="checkbox"/>		C.1 List of foods likely to contain the food additive
<input type="checkbox"/>		C.2 Proposed levels in foods
<input type="checkbox"/>		C.3 Likely level of consumption
<input type="checkbox"/>		C.4 Percentage of food group to contain the food additive
<input type="checkbox"/>		C.5 Use in other countries (if applicable)
<input type="checkbox"/>		C.6 Where consumption has changed, information on likely consumption
Processing aids (3.3.2)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Type of processing aid
<input type="checkbox"/>		A.2 Identification information
<input type="checkbox"/>		A.3 Chemical and physical properties
<input type="checkbox"/>		A.4 Manufacturing process
<input type="checkbox"/>		A.5 Specification information
<input type="checkbox"/>		A.6 Analytical method for detection
<input type="checkbox"/>		B.1 Industrial use information (chemical only)
<input type="checkbox"/>		B.2 Information on use in other countries (chemical only)
<input type="checkbox"/>		B.3 Toxicokinetics and metabolism information (chemical only)
<input type="checkbox"/>		B.4 Toxicity information (chemical only)
<input type="checkbox"/>		B.5 Safety assessments from international agencies (chemical only)
<input type="checkbox"/>		C.1 Information on enzyme use on other countries (enzyme only)

- C.2 Toxicity information of enzyme (enzyme only)
- C.3. Allergenicity information of enzyme (enzyme only)
- C.4. Overseas safety Assessment Reports
- D.1 Information on source organism (enzyme from microorganism only)
- D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)
- D.3 Genetic stability of source organism (enzyme from microorganism only)
- E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)
- F.1 List of foods likely to contain the processing aid
- F.2 Anticipated residue levels in foods
- F.3 Information on likely level of consumption
- F.4 Percentage of food group to use processing aid
- F.5 Information on residues in foods in other countries (if available)
- F.6 Where consumption has changed, information on likely consumption

Substances used of a nutritive purpose (3.3.3)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Purpose of the use of the substance
<input type="checkbox"/>		A.2 General data requirements for supporting evidence
<input type="checkbox"/>		B.1 Identification
<input type="checkbox"/>		B.2 Chemical and physical properties
<input type="checkbox"/>		B.3 Impurity profile
<input type="checkbox"/>		B.4 manufacturing process
<input type="checkbox"/>		B.5 Specification for identity and purity
<input type="checkbox"/>		B.6 Analytical method for detection
<input type="checkbox"/>		B.7 Proposed food label
<input type="checkbox"/>		C.1 Toxicokinetics and metabolism, degradation products and major metabolites
<input type="checkbox"/>		C.2 Animal or human studies
<input type="checkbox"/>		C.3 International safety assessments
<input type="checkbox"/>		D.1 List of food groups or foods likely to contain the nutritive substance
<input type="checkbox"/>		D.2 Proposed maximum levels in food groups or foods
<input type="checkbox"/>		D.3 Likely level of consumption
<input type="checkbox"/>		D.4 Percentage of food group to use nutritive substance
<input type="checkbox"/>		D.5 Use in other countries (if available)
<input type="checkbox"/>		D.6 Where consumption has changed, information on likely consumption
<input type="checkbox"/>		E.1 Need to permit addition of vitamin or mineral
<input type="checkbox"/>		E.2 Demonstrated potential to address deficit or health benefit
<input type="checkbox"/>		F.1 Nutritional purpose (other than vitamins and minerals)
<input type="checkbox"/>		G.1 Consumer awareness and understanding

- G.2 Actual or potential behaviour of consumers
 - H.3 Demonstration of no adverse effects on any population groups
 - H.3 Demonstration of no adverse effects on any population groups
-

Checklist for applications for contaminants and natural toxicants

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 3.4.1–3.4.3.

Chemical contaminant and natural toxicant maximum levels (3.4.1)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Nature of contaminant or natural toxicant
<input type="checkbox"/>		A.2 Analytical detection method
<input type="checkbox"/>		B.1 Toxicokinetics & metabolism information
<input type="checkbox"/>		B.2 Toxicity studies
<input type="checkbox"/>		B.3 Human studies relevant to safety
<input type="checkbox"/>		C.1 List of foods where maximum level is proposed
<input type="checkbox"/>		C.2 Survey data on contaminant or toxicant levels in foods
<input type="checkbox"/>		C.3 Information on levels of consumption
<input type="checkbox"/>		C.4 Where consumption has changed, information on likely consumption
Microbiological limits (3.4.2)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Raw inputs, production and manufacturing process
<input type="checkbox"/>		A.2 Food technology
<input type="checkbox"/>		B.1 Nature of the microbiological hazard
<input type="checkbox"/>		B.2 Source & prevalence of contamination
<input type="checkbox"/>		B.3 Consumer handling and use
<input type="checkbox"/>		C.1 Nutritional impact
<input type="checkbox"/>		D.1 Dietary exposure
Prohibited and restricted plants and fungi (3.4.3)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Nature of plant or fungi
<input type="checkbox"/>		A.2 Identity and levels of natural toxicants
<input type="checkbox"/>		B.1 Toxicity studies
<input type="checkbox"/>		B.2 Human toxicity case studies
<input type="checkbox"/>		B.3 Use in other countries

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
<input type="checkbox"/>		A.1 Nature and identity
<input type="checkbox"/>		A.2 History of use of host and donor organisms
<input type="checkbox"/>		A.3 Nature of genetic modification
<input type="checkbox"/>		B.1 Characterisation and safety assessment
<input type="checkbox"/>		B.2 New proteins
<input type="checkbox"/>		B.3 Other (non-protein) new substances
<input type="checkbox"/>		B.4 Novel herbicide metabolites in GM herbicide-tolerant plants
<input type="checkbox"/>		B.5 Compositional analyses
<input type="checkbox"/>		C Nutritional impact of GM food
<input type="checkbox"/>		D Other information

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

- C.6.1 Safety of the source organism, including allergen statement
- C.6.2 Composition
- C.6.3 Toxicity studies
- 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
 - D.1 List of foods likely to contain the novel food or novel food ingredient
 - D.2 Proposed levels in foods
 - D.3 Information on levels of consumption
 - D.4 Percentage of food group or market
 - D.5 Where consumption has changed, information on likely consumption
 - D.6 Information to show whether the food or ingredient will replace another food
 - D.7 Use in other countries
 - E.1 Nutritional impact information
 - E.2 Public health impact
 - F.1 Demonstrated consumer awareness and understanding
 - F.2 Potential behaviour in response to foods
 - F.3 Demonstration of no adverse effects on any population groups
-

Irradiated foods (3.5.3)

Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Nature of the food or food ingredient to be irradiated
<input type="checkbox"/>		A.2 Technological need
<input type="checkbox"/>		A.3 Food products likely to contain irradiated food
<input type="checkbox"/>		B Safety information
<input type="checkbox"/>		C Nutritional impact

Checklist for applications for special purpose foods and standardised 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 3.6.1–3.6.3.

Standardised foods (3.6.1)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Proposed compositional change
<input type="checkbox"/>		A.2 List of foods likely to be affected
<input type="checkbox"/>		B.1 Nutritional content
<input type="checkbox"/>		C.1 Demonstrated consumer understanding of proposed change
<input type="checkbox"/>		C.2 Potential adverse health or diet impacts
Special purpose foods – Infant formula products (3.6.2)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Purpose of compositional change
<input type="checkbox"/>		A.2 Data for supporting evidence
<input type="checkbox"/>		A.3 Specific information requirements <input type="checkbox"/> <i>Characterisation of proposed substance in breast milk</i> <input type="checkbox"/> <i>Nutritional safety and tolerance</i> <input type="checkbox"/> <i>Efficacy of proposed compositional change</i> <input type="checkbox"/> <i>Tolerance of proposed compositional change</i>
<input type="checkbox"/>		B.1 Dietary intake or exposure of target population
<input type="checkbox"/>		B.2 Level of consumption
<input type="checkbox"/>		B.3 Information relating to the substance
<input type="checkbox"/>		C.1 Safety or nutritional impact of labelling change
<input type="checkbox"/>		C.2 Demonstrated consumer understanding of labelling change
<input type="checkbox"/>		D Internationally recognised codes of practice and guidelines on labelling
Special purpose foods – Other foods (3.6.3)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Identity and need of target population
<input type="checkbox"/>		A.2 Purpose of compositional change
<input type="checkbox"/>		A.3 Safety of proposed compositional change
<input type="checkbox"/>		A.4 Nutritional or performance impact
<input type="checkbox"/>		B.1 Dietary exposure data
<input type="checkbox"/>		B.2 Level of consumption
<input type="checkbox"/>		C.1 Safety and nutritional impact of labelling change
<input type="checkbox"/>		C.2 Demonstrated consumer understanding of labelling change
<input type="checkbox"/>		D Internationally recognised codes of practice and guidelines

Checklist for applications for food production

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 Sections 3.7.1–3.7.2.

Food safety standards (3.7.1)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Public health and safety data
<input type="checkbox"/>		B.1 Projected costs to food industry

Food processing and primary production (3.7.2)		
Check	Page No.	Mandatory requirements
<input type="checkbox"/>		A.1 Public health and safety data

Amendment history

Note 1

Part 3 of the *FSANZ Application Handbook* (in force under section 23 of the *Food Standards Australia New Zealand Act 1991*) as shown in this compilation is amended as indicated in the Tables below.

This is a compilation of Part 3 as in force on **1 March 2016** (up to Amendment No. 7 – 2016).

Prepared by Food Standards Australia New Zealand on **5 January 2016**.

Table of instruments

Title	Date of FRLI Registration	Date of Commencement	Application, Saving or Transitional Provisions
<i>FSANZ Application Handbook – Part 3</i>	1 August 2007 (F2007L02114).	2 August 2007	
<i>FSANZ Application Handbook – Part 3 – Amendment No. 1 – 2008</i>	5 June 2008 (F2008L01697)	5 June 2008	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 2 – 2008</i>	9 December 2008 (F2008L04594)	9 December 2008	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 3 – 2009</i>	25 August 2009 (F2009L03244)	25 August 2009	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 4 – 2010</i>	2 June 2010 (F2010L01483)	1 July 2010	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 5 – 2011</i>	7 July 2011 (F2011L01439)	1 August 2011	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 6 – 2013</i>	19 August 2013 (F2013L01586)	1 September 2013	-
<i>FSANZ Application Handbook – Part 3 – Amendment No. 7 – 2016</i>	5 January 2016 (F2016L00022)	1 March 2016	-

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ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

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Checklist for General requirements	am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 6 – 2013, rs. No. 7 – 2016
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Checklist for Standards related to substances added to food	am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 7 – 2016
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Checklist for Standards related to new foods	am. No. 1 – 2008, am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 7 – 2016
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Checklist for Standards related to special purpose foods and standardised foods	ad. No. 6 – 2013, rs. No. 7 – 2016
Checklist for Standards related to food production	rs. No. 5 – 2011, rs. No. 7 – 2016