

AUSTRALIA NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

PROTOCOL for the development of Primary Production and Processing Standards by FSANZ

Note: This paper deals with arrangements due to come into effect upon commencement of the *Food Standards Australia New Zealand Act 2001*.

OBJECTIVE

This Protocol outlines the process for the development of a Primary Production and Processing Standard by a FSANZ Standards Development Committee (SDC). The protocol has been developed to:

- inform stakeholders of the process for the development of a Primary Production and Processing Standard
- ensure that a consistent approach is undertaken by all SDCs in the development of standards;
- guide SDCs in the process of developing standards;
- ensure that standards are developed within the overarching policy framework set by Ministers; and
- ensure that the process satisfies the statutory requirements of the *FSANZ Act*.

BACKGROUND

In 1997 the Commonwealth, State and Territory governments agreed to a comprehensive review of food regulation throughout the whole food chain in consultation with all affected stakeholders. The resultant Blair Report recommended that food regulation be reformed to ensure a nationally consistent approach within Australia and New Zealand and a Council of Australian Government (COAG) Senior Officials Working Group on Food Regulation (SOWG) was formed in 1999 to develop the Commonwealth and State and Territory governments' response to the review.

The SOWG report recommended that all existing domestic food standards, including primary product standards, be combined to produce a single set of standards consistent with internationally recognised Codex Alimentarius Commission ('Codex') standards. The development of the standards would be the responsibility of Food Standards Australia New Zealand (FSANZ)¹. Once the new standards have been approved and gazetted they will automatically come into force by reference and without amendment under the State and Territory *Food Acts*.

¹ For ease of use, all references to FSANZ include references to its predecessor organization, the Australia New Zealand Food Authority (ANZFA)

SCOPE

The objectives of the FSANZ under section 10(1) of the *Food Standards Australia New Zealand Act 2001* ('the Act') in developing or reviewing food regulatory measures and variations of food regulatory measures are:

- (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.

In addition, section 10(2) requires FSANZ to also have regard to the following in developing or reviewing food regulatory measures and variations of food regulatory measures:

- (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;
- (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

Since the Blair Review FSANZ has undertaken extensive work in the area of food law reform which has resulted in the formulation of the new *Australia New Zealand Food Standards Code* ('Food Standards Code'). In an extension of this comprehensive and integrated approach to food safety, a new Chapter 4 of the *Food Standards Code* will incorporate primary production and processing standards.

This protocol outlines the processes involved in developing a primary production and processing standard. Such standards form part of an effective food safety system. This is consistent with international approaches to managing food safety and associated human health risks where it has been realised that in order to ensure safe food, responsibility must be taken at all points across the food chain (the 'paddock to plate' approach).

The development of primary production and processing standards requires extensive consultation with all primary industry sectors, stakeholders and interested parties. The emphasis will be on food safety and not food quality and will deliver outcome based, rather than prescriptive requirements. The primary production and processing standards will be consistent with the Food Safety Standards contained in Chapter 3 of the *Food Standards Code*. Chapter 3 of the *Food Standards Code* applies to Australia only.

(Note – As with the Food Safety Standards the Primary Production and Processing Standards will not apply in New Zealand. The treaty that was signed between the Australian and New Zealand Governments in 1995 to develop joint food standards did not include standards relating to food hygiene).

Quality attributes or specific production methodologies that do not relate to food safety will in general be handled through industry mechanisms. Primary production and processing standards will not include labelling, compositional or additive/contaminant/residue standards, which will continue to be developed through the usual FSANZ process and be included in Chapters 1 and 2 of the *Food Standards Code*. Under the Food Safety Standards (Chapter 3 of the *Code*) the terms *food safety* and *food suitability* are defined as referring to food safety only.

As defined in Chapter 3 of the *Food Standards Code*, food is not safe if it would be likely to pose a risk to the health and safety of a person who might later consume it, assuming it was:

- after that time and before being consumed by the person, properly subjected to all processes (if any) that are relevant to its reasonable intended use; and,
- consumed by the person according to its reasonable intended use.

However, food is not necessarily unsafe because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions in persons with allergies or sensitivities that are not common in the majority of persons. In such circumstances advisory labels may be all that is required.

There may be certain situations where it is appropriate to include quality elements in the standards, however it is most likely that these elements would only be included where it appears likely that such an approach is justified in the circumstances and would meet with strong government and stakeholder support.

The sectors the primary production and processing standards are expected to apply to include:

- Seafood
- Meat
- Dairy
- Grains
- Horticulture
- Honey
- Eggs / Poultry

It is expected that the need will arise from time to time for such standards to be developed also for other sectors

Standard Development Committee model

FSANZ must, in relation to all Applications and Proposals to amend the *Food Standards Code*, meet its obligations under the *FSANZ Act*, and Primary Production and Processing Standards are no exceptions to this requirement. While complying with its statutory obligations, FSANZ intends to implement a new approach when developing the Primary Production and Processing Standards. This is through the establishment by the FSANZ Board of Standard Development Committees (SDCs). SDCs will consist of representatives of affected stakeholders (see section 4) and relevant FSANZ staff. The SDC will be responsible for ensuring ongoing liaison with stakeholders and the gathering of necessary expertise, and will play an active role in the development of draft standards, should they be required.

FSANZ's intention is that all relevant stakeholders are actively involved in the development of recommendations on primary production and processing standards and that transparency is maintained throughout the process.

FSANZ's Risk Assessment and Management Framework

In order to progress an application or proposal to a gazetted Primary Production and Processing Standard, FSANZ must, in addition to its legislative requirements, comply with the overarching policies as set out by the ANZFRMC guidelines. FSANZ has developed a rigorous risk management system to deliver against these obligations.

The analysis of risk can be divided into three distinct processes, namely:

- Risk assessment – the scientific process of hazard identification, using available information to identify, characterise, and quantify the adverse health effects of exposure, with respect to biological, chemical or physical agents.
- Risk management – examining risk assessment results in the context of FSANZ's social and economic goals, and after considering relevant policy guidelines, identifying a strategy to control the risk. FSANZ's risk assessment policy guidelines provide a systematic approach to decision making, with clear steps which focus on the context of the risks and options for managing those risks.
- Risk communication – communication commences at the very outset of the project with the provision of information on the need for regulatory intervention and the exchange of ideas, options, issues right through to the final stage when a decision has been made and needs to be communicated to all interested parties.

FSANZ's integrated approach to scientific risk assessment is based on the *Australian/New Zealand Risk Management Standard 1999* and also incorporates the risk analysis process endorsed by Codex under the joint FAO/WHO Food Standards Programme and the International Programme on Chemical Safety in cooperation with the Joint FAO/WHO Expert Committee in Food Additives (JECFA). Using this process, the most appropriate level of scientific risk assessment can be made.

Once the risk assessment has been completed a risk management strategy can be identified based on an assessment of the costs and benefits of the risks. This is achieved by ascertaining and evaluating the most appropriate options for addressing these risks and identifying the risk management measure that optimally serves the diverse interests of industry and the wider community. This must reflect the statutory objectives specified in the *FSANZ Act*.

This approach will ensure that all risks are systematically identified and considered in the regulatory decision-making process as required under the Council of Australian Governments *Principles and Guidelines for National Standards Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*, agreed in November 1997. In addition the Office of Regulatory Review has provided more detailed information in their *Guide to Regulation* issued in December 1998.

MECHANISM FOR STANDARDS DEVELOPMENT

Step 1. THE TRIGGER FOR STANDARD DEVELOPMENT

Applications can be submitted to FSANZ for the development or variation of an existing primary production and processing standard. These applications will routinely be completed within 12 working months from commencement of the initial assessment.

Alternatively, a proposal for the development or variation of a standard can be initiated by FSANZ. The ANZFRMC² can recommend that FSANZ initiate such a proposal.

All applications and proposals once received are placed on the FSANZ workplan in one of three groups:

- Group 1 deals with applications where a threat to public health and safety has been identified and immediate action is required.
- Group 2 contains the bulk of applications and proposals and are dealt with on a first come first served basis.
- Group 3 includes those applications for which the full cost of processing an application is met by the applicant.

Step 2. FSANZ NOTIFIES ITS INTENTION TO DEVELOP A STANDARD

All applications and proposals received by FSANZ are considered by an internal scoping group which identifies the nature of each application or proposal, its complexity, and a strategy for its assessment. FSANZ will then propose the establishment of a Standards Development Committee (SDC) (see Step 4) for a particular commodity type (e.g. meat, dairy, seafood.) and develop draft terms of reference for the SDC, based on the information provided in the application or proposal, Ministerial policy guidelines and this protocol.

² A reference to ANZFRMC includes a reference to the Australia New Zealand Food Standards Council (ANZFSC)

FSANZ will inform the Food Regulation Standing Committee (FRSC) and ANZFRMC of the application or proposal and of its intention to establish a SDC to provide the necessary expertise in the development of the draft standard. This step would not be required if the trigger for standard development was based on a ANZFRMC request or review.

Step 3. MINISTERS PROVIDE THE POLICY FRAMEWORK

ANZFRMC will provide relevant overarching policy guidelines and recommendations to FSANZ that can specifically relate to the commodity for which a standard is to be developed or varied. These will include:

- policy guidelines to cover the scope of the standard or variation of a standard (products/commodities covered and the extent of the food chain covered); and
- other matters to be considered by FSANZ, such as industry issues, alignment with Codex standards and World Trade Organization considerations. Existing policy guidelines may also need to be referred to for these issues.

Step 4. FSANZ ESTABLISHES THE STANDARDS DEVELOPMENT COMMITTEE

Following receipt of the policy guidelines and consideration of them, the FSANZ Board will establish the Standards Development Committee. In most cases, this will occur following a call for nominations from affected stakeholders. There may also be a process of public advertisement to seek nominations. If an existing body is found to possess the relevant expertise required of a particular SDC, then it would be appropriate for FSANZ to designate that body, or members of the body, as part of an SDC. Relevant FSANZ staff and, as necessary, other experts, will also be appointed to the SDC to provide expert scientific, technical, legal and policy advice.

The FSANZ Board may choose to supplement the policy guidelines with more detailed requirements and will also indicate which organisations and/or individuals it considers should be consulted. It will also give the SDC an indicative timeline and terms of reference. These guidelines, terms of reference and indicative timeline will form the protocol for the SDC.

Step 5. OPERATIONS OF THE STANDARDS DEVELOPMENT COMMITTEE

The SDC will have responsibility for:

- undertaking a scoping exercise to determine the scope of a proposed standard (if not already explicitly outlined by Ministerial policy guidelines or within the application or proposal);
- ensuring that draft standards are developed within the appropriate policy guideline and that all processes are conducted according to the FSANZ protocol;
- reporting and making recommendations to FSANZ on technical issues associated with standards development;

- reporting and making recommendations to FRSC (having notified FSANZ) on policy issues associated with standards development;
- identifying relevant linkages for food related standards within the primary production sector; and
- identifying relevant linkages with non-food related standards or relevant bodies charged with policy development in the primary production sector to ensure through-chain consideration of issues (such as the rendering industry which impacts on both human and animal health).

It is expected that external members or key organizations having representation on a SDC will maintain financial responsibility for their particular role within that committee and meet any costs involved with respect to travel arrangements and accommodation (such as the travel or accommodation required to attend a SDC/Workgroup meeting).

FSANZ will provide the Secretariat, convene the SDC and meet the costs of advertising, meeting venue, etc.

Step 6. INITIAL ASSESSMENT

The process of creation of primary production and processing standards must conform with the requirements of the *FSANZ Act*, which consist of:

1. Initial assessment (only for applications)
2. Draft assessment; and
3. Final assessment.

If the application is accepted, FSANZ will release for public comment and stakeholder input an Initial Assessment Report, based on the work of the SDC, identifying the issues required to be addressed in the food regulatory measure and raising questions that will need to be answered. FSANZ's statutory processes require at least one round of public consultation with stakeholders as part of the process of gathering information and evidence in order to undertake a rigorous scientific risk assessment and analysis of the regulatory impacts.

FSANZ will undertake all public notification and convene any stakeholder consultative processes that need to be undertaken by the SDC. This will include the publishing of notifications concerning proposals and applications in prominent Australian newspapers, mail outs to all interested stakeholders, and the provision of information on the FSANZ web site. All reports will be made available for public comment.

All FSANZ submitters and subscribers to the assessment processes will be kept informed via this process as transparency within the consultative stage is essential if all groups, competing interests and stakeholders are to be actively involved in the development of the standards.

Step 7. DRAFT ASSESSMENT REPORT

Based on the response to the initial round of public comment on the Initial Assessment, expert opinion and evidence, and its own expertise, the SDC will prepare a risk assessment, consider a range of regulatory options and, if satisfied that a standard is appropriate, instruct the FSANZ Office of Legal Counsel on the drafting of a primary production and processing standard. The risk assessment and draft standard forms a Draft Assessment Report, written in the FSANZ regulatory impact statement (RIS) format for the FSANZ Board. The report will need to be prepared in accordance with:

- the objectives outlined in section 10(1) and other matters listed in section 10(2) which FSANZ must also have regard to;
- any relevant ANZFRMC policy guidelines;
- the Council of Australian Governments Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies; and
- other relevant statutory requirements and legal considerations.

Regulatory impact analysis must take into account the impacts on, and views of all affected stakeholder groups – including industry, consumers, and governments. These issues will be explicitly referred to in the Initial Assessment, Draft Assessment and Final Assessment Reports and meet the requirement of the guidelines provided by the Office of Regulation Review.

Where appropriate to protect public health and safety, FSANZ may under section 24 of the *FSANZ Act* declare in writing that an application or proposal is urgent, where that application or proposal relates to the development or variation of a standard. This enables FSANZ to expedite a matter on the basis it may omit to do any one or more of the actions it would normally undertake in an assessment process. In order to avoid compromising the objectives set out in section 10 of the *Act*, FSANZ must, as soon as practicable, undertake a round of consultation and conduct a Final Assessment.

Under section 36 of the *Act* FSANZ is able to simplify and expedite the assessment procedure in cases where to do so would not have a significant adverse effect on the interests of anyone, or the application or proposal only raises issues that are of minor significance or complexity. Usually such matters involve simple administrative changes such as correcting minor errors, or clarifying an explanation in a food standard. In this case FSANZ is able to forego one round of public consultation or shorten the timeframe (while maintaining the full consultation process) in consultation with the ANZFRMC and stakeholders.

Upon FSANZ being satisfied that the Draft Assessment Report meets the objectives outlined above, it is presented to the FSANZ Board for consideration and then sent out for a further round of stakeholder and public comment.

Step 8. FINAL ASSESSMENT

FSANZ prepares a Final Assessment Report with the assistance of the SDC, which will be the Draft Assessment Report amended to take account of any further public comments received and any necessary revisions to the draft food regulatory measure. The Final Assessment Report, including the draft food regulatory measure and draft RIS, are then sent to the FSANZ Board for approval. The FSANZ Board may approve the draft food regulatory measure or variation, or approve the draft subject to amendments, or reject the draft, or reject the draft and request further work be undertaken.

The FSANZ Board may also seek further information if required.

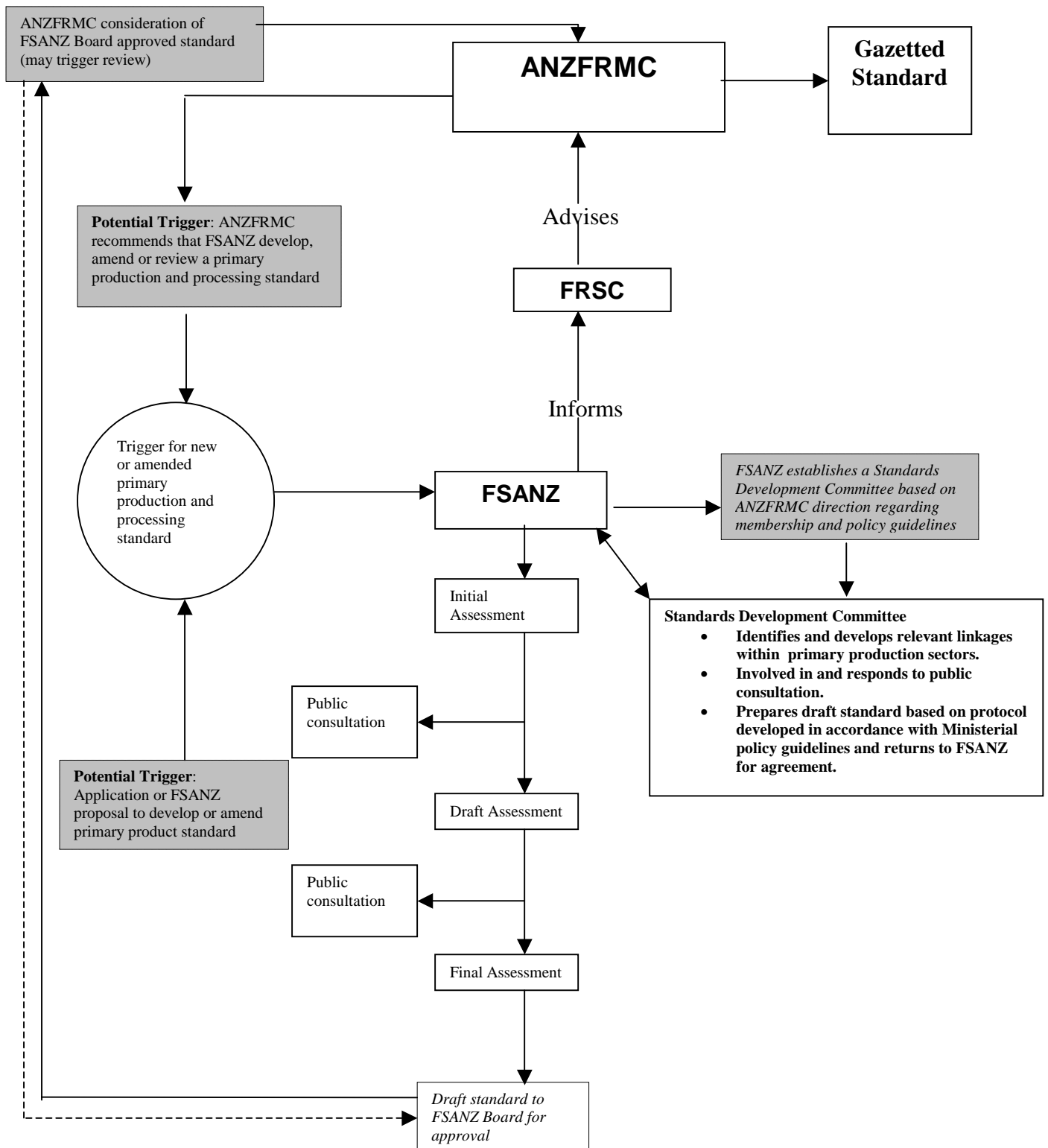
Step 9. COUNCIL NOTIFICATION

Once the FSANZ Board makes a final assessment and approves a draft standard or variation, the ANZFRMC is notified within 14 days after approval and the Ministerial Council review period (60 days) begins. Public notification is also required. Ministerial consideration may trigger further reviews by FSANZ of the draft standard or variation.

Step 10. GAZETTAL

Once the Ministerial review process is complete and the standard or variation is approved, the standard is gazetted and incorporated into Chapter 4 of the *Food Standards Code* when it will automatically come into force by reference and without amendment into the *Food Acts*, or other applicable legislation, of each of the States and Territories.

How primary production and processing standards are developed under FSANZ



The reporting mechanisms for Standards Development Committees

