



Streamlining the process

**2007 Amendments to the
*Food Standards Australia
New Zealand Act 1991***

Key Elements



Overview of Assessment processes:

- 3 Procedures for assessment of applications and proposals (Initial, Draft and Final Assessment concepts will not exist)
- New treatment for applications for high level health claims
- Use of mandatory application Guidelines (*Application Handbook*) by FSANZ to determine acceptance of an application
- Proposals not time-affected



Ministerial Council:

- Review process to be shortened

Proposed date of effect

- for all proposals prepared and applications received 3 months after Act is proclaimed (from 1 October 2007 onwards)
- Applications and proposals which had started before the date of effect, assessed under current Act arrangements



Application requirements

- All applications will be required to include certain minimum information as outlined in Part 3 of FSANZ's *Application Handbook*
- FSANZ will be able to reject an application on the basis that it does not meet information requirements set out in Part 3 of the *Application Handbook*
- Fees will be payable after Administrative Assessment completed



Administrative Assessment (15 working days)



- To determine whether an application meets the application requirements
- To determine the Procedure (General, Minor or Major) under which an application will be assessed
- To determine charges for an application which has an ECCB for the applicant, or if the applicant wishes to expedite consideration of the application. If an applicant with an ECCB does not pay the fees within 20 business days of the notification that the Admin Assessment has been made, the application is rejected.
- Determination of timeframes
- Assessment (from receipt of application to notification to applicant) must be undertaken within 15 business days
- If application is accepted → then placed on the Work Plan
- After the Administrative Assessment is completed, an 'early bird' notification to the public occurs

GENERAL PROCEDURE – Default process (9 months to complete assessment)



Applications or proposals to:

- vary a food regulatory measure (other than those which are a Major or Minor Procedure) e.g. allowing / extending a permission for a processing aid or food additive, MRLs, most pre-market safety assessments

Includes:

- Widespread consultation (1 round of public consultation)
- an assessment of the risk to public health and safety of average complexity, including toxicological, nutritional, food technology, dietary modelling or microbiological assessment

Process:

- Administrative Assessment stage → 'early bird' Notice → Assessment (including development of draft regulatory measure) → Consultation → Approval → Notification to Ministerial Council



MAJOR PROCEDURE - New food regulatory measure or major variation to food regulatory measure (12 months to complete assessment)



Applications or proposals to:

- develop a new standard or a major variation to a food regulatory measure e.g. major labelling or compositional amendment

Includes:

- extensive consultation, including use of SDACs and EAGs (2 rounds of public consultation)
- comprehensive assessment – risk management options, benefit/cost analysis
- Independent peer review of the risk analysis

Process:

- Administrative Assessment stage → 'early bird' Notice → 1st Assessment → Consultation → 2nd Assessment (including development of draft regulatory measure) → Consultation → Approval → Notification to Ministerial Council





MINOR PROCEDURE – Minor variation (3 months to complete assessment)

Applications or proposals to:

- make minor variations to food regulatory measures e.g. correction of a typographical error, editorial change or an amendment designed to improve clarity

Includes:

- minimal consultation (1 round of consultation)
- no or low additional risk to public safety
- no change to existing social or economic impact



Process:

- Administrative Assessment stage → ‘early bird’ Notice → Assessment (including development of draft regulatory measure) → Consultation (Govt agencies only + affected stakeholders) → Approval → Notification to Ministerial Council

Amendments to the Health Claims Standard (9 months to complete assessment)



Applications only to:

- vary the health claims Standard to allow the use of a high-level health claim

Includes:

- Use of FRSC and a High Level Health Claims Expert Committee as key parts of the consultation process
- where the applicant has requested that the application be dealt with confidentially, no public consultation - consultation with appropriate government authorities and an expert committee only. No public notification of the proposed change to the Standard until Gazettal

Confidentiality requirements:

- Anyone to whom information is provided in accordance with this process is subject to the confidentiality provisions, including all appropriate government agencies and expert committee





Treatment of Specific Types of Applications

MRLs

- FSANZ to prepare proposals to reflect APVMA applications for MRL amendments
- Proposals must be completed in 9 months – the clock will commence once we receive the application from the APVMA
- Allows the APVMA and FSANZ processes generally to run in parallel

Cost-recovered applications



- 2 types of cost-recovered (paid) applications – those with an exclusive capturable commercial benefit (ECCB), and those where the consideration of the application is expedited (work to start on receipt of fees)
- Fees for the General and Minor Procedures are due in full (no instalments) after the Admin Assessment is completed:
 - General - Level 1 (up to 500 hours) \$53,500
 - General – Level 2 (up to 850 hours) \$90,950

 - Minor (up to 175 hours) \$18,725
- Fees for the Major Procedure can either be paid in full, or in 2 instalments (25% of the full fee and 75% of the full fee)
 - up to 1050 hours \$112,350
 - over 1050 hours \$112,350 + \$107 for each hour over 1050 hours

Cost-recovered applications (cont)



- If fees are paid in instalments, the 2nd instalment is due on the date submissions on the 1st Assessment Report close
- Fees will be refunded if an application is withdrawn or rejected. The refund will be based on the fee paid, less the amount of hours of work completed (\$107 per hour)
- If FSANZ completes an application and the amount of hours taken to complete the assessment is less than the fee paid by the applicant, the applicant will receive a refund for the number of hours not used (\$107 per hour)



Ministerial Council

- The Ministerial Council will only have one opportunity to request a review – only 1 jurisdiction required (this change is dependent on amendments to the Treaty and may not be implemented before September 2008)
- Following the Review, the Ministerial Council must make one of the decisions that is currently available after the Second Review, that is:
 - inform FSANZ that it does not intend to amend or reject the draft; or
 - amend the draft; or
 - reject the draft
- Matters on the books before 1 October 2007 will continue to have the possibility of 2 reviews



Other Changes

FSANZ functions

- FSANZ's functions are to be extended to cover the provision of information about the Code and individual standards e.g. Advice Line

Urgency Provisions

- Extended to address an unintended negative impact on trade.

Clock Start

- The clock for unpaid applications and proposals will start at earlier in the process (currently starts on the date the Initial Assessment is made)

Other Changes (cont)



Stop clocks

- The clock can be stopped for up to 18 months where the Ministerial Council has notified FSANZ that it is developing policy guidelines – this stop clock is automatic for unpaid applications, however, for paid applications, the applicant must consent to the stop-clock

Extensions of time

- FSANZ may extend the application timeframe for up to 6 months only in relation to the Major Procedure

Renumbering of Act

- As part of the amendments, the numbering of nearly every section has changed. For example, our section 10 objectives are now section 18 objectives.



s.36 – to omit a round of public consultation

- Deleted as no longer necessary – the default Procedure has only 1 round of consultation

Regulations



- The FSANZ Regulations have been amended to reflect the changes to the Act, reflect the assessment Procedures and set the cost-recovery fees

What's happened so far?



- FSANZ *Application Handbook* approved by Board in March 2007 and registered as a Legislative Instrument in July 2007
- FSANZ Act Amendment Bill proclaimed on 1 July 2007
- An amendment to the Novel Food Standard to allow for 15 months' exclusivity of use was approved by the FSANZ Board in September 2007. If no review is requested by the Ministerial Council, the amendment is expected to be gazetted before the end of the year. Exclusivity will only apply to the applicant (or those named in the application) and to the specific brands of novel food approved for 15 months. After that approval will revert to a generic approval.



What needs to be done now?

- Members of the public will be able to access a limited view of FSANZ's Standards Management System (SMS) database* through the FSANZ website. They will also be able to access applications and submissions through SMS. This access is currently under development and testing and expected to be available before the end of the year.
- Applicants will be able to complete their applications via the web through a web-based version of the *Application Handbook*. This enhancement is currently under development and is expected to be available before the end of the year. The enhancements will allow applicants to lodge simple or complex applications. It will also allow applicants to save and edit draft applications until an application is formally lodged.
- The process by which submissions are lodged via the FSANZ website is also being upgraded. This enhancement is currently under development and is expected to be available before the end of the year.

*The database tracks an application/proposal from its receipt/preparation to gazettal



Conclusion

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