



DEVELOP FOOD REGULATORY STANDARDS — OR CONTRIBUTE TO OTHER CONTROL MEASURES USING THE RISK ANALYSIS PROCESS

Highlights

Consumer and social sciences research

Standards development

Australia and New Zealand Ministerial Forum
on Food Regulation (the Forum)



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Highlights

Review of microbiological criteria

FSANZ continued its review of microbiological criteria in the Food Standards Code during 2016–17, publishing the [Compendium of Microbiological Criteria for Food](#)¹ on the FSANZ website in October 2016. The Compendium includes revised guideline criteria for ready-to-eat foods and process hygiene criteria (microbiological criteria applied to verify hygiene measures or control of process) for powdered infant formula products and chicken meat. The compendium will be updated and added to as the review continues. Assessment of the meat and dairy sectors and low moisture foods will be progressed during 2017.

P1042 – Low-THC hemp seeds as food

During 2016–17, FSANZ completed work relating to the proposal to permit the sale of food containing low-THC hemp. This work included a consideration of law enforcement issues, marketing and labelling, and cannabinoids other than THC that may be present in hemp foods. In April 2017, ministers responsible for food regulation considered FSANZ's approval of a proposal to permit the sale of low-THC hemp foods. Ministers did not seek a review of the

decision, which meant low-THC foods would be permitted for sale six months after gazettal. The six month period allowed jurisdictions time to amend respective legislation, which is required to support the legal sale of low-THC hemp seed foods in Australia and New Zealand.

P1026 – Lupin as an allergen

During 2016–17, FSANZ completed work on the analysis of the cost and benefits associated with managing the risk of allergy arising from food containing lupin. In May 2017, the Food Standards Code was changed to require lupin to be declared when present in a food as an ingredient or component of ingredients including food additives and processing aids. However, there is a 12-month transition period to allow food businesses time to comply with the mandatory declaration. From 26 May 2018, all foods must comply with the new requirement.

Health claims

Since Standard 1.2.7 – Nutrition, Health and Related Claims was gazetted in 2013, FSANZ has been considering whether to include food-health relationships from 32 EU-authorized health claims in the Food Standards Code. These relationships are in addition to 183 food-health relationships from EU-authorized claims that were already in the Food Standards Code at gazettal. FSANZ has started work on developing a way to maintain the scientific currency of pre-approved food-health relationships in the Food Standards Code.

1 <http://www.foodstandards.gov.au/publications/Pages/Compendium-of-Microbiological-Criteria-for-Food.aspx>

In August 2016, FSANZ publicly released decisions about food-health relationships from nine EU-authorised health claims. This work included a systematic review of the evidence for relationships between docosahexaenoic acid and normal brain and vision function. Consideration of a further 17 relationships is nearing completion. The review of the currency of three existing high level health claims relationships is also nearing completion.

The Health Claims Scientific Advisory Group met in August and November 2016 to provide expert advice on outcomes from three systematic reviews. FSANZ has also continued to monitor overseas health claims approvals via participation in an international health claims liaison group which includes representatives from the European Food Safety Authority, the United States Food and Drug Administration, Health Canada and the New Zealand Ministry for Primary Industries.

Proposal P1044 – Plain English Allergen Labelling

In 2016 FSANZ began working on a new proposal to investigate changes to the Code to ensure allergens are declared on food labels more clearly. FSANZ will seek to improve the clarity of labelling by looking at the use of plain English words and terms. Improving allergen labelling requirements will mean allergen-sensitive consumers can better identify foods that are safe to purchase. The changes will also make it easier for the food industry to provide safe and accurate information about food allergens.

FSANZ will be seeking public comments on the proposed changes to allergen labelling later in 2017.

New breeding techniques

New breeding techniques (NBTs) are new approaches being used in plant and animal breeding and development. These techniques were not in existence at the time the standard for genetically modified (GM) foods was introduced seventeen years ago. It is unclear whether foods derived using the NBTs currently come within the scope of the GM food standard (Standard 1.5.2 Food produced using gene technology) and would be subject to pre-market safety assessment and approval.

FSANZ has started reviewing Standard 1.5.2 to consider whether foods derived from NBTs should be subject to pre-market approval as GM foods under the standard and also whether changes to the definitions in the standard may be needed to clarify the status of these products.

The review will not make any changes to the standard but will result in recommendations for FSANZ to consider. FSANZ has established an Expert Advisory Group on New Breeding Techniques (Appendix 8) to assist with the review. The group's main role will be to provide advice on the current science of NBTs and any related safety issues as well as stakeholder concerns about the application of Standard 1.5.2 to foods derived from NBTs. During the course of the review, FSANZ intends to seek input from a wide range of stakeholders through public consultation.

The review is expected to take about 12 months to complete. One possible outcome of the review is that FSANZ may prepare a proposal to amend Standard 1.5.2. If this occurs, it will be a separate process involving additional public consultation.

P1024 – Revision of the Regulation of Nutritive Substances and Novel Food

Based on extensive feedback received following an earlier call for submissions, FSANZ undertook additional public consultation in June 2017 to help refine the proposed new regulatory pathways for nutritive substances and novel foods. Additional consultation will be undertaken during 2017–18 to develop eligible food criteria that will help fast-track low risk foods with a history of safe use onto the market.

Bovine spongiform encephalopathy (BSE)

FSANZ completed the full assessment on Sweden in August 2016, and Sweden was assigned a Category 1 status for its BSE food safety risk. No further applications for an Australian assessment of country BSE food safety risk were submitted to FSANZ in 2016–17. Annual BSE update data was received from Argentina, Brazil, Chile, Croatia, Japan, Latvia, Lithuania, Mexico, the Netherlands, New Zealand, Sweden, the United States, and Vanuatu. The previously assigned BSE food safety status was reconfirmed for all these countries. The assessment of new countries seeking BSE food safety status, and annual monitoring of countries with existing safety status, will continue to be conducted according to the [Australian Government's BSE policy](#)².

Maximum Residue Limits (MRLs) of agricultural chemicals in food commodities

Proposal P1027 Low level MRLs for inadvertent agricultural chemical residues in food commodities and Application A1133 MRLs for Avilamycin were completed and gazetted. Work continues on the 2016 MRL

2 <http://www.foodstandards.gov.au/industry/bse/bseimports/pages/default.aspx>

harmonisation proposal M1014 to complete it before the end of the calendar year. M1014 was delayed due to the unprecedented number of requests (546 chemical-food commodity combinations) and the need to use the newly available food consumption data from the 2011–13 Australian Health Survey in estimating dietary exposure.

FSANZ continues to liaise closely with the Australian Pesticides and Veterinary Medicines Authority and the Australian Government Department of Agriculture and Water Resources to ensure the safety of chemical residues that may be present in the Australian food supply.

Voluntary addition of vitamin D to breakfast cereal

FSANZ completed a review of its decision to permit the addition of vitamin D to all breakfast cereal to a maximum claim amount of 2.5 micrograms per normal serve. FSANZ carefully considered the Forum's clarification of the Policy Guideline Fortification of Food with Vitamins and Minerals notified in 2015. FSANZ proposed to amend its previous decision by restricting the permission to breakfast cereal that met the Food Standards Code's nutrition profiling scoring criterion. FSANZ consulted on amended drafting in July 2016 and, without further amendment, completed its review report in October 2016.

Regulatory analysis

FSANZ has continued to meet the requirements of the Council of Australian Governments Best Practice Regulation Guidelines for the 2016–17 financial year. This included approval by the Office of Best Practice Regulation of a Decision Regulatory Impact Statement on the mandatory allergen labelling of lupin.

In support of FSANZ's regulatory analysis, a methodological framework for estimating government costs has been created and work has continued on updating and improving our cost of illness modelling.

Consumer and social sciences research

A key focus for consumer and social sciences at FSANZ in 2016–17 has been developing the evidence base for Proposal P1028 – Infant Formula. FSANZ supported an Australian Research Council (ARC) Linkage Project application by the University of Adelaide to conduct social science research to support the assessment of P1028. The application was submitted in December 2016. Outcomes are generally announced within six months of an application being submitted. In April 2017 FSANZ commissioned an online survey to support the assessment of P1028. The survey, which will be conducted across Australia and New Zealand, will explore caregivers' infant formula information use, the preferences of caregivers and their infant formula related knowledge, attitudes and behaviours.

The publication of a Consumer Label Survey in October 2016 was a significant achievement for FSANZ. The survey examined consumers' food label use and understanding in Australia and New Zealand. The findings informed FSANZ's response to Recommendation 12 of the Labelling Review. The survey also provided information on consumers' use of a range of food label elements, which will be valuable for a range of future FSANZ projects.

FSANZ continued to draw on international expertise in applying the economic and behavioural sciences to FSANZ's regulatory practice. The International Social Sciences Liaison Group and the Food Safety Regulatory Economics Working Group—both chaired by FSANZ—provided input from and exchange among, economists and social scientists from international risk agencies from the United States, Canada, the United Kingdom, New Zealand and Australia.

Standards development

Information about how FSANZ assesses applications and proposals (including different assessment procedures) can be found in the [Application Handbook](#)³. The assessment process is open and transparent. Applications and proposal documents and related materials are published on the FSANZ website unless the information is confidential commercial information or when we have been asked to keep certain information confidential.

Stakeholders can [subscribe to a number of publications](#)⁴ to stay up to date on the progress of applications and proposals and other FSANZ work. The [FSANZ Work Plan](#)⁵ also details all applications and proposals FSANZ is working on. The plan is reviewed regularly.

Work Plan

FSANZ is required to develop and publish a three-year forward plan for applications and proposals on which it intends to develop standards or variations to standards, no later than 30 June each year.

The FSANZ Executive formally reviews the Work Plan every month. New unpaid applications and proposals do not appear on the plan until the executive considers their priority and approves timeframes and resources.

FSANZ called for submissions on the Work Plan on 16 May 2016. One submission was received.

Applications received, or proposals prepared before 1 October 2007, continue to be assessed under the procedures in place at that time. The tables in this section reflect the two types of approaches.

3 <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

4 <http://www.foodstandards.gov.au/media/Pages/default.aspx>

5 <http://www.foodstandards.gov.au/code/changes/workplan/Pages/default.aspx>

Table 1: Applications and proposals on the Work Plan (received or prepared from 1 October 2007 onwards)*

As at	30 June 2014	30 June 2015	30 June 2016	30 June 2017
General procedure	14 (2 paid)	19 (7 paid)	17 (1 paid)	15 (4 paid)
Minor procedure	0	0	0	0
Major procedure	4	3	3	4
High level health claims	0	0	0	0
Urgent applications or proposals	0	0	0	0
Under review	1	0	1	0
TOTAL	19	22	21	19
With the Forum or awaiting notification to the Forum	2	8	5	5
Estimated waiting time for unpaid applications (approx)	6 months	9 months	7 months	7 months

* Table 1 does not include potential applications and proposals for which an administrative assessment has commenced, but is not yet completed, as these have not yet been placed on the Work Plan, or where an application has been accepted and proposal prepared, but was not on the Work Plan as at 30 June.

Table 2: Applications and proposals on the Work Plan (received or prepared before 1 October 2007)

As at	30 June 2014	30 June 2015	30 June 2016	30 June 2017
Group 1	4	2	1	1
Group 2	4	4	4	4
Under review	0	0	0	0
TOTAL	8	6	5	5
With the Forum or awaiting notification to the Forum	0	0	0	0
Estimated waiting time Group 2	Unknown	Unknown	Unknown	Unknown

Table 3: Total applications received and accepted onto the work plan and proposals prepared

	2013–14	2014–15	2015–16	2016–17
Applications	4 ¹	18	19 ²	12
Proposals	6 ³	6	5	3
TOTAL	10	24	23	15

1 This includes one cost-recovered application which was rejected because the applicant chose not to pay the fees owing for an exclusive capturable commercial benefit by the due date.

2 This includes any applications received in one financial year and accepted onto the Work Plan in the following year. This figure therefore may be adjusted in the next Annual Report.

3 This includes one proposal which was prepared and then abandoned within this financial year.

Table 4: Applications and proposals finalised

	2013–14	2014–15	2015–16	2016–17
Approvals made by the FSANZ Board	11	18	23	19
Final assessments made by the FSANZ Board	0	1	0	0
Applications withdrawn or rejected*	5	2	1	3
Proposals abandoned				
TOTAL completed	16	21	24	22

* This includes potential applications rejected following an administrative assessment or withdrawn before an administrative assessment was completed

Tables 3 and 4 summarise FSANZ's performance in developing food standards.

Further information on the above can be obtained from Appendix 2. There also may be some discrepancies between Tables 5 and 8 where decisions have been made in one financial year and the notification of decisions are made in the next financial year.

Table 5 provides information about any significant variation from the timetable established in the Work Plan for the consideration of applications and proposals during 2016–17.

Table 5: Reasons for significant delays in considering applications and proposals in 2016–17

Application/ Proposal	Step	Variation*	Reason
A1102 – L-carnitine in Food	Assessment, preparation of draft food regulatory measure and call for submissions	2 years	Delay due to other work priorities, resourcing issues and the complexity and scope of the application.
A576 – Labelling of Alcoholic Beverages with a Pregnancy Health Advisory Label	Draft assessment	8 years 5 months (from date final assessment due)	Work has been deferred until 2017 at the request of the applicant.
P1024 – Revision of the Regulation of Nutritive Substances & Novel Food	Assessment	3 years 8 months	Delay due to the complexity of issues. There are also resourcing issues.
P1028 – Infant Formula Products	Assessment	2 years	Delay due to complexity of issues and delay to release of consultation paper. Note: Scope of project has been limited to infant formula due to resourcing issues. Timelines have therefore been changed and consultation opportunities reduced.
P1030 – Health Claims – Formulated Supplementary Sports Foods & Electrolyte Drinks	Approval	2 years 9 months	Delay due to complexity of issues raised in submissions and other work priorities. An additional call for comment is planned.
P290 – Food Safety Programs for Catering Operations to the General Public	Final Assessment	12 years (from date final assessment due)	Delayed pending further implementation strategy work required by jurisdictions.

* Variation based on indicative timeframes in the administrative assessment report against timeframe indicated in the Work Plan as at 30 June.

Table 6: Status of remaining applications and proposals received or prepared before 1 October 2007

Application/Proposal	Step	Reason
A530 – Permission for English Farmhouse Cheddar made from Raw Milk	Initial assessment	Received 12 Feb 2004 – awaiting advice from the applicant following completion of work on raw milk products (P1022).
A531 – Use of Raw Milk in Cheese Production	Initial assessment	Received 16 Feb 2004 – awaiting advice from the applicant following completion of work on raw milk products (P1022).
A576 – Labelling of Alcoholic Beverages with a Pregnancy Health Advisory Label	Draft assessment	Received 17 Feb 2006 – see <i>Table 5</i> .
A613 – Definitions for Nutritive Substance & Nutritive Ingredient	Initial assessment	Received 11 Aug 2007 – awaiting advice from the Applicant and consideration of P1024.
P290 – Food Safety Programs for Catering Operations to the General Public	Final assessment	Prepared 13 May 2004 – see <i>Table 5</i> .

Australia and New Zealand Ministerial Forum on Food Regulation (Forum)

Table 7: Notification outcomes

	2013–14	2014–15	2015–16*	2016–17
Approval decisions notified	12	18	23	15
Final assessment decisions notified	0	1	0	0
Requests for review	0 (0%)	1 (5.5%)	0 (0%)	0 (0%)
Review decisions notified	0	1	0	0

* The figures in this column may differ from those provided in the previous year's annual report as review requests may be received by FSANZ after the deadline for publication.

Reviews requested by the Forum

A request for the review of a FSANZ decision to amend the Code may be sought by a majority of members of the Forum, that is, six out of 10 following a notification of the FSANZ Board's decision on a draft standard or variation to a standard.

No reviews were requested in 2016–17.

Ministerial policy guidelines and statements

The Forum is responsible for developing food regulatory policy for domestic and imported foods and the development of policy guidelines for setting food standards for domestic and imported foods. In developing or reviewing food regulatory measures and variations to food regulatory measures, under section 18 of the FSANZ Act, FSANZ must have regard to any written policy guidelines formulated by Ministers and notified to FSANZ for these purposes.

No guidelines were notified.

Additional work requested by the Forum

In **November 2016 ministers**⁶ discussed the current food regulation system and while noting that it continues to deliver a high level of protection to public health and safety, there is a need to ensure it is responsive to changing trends in the food supply chain including foods that are new to the Australian and New Zealand diets. Ministers identified synthetic foods as an emerging area of interest and asked FSANZ to prepare a report for the next Forum meeting on the potential safety, nutritional and labelling issues that might need to be considered to maintain Australia's and New Zealand's reputation as producers of safe, high quality food.

At the same meeting ministers agreed that in relation to allergen labelling, further work be undertaken by FSANZ through the Allergen Collaboration to promote the uptake of voluntary labelling initiatives and that a report be provided to the Forum within 12 months. Ministers also acknowledged the work to date by industry.

6 <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2016-november>

Ministers also asked FSANZ, in consultation with the Food Regulation Standing Committee to prepare a program of work to further investigate labelling approaches to providing information on sugars in food.

In April 2017 Ministers agreed to further work, including more evidence gathering by FSANZ on consumer understanding and behaviour and international approaches to sugar labelling. The Australian Government Department of Health will provide an update on the policy context. That work is expected to be presented at the Forum’s next meeting in November 2017.

Ministers also considered FSANZ’s report on synthetic foods and no further action was required by FSANZ.

Gazettal of variations 1 July 2016 to 30 June 2017

Variations to standards arising from 15 applications were gazetted (compared to 14 in 2015–16). Variations to standards arising from 4 proposals were gazetted (compared to 11 in 2015–16). The decrease from last year is explained by numbers returning to more average figures after last financial year’s larger figures. See Appendix 4 for more detail.

Table 8: Gazettal of variations to the Code

	2013–14	2014–15	2015–16	2016–17
Arising from applications	9	5	14	15
Arising from proposals	2	7	11	4
TOTAL	11	12	25	19

Maximum residue limits

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has the power to amend permitted maximum residue limits (MRLs) in Schedule 20 as a result of amendments to domestic use of agricultural and veterinary chemicals (see Appendix 4 for further information).

FSANZ is required by the FSANZ Act to provide advice about applications and variations that are being considered by the APVMA that may result in an amendment to the Code. FSANZ notifies the public via its Notification Circular of progress with any proposed amendments during the APVMA’s MRL consideration process.

Maximum residue limits— Assessment of APVMA dietary exposure assessments

FSANZ works closely with the APVMA to approve dietary exposure assessments (DEA) conducted by the APVMA relating to its regular agricultural chemical residue evaluations.

Table 9: DEA notifications and approvals

	2012–13	2013–14	2014–15	2015–16	2016–17
Number of regular DEA notifications	29	27	29	38	27
Number of DEA approved	93	112	92	122	84
Emergency permit DEA notifications	1	5	1	0	0
DEAs relating to pesticide contamination incident(s)					13