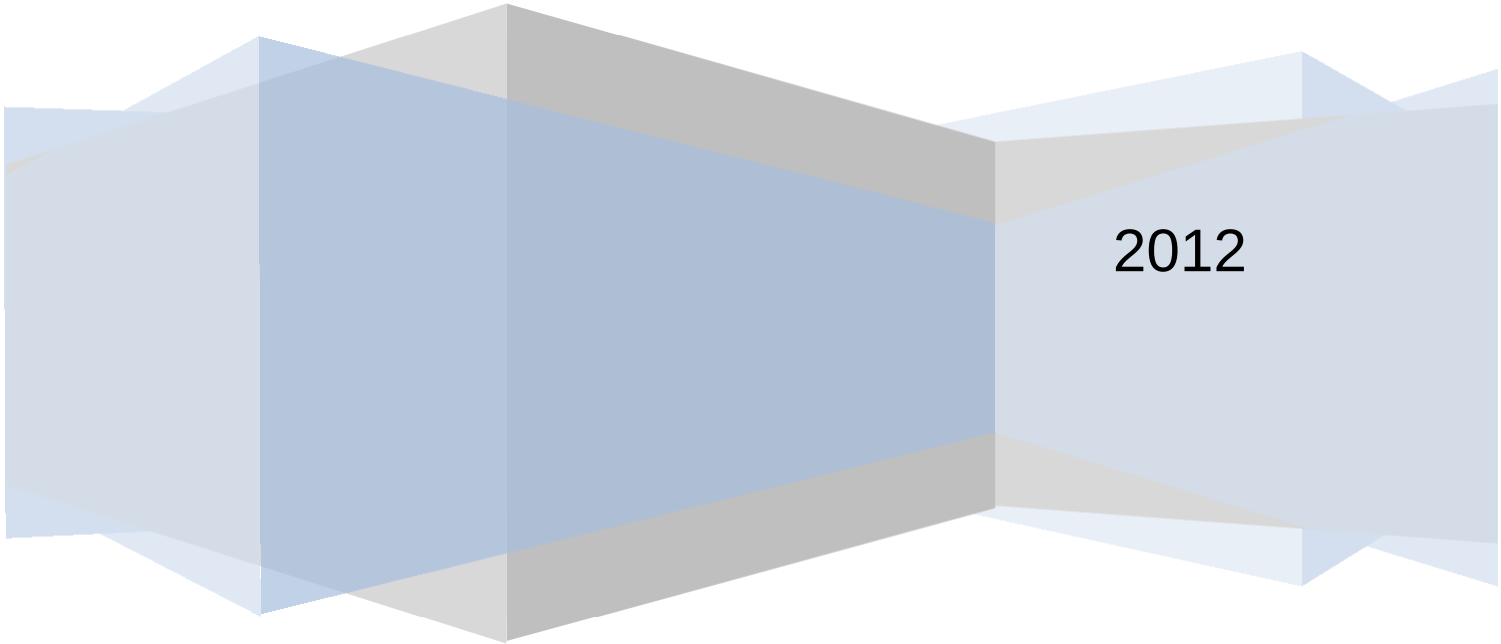
Food Standards Australia New Zealand

External peer review of FSANZ risk assessment practices and procedures

Dr Angelika Tritscher, World Health Organization



2012

Prepared by

Dr Angelika Tritscher

Department of Food Safety and Zoonoses

World Health Organization

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Executive summary

This review was undertaken to fulfil one of the key strategic objectives of the FSANZ science strategy for 2012–2015. The purpose was to undertake a high-level review of risk assessment practices and procedures across sections, including chemical and microbiological risk; genetically modified (GM) foods; and nutrition risk assessment. The focus was on overall principles, in particular the soundness and transparency of the process, rather than on a detailed review of the content of specific risk assessments. The objective was to evaluate the current rigour of FSANZ risk assessment practices and procedures taking international practices into account; identify areas of improvements; and provide clear recommendations.

The review was conducted in a manner consistent with the core principles for providing scientific advice in food safety and nutrition, as defined through a Food and Agricultural Organization (FAO) and World Health Organization (WHO) consultative process, and adapted for this regulatory setting. These core principles are soundness, responsibility, objectivity, fairness, transparency and inclusiveness. A series of key FSANZ documents were consulted and interviews were held with key staff at FSANZ (Executive members, scientific section managers and senior scientists) and key stakeholders (other government agencies, a FSANZ fellow, industry sector).

The risk analysis paradigm has been adopted internationally and consists of the three parts—risk assessment, risk management and risk communication. Risk assessment is the scientific part of the risk analysis process, and is comprised of the following steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

FSANZ has adopted the risk analysis paradigm and associated principles and works within this framework. The Analysis of Food Related Health Risks is a FSANZ publication developed to describe how FSANZ uses the risk analysis framework. FSANZ's main role is developing or revising food standards in the Australia New Zealand Food Standards Code (the Code). There are two main processes leading to a risk assessment request. The first is an application, which is an outside request for a change to the Code, such as approval of a food, food ingredient, additive etc. The other is a proposal, which reflects an internally identified concern that may result in a change to the Code that requires a risk assessment. Risk assessments are also required for assessing surveillance data, emerging and emergency issues. FSANZ employs a matrix management approach to consider such projects. Specifically, multi-disciplinary teams are established for each project comprising risk assessors, risk managers and risk communicators, including staff with specific expertise relevant to the particular project.

FSANZ undertakes risk assessments for microbiological agents and chemicals, genetically modified organisms (and products of these organisms, e.g. enzymes), production processes (mainly related to Bovine spongiform encephalopathy; BSE), and public health nutrition. The links between the different disciplines have become more important due to increasingly complex risk assessment questions. Health risk-benefit considerations are also of increasing importance in the food area. Dietary exposure assessments and food surveillance is an important part of the overall risk assessments.

A review was undertaken of each of the relevant areas and of combined risk assessments (those involving several disciplines), and the strengths and challenges of each are described in the report.

With respect to stakeholders' views, the key point is that FSANZ is consistently seen as an independent scientific expert body, but that it lacks recognition nationally. Risk assessments are seen as being high quality and there is now increased transparency. FSANZ's risk assessment staff also provide their expertise to many other government agencies. A particularly positive aspect raised by stakeholders is that FSANZ documents are provided for community consultation and stakeholder input. The public comment period on draft risk assessments is seen as very positive. Suggestions for further improvements have been provided by stakeholders as described in the report. These suggestions are largely consistent with the findings of this reviewer and are captured in the recommendations briefly described below.

Overall finding summary

In its risk assessments and interaction with risk managers, FSANZ follows a clear and structured process in line with international recommendations. FSANZ's risk assessment processes and capabilities have improved in recent years and this has led to improved clarity, consistency and transparency of the process and output. Specific recent improvements relate to clearer project management lines, e.g. development of a business case, a project plan, or improved structure of risk assessment reports. FSANZ's risk assessment staff are highly competent, but only a few experts cover each work area. Recent scientific developments and knowledge are being integrated into the risk assessment process, and FSANZ staff actively participate in international scientific expert groups.

Overall, no important gaps or faults in the risk assessment practices and procedures have been identified. However, further improvements are possible; subject to FSANZ's overall priorities and available resources and specific recommendations are briefly summarized below.

For improvements of risk assessment process and documentation, FSANZ should consider the following:

- developing guidance for a tiered risk assessment approach, including rapid risk assessments and qualitative approaches
- improved planning processes for complex combined risk assessments; development of a template for risk assessment report structure, in particular for combined risk assessments
- the introduction of a systematic approach for evidence-retrieval (application of principles for a systematic review) for all risk assessment areas
- the development of guidance on risk-benefit considerations.

Regarding scientific competence, consideration should be given to the need for additional competence in epidemiology and statistics across disciplines. The public image of FSANZ's scientific competence should be improved and there is a need to retain experienced staff and competence in house.

To further increase transparency and the prioritization process, there is a need for clearer/more transparent prioritization processes including all risk assessment work; and a simple scoping form should be developed for ad hoc risk assessment requests.

Regarding external peer reviews; a clear process should be developed to clarify when and how an external review should be undertaken. A declaration of interest form and evaluation process should be established for reviewers and FSANZ fellows.

To improve the interaction between risk assessors and risk managers, including the systematic consideration of the outcome of the risk assessment by risk managers, there is a need to increase the transparency in the risk management decision-making process. Consideration may also be given to establishing a monitoring and evaluation framework to follow the impact of decisions taken, however it is clear that this is quite challenging and costly and should therefore focus on key public health issues. Guidance should be developed on how to express uncertainty in risk assessment and its consideration in the risk management decision-making process.

It is important to note that the recommendations described above for development of further tools and guidance are intended to help risk assessors and also ensure a consistent and transparent approach. Care has to be taken to not simply increase the administrative burden on risk assessors. A balance between increased 'process' and clear benefit is important. Moreover, some of the recommendations, e.g. developing a tiered approach for risk assessment and improved interaction between risk assessors and risk managers, are more general issues that are common to other

authorities. FSANZ may consider interacting with other authorities and international organizations on these recommendations.

Acronyms

FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
AFGC	Australian Food and Grocery Council
APVMA	Australian Pesticides and Veterinary Medicine Authority
AQIS	Australian Quarantine and Inspection Service, now known as DAFF
DAFF	Department of Agriculture Fisheries and Forestry
DoHA	Department of Health and Ageing
NZ MAF	New Zealand Ministry of Agriculture and Fisheries, now known as New Zealand Ministry for Primary Industries
OCS	Office of Chemical Safety, DoHA
OGTR	Office of the Gene Technology Regulator
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Expert Meeting on Pesticides Residues
JEMRA	Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment
FAO	Food and Agriculture Organization of the United Nations
WHO	World Health Organization

1. Background

A review of FSANZ's risk assessment practices and procedures across different scientific disciplines is one of the key strategic objectives of the FSANZ Science Strategy for 2010–2015. The primary aim of the Science Strategy is to ensure that FSANZ's science is consistently of the highest quality in order to inform food regulatory measures. As part of the 2006–2009 Science Strategy, FSANZ commissioned independent peer reviews of its GM food safety practices and procedures, dietary exposure assessment practices and procedures and the food composition program and databases. However, this is the first time FSANZ has requested a review of its risk assessment practices and procedures across the scientific disciplines concurrently.

The areas covered by this high level review included chemical, microbiological, GM food and nutritional risk assessment, and surveillance and dietary exposure. The focus was on overall principles, in particular soundness and transparency of process, rather than on a detailed review of the content of specific risk assessments.

FSANZ's Chief Scientist, Dr Paul Brent, approached Dr Angelika Tritscher in the 3rd quarter of 2011 to undertake the review. Detailed terms of reference were prepared and a teleconference was held to elaborate details and agree on the final TORs, see annex 1. Staff in the Chief Scientist's branch prepared relevant background information for the review and assisted Dr Tritscher throughout the review.

2. Objectives

- To evaluate the current rigour of FSANZ's risk assessment practices and procedures across the scientific disciplines at a high level and benchmark these against international best practice.
- To identify areas for improvement so that FSANZ's standards development process continues to be supported by robust risk assessments.
- To provide recommendations to enhance these areas to ensure that FSANZ's scientific capability continues to inform global risk assessments.

3. Terms of reference

Conduct a review of FSANZ's risk assessment practices and procedures underpinning standards development. This included the following:

- Benchmark FSANZ's current risk assessment practices and procedures against international best practice, taking into consideration FSANZ's available resources.

- Review the format, content and presentation of FSANZ risk assessment reports and make recommendations on areas for improvement.

- Review the integration of risk assessment work across the different scientific disciplines—chemical, consumer and social science, data collection, exposure assessment, GM foods, microbiology and nutrition.

- Provide suggestions to improve the inputs from and integration of different scientific disciplines in the risk assessment report.

- Provide advice in relation to when it is reasonable to undertake a small scale versus full risk assessment.

- Review the process undertaken to formulate risk assessment questions and how they are subsequently addressed, including the interface between risk assessment and risk management functions.

The full terms of reference are presented in Annex 1.

4. Approach and process

Key documentation was provided to prepare for the review, and also for a two week stay at FSANZ's offices in Canberra. During the stay at FSANZ, detailed interviews were conducted with FSANZ staff and external stakeholders. The report was prepared subsequently and submitted to FSANZ. A detailed program of the work in Canberra is attached in Annex 2.

4.1. Documentation consulted

In preparation for the review a number of documents were provided, describing the general principles and process of FSANZ risk assessment work. These included basic documents such as the Application Handbook, the FSANZ project management handbook, FSANZ Science Strategy for 2010–2015 and the 2011 Science Strategy implementation plan; reports of previous reviews undertaken in specific risk assessment areas such as the report on the 2009 peer review of the FSANZ food composition program and databases, the report on the 2008 peer review of FSANZ GM food safety practices and procedures and the report on the 2007 peer review of the FSANZ dietary exposure assessment practices and procedures. Recent FSANZ risk assessment reports and an example of the regular scientific and international activities report were also provided. Additional material was consulted throughout the review process, in particular specific risk assessment documents.

A list of key documents consulted before and during the review is attached in Annex 3.

4.2. Direct discussions/interviews

Direct discussions were held with the following FSANZ staff:

- CEO (Mr Steve McCutcheon), Deputy CEO (Ms Melanie Fisher), Chief Scientist (Dr Paul Brent), General Manager Risk Assessment (Dr Andrew Bartholomaeus)
- all Executive members as a group
- scientific and risk management section managers and some additional senior scientists.

Discussions were held either individually or as part of broader groups of similar interest.

Discussions were also held with key stakeholders:

- Other government agencies:
  - Department of Agriculture Fisheries and Forestry (DAFF)
  - Australian Quarantine and Inspection Service (AQIS), now known as DAFF
  - Australian Pesticides and Veterinary Medicine Authority (APVMA)
  - Office of the Gene Technology Regulator (OGTR)
  - New Zealand Ministry of Agriculture and Fisheries (NZ MAF), now known as New Zealand Ministry for Primary Industries.
- Industry sector: Australian Food and Grocery Council (AFGC)
- One of the FSANZ fellows.

4.3. Workshop with jurisdictions

A half day workshop with representatives of Australian state and territory food regulators was held on Monday 13th February 2012 to obtain their views on the soundness and applicability of FSANZ risk assessments, and views on the overall process.

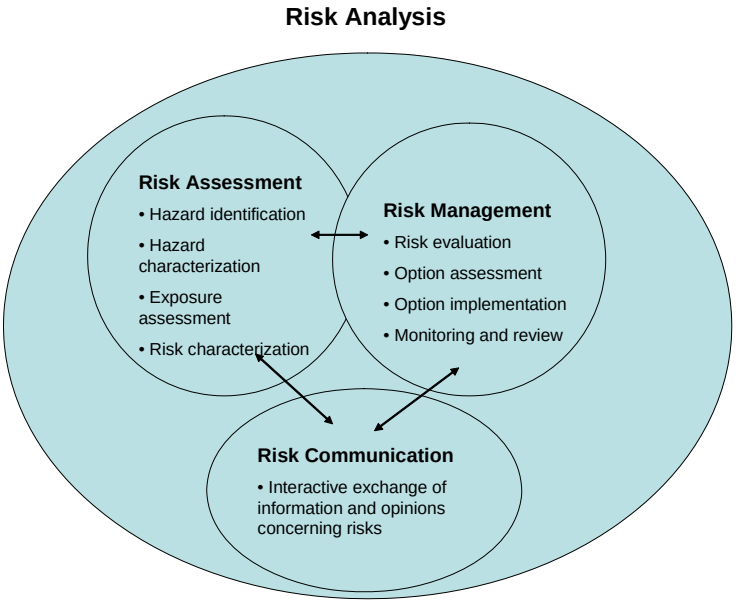
5. Food risk assessment principles internationally

5.1. Risk assessment in the context of risk analysis

Risk assessment is the central scientific component of risk analysis and a well-defined process consisting of the following steps: hazard identification, hazard characterization, exposure assessment and risk characterization. Food risk assessment can generally be described as characterizing the potential hazards and associated risks to the life and health of humans resulting from exposure over a specified period of time to hazards present in food.

Risk assessment is part of risk analysis, which is composed of the three components risk assessment, risk management and risk communication. The risk analysis paradigm (see Figure below) is a formal description of the risk analysis process that emphasizes the functional separation of its three components while at the same time demanding the need for communication and interaction between

those with responsibility for each of the three components. Within risk analysis, the functional separation between risk assessors and risk managers is essential to ensure scientific objectivity of the risk assessment process. Further background information can be found in an FAO/WHO publication on food safety risk analysis (FAO/WHO, 2006).



The use of a structured risk analysis process facilitates consistent, science-based and orderly decision-making in the area of food safety. The scientific part of this process, the risk assessment for food safety matters, is undertaken at an international level by joint FAO/WHO expert bodies. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) have provided scientific advice to Member States of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) since 1956 and 1961, respectively, and to several general subject committees of the Codex Alimentarius Commission (CAC) since its formation in 1963. However, the structural framework for the interaction between both scientific bodies and the Codex committees was not formalized until the development and the adoption of the risk analysis paradigm, which was introduced in the work of Codex in 1996 and formally adopted in 2003.

Joint expert committees base their evaluations on scientific principles and ensure necessary consistency in their risk assessment determinations. CAC and its respective committees that deal with hazards in food are responsible, as risk managers, for the final decisions on establishing measures e.g. maximum limits for pesticide residues, veterinary drug residues, contaminants and additives in food and adopting other related measures.

5.2. Risk assessment principles and methods

Risk assessments of chemical substances used on or present in food, have been undertaken for over 50 years by FAO and WHO, through JECFA and JMPR. These organizations are long-standing global leaders in method development as well as in applied risk assessments. Microbiological risk assessment following the same steps and principles has been undertaken internationally, on a systematic basis, for over ten years generally following the same steps and principles as those applied in chemical risk assessment. Risk assessments of nutrition or nutrient substances are also increasingly important.

Risk assessment principles and methods have been developed and are consistently updated to reflect new scientific knowledge. A series of publications describing microbiological risk assessment, and chemical risk assessment principles was first published in the late 1980s and early 1990s. These principles have recently been updated and published in a comprehensive monograph Environmental Health Criteria 240: Principles for the risk assessment of chemicals in food. Nutrient risk assessment has been described in the report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment: A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances.

Risk benefit considerations are of increasing importance in food-related assessments, and while no systematic framework has been developed yet, examples are available looking at qualitative and semi-quantitative risk benefit considerations (e.g. benefits and risks of the use of chlorine-containing disinfectants in food production and food processing, 2009) or quantitative assessments (e.g. risk benefit assessment of fish consumption, 2010).

Through a consultative process, FAO and WHO have developed a framework for providing scientific advice on food safety and nutrition (FAO and WHO 2007). This framework lays out the legal framework in which the organisations operate; their management and organisation, as well as procedures for international expert advisory groups. It also lays down core principles for scientific advice, which adapted to the national setting, were considered when undertaking this review of FSANZ risk assessment practices and procedures. These core principles are soundness, responsibility, objectivity, fairness, transparency and inclusiveness.

Annex 3 provides a list of FAO/WHO publications referenced in this section.

6. FSANZ food risk assessment

FSANZ has adopted the risk analysis paradigm and associated principles described above and works within this framework, as articulated in the FSANZ document the Analysis of Food Related Health Risks.

FSANZ is a bi-national statutory authority and was established to:

- provide a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand
- provide an effective, transparent and accountable food regulatory framework
- provide information for consumers that is adequate to enable them to make informed food choices
- provide common rules for Australia and New Zealand and consistency with international food regulatory standards, without compromising public health and consumer protection.

To achieve this, FSANZ develops or reviews food standards, collectively called the *Australia New Zealand Food Standards Code* (the Code). When developing food standards, FSANZ is required by its legislation to meet three primary objectives:

- Protection of public health and safety
- Provision of adequate information relating to food to enable consumers to make informed choices
- Prevention of misleading and deceptive conduct.

In doing so, FSANZ must also have regard to the following:

- The need for standards to be based on risk analysis using the best available scientific evidence
- The promotion of consistency between domestic and international food standards
- The desirability of an efficient and internationally competitive food industry
- The promotion of fair trading in food
- Any written policy guidelines formulated by the Ministerial Council.

Food standards are based on a scientific risk assessment. This risk assessment process was the subject of this review.

6.1 Principle processes leading to a risk assessment

There are two main ways to change the Code that may trigger risk assessment requests:

1. **Applications**: outside requests (mainly by industry)
2. **Proposals**: inside identified needs

Additional proposals to change the Code and/or undertake risk assessments can arise from Ministerial requests, from states and territories requests, through food incidents (which then may lead to the development of a proposal), reporting on surveillance activities and emerging issues.

Detailed guidance on how to apply to amend the Code is available in the FSANZ Application Handbook available on the FSANZ website at:
www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm).

Proposals are prepared by FSANZ to consider changes to the Food Standards Code. A list of current and completed proposals is available on the FSANZ website at:
http://www.foodstandards.gov.au/foodstandards/proposals/

All documents used in the assessments are publicly (electronically) available, except those considered to meet the definition of confidential commercial information in the FSANZ Act. Depending on the complexity of the assessment there will be one or two rounds of public consultation.

FSANZ employs a matrix management approach to consider such projects. Specifically, multi-disciplinary teams are established for each project comprising risk assessors, risk managers and risk communicators, including staff with specific expertise relevant to the particular project.

6.2. Risk assessments covered by FSANZ

FSANZ conducts microbiological, nutrient and food chemical risk assessments, and risk assessments of GM organisms (and products thereof, e.g. enzymes), production processes (BSE) and assessments of public health impact. Of increasing importance is the link between the different disciplines for increasingly complex risk assessment questions. Risk benefit considerations are also of increasing importance in the food area.

Dietary exposure assessments and data inputs from food surveillance work are an important part of the overall risk assessment.

6.2.1. Microbiological Risk Assessments

Microbiological risk assessments have to address very different needs. In relation to applications it is very targeted, often addressing one specific aspect and is used in combination with other risk assessments. Very complex assessments have to be undertaken for primary production standards, i.e. when undertaking food-chain assessments where potentially multiple hazards and multiple commodities have to be considered. These complex assessments can be qualitative or quantitative. The decision to do a more complex and resource intensive quantitative assessment versus a qualitative assessment is currently mainly driven by data availability, i.e. by what is possible.

Overall microbiological risk assessments are well defined and well-structured, and clearly follow internationally accepted approaches. Where appropriate, international assessments are being taken up and adapted to the national situation (e.g. salmonella in chicken). The strength of FSANZ's microbiological risk assessments is its scientific competence in house and the application of qualitative as well as quantitative risk assessments.

However, there is a need to develop decision criteria for qualitative rather than quantitative approaches for complex microbiological risk assessments, and when risk profiling rather than full risk assessments is sufficient. These criteria need to include considerations of the effect of different decision criteria, severity of health effects, proportion of population potentially affected and others. In

this context it would be beneficial to develop a more systematic approach for qualitative assessments, with a clear description of underlying uncertainties and their consequences (e.g. overestimation of risk).

6.2.2. Chemical risk assessments

Chemical risk assessments also address different needs and can contribute to more complex assessments or be the main focus of a specific assessment.

Chemical risk assessments assess the public health and safety risks associated with foods, ingredients of foods, contaminants in food and substances added to foods. Such assessments are required for most applications and proposals considered by FSANZ and encompass novel foods, irradiated foods, nutritive substances, naturally-occurring toxins, food contaminants, food additives, processing aids and pesticide residues which may be present in imported genetically modified foods. The risk assessments are performed by staff with a high standard of technical knowledge who also cooperate actively with regulatory and other agencies to address chemical food safety issues. In addition to working with relevant groups in Australia (such as the Office of Chemical Safety, Therapeutic Goods Administration and Allergen Bureau), members of the chemical risk assessment team also participate in the work of independent international scientific expert committees such as JECFA, JMPR, and in international research groups such as Europreval. Additionally, there is also a strong commitment to contributing to the work of international groups such as Codex, ILSI and the OECD.

Chemical risk assessments are also well-structured and follow internationally accepted methods and principles. Existing international assessments are taken into account as appropriate.

The strong points of FSANZ's chemical risk assessments are the competence in house, which is well acknowledged including in international risk assessment expert groups. The main challenge is to target the risk assessment to the needs, i.e. the level of detail and complexity needs to be targeted to the scope of the public health issue and should consider international risk assessments to the extent that these are useful. Another challenge is the initial and continued training of staff.

6.2.3. Genetically modified organisms (and products thereof)

FSANZ is responsible for assessing food (including food additives and processing aids) derived from GM organisms. This has been part of Australia's and New Zealand's food regulation requirements since 1999. A number of GM plants have been approved, and over one third of enzymes approved for food use are now derived from GM microorganisms. To date there have been no approvals for food derived from GM animals.

Regulatory oversight for growing GM crops in Australia is administered though the Office of the Gene Technology Regulator (OGTR) and there is a close working relationship between FSANZ and the OGTR. In New Zealand, similar functions are undertaken by the Environmental Protection Authority, under the Hazardous Substances and New Organisms (HSNO) Act 1996.

The methods and approach used by FSANZ for the safety assessment of GM food are consistent with international guidelines developed by the WHO, FAO and the Organisation for Economic Co-operation and Development (OECD). In line with these guidelines, the safety assessment of GM processing aids (which include enzymes) and additives is considered separately from the safety assessment of other GM foods and food products. A recent improvement is the streamlining of the data requirements for GM processing aids so that there is consistency with the requirements for the protein characterisation component of the safety assessment of food derived from GM crops.

The data requirements for applications are clearly stated in the FSANZ Application Handbook. Submitted data, together with information from the scientific literature, other applications and other government agencies, are assessed by FSANZ staff with expertise in molecular biology, toxicology, allergenicity and human nutrition. In addition to the public review process, draft assessments may be sent to experts outside FSANZ for review.

6.2.4. Production process

This work area currently focusses mainly on BSE and is an Australia only function. Country (geographical) risks are being established through country validation and inspection, following approaches applied by other national or regional authorities. Some other aspects of zoonotic risks are also being covered. This risk assessment work represents a separate and specific area and is therefore less integrated in the other risk assessment areas. It was not considered in further detail in this review.

6.2.5. Public Health Nutrition

At FSANZ, like at other authorities, this area has changed from classical nutrition aspects, pure safety aspects such as micronutrient excess or deficiency, to a more public health approach. This is partially driven by the discussion about health claims, but also by increasing problems of non-communicable diseases such as obesity and diabetes. As a consequence more epidemiological and statistical expertise is needed in such assessments, and approaches and principles are less well established at this point as compared with other risk assessment areas.

Overall, this area is in transition, with less clear developed international approaches and guidance, as well as less practical experience as compared, for example, with chemical risk assessment. FSANZ is taking a systematic approach to this area applying international risk analysis principles and is rapidly advancing in these aspects.

Strong points are the detailed literature search and systematic reviews with grading of the evidence, which is well documented in the reports. This systematic approach for evidence-based decision making is being discussed and more systematically implemented in many different organizations and authorities. While these approaches are traditionally applied more to evaluating the evidence from epidemiological studies there are increasing efforts to adapt them to toxicological studies. It would be beneficial to apply this more systematic approach to evidence retrieval and evaluation in other risk assessment areas.

The main challenge is to identify critical issues early in the planning phase of risk assessments, and ensuring the more systematic involvement of key scientific staff, including those who are not routinely involved in the risk assessments (e.g. Chief Public Health Nutrition Advisor), as this would be beneficial.

6.2.6. Food composition, evaluation and modelling

This section works across different areas in FSANZ, providing input to FSANZ risk assessments, risk assessments for states and territories and New Zealand on request, and to international work such as independent international expert committees including JECFA. The unit also works with other Australian Government agencies, in particular with the Australian Pesticides and Veterinary Medicine Authority (APVMA) on dietary exposure assessment of pesticide and veterinary drug residues in food.

Recent improvements to the process on dietary exposure modelling include the publication of a handbook on principles and procedures, which also includes explanation on assumptions; the presentation of data (which is now more concise when included in the risk assessment report); as well as a clearer defined scope allowing the work to be more targeted. Projects are underway to further improve the modelling of dietary exposure, mainly by improving underlying databases. These include improved data management and analysis techniques with access to the national nutrition survey databases held by FSANZ and expansion of food composition tables in a related database, through an IT project to combine data sources (HARVEST). This will facilitate the use of probabilistic modelling approaches, to complement deterministic approaches where appropriate.

This area is well established and provides exposure assessments, which are an important part of risk assessment work. FSANZ's expertise is well acknowledged in this area and other government agencies draw on this expertise (e.g. APVMA). Moreover, continuous improvement and active methods development in dietary exposure modelling is exemplary and provides important input to international work in this field.

The main challenges in this area are the prioritization of the work, as well as providing the appropriate level of detail targeted to respective risk assessment questions. A further challenge is the training of new staff and retaining experienced staff.

6.2.7. Scientific strategy, international and surveillance

The work in this unit is quite diverse. Responsibilities include the development and review of the FSANZ Science Strategy and the yearly implementation plans, including organising this review. Further activities relate to specific scientific projects not included in routine risk assessment work, such as nanotechnology and approaches for the risk assessment of compounds migrating from packaging material. Other work areas include the coordination of international work (APEC, MOUs, Codex, visiting country delegations, etc.)

In the context of risk assessment, the work on surveillance provides important data for dietary modelling work. Regular total diet studies (TDS) and ad hoc surveillance (also to address risk

perception, e.g. BPA) are conducted. Some monitoring activities are collaborative projects with the states and territories and NZ MPI.

Recent improvements in this work area include the establishment of a network of analytical laboratories, which will allow for a faster response to incidents.

The main challenge is to prioritize the work (surveillance is very costly), in particular because it is a small group with quite limited resources and in light of public perceptions, which are sometimes not aligned with real public health needs. Involvement of risk management early on when deciding and prioritizing surveillance work is important, to ensure that surveillance studies are targeted to the actual concern, and that the surveillance data is not being over interpreted. Reporting of data with the appropriate level of detail depending on type and purpose of survey can be challenging and the development of a concise guidance on this could be considered.

A particularly difficult area related to surveillance and dietary exposure assessment is interpretation and communication when health-based guidance values (ADI, TDI) are exceeded or when a margin of exposure (MoE) approach is used in the risk assessment. The development of guidance on interpretation of data, taking exposure assessment and hazard assessment into account, and communication of relevant aspects in this context could be useful. It is understood that such guidance has been developed[1] (although not considered as part of this review), and application of this guidance was being trialled by FSANZ at the time this review was undertaken, and this will therefore not be included in the list of recommendations.

6.2.8. Consumer and social science

This designated unit provides specialized advice on consumer and social science issues to a range of major standard-development projects. Advice is derived from commissioned studies into consumer behaviour and/or from critical analysis of available information. This area of work is distinct and less integrated in the other risk assessment areas, and was not considered in detail as part of this review.

6.2.9. Combined risk assessments

Increasingly food risk assessment questions get more complex and require input from several of the areas described above. This has led to the development of combined risk assessment reports at FSANZ, for example see the risk assessment report on the equivalence of plant sterols, stanols and their fatty acid esters[2].

[1] The significance of a transient excursion of dietary exposure of a food chemical above a reference health standard. Internal FSANZ document (2012). Draft principles for assessing, managing and communicating the significance of small or transient exceedances of reference health standards. Internal FSANZ document (2012).

[2] http://www.foodstandards.gov.au/_srcfiles/A1024%20Plant%20Stanols%20AppR%20SD1%20Risk%20Assess.pdf

Moreover, there is an increasing need to take risk benefit considerations into account (e.g. nitrate risk assessment), which further increases the complexity as well as cost for the assessments. Strong points are that the key relevant expertise is available in house and project teams can be easily assembled that can cover all relevant aspects.

Challenges in this area relate to the early identification of all relevant aspects, as well as to the structure of the combined risk assessment report. To address the first point, there is a need for a clear and practicable approach for early input and better integration of all relevant expertise early on in the risk assessment planning process. Regarding the report, the problem is that each risk assessment section is prepared separately and then combined into one report. This can lead to some repetition, e.g. each section has a summary and conclusions, that are then repeated in the overall summary, or introductory and background text can be repetitive. This can make it quite challenging for the project leader to combine the different parts into one final concise report. Also there may be some problems with terminology which may be used somewhat differently in the different sections. When risk and benefit considerations are included they need a clear rationale and description on decisions.

6.2.10. Recommendations for improvement in the risk assessment process and documentation

- Develop guidance for a tiered risk assessment approach, including for rapid risk assessments and including qualitative approaches, define specific scenarios requiring a different level of detail in the risk assessment approach.
    - Include decision criteria for qualitative rather than quantitative approaches for microbiological risk assessments, and when risk profiling rather than full risk assessments are sufficient.
    - Include guidance on when, and to what extent and under what circumstances existing authoritative risk assessments can be used.

- For combined (and complex) risk assessments, apply a clear and practicable approach for early input from all relevant expertise early on in the risk assessment planning process. This could occur early in a consultative process with all available expertise (in particular special advisors e.g. in nutrition); and include ‘check-points’ throughout the risk assessment development process to make sure no aspect is overlooked, or to decide whether some aspects can be dropped.

- Develop a template on report structure and content for combined risk assessment reports, which involve input from several disciplines, including a brief description of content and level of detail for each section, including examples (reference to existing reports).

- Strengthen the evidence base by introducing a systematic and transparent approach on evidence-retrieval (literature searches) and evaluation (grading) of the evidence (including criteria for ‘inclusion’ and ‘exclusion’) for all risk assessment areas.

- Develop guidance on how to balance risks and benefits in risk assessments.

It is important to note that the recommendations listed above for development of further tools and guidance is intended to help risk assessors and also ensure a consistent and transparent approach. Care has to be taken to not simply increase the administrative burden of risk assessors, but there needs to be a balance between increased 'process' versus clear benefit.

6.3. Scientific competence

Each risk assessment area described above is covered by only a few staff (usually 2-3). This clearly presents a challenge, but it also allows for close collaboration between work areas. In risk assessment, in general, experts have to first be trained, i.e. scientists can be trained in elements of risk assessment, however the practical application of hazard assessment, exposure assessment, and then risk characterization when doing a food risk assessment in the regulatory context has to be learned first 'on the job'. This is a challenge, to first train new staff, and then keep the job opportunities attractive enough to keep experienced trained staff.

Generally there seems to be sufficient in-house expertise in all key areas. However, due to changing needs, e.g. more complex combined assessments, increased availability of (surveillance) data, and increased use of epidemiological data, there seems to be an overall need for more epidemiological and statistical competence.

To complement in house expertise and provide scientific input and training, in 2000 FSANZ established the Science Fellows Program. FSANZ Fellows provide expert advice on applications, proposals and other risk assessment activities of the agency. FSANZ Fellows, within their relevant areas of expertise, also peer review FSANZ work and provide training to FSANZ staff.

The scientific competence and excellence of FSANZ risk assessment staff is well acknowledged by key stakeholders (see chapter 8), and in the international food risk assessment community. However, there seems to be a lack of such acknowledgement in the public, which may create problems in particular on controversial subjects or in crises situations. Improving FSANZ's scientific image may also help to positively influence consumer views and behaviours, and may help to address public perceptions. To achieve this, it may be useful to consider more publication in the scientific literature of work undertaken by FSANZ scientists, and more public (e.g. media, town hall meetings) presence of key scientific staff.

6.3.1. Recommendations related to scientific competence

- Consider the need for additional competence in epidemiology and statistics, to be used across all disciplines, for improved data mining (e.g. surveillance data) and improved integration of all data in risk assessment.
- Consider the need to undertake efforts to improve the public image of FSANZ in terms of scientific competence.
- Continue to ensure a high level of staff training and to provide opportunities to retain scientific staff experienced in risk assessment.

6.4. Transparency of the process (including prioritization)

This part of the report refers the clarity of the process and explicit documentation of all procedures, policies and practices. The prioritization process for risk assessment work is also considered.

Regarding documentation of the process, FSANZ has developed, and updates as necessary, critical documents. The Applications Handbook is an important public document explaining the process for all stakeholders and laying out the requirements for submitting applications. The in-house staff guide for assessing applications and proposals is a very detailed and clear document, which assists the consistency of the risk assessment process. Other in-house guidance documents, some of them more recently implemented to improve overall project management, are established as a guide for risk assessors, e.g. the quick guide for the risk assessment plan. The requirement to establish a risk assessment plan is an important improvement and can be an important decision-making tool, in particular for complex risk assessments.

A strength of FSANZ is that all risk assessments for applications and proposals are publicly notified and all data considered in applications is now publicly available.

There is a process in place, to ensure that all risk assessment requests and needs are prioritized. All risk assessments above certain resource requirements are included in a plan discussed by the FSANZ Executive. Smaller tasks are prioritised by section mangers. Many priorities are dictated by the regulatory framework (applications and proposals), with the risk assessment being part of a larger project, which is also prioritised. For smaller tasks and ad hoc requests the prioritization process is less clear and may present a challenge in specific areas (see under 6.2.). A better documented overall prioritization process could be helpful in resource tracking and allocation.

6.4.1. Recommendation regarding transparency and prioritization

- There is a need for a clearer/more transparent prioritization process for all work, including those that are decided at the section level.

6.5. Soundness of the process and the applied principles

This part of the report relates to the application of current scientific knowledge and considers whether the outcome of the risk assessment withstands scrutiny by peers.

FSANZ risk assessment process follows internationally agreed principles and processes for risk assessment, incorporating current scientific knowledge to the extent possible in the regulatory risk assessment process.

Active participation in international risk assessment activities, including the update and improvements of principles and processes, is an important aspect for FSANZ risk assessment work. In several areas,

e.g. dietary exposure assessment modelling, FSANZ is leading new developments and providing important input in international developments.

The clarity of the risk assessment output and accessibility of underlying data is critical to allow scrutiny of the outcome. Possible improvements to the risk assessment reports are described in section 6.2., which will also allow better demonstration of the application of sound scientific risk assessment principles.

6.6. Inclusiveness

This relates to whether all relevant aspects are considered and appropriately addressed, and that stakeholder views are considered in the process.

In FSANZ, this is facilitated through a defined process, in that a risk assessment plan has to be established. Risk assessment teams are also established, to identify all required aspects, and a regular review of needs and risks is undertaken by the team. Care has to be taken that this process is applied as appropriate and does not lead to an overly administrative (rather than scientific) process. The overall process has to be adapted to the actual question, and risk assessment efforts should be proportional to the public health risk (to the extent possible). This, however, is a particular challenge, and targeting the risk assessment effort to be 'fit-for-purpose' requires a clear rationale, and clear definition of the scope and interaction between risk assessor and risk manager.

The process of public review and comment period allows for stakeholder input, which is an important element of inclusiveness. Including stakeholder views in the process as appropriate to contribute to the development of risk management options, is a positive element.

6.7. Internal review and approval process

Draft risk assessments are first discussed in the project team, and once agreed have to be approved by the direct line manager, followed by the executive sponsor, the Chief Scientist and the relevant direct line general manager. Final internal approval is then with the FSANZ board. Although the main role of the board in this is to ensure adherence to government policies and regulations and to make decisions about varying the Code, they are often interested in the scientific reasoning behind risk assessment conclusions. They frequently offer helpful suggestions to improve the risk communication of decisions.

6.8. External peer-review process

External peer-reviews of draft risk assessments are undertaken on an ad hoc basis. A decision on the need for a peer review is made by senior management. Reviews are undertaken by external experts who may be a FSANZ Fellows. The FSANZ Fellows program is a network of experts who can provide FSANZ with objective expert advice and critical review.

Independent peer-review is an important tool to ensure the soundness and appropriateness of the risk assessment. There are different options, either by a standing review body or on an ad hoc basis. Both

options are valid and there are pros and cons for each, depending on the situation and intent for the review.

There is a need to define a clear process for rationale, when and why a peer-review is to be undertaken, as well as a process for selection of reviewers. This needs to include a process for the declaration of interests, evaluation of declared interests and handling of potential conflicts of interests.

6.8.1. Recommendations regarding external peer reviews

- Establish a process, including rationale, for when and how external reviews should be undertaken.
- Establish a Declaration of Interest form and evaluation process for reviewers and FSANZ fellows.

7. Risk management aspects

The functional separation of risk assessment and risk management is an important element to safeguard the independence of the scientific advice underlying risk management decisions. However, it is acknowledged that risk managers should communicate and interact with risk assessors throughout the process, particularly during the problem formulation and planning and scoping phases at the beginning of the risk analysis process. This will ensure that the risk assessment addresses appropriately the actual health concern and that risk managers understand the outcome, limitations and implications of the risk assessment.

This is achieved in FSANZ through a structural separation of risk assessment and management, and clearly defined interactions between the relevant sections. In particular in routine work, addressing applications and proposals, this separation and communication works well. Risk assessors and risk managers communicate on progress via the multi-disciplinary teams that are established. The respective roles of risk assessment and management can become less clear during issues management and interactions are more challenging.

7.1. FSANZ risk management views on the risk assessments

A specific point raised by FSANZ risk managers was that there could be more use of existing risk assessments from other authorities, especially if dietary exposure is estimated to be low. However, when adopting such an approach, care has to be taken that relevant existing risk assessments are addressing the same concern and are established according to the internationally accepted principles that have been adopted and implemented by FSANZ. It is noted that existing international (FAO/WHO) microbiological and chemical risk assessments are taken into account in the current FSANZ risk assessment process. It is suggested that for certain sections in the risk assessment documents only a short summary is given and reference then made to the relevant existing assessments, rather then re-

writing what has already been done elsewhere. Of course this still requires a rapid peer-review of the existing assessment.

Further points raised were that the internal coordination of risk assessments has improved over recent years and that they are more multidisciplinary. Suggestions raised for further improvement relate to the risk assessment report. New reports, on applications, are seen to become too 'bureaucratic', e.g. the risk assessment part is so short that risk management decisions may not be clear. To understand the risk assessment, one has to refer back to the detailed risk assessments. Therefore it would be beneficial to include the key decision points of the risk assessment in the final report. Concern was also raised that there are statutory time-lines for applications and that often after the finalization of the risk assessment there is not enough time for risk management decisions, raising the question if risk assessors sufficiently understand the potentially complex risk management decision process. As risk assessments become increasingly more complex, so may the risk management decision process increase in complexity. One specific example is the area of uncertainty in risk assessment, which requires a lot of interaction between risk assessment and risk management to understand the reasons and implications of uncertainties underlying the risk assessment. Clearly expressing uncertainty in risk assessment and proper consideration of such uncertainties in the risk management decision-making process is an area of intense debate internationally.

7.2. Interaction of risk assessment and risk management

The risk assessment process has been improved in detail, clarity and transparency internationally and at FSANZ over recent years. However, the same level of further development and improvement, in particular the transparency in the decision-making process, has not followed in the risk management area. This is of concern also for the risk assessment process, in that it may not be clear in the final risk management outcome, how the risk assessment was used in the decision-making process.

It is understood that recent efforts have been undertaken at FSANZ to develop a common risk management framework, i.e. a structured approach to decision-making, in order to address this concern. It is recommended to further develop and implement such approaches, and interaction or collaboration with other authorities may be useful, since they often struggle with the same problem.

The relationship between risk assessment and risk management is an interactive, often iterative, process. Further suggestions on how to improve the interaction between risk assessor and risk manager include more involvement of the risk assessor throughout the decision-making process, including in discussion on risk management options and implications, where the risk assessment can inform the process. Furthermore, risk assessment advice can be requested for different risk management options, e.g. impact on exposure and health outcome of different interventions or limits. This is currently done in some cases for microbiological risk assessment and primary production standards, but could also be beneficial for the risk management decision process in other areas.

One work area that could contribute to risk assessment and risk management is the consumer and social sciences area, e.g. by helping to scope the risk assessment questions or to help target risk management actions (change in behaviour).

Lastly, there is no evaluation of the effectiveness of regulatory measures taken, i.e. if the risk management measures proposed achieve the public health goal. Such a monitoring and evaluation framework can be elaborate but would be important for key public health issues. This has to be done in collaboration with New Zealand and the states and territories, which are responsible for implementing measures.

7.2.1. Recommendations regarding the interaction between risk assessment and risk management

- Increase the transparency in the risk management decision-making process.
- Consideration may be given to the establishment of a monitoring and evaluation framework for key public health issues, subject to priorities and available resources.
- Develop guidance on how to express uncertainty in risk assessment and for proper consideration of such uncertainties in the risk management decision-making process.

8. Stakeholder views

8.1. States and territories

The states and territories in Australia are responsible for implementing the Code (note: NZ MPI is responsible for implementing joint standards in New Zealand but not all standards are joint standards). A workshop was organized to obtain the views of states and territories on FSANZ risk assessment processes and procedures. Of the six states and two territories, three (Victoria, NSW, Western Territory) were able to participate.

FSANZ risk assessment work was seen as significantly improved, with the biggest improvement in providing advice in incidents and for rapid risk assessments, i.e. being more responsive to urgent needs. Moreover the format and language in rapid risk assessments has improved, and is seen as more helpful, leaving more 'decision-space' for risk management implementation. With respect to regular risk assessments, the openness of the process was seen as positive, i.e. jurisdictions can give input during the peer review period. With respect to the risk assessment reports, it was noted that not too much less relevant detail should be provided that may create unnecessary concern (e.g. description of toxicity study showing effects which are then dismissed for valid scientific reasons). These details should be in detailed risk assessment report, but not in summary. It is important to communicate the outcome of the risk assessments in a way that it can be used in the legal framework.

Regarding work efficiencies, it was supported in-principle that FSANZ could build its risk assessments on existing national and international assessments, however this needs to be done in a tiered approach, and targeted to the type of hazard (i.e. the lower the concern the more existing risk assessments should be used). It was noted, however, that for risk benefit assessments a more

national rather than international approach may be required (i.e. different dietary habits, production methods etc.).

In relation to integrating the different risk assessment disciplines, it was noted that combined risk assessment reports have greatly improved in structure and level of detail, but there is room for further improvement, such as consistency between sections, and a more plain language summary that could be used directly for communication purposes, thereby reducing the risk of 'distortion' of the original message.

Communication flow between FSANZ and the jurisdictions is seen as satisfactory. However it was noted that the jurisdictions need to better embrace the networking idea and share information to avoid duplication of efforts.

For potential improvements, it was suggested that ways be explored to make the risk assessments more easily accessible, also outside the original context, since they could be of broader use (e.g. an assessment in response to a specific application could be of use in other circumstances).

An area of concern is the potential huge staff drain to respond to ad hoc requests for risk assessments from jurisdictions. There is no formalized process for this, and sometimes there are problems with insufficient information and data provided to perform a risk assessment (e.g. quality of data provided by states is sometimes too limited, or being provided in different sets while the risk assessment is ongoing). A more formal approach for such requests would be clearly beneficial, to guide the requester on what information needs to be provided, but also to help FSANZ to frame and prioritize such requests.

Overall the jurisdictions are very satisfied with FSANZ's risk assessment work. Some areas for improvement have been detailed in the text above. FSANZ is seen as an independent body by the jurisdictions. This can be important when communicating risk management measures, by relaying that actions are based on advice from an independent expert body.

8.1.1. Recommendation resulting from discussions with stakeholders

- Establish a simple 'scoping/request' form to require the requester, for example, Australian state and territory jurisdictions, to clearly formulate the risk assessment need and to provide appropriate information and data. This will also allow FSANZ to estimate resource needs and consider additional work as well as to prioritize the request.

8.2. Other government agencies

NZ MAF[3]

There are close interactions in the risk assessment area between FSANZ and NZ MAF, recognising that NZ have their own requirements for primary production and food safety standards.

Risk assessments undertaken by NZ MAF in the microbiological area are specific to New Zealand. Often risk profiles are established for prioritisation and identification of research needs. These microbiological risk profiles are published on the web and frequently updated. NZ MAF interacts regularly with FSANZ to avoid duplication of efforts.

For chemical risk assessments, NZ MAF evaluates pesticides and veterinary drugs separately for the purpose of registration in New Zealand. Common areas on other chemicals relate to work on the Code, in these cases FSANZ drafts the risk assessments for NZ MAF to provide comments, usually as a part of the public review process. For complex risk assessments NZ MAF input can be requested earlier. Other areas of joint work are triggered by food incidents, where the agencies collaborate closely on the risk assessment, even if the incident is managed under separate processes.

Overall there is constant interaction with FSANZ, through direct communication between relevant risk assessment staff, for example NZ MAF staff participate in some FSANZ discipline group meetings via videoconference. Moreover, a number of joint research projects are undertaken, e.g. a survey of caffeine in special products, and a survey of furan. Formal meetings are held twice per year.

Other areas of interaction and collaboration relate to the sharing of national positions to prepare for Codex meetings, sharing of national dietary exposure assessments, and sharing and harmonizing of press releases.

Suggestions for improvement relate to further improved communication: further encouragement of regular discussions including in the planning stage before starting more complex risk assessments. For existing risk assessments with different outcomes, it is important to harmonize approaches (e.g. iodine in bread). It is also important when talking to industry to have NZ MAF staff involved to speak in 'one voice', in order to avoid public confusion about the roles of FSANZ and NZ MAF.

Areas of concern are the prioritization of risk assessment work, where NZ MAF perceives it has less influence than other stakeholders e.g. states and territories. For toxicological assessments there is sometimes a difference in the level of conservatism underlying the risk assessment, and further work to harmonize this is important.

DAFF

Interaction between FSANZ and DAFF is in specific areas and more on the risk management rather than the risk assessment side. Regarding interactions in relation to risk assessment, DAFF provides input to the development of primary production and processing standards, in particular input from the farm level, and on occasions provides data input to surveillance studies. Data from the national residues survey (NRS) is provided to FSANZ to consider as a part of risk assessments.

[3] now called Ministry for Primary Industries

In relation to the imported food program which is the responsibility of DAFF, FSANZ provides the risk assessment and input to the development of a risk-based monitoring plan.

FSANZ provides risk assessment advice on an ad hoc basis to DAFF, as well as input to (ministerial) briefings, Codex briefs etc.

An area for improvement was identified for the imported food program, and in particular on the joint project 'imported food risks'. There is a need for a clear rationale for including certain hazards, e.g. via a risk ranking and risk profiling, to better link to the Code and real health risk.

More collaboration on data formats (for surveillance data) for easier sharing and to better complement FSANZ work would be helpful.

Overall FSANZ is seen as the national risk assessment authority. FSANZ's openness to stakeholder input was seen as positive, but it has to be ensured that this does not influence the process.

Concern was raised that the risk assessment area is 'overstretched' and does not leave enough time and resources to run small research projects to fill risk assessment gaps. More scientific publications on FSANZ work would be beneficial for more transparency and credibility. Concern was also raised on the lack of transparency in risk management decision-making, thereby potentially losing the link to risk assessment. There was also a view that a sort of 'validation' that risk management decisions actually achieve stated goals was missing.

APVMA

Interaction between FSANZ and the APVMA occurs mainly on the policy level.

In relation to risk assessment, APVMA performs dietary exposure assessments for pesticide residues in food, utilizing FSANZ food consumption data. FSANZ reviews the draft exposure assessment, before maximum residue limits (MRLs) are finalized. Similar interaction occurs when evaluating veterinary drug residues.

Toxicological assessments for pesticides and veterinary drugs are undertaken by DOHA/OCS, residue and exposure assessment is then performed by the APVMA. Ad hoc input from FSANZ on the toxicological assessments is sometimes requested, e.g. the dimethoate review. In special risk assessment cases, the APVMA builds on existing FSANZ assessments, e.g. streptomycin in apples, and collaborates with FSANZ scientists before finalizing such assessments.

A strong aspect of FSANZ risk assessment work is that it is seen as based on good science, the existence of a detailed science strategy and implementation plan, and stakeholder input. In addition, the website is seen as a strong point.

The lack of clear responsibilities or a legal framework between the organizations in some specific areas, e.g. water re-use (in case of drought) is seen as problematic for the risk assessment area.

Office of the Gene Technology Regulator (OGTR)

The Gene Technology Regulator is the primary regulator in Australia for any dealings involving a genetically modified organism (GMO). A GMO is an organism that has been modified by gene technology; or that has inherited particular traits from an organism that has been modified by gene technology.

OGTR has two branches, one which deals with the scientific assessment (risk assessment part) and one for monitoring (risk management part).

There are many links with FSANZ, with long-standing good collaborations under an official MOU. OGTR and FSANZ collaborate on GMOs with FSANZ being responsible for all GM food-related aspects irrespective of whether it is imported or domestically grown. For all other GMO matters the OGTR has sole responsibility. Under a 'no-split use' approval policy between OGTR and FSANZ, no GM crop will receive an approval for use as an animal feed but not for human food applications. This policy illustrates the importance of a close collaboration to avoid an occurrence of the 'Starlink' corn problem which occurred in the United States about a decade ago.

As judged by a previous external assessment, FSANZ's risk assessment science for GM food is considered to be strong. FSANZ is expected to consider all risk assessment aspects that have been raised globally on a specific GMO.

8.3. Industry

The Australian Food and Grocery Council (AFGC)[4] represents food and drinks manufacturers of Australia. There is a close and good working relationships with FSANZ, less so on the regulatory role of FSANZ, but more on the operational role of FSANZ such as food recalls. Here FSANZ has an important national role, and close interaction and networking is critical for rapid reaction.

It is seen that the risk assessment process has improved over the years, with strengthened data requirements and improved turnaround time for applications. FSANZ is seen to have a strong and clear process, including consultation with stakeholders. However the process may be less transparent for controversial areas, such as biotechnology and health claims, where it is perceived that FSANZ's risk assessment efforts may not always reflect the actual health concern. Examples where it was perceived that the risk assessment was 'overboard' in relation to actual health concern were cyanogenic glycosides in cassava chips, and oligosaccharides in infant formula. In the first case it was argued that voluntary measures may have been sufficient, and in the second case it was argued that it was a compliance rather than a safety issue, and regulatory measures implemented had big economic impacts.

Overall it was argued that there is a need for targeted risk assessments, i.e. proportional to actual health risk and taking the economic impact of proposed measures into account, and that there needs to be a stronger role for the risk assessment in the regulatory decision making process.

A specific concern that was raised referred to the lack of a public voice and recognition of FSANZ nationally, especially in the risk assessment area. Also, the need for a more prominent national role for FSANZ in risk communication was mentioned, i.e. the need for a more prominent public image and stronger national voice, as the leading independent national food risk assessment authority.

Proposals for improvement in risk assessments were to have a stronger risk assessment for nutrition and fortification, with a need for more consideration of epidemiology and statistics and more interaction with toxicology. In addition, more consideration should be given to different risk management options, including voluntary actions rather than regulation, e.g. for labelling.

Overall the AFGC is very supportive of the FSANZ risk assessment process, but there are some areas of controversy where industry sees FSANZ to be too 'regulatory', and concern was raised about the lack

[4] http://www.afgc.org.au/

of a public image of FSANZ as the national risk assessment authority, and sometimes insufficient consideration of the risk assessment outcome in the risk management decisions.

While it is very important for FSANZ to have good working relationship with the industry sector, care has to be taken to not give an impression or perception of undue influence. This is achieved through a clear and transparent process of interaction with the industry sector.

9. Consolidated list of recommendations:

The following is a list of main recommendations. Additional minor suggestions are included in the text under the specific sections.

Recommendations for improvement in the risk assessment process and documentation:

1. Develop guidance for a tiered risk assessment approach, also for rapid risk assessments; including qualitative approaches and defining specific scenarios requiring a different level of detail in the risk assessment approach.
    a. Include decision criteria for qualitative rather than quantitative approaches for microbiological risk assessments, and when risk profiling rather than full risk assessments are sufficient.
    b. Include guidance on when, and to what extent and under what circumstances, existing authoritative risk assessments can be utilized.

2. For combined (and complex) risk assessments, apply a clear and practical approach for early input from all relevant expertise early on in the risk assessment planning process. This could occur early in a consultative process with all available expertise (in particular special advisors e.g. in nutrition); and include 'check-points' throughout the risk assessment development process to make sure no aspect is overlooked, or decide whether some aspects can be dropped.

3. Develop a template on report structure and content for combined risk assessment reports, which involve input from several disciplines, including a brief description of content and level of detail for each section, including examples (reference to existing reports).

4. Strengthen the evidence base by introducing a systematic and transparent approach on evidence-retrieval (literature searches) and evaluation (grading) of the evidence (including criteria for 'inclusion' and 'exclusion') for all risk assessment areas.

5. Develop guidance on how to balance risks and benefits in risk assessments.

Recommendations related to scientific competence:

6. Consider the need for additional competence in epidemiology and statistics, to be used across all disciplines, for improved data mining (e.g. surveillance data) and improved integration of all data in risk assessment.

7. Consider the need to undertake efforts to improve the public image of FSANZ in terms of scientific competence.

8. Continue to ensure a high level of staff training and to provide opportunities to retain scientific staff experienced in risk assessment.

Recommendation related to transparency and prioritization:

9. There is a need for a clearer/more transparent prioritization process for all work, including those that are decided at the section level.

10. Establish a simple 'scoping/request' form to require the requester, for example, Australian state and territory jurisdictions, to clearly formulate the risk assessment need and to provide appropriate information and data. This will also allow FSANZ to estimate resource needs, and consider additional work as well as to prioritize the request.

Recommendations regarding external peer reviews:

11. Establish a process, including rationale, for when and how external reviews should be undertaken.

12. Establish a Declaration of Interest form and evaluation process for reviewers and FSANZ fellows.

Recommendation regarding the interaction between risk assessment and risk management:

13. Increase the transparency in the risk management decision-making process.

14. Consideration may be given to the establishment of a monitoring and evaluation framework for key public health issues, subject to priorities and available resources.

15. Develop guidance on how to express uncertainty in risk assessment and for proper consideration of such uncertainties in the risk management decision-making process.

It is important to note that the recommendations listed above for development of further tools and guidance are intended to help risk assessors and also ensure a consistent and transparent approach. Care has to be taken to not just increase the administrative burden of risk assessors, but there needs to be a balance between increased 'process' versus clear benefit. Moreover, some of the recommendations are of a more general nature, and in particular in the area of interaction between risk assessment and risk management, are not unique to FSANZ as other authorities struggle with the same issues. In these cases, interaction with other authorities may be considered.

Annex 1: Detailed Terms of References

Objectives

- To evaluate the current rigour of FSANZ's risk assessment practices and procedures across the scientific disciplines at a high level and benchmark these against international best practice.
- To identify areas for improvement so that FSANZ's standards development process continues to be supported by robust risk assessments.
- To provide recommendations to enhance these areas to ensure that FSANZ's scientific capability continues to inform global risk assessments.

Terms of Reference

Conduct a review of FSANZ's risk assessment practices and procedures underpinning our standards development. This will include the following:

- Benchmark FSANZ's current risk assessment practices and procedures against international best practice, taking into consideration FSANZ's available resources.
- Review the format, content and presentation of FSANZ risk assessment reports and make recommendations on areas for improvement.
- Review the integration of risk assessment work across the different scientific disciplines- chemical, consumer and social science, data collection, exposure assessment, genetically modified (GM) foods, microbiology and nutrition.
- Provide suggestions to improve the inputs from and integration of different scientific disciplines in the risk assessment report.
- Provide advice in relation to when it is reasonable to undertake a small scale versus full risk assessment.
- Review the process undertaken to formulate risk assessment questions and how they are subsequently addressed, including the interface between risk assessment and risk management functions.

Tasks

Information gathering to inform the review of FSANZ's risk assessment practices and procedures across the scientific disciplines which will include:

1. Background reading of the following material:

- Cross section of FSANZ risk assessment reports
- Report on the 2009 peer review of the FSANZ food composition program and databases.
- Report on the 2008 peer review of FSANZ GM food safety practices and procedures.
- Report on the 2007 peer review of the FSANZ Dietary Modelling Team practices and procedures.
- FSANZ Science Strategy for 2010-2015 and the 2011 implementation plan.
- Analysis of food related health risks
- Application handbook
- FSANZ project management handbook
- An example of the regular scientific and international activities report.

2. Discussions with the FSANZ CEO, the Deputy CEO, Chief Scientist, General Manager Risk Assessment and other members of the Executive as required for the purpose of seeking their individual perspective on the risk assessment process at FSANZ and potential areas for improvement.

3. Discussions with FSANZ Section Managers from the following areas for the purpose of obtaining their feedback on the risk assessment process at FSANZ:

- Risk Assessment Chemical Safety
- Risk Assessment Microbiology
- Production Process Risk Assessment
- Risk Assessment Public Health Nutrition
- Product Safety Standards
- Public Health Nutrition Standards
- Scientific Strategy, International and Surveillance
- Labelling and Information Standards
- Consumer and Social Science
- Food Composition, Evaluation and Modelling
- Food Safety.

4. Discussions with key Australian government agencies to determine areas of mutual interest, collaboration and to seek an objective view of FSANZ risk assessment performance, including:

- Australian Quarantine and Inspection Service (AQIS)

- Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Department of Agriculture, Fisheries and Forestry (DAFF)
- Department of Health and Ageing (DoHA) – OCS, OHP, OzFoodNet, TGA

5. Discussions with Australian state and territory health departments and food regulatory agencies to seek feedback on the transparency of the FSANZ risk assessment process, whether issues raised are adequately considered by FSANZ and if the process effectively meets the requirements for compliance and enforcement activities.

6. Discussions with the New Zealand Ministry of Agriculture and Forestry (NZ MAF).

Deliverables

1. Key input to and delivery at a workshop organised by FSANZ to relevant stakeholders on current international best practice risk assessments.

2. Meet with the CEO, the Deputy CEO, Chief Scientist, General Manager Risk Assessment and other relevant FSANZ staff to provide a verbal debrief on the initial findings and recommendations of the review prior to departing Australia/New Zealand.

3. Deliver a seminar to FSANZ staff on the risk assessment process from a WHO perspective.

4. Written draft report on the review of FSANZ'S risk assessment practices and procedures across the different scientific disciplines within *2 months* of departing Australia/New Zealand.

5. Provide the final report on the review of FSANZ'S risk assessment practices and procedures across the different scientific discipline within *2 months* of submitting the draft report.

Annex 2: Workprogram (in Canberra)

List of consultations

Food Standards Australia New Zealand

Executive

Chief Executive officer	Steve McCutcheon
General Manager Food Standards (Canberra)	Melanie Fisher
General Manager Officer of the Chief Scientist	Paul Brent
General Manager Risk Assessment	Andrew Bartholomaeus
General Manager Food Standards (Wellington	Dean Stockwell
Chief Public Health Nutrition Advisor	Dorothy Mackerras

Section Managers: Risk Assessment – Chemical Safety (RACS), Risk Assessment Microbiology Section (RAMS), Risk Assessment Public Health Nutrition (RAPHN), Scientific Strategy International and Surveillance (SSIS), Food Composition Evaluation and Monitoring (FEMS), Product Safety Standards (PSS), Labelling and information Standards (LIS), Consumer and Social Science (CASS)

FSANZ Fellow	Brian Priestly

Stakeholder consultation

Department of Agriculture Fisheries and Forestry (DAFF)

Australian Quarantine and Inspection Service (AQIS)

Australian Pesticides and Veterinary Medicine Authority (APVMA)

Office of the Gene Technology Regulator (OGTR)

State and Territory regulatory authorities

New Zealand Ministry of Agriculture and Fisheries (NZ MAF),

Australian Food and Groceries Council (AFGC)

Annex 3: List of references

FAO/WHO Documents:

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