Australian Government

Department of Agriculture, Fisheries and Forestry

Bureau of Rural Sciences

REVIEW OF METHODOLOGY FOR CONSEQUENCE ASSESSMENT

Broadleaf

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25 November, 2005

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Acronyms and Abbreviations

Commonly used acronyms and abbreviations are listed below. Each of the Government divisions and agencies also has its own business-specific acronyms and abbreviations – these have been explained within the text.

ABARE	Australian Bureau of Agricultural and Resource Economics
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARTG	Australian Register of Therapeutic Goods
AQIS	Australian Quarantine and Inspection Service
BRS	Bureau of Rural Sciences
COAG	Council of Australian Governments
Codex	Codex Alimentarius Commission
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DEH	Australian Government Department of Environment and Heritage (now the Department of Environment and Water Resources)
DHA	Australian Government Department of Health and Aging
DITR	Australian Government Department of Industry, Tourism and Resources
EPBC Act	Environmental Protection and Biodiversity Conservation Act
FAO	Food and Agriculture Organisation of the United Nations
FMD	Foot-and-mouth disease
FSANZ	Food Standards Australia New Zealand
GMO	Genetically modified organism
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
MA	Market Access
OGTR	Office of the Gene Technology Regulator
OIE Code	Terrestrial Animal Health Code
OIE Manual	Manual of Standards for Diagnostic Tests and Vaccines
OIE	Office International des Epizooties (the World Organisation for Animal Health)
PHA	Plant Health Australia
PIAPH	Product Integrity Animal and Plant Health
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TG Act	Therapeutic Goods Act
TRAAC	Technical Risk Assessment Advisory Committee
TRPS Agreement	Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
WTO	World Trade Organisation

1 SUMMARY

1.1 Background

The objectives of this project were to catalogue the range of approaches to consequence assessment currently used by Government, to draw on the experience of others to further develop and improve Biosecurity Australia's approach to consequence assessment and to identify areas where further work in this field might be undertaken by the Centre of Excellence.

It has been suggested that an improved approach to consequence assessment that takes into account the best available information would lead to improved decision making, greater public understanding of, and engagement with, the biosecurity policy-making process, and more consistent and repeatable import risk analysis outcomes. Other program areas within the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF), and other departments and agencies, would also benefit from an understanding of the breadth of methodologies used in Australian Government.

We approached the project in two steps.

First, we carried out a survey of three key Australian Government departments to identify the divisions and agencies that carry out risk analysis, and therefore consequence assessment, as a part of their core business.[1] The Government departments included were DAFF, the Department of Environment and Heritage (DEH)[2] and the Department of Health and Aging (DHA). Two non-departmental agencies – the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Productivity Commission – and the Department of Industry, Tourism and Resources (DITR) Geoscience Australia, were also included in the survey. In the latter stages of the project, and at the recommendation of Biosecurity Australia, the Plant Health Australia (PHA) Regional Economic Impact Model was added to the survey. The project's Steering Committee judged that although most other Commonwealth departments and agencies carry out risk analysis, and, as an element of this, consequence assessment, their methods and approaches are likely to be directed at issues too disparate from pest and disease analysis to be of significant value to the study.

Next, we held interviews with representatives from the key divisions and agencies (including Biosecurity Australia), and collated a cross-section of relevant published and internet materials. These formed the knowledge base for a systematic review of the context within which each division or agency carries out risk analysis, the frameworks used, and, most specifically, the methods employed to assess consequences. Each review led to concluding comments which were used as the basis for discussion and analysis. The analysis in turn led to a set of project recommendations.

After preliminary analysis of the three departments, their portfolio agencies and the various non-departmental agencies, the following were included in the review:

- Australian Bureau of Agricultural and Resource Economics (ABARE);
- Approvals and Wildlife Division, DEH;
- Australian Greenhouse Office;
- Biosecurity Australia;
- Biotechnology, DEH;
- Marine Division, DEH;
- Food Standards Australia New Zealand (FSANZ);
- Therapeutic Goods Administration (TGA);
- Office of the Gene Technology Regulator (OGTR);
- Geoscience Australia;
- APVMA; and
- Productivity Commission.

Of these, Biotechnology and APVMA were not found to be using methods or approaches likely to be of value to Biosecurity Australia. The analysis therefore focused on Biosecurity Australia and the remaining nine divisions and agencies.

In brief, the analysis found that three key difficulties could be encountered when applying Biosecurity Australia's current method for consequence assessment.

- The assessment of impact at systematic sub-national levels: this approach becomes difficult for impacts that are not naturally associated with levels of government. The approach is also

[1] Risk analysis is used here as a generic term, and synonymous with the Australian and New Zealand Standard (AS/NZS 4360) concept of 'risk management'. In other parts of the report it has different and more specific meanings.

[2] Now the Department of Environment and Water Resources

difficult when assessing impacts accrued from multifocal outbreaks.

- The period over which impacts occur: it is currently difficult to estimate the impacts of pests and diseases that cannot be eradicated quickly, or are likely to become endemic. It is also difficult to estimate impacts that continue to be accrued after eradication of the pest or disease, or its containment in a controlled zone.
- The generic qualitative descriptors for the significance of national impact: because these descriptors apply to each of the direct and indirect forms of impact that Biosecurity Australia considers (termed 'criteria'), they have no absolute meaning and tend to be used as a *de facto* ranking system.

The simple solution to the first difficulty is to accept that national impact is the goal, and that estimating impact at sub-national levels, whilst important for evaluating some Government costs, should not be carried out for all of the direct and indirect impact criteria.

The second difficulty does not have an immediate solution, and would be faced under any qualitative or quantitative model for consequence assessment. That said, the difficulty could be ameliorated by standardising the way in which longer-term or permanent impacts are handled, thus ensuring consistency within and between analyses.

The third difficulty could be addressed by assessing the significance of each direct and indirect impact against a different scale, or benchmark. We stress here that the development of suitable 'scales' for assessing direct and indirect impacts is a separate objective to the development of methods for assessing impacts *per se*. Scales should be transparent, and should equate to a measure or quantity that analysts and readers can readily relate to. Once developed, such scales can be adopted as the benchmarks against which the significance of direct and indirect impacts will be assessed. Individual pest or disease assessments, which can utilise a range of analytic or descriptive tools, methods and approaches, can then be compared with each of the scales and rated accordingly. Under the current system the single qualitative scale is not adequately defined, and this crucial step of the consequence assessment is made difficult and relatively non-transparent.

The Discussion and Analysis (Section 10, page 70) correlates these difficulties with the apparent strengths of the methods for consequence assessment employed by each of the agencies reviewed. The objective of this was to identify areas in which Biosecurity Australia or the Centre of Excellence could best focus ongoing collaborative research and development into this important aspect of risk analysis. In this part of the document, the agencies were arranged into three groups; based on their core expertise or the focus of their work. The first group of agencies provided strength in economic analysis; the second in the assessment of environmental impacts, of climate change and of vulnerability; and the third in qualitative risk analysis under legislated guidelines.

The process led to the development of nine key recommendations (below). For detail about these recommendations, the reader is referred to the Discussion and Analysis and to relevant parts of the body of the review.

1.2 Recommendations: Economic Analysis

Recommendation 1

Economic methods have a potential role in consequence assessment for import risk analyses in assisting to put a dollar measure on adverse outcomes associated with a pest or disease outbreak. Such methods should be capable of generating a quantitative basis for the scales against which Biosecurity Australia's estimates the national significance of:

- The direct impact on the life or health (including production effects) of production, domestic or feral animals; or the life or health (including production effects) of commercially cultivated, garden or feral plants;
- The indirect impact of new or modified eradication, control, surveillance or monitoring and compensation strategies or programs;
- The indirect impact on domestic trade or industry, including changes in consumer demand and impacts on other industries supplying inputs to, or utilising outputs from, directly affected industries;
- The indirect impact on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand; and some aspects of
- The indirect impact on communities, including reduced tourism, reduced rural and regional economic viability, the loss of social amenity and any 'side impacts' of control measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with ABARE with a view to developing quantitative scales for the national significance of these five direct and indirect impacts. Such scales could then be used as a transparent benchmark for ongoing routine qualitative assessments.

Biosecurity Australia and the Centre of Excellence should also investigate the development of a generic model, or suite of models, that could be used routinely to quantify relevant parts of individual pest or disease risk assessments.

Recommendation 2

Biosecurity Australia and the Centre of Excellence should consider dialogue with PHA, with a view to maintaining awareness of the Regional Economic Impact Model project and its implications for Biosecurity Australia's import risk analyses.

Recommendation 3

A systematic review of available economic models that might add value to Biosecurity Australia's consequence assessments would augment work undertaken in collaboration with ABARE, and provide Biosecurity Australia and other interested parties with a clearer understanding of the breadth and focus of economic modelling in Australia.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Government Treasury with a view to commissioning a review by the Productivity Commission of economic models from Government, academic and private sources relevant to Biosecurity Australia's import risk analyses.

1.3 Recommendations: Environmental Impacts, Climate Change and Vulnerability

Recommendation 4

DEH Approvals and Wildlife Division has guidelines for assessing direct and indirect environmental consequences that are relevant to Biosecurity Australia. Aspects of the approach have the potential for adaptation for use in import risk analyses, and would complement the development of quantitative models and measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with DEH Approvals and Wildlife Division, with a view to developing a qualitative ranking system for assessing the significance of direct and indirect terrestrial environmental impacts.

Recommendation 5

The multiple use risk assessments to be included in DEH Marine Division's Regional Marine Plans could assist with the development of approaches for assessing the consequences of marine pests and diseases. Such approaches would complement the development of quantitative models and measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with DEH Marine Division, with a view to developing a qualitative ranking system for assessing the significance of direct and indirect impacts on the marine environment.

Recommendation 6

Qualitative methods for estimating the vulnerability of Australia to pest and disease incursions would provide a different perspective from which to approach import risk analysis from that currently used by Biosecurity Australia. Such methods would complement the current approach.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Greenhouse Office and Geoscience Australia, with a view to developing a qualitative method for estimating the vulnerability of Australian communities to pest and disease incursions.

Recommendation 7

Quantitative models for examining the effects of long-term changes or shocks due to climate change or natural disasters may provide a different approach to examining the impacts of pest and disease incursions. Such models might be adapted to augment qualitative or quantitative aspects of consequence assessments for import risk analyses.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Greenhouse Office and Geoscience Australia, with a view to reviewing practical aspects of quantitative analytic tools used in the fields of climate change and natural disasters.

Recommendation 8

Geoscience Australia's initiatives with the Technical Risk Assessment Advisory Committee (TRAAC) and the development of a National Risk Assessment Framework both draw on its substantial technical skills base and corporate experience in estimating and evaluating the components of risk. Exposure to this skills base is likely to be of benefit to the Centre of Excellence as well as to Biosecurity Australia.

Biosecurity Australia and the Centre of Excellence should consider dialogue with Geoscience Australia, with a view to establishing links to TRAAC and the National Risk Assessment Framework.

1.4 Recommendation: Qualitative Risk Analysis

Recommendation 9

OGTR's qualitative ranking system for assessing and evaluating risk has some similarities to Biosecurity Australia's approach, although it differs in detail, and both agencies operate in an environment often characterised by powerful stakeholders and competing interests.

Biosecurity Australia and the Centre of Excellence should consider dialogue with OGTR with a view to sharing experiences and augmenting the qualitative approaches they each use for consequence assessment.

2 STUDY OBJECTIVES AND DESIGN

2.1 Study Objectives

The objectives of this project, as explained in the documentation of the Request for Tender, were:

– To catalogue the range of approaches currently used in consequence analysis;
– To draw on the experience of others to further develop and improve Biosecurity Australia's approach to the consequence analysis component of import risk assessments; and
– To identify areas where further work might be undertaken by the Centre of Excellence or Biosecurity Australia to further improve this aspect of import risk analyses.

It was suggested that an improved consequence assessment, that accurately and transparently takes into account the best available information, will provide for improved decision making, consistent with Government policy objectives, and will inform risk assessors in other program areas of DAFF and other departments of the breadth of methodologies used. It was also suggested that improved consequence assessments, using better defined methodologies, will allow greater public understanding of, and engagement with, the biosecurity policy-making process and provide for more consistent, repeatable outcomes. Cleary this will be of benefit to both the public and business.

2.2 Survey and Analysis of Government Agencies

To address the study objectives, we undertook a systematic review of the methods for consequence assessment employed within three key Australian Government departments and their portfolio agencies, and two key non-departmental Government agencies. The Government departments included were DAFF, DEH and DHA. The two key agencies were APVMA and the Productivity Commission.

Geoscience Australia, which resides within DITR, was also included in the review on the basis of its technical interactions with other departments and its breadth of experience in disaster risk management. In the latter stages of the project, and at the recommendation of Biosecurity Australia, the PHA Regional Economic Impact Model was added to the survey.

The project's Steering Committee judged that although most other Commonwealth departments and agencies carry out risk management, and, as an element of this, consequence assessment, their methods and approaches are likely to be directed at issues too disparate from pest and disease analysis to be of value to the study. By contrast, it was felt that detailed analysis of the chosen departments and agencies would be likely to encompass most of the methods and approaches of benefit to Biosecurity Australia – whether directly or as examples of alternative perspectives on consequence assessment.

Given this, we carried out a three-step survey of the three departments and two agencies.

– The first step was to examine the structure of each of the three departments in detail, and to identify and describe their component divisions and agencies. It was also as a part of this step that we identified and examined the various portfolio agencies.
– The second step was to carry out a systematic review of internet and published materials from each of the divisions and agencies, to determine those that carried out risk management as a part of their core business and were therefore likely to have developed or adopted methods for consequence assessment. This step resulted in a reasonably concise list of divisions and agencies, which were then the focus of step 3.
– The third step of the survey involved interviews with representatives from the subset of divisions and agencies in each of the three departments, as well as the two non-departmental agencies. Here there were two objectives. The first was to gain a human perspective on the risk management context within each division or agency, and to request key documents that might assist the review. The second was to provide a face to the project, and to work toward eliciting the participation of each representative in the interactive project workshop.

Having completed the three-step survey, we prepared the written reviews (Sections 6 to 9). These reviews address divisions or agencies from the three departments in turn, plus a small selection of other relevant agencies. For each, a discussion is provided of their core business, the context of the risk management exercises they perform as part of that business, the framework they employ for such exercises, and, most specifically, the methods that they apply for the assessment of consequences. Each review has some concluding comments which are used as the basis for analysis.

The discussion and analysis (Section 1) was the final step in the project. Here we took the outcomes from the divisional and agency reviews and correlated them with Biosecurity Australia's objectives and method for consequence assessment. The purpose of this exercise was to determine whether any of the methods employed by the divisions and agencies could be used to address the identified difficulties with Biosecurity Australia's existing approach. In doing this, we were careful not to consider only 'patch-up' forms of contribution, but, as relevant, to consider holistically the value that might be taken from the perspectives and frameworks used by other divisions and agencies.

The discussion and analysis resulted in a series of recommendations (Section 1), which, along with the data and analysis on which they were based, were taken to the interactive workshop for discussion (Section 11, page 80).

3 STANDARDS AND GUIDELINES

3.1 Australian and New Zealand Standard for Risk Management

The default best-practice process for risk management amongst Government agencies is the Australian and New Zealand Standard AS/NZS 4360:2004, Risk Management. However, AS/NZS 4360 describes a generic process, so inevitably a degree of tailoring is required before it can be applied in any particular agency.

The structure of the risk management process is shown in Figure 1. Most of the risk management processes discussed in this report are broadly compatible with the Standard, although there are some wide differences in the terms used for each stage, and stages are often decomposed into separate steps to facilitate more detailed analysis.

The Standard defines risk in terms of consequences and likelihoods, where consequences are themselves defined in terms of the objectives or criteria that are important for the organisation or activity being examined. The criteria are developed during the context stage of the process, and used in the analysis stage. The Standard itself provides no guidance on the particular criteria to be used for a risk assessment, but it does make some relevant comments:

- Events may have multiple consequences and affect multiple objectives;
- Consequences may be estimated using statistical analysis and calculations, but subjective estimates may be used where no reliable or relevant past data is available;
- The most pertinent information sources should be used when analysing consequences.

For the purpose of this project, two specific matters are important:

- The varying and inconsistent terminology that is used for different parts of the process; and
- The relationship between aspects of consequences and other parts of the identification, analysis and evaluation stages in Figure 1.

3.2 Terminology

Despite the acknowledged desire of many divisions and agencies to follow the Standard, there are wide differences in the terminology used to describe each stage of the process. There are several reasons for this:

- Some divisions and agencies, including Biosecurity Australia, must comply with the processes used by international organisations (see Section 1), and it is convenient to use the terminology from those specific domains.

Figure 1: The Australian and New Zealand Standard AS/NZS 4360:2004

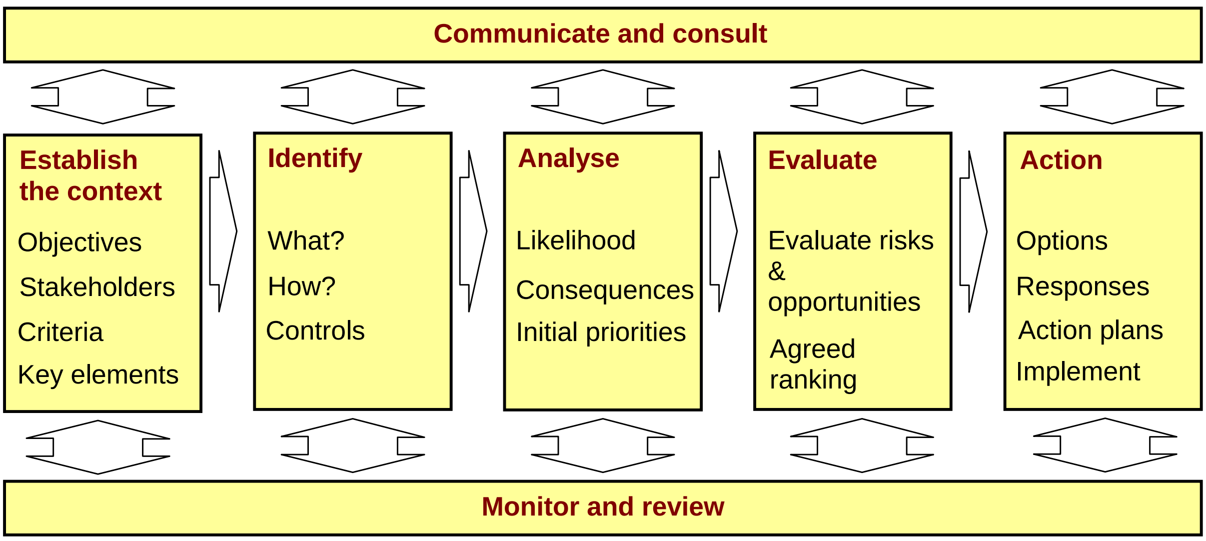
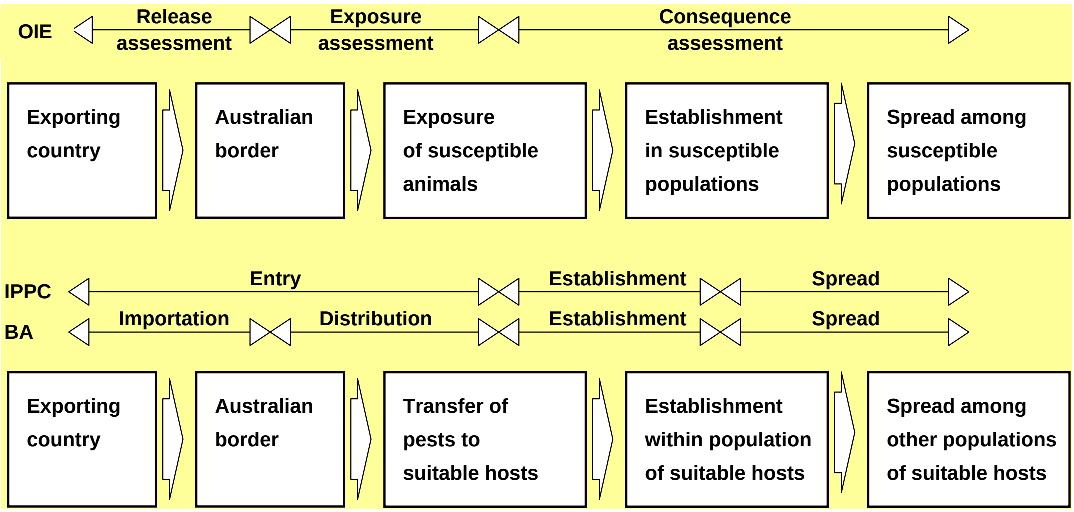


Table 1: Risk management terminology

Terms used in the Standard AS/NZS 4360	Notes and discussion
Establish the context	This term is not always used, as the context for many departments and agencies is set by the governing legislation or regulations or as a matter of policy.
Identify the risks Analyse the risks Evaluate the risks	These stages are often aggregated into a single 'risk assessment' stage. In many instances, there are detailed sets of activities within this. Some examples are shown in Figure 2.
Treat the risks	This is the action or decision-making or policy-setting stage. It is often called 'risk management'.
Communicate and consult	Risk communication is becoming a more important part of the risk management process and is often addressed explicitly. Consultation with stakeholders is also a key part of the overall process for some departments and agencies.
Monitor and review	Monitor and review is sometimes part of wider management process, but many of the risk management processes reviewed by us did not consider it explicitly.

Figure 2: Terms used in biosecurity assessments by Biosecurity Australia, OIE and IPPC



– Some divisions and agencies follow the US approach of separating the analytic and scientific activities of identifying and assessing risks from the managerial or policy-making aspects of responding to the identified risks, on the basis that the first set of activities should be more-or-less 'value-free', while the latter take into account broader non-scientific or 'political' factors.

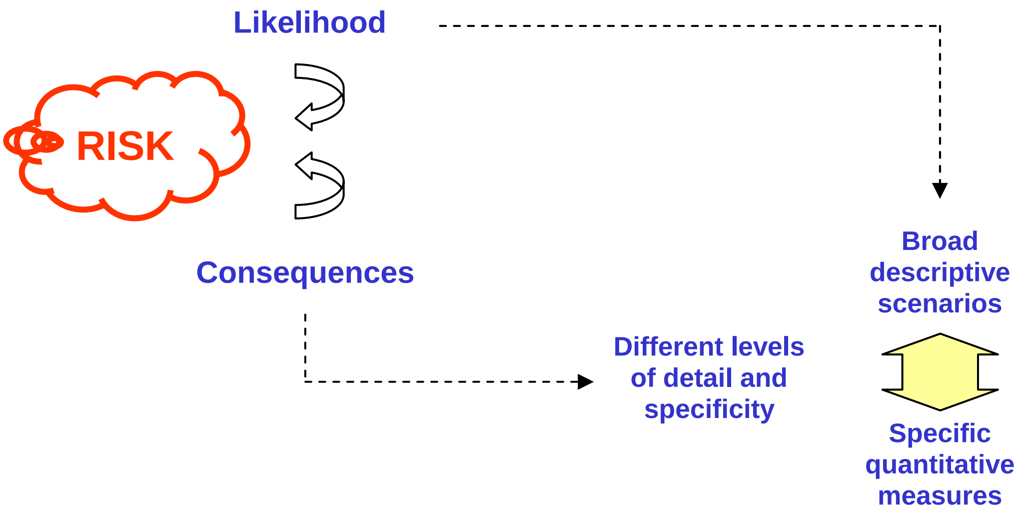
Specific terms used in the Standard and equivalent terms used elsewhere are discussed in Table 1.

3.3 Components of Risk Analysis

While the focus of this project is on consequence assessment, consequences cannot be examined in isolation from the rest of the risk management process. The nature of the risks, and the way in which consequences are to be measured and combined with other aspects of the analysis all affect the way in which they are interpreted.

In the most general interpretation, risk is measured in terms of consequences and likelihood (Figure 3). Consequences can be addressed at different levels of detail and specificity, in terms ranging from general scenarios through to very detailed quantitative measures.

Figure 3: Aspects of consequences and scenarios

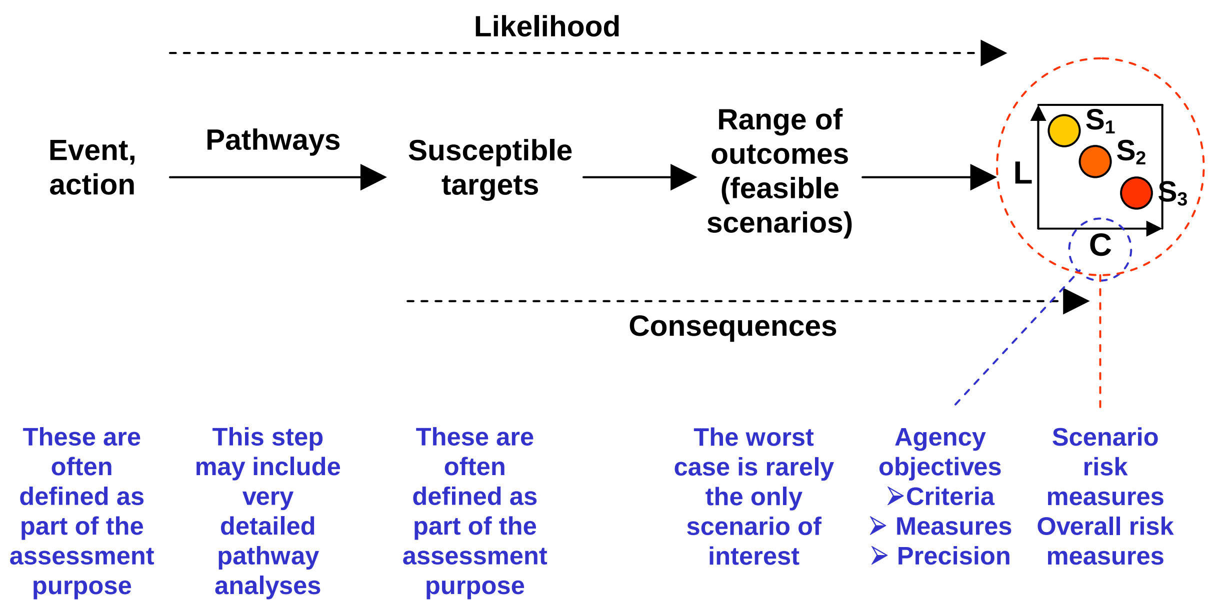


For many biosecurity and related assessments, the analysis of likelihoods and consequences follows a structure that relates initiating events or actions through to specific scenarios to which specific assessments of likelihoods and consequences can be attached. Figure 4 provides a general example of the process and its components – compare this with the specific processes and components in Figure 3.

As the process in Figure 4 is made more specific for a particular application, several aspects must be considered:

– Events and actions, and susceptible target populations, are often defined as part of the assessment context, linked to the purpose and policy of the division or agency.
– Pathway analysis is often very detailed and specific, and is usually undertaken as part of likelihood assessment. In some circumstances, sub-populations with particular susceptibilities are considered as inputs to either the scenario analysis or as part of later policy setting – examples include the setting of exposure thresholds for the very young or the very old.
– The consequences of the events or actions on the susceptible population are considered in the form of scenarios. The 'worst case' is rarely the only scenario of interest.

Figure 4: Outline of the risk analysis process and its components



- Specific aspects of consequences assessment for individual scenarios take into account the policy objectives and purpose of the division or agency, the specific criteria into which these are translated, the particular measures for assessing potential outcomes against the criteria, and the precision with which the measures can be estimated.
- Consequences for individual scenarios must be combined with the corresponding likelihood measures to develop estimates of scenario risk, and scenario risk measures may need to be combined the develop overall measures of risk associated with the event or action of interest.

The way in which consequence assessment is interpreted for a particular division or agency depends on a wide range of factors. In most of our reviews, we have outlined the division or agency's risk management context and its risk management framework to facilitate a better understanding of the way in which it addresses consequences.

4 THE INTERNATIONAL BIOSECURITY CONTEXT

4.1 Overview

As a member of the World Trade Organisation (WTO), Australia must comply with a range of international agreements and processes. Of particular relevance to Biosecurity Australia, Australia must comply with the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). The SPS Agreement obliges Australia to consider all import requests from other countries concerning agricultural products, just as other member countries are obliged to consider Australia's requests. This imposes constraints on the way in which Biosecurity Australia structures and conducts its import risk analyses.

The SPS Agreement confers responsibilities on three international organisations by requiring WTO members to harmonise their sanitary and phytosanitary measures on the standards, guidelines and recommendations produced by those organisations, unless there is scientific justification for an alternative or more stringent measure. The three international organisations referenced in Annex A of the SPS Agreement are:

- For animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of OIE, the World Organisation for Animal Health;
- For plant health, the international standards, guidelines and recommendations developed under the auspices of IPPC; and
- For food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission (Codex) relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.

In simple terms, the consequence of the SPS Agreement is that WTO member countries such as Australia *may* base their SPS measures (quarantine conditions) on the standards developed by these organisations. Where a standard does not exist, or is not seen to provide an appropriate level of protection, then WTO member countries *must* then base their SPS measures on a proper and scientific risk assessment.

4.2 World Organisation for Animal Health

OIE, the World Organisation for Animal Health, is an inter-Governmental organisation created by the International Agreement of 25 January 1924, and signed by 28 countries. The objectives of OIE are:

- To keep member countries informed of the occurrence and course of significant animal diseases throughout the world, and of means of controlling these diseases;
- To coordinate, at the international level, studies devoted to the surveillance and control of significant animal diseases; and
- To harmonise health standards covering trade in animals and animal products.
- OIE currently comprises 155 member countries and operates under the authority of an International Committee formed by permanent delegates designated by the Governments of all member countries.
- Animal health standards and guidelines relevant to the conduct of import risk analysis include the following:
- The Terrestrial Animal Health Code (the OIE Code): this is prepared by the International Animal Health Code Commission and contains standards, guidelines and recommendations designed to prevent the introduction of pests and diseases into the importing member country during trade in animals, animal genetic material and animal products.
- The Manual of Standards for Diagnostic Tests and Vaccines (the Manual): this is prepared by the Standards Commission and lists laboratory diagnostic techniques and requirements for production and control of biological products (mainly vaccines).
- The Aquatic Animal Health Code (the OIE Aquatic Code) and the Diagnostic Manual for Aquatic Animal Diseases (the Aquatic Manual): these are prepared by the Fish Diseases Commission and are sister publications to the OIE Code and Manual.

OIE has developed guidelines for import risk analysis which recognise that the importation of animals and animal products may involve a degree of risk to the importing member country. OIE supports risk analysis by providing importing countries with an objective method for assessing risks, and for determining how those risks may be managed. It notes that analysis should be

transparent, so that the exporting member country is provided with a clear and documented decision on the measures imposed on imports or the reasons for refusing to allow importation.
In the OIE Code, import risk analysis is described according to the sequence of steps outlined in Figure 5.

These steps and terms are defined as follows in the OIE Code.

- Hazard identification: The process of identifying the pathogenic agents that could potentially be introduced in the commodity considered for importation.

- Risk: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified period.

- Risk assessment: The evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country.

- Release assessment: A description of the biological pathways necessary for an importation activity to 'release' (i.e. introduce) pathogenic agents into a particular environment, and an estimation of the probability (qualitative or quantitative) of the complete process occurring.

- Exposure assessment: A description of the biological pathways necessary for the exposure of animals and humans in the importing country to the hazards released from a given risk source, and an estimation of the probability of this occurring.

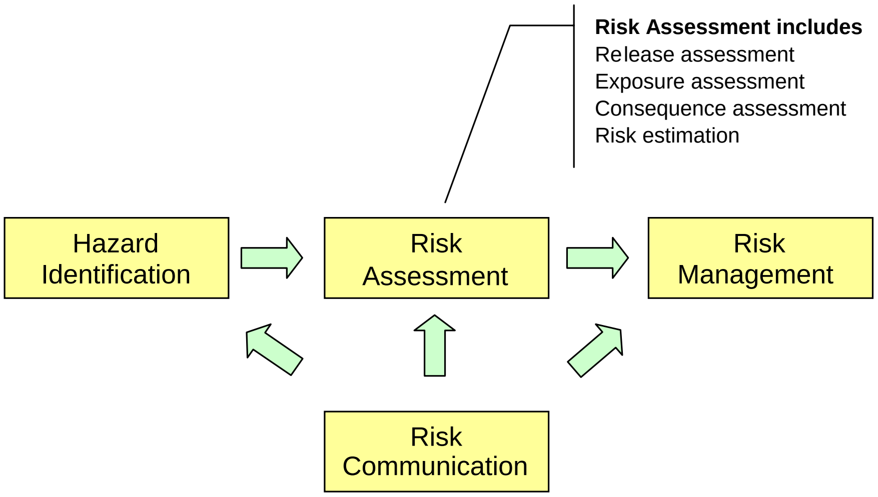
- Consequence assessment: A description of the potential consequences of a given exposure and an estimate of the likelihood that each will occur.

- Risk estimation: An integration of the results of the release assessment, exposure assessment and consequence assessment to produce an overall measure of the risk associated with each identified hazard.

- Risk management: The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

- Risk communication: The process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties in the importing and exporting countries.

Figure 5: OIE framework for import risk analysis



4.3 International Plant Protection Convention

Whilst OIE is a discrete organisation, IPPC is a multilateral treaty deposited with the Director-General of the Food and Agriculture Organization (FAO) of the United Nations (UN). IPPC provides a framework and forum for international cooperation, standards harmonisation and information exchange on plant health. This is undertaken in collaboration with regional and national plant protection organisations. The principal purpose of IPPC is to help prevent the introduction and spread of pests of plants and plant products, and to promote measures for their control. Currently, 111 Governments are contracting parties to the IPPC.

The so-called 'New Revised Text' of IPPC provides for the establishment of a Commission on Phytosanitary Measures to serve as its governing body. Membership in the Commission is open to all contracting parties of IPPC. The Commission, in coordination with the IPPC Secretariat, meets annually to establish priorities for standard-setting and harmonisation of phytosanitary measures.

The functions of the Commission are to provide direction to the work program of the IPPC Secretariat, and promote the full implementation of the objectives of the Convention. In particular, this includes:

– Review the state of plant protection in the world and the need for action to control the international spread of pests and control their introduction into endangered areas;
– Establish and review procedures for the development and adoption of international standards;
– Establish rules and procedures for the resolution of disputes; and
– Cooperate with other relevant international organisations.

IPPC standards and guidelines are termed International Standards for Phytosanitary Measures, or ISPMs. There are currently 17 numbered ISPMs, and several draft unnumbered amendments and new documents, available on the IPPC internet site. Of these, ISPM 11 (Pest Risk Analysis for Quarantine Pests)[3] is the most directly relevant to the technical carriage of import risk analysis. ISPM 11 provides a comprehensive framework and terminology for import risk analysis that is many ways similar to that outlined in the OIE Code.

Figure 6 illustrates the IPPC framework for pest risk analysis. The steps in Figure 6 are defined as:

– Stage 1 (initiation): Identification of the pest(s) and pathways of quarantine concern that should be considered for risk analysis in relation to the identified PRA area.[4] In this instance, it would appear that the term 'risk analysis' should read 'risk assessment', as the risk analysis includes Stage 1.

– Stage 2 (risk assessment): Contains three steps: (a) pest categorisation (the delineation of quarantine pests);5 (b) assessment (for each quarantine pest) of the probability of entry, establishment or spread; and, (c) assessment (for each quarantine pest) of potential economic consequences.

– Stage 3 (risk management): Identification of management options for reducing the risks[6] estimated at Stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

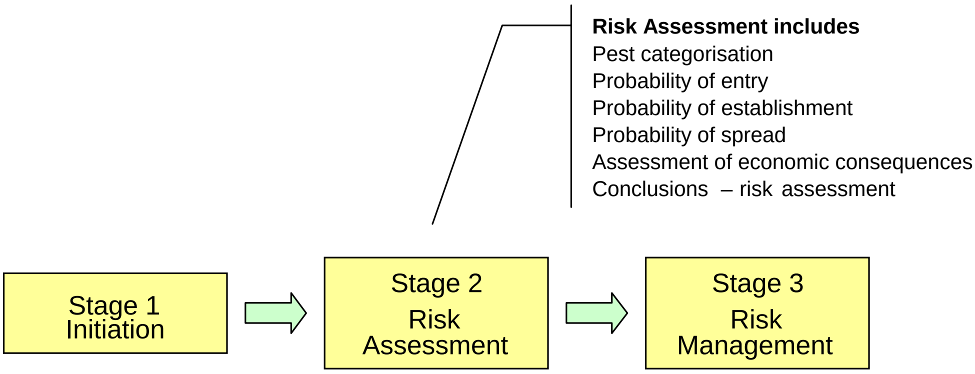
[3] Available at: https://www.ippc.int/servlet/BinaryDownloaderServlet?filename=1107531644613_ISPM_11_2004_A5.pdf&refID=34163.

[4] A 'PRA area' is the area in relation to which a pest risk analysis is conducted, where an 'area' denotes an officially defined country, part of a country or all or parts of several countries.

[5] A 'quarantine pest' is a pest of potential economic importance to the area endangered and therefore not present there, or present but not widely distributed and being officially controlled. A 'pest' is any species, strain or biotype of plant or animal or any pathogenic agent, injurious to plants or plant products.

[6] Risk management is planned if the unrestricted risk is considered 'unacceptable'. The acceptable level of risk may be expressed in several ways, including:
- Reference to existing phytosanitary requirements;
- Indexed to estimated economic loss;
- Expressed on a scale of risk tolerance; and
- Compared with the level of risk tolerated by other countries.

Figure 6: IPPC framework for pest risk analysis



It is important that IPPC (and FAO) terms and definitions are not completely internally consistent. Pest risk analysis, for example, is defined by IPPC as "*the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it*". This definition suggests that a pest risk analysis would be carried out for each pest of potential concern. In ISPM 11, however, pest risk analysis for quarantine pests is aimed at a commodity, and includes the step termed 'pest categorisation', which is intended as a means by which to delineate quarantine pests from other pests that may be associated with a commodity. To further confuse the issue, pest risk 'assessment' (cf. analysis) is defined by IPPC as "*evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences*", and yet appears in ISPM 11 as Stage 2 of a 'pest risk analysis' and includes, again, pest categorisation. The terms 'area', 'PRA area' and 'endangered area' are also difficult, and appear to be based on circular definitions.

In view of this, Biosecurity Australia has made some simplifying assumptions when interpreting IPPC terms and definitions. These assumptions are identified and explained in the discussion or footnotes in this report.

4.4 Codex Alimentarius Commission

Codex was established in 1962 with the following objectives:

- To guide and promote the elaboration and establishment of definitions and requirements for foods;
- To assist in the harmonisation of the above; and
- To facilitate international trade in foods and foodstuffs.

Codex, with a membership in 1997 of 147 countries, has produced 250 commodity standards and more than 40 hygiene and technology codes of practice, has evaluated more than 700 food additives and contaminants, and developed more than 3200 maximum residue limits for pesticide-commodity combinations.

The importance of Codex to international trade lies in the fact that both the SPS Agreement and the Agreement on Technical Barriers to Trade (TBT Agreement) of the WTO have accorded special status to its standards, guidelines and recommendations. Importing countries demanding that their exporting counterparts meet or impose standards over and above those recommended by Codex must justify their position scientifically or face penalisation for breaching the relevant sections of the SPS or TBT Agreements.

For all food or feed contaminants, a broad approach is applied for the assessment of risks and for the development of recommendations and measures, including the setting of maximum levels.[7] Maximum levels are based on sound scientific principles leading to levels that are acceptable worldwide, so that international trade in these foods is facilitated.

The following criteria are considered when developing recommendations and making decisions in connection with the Codex General Standard for Contaminants in Food, but the use of other relevant criteria is permitted where appropriate:

- Toxicological information;
  - Identification of the toxic substance(s); metabolism by humans and animals, as appropriate; toxicokinetics and toxicodynamics; information about acute and long term toxicity and other relevant

[7] Codex General Standard for Contaminants and Toxins in Foods, Codex STAN 193-1995 (Rev.1-1997).

toxicity; integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable

- Analytical data;
  - Validated qualitative and quantitative data on representative samples; appropriate sampling procedures
- Intake data;
  - Presence in foods of dietary significance for the contaminant intake; presence in foods that are widely consumed; food intake data for average and most exposed consumer groups; results from total diet studies.
  - Calculated contaminant intake data from food consumption models
  - Data on intake by susceptible groups
- Fair trade considerations;
  - Existing or potential problems in international trade
  - Commodities concerned moving in international trade
  - Information about national regulations, in particular on the data and considerations on which these regulations are based
- Technological considerations;
  - Information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant level management and control.
- Risk assessment and risk management considerations;
  - Risk assessment
  - Risk management options and considerations
  - Consideration of possible maximum levels in foods based on the criteria mentioned above.
  - Consideration of alternative solutions.

For microbiological risk assessment, Codex specifies the steps to be undertaken:[8]

- Statement of purpose of risk assessment;
- Hazard identification;
- Exposure assessment;
- Hazard characterisation;
- Risk characterisation
- Documentation; and
- Reassessment.

Consequences are defined solely in terms of adverse health effects.

Many of the processes used by Codex are also used by FSANZ. Risk management in FSANZ is discussed in more detail in Section 8.2.

[8] Principles and Guidelines for the Conduct of Microbiological Risk Assessment, CAC/GL-30 (1999).

5 BIOSECURITY AUSTRALIA

5.1 Introduction

Biosecurity Australia, a Prescribed Agency within DAFF, provides science-based quarantine assessments and policy advice to protect Australia's favourable pest and disease status and enhance Australia's access to international animal and plant related markets. Biosecurity Australia is also active in the development of international quarantine standards, and helps to develop quarantine expertise in our region.

5.2 Risk Management Context

As noted in Section 1, Australia is obliged under the WTO SPS Agreement to consider all import requests from other countries concerning agricultural products, just as other member countries are obliged to consider Australia's requests, and this imposes constraints on the way in which Biosecurity Australia structures and conducts its import risk analyses.

Decisions to permit or reject an import application can be made only on sound scientific grounds. In many cases, such grounds are provided by precedents in the form of existing conditions, or by the application of international standards. In other cases, a review of existing conditions will be sufficient to elaborate the particular differences about an access request and to develop appropriate quarantine measures. In a small minority of cases, a formal import risk analysis will be required. This can vary from a simple qualitative analysis to a detailed and lengthy quantitative analysis. The latter require significant resources and generally take a period of years to complete. The balance of this discussion is restricted to detailed import risk analysis, as carried out for the small minority of access requests.

Import risk analyses carried out by Biosecurity Australia conform to Australia's international obligations; principally to the tenets of the SPS Agreement and to case law from the WTO dispute settlement understanding. In-depth discussion of the SPS Agreement is beyond the scope of this review. Of key importance, however, is that the Appellate Body examining Australia's appeal against the Dispute Settlement Panel's finding on Australia's prohibition of imports of Canadian salmon considered that a risk assessment, within the meaning of Article 5.1 of the SPS Agreement, must:

- Identify the hazards whose entry, establishment or spread within its territory a Member wants to prevent, as well as the associated potential biological and economic consequences;
- Evaluate the likelihood of entry, establishment or spread of these hazards, as well as the associated potential biological and economic consequences; and
- Evaluate the likelihood of entry, establishment or spread of these hazards according to the SPS measures that might be applied. Measures that might be applied are those which reduce the risks to the appropriate level, with the aim of being least trade restrictive.

5.3 Risk Management Framework

Biosecurity Australia has an administrative framework under which it carries out import risk analyses and consults with stakeholders. This framework is described in the Import Risk Analysis Handbook.[9] Biosecurity Australia also has draft Guidelines for Import Risk Analysis,[10] which contain the technical detail of each component of an import risk analysis. These guidelines are described as a 'living document' that is evolving as Biosecurity Australia's corporate knowledge about import risk analysis becomes more sophisticated. Discussion here of the Biosecurity Australia risk management framework and the approach to consequence assessment is based largely on the Guidelines for Import Risk Analysis.

To promote harmonisation, the three international organisations (Codex, OIE and IPPC; Section 1) have developed guidelines for carrying out proper and scientific import risk analyses. Although it is not mandatory to comply absolutely with the terms and definitions in these guidelines, the 'framework' of a compliant risk analysis cannot be criticised in the WTO dispute settlement forum. In recognition of this, the Biosecurity Australia Guidelines for Import Risk Analysis uses the OIE framework for import risk analyses for animals and animal

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[9] Available at: http://www.daff.gov.au/corporate_docs/publications/pdf/market_access/biosecurity/bde/ira_handbook_revised.pdf.

[10] Available at: http://www.affa.gov.au/content/publications.cfm?ObjectID=85B98CC3-86DE-48AE-8A76D4A40F33245A.

products, and the IPPC framework for plants and plant products. These frameworks have been described earlier in the review (Section 1, pages 15 and 17, respectively).

5.4 Approach to Consequence Assessment

1 Key Characteristics

The objective of the Biosecurity Australia method for consequence assessment is to provide a structured and transparent analysis of the likely consequences, or likely impact, of each pest or disease agent. In this context, the term 'likely consequences' is used to draw attention to the fact that Biosecurity Australia does not base the assessment of consequences solely on worst-case scenarios. The assessment is predicated on the assumption that the pest or disease agent has entered Australia and gained access to a suitable host or environment.

The Biosecurity Australia method for consequence assessment has three key characteristics:

- It incorporates the direct and indirect consequences of each pest and disease;
- It is a qualitative ranking scheme in which pests and diseases are divided into categories based on their expected consequences on a national scale. To assist in describing consequences, especially for those pests and diseases where the impact will be less easily discerned on a national scale, consequences at various sub-national levels are also considered; and
- It provides an outcome relevant to the Australian community as a whole, rather than to directly affected parties.

Also central to the Biosecurity Australia method for consequence assessment are the qualitative constructs represented by 'exposure groups' and 'outbreak scenarios'. In brief, exposure groups are groups of susceptible animals or plants for which the likelihood of exposure and likely consequences of exposure differ from the likelihood and consequences associated with other groups. A set of discrete outbreak scenarios, on the other hand, represents the range of possible outcomes of exposing susceptible animals or plants (or a particular group of susceptible animals or plants) to a pest or disease agent. Alternatively, the set of selected scenarios can be seen as capturing defining differences in the course of establishment or spread, given some uncertainty about the epidemiology of a pest or disease in a new environment or the effectiveness of mitigation actions. It follows that outbreak scenarios may be specific to particular exposure groups or may be common across all exposure groups.

The importance of exposure groups and outbreak scenarios is that they provide a framework for 'putting back together' a complicated exposure assessment or consequence assessment.

Three situations are described:

- In the simplest case, where there is a single exposure group and a single 'most likely' outbreak scenario, the consequence assessment is limited to assessment of the likelihood that the pest or disease would establish or spread to that extent, and an estimate of its impact should the scenario occur. Here, likelihood would be estimated qualitatively or quantitatively, and the impact of the pest or disease would be estimated according to the qualitative Biosecurity Australia method. The two would then be combined using the matrix shown in Table 3 (page 27). This simplest case provides the framework for the discussion below.
- Where there is more than a single exposure group, then a separate estimate of 'likely consequences' would generally be obtained for each using the steps outlined above. These separate estimates would then be incorporated in the overall risk estimate during the risk estimation step.
- Where there is more than a single outbreak scenario, then the likelihood and impact associated with each would be estimated using the steps outlined above. These would be combined using the matrix in Table 3 to give an estimate of the likely consequences associated with each outbreak scenario. The individual estimates of likely consequences would then be combined using Biosecurity Australia's rule-based system to give an overall estimate of the likely consequences of exposure. If there are also several exposure groups, then, as described above, separate estimates would be obtained for each and subsequently incorporated in the overall risk estimate during the risk estimation step.

The outbreak scenario construct, which is considered the cornerstone of the Biosecurity Australia approach to consequence assessment, was developed as an alternative to what was thought to be the essentially infeasible option of carrying out an epidemiologic simulation analysis for each pest or disease agent in each new import risk analysis. The construct has generally proved to be intuitive to the Risk Analysis Teams carrying out import risk analyses, and, if drafted correctly, discussions based on the construct are understood by stakeholders.

2 Likely Consequences for an Outbreak Scenario

Under the qualitative Biosecurity Australia method, the likely consequences associated with each outbreak scenario are obtained in the six steps described below.

Step 1: Careful description of the outbreak scenario under consideration;
Step 2: Estimation of the likelihood of establishment or spread to the extent dictated by the outbreak scenario;
Step 3: Assessment of magnitude of each direct and indirect impact under the constraints of the outbreak scenario;
Step 4: Combination of direct and indirect impacts to give the overall national impact associated with the outbreak scenario;
Step 5: For zoonotic pests or disease agents, assessment of consequences to human life or health and adjustment of national impact accordingly; and
Step 6: Combination of the likelihood of establishment or spread and national impact, to give the likely consequences associated with the outbreak scenario.

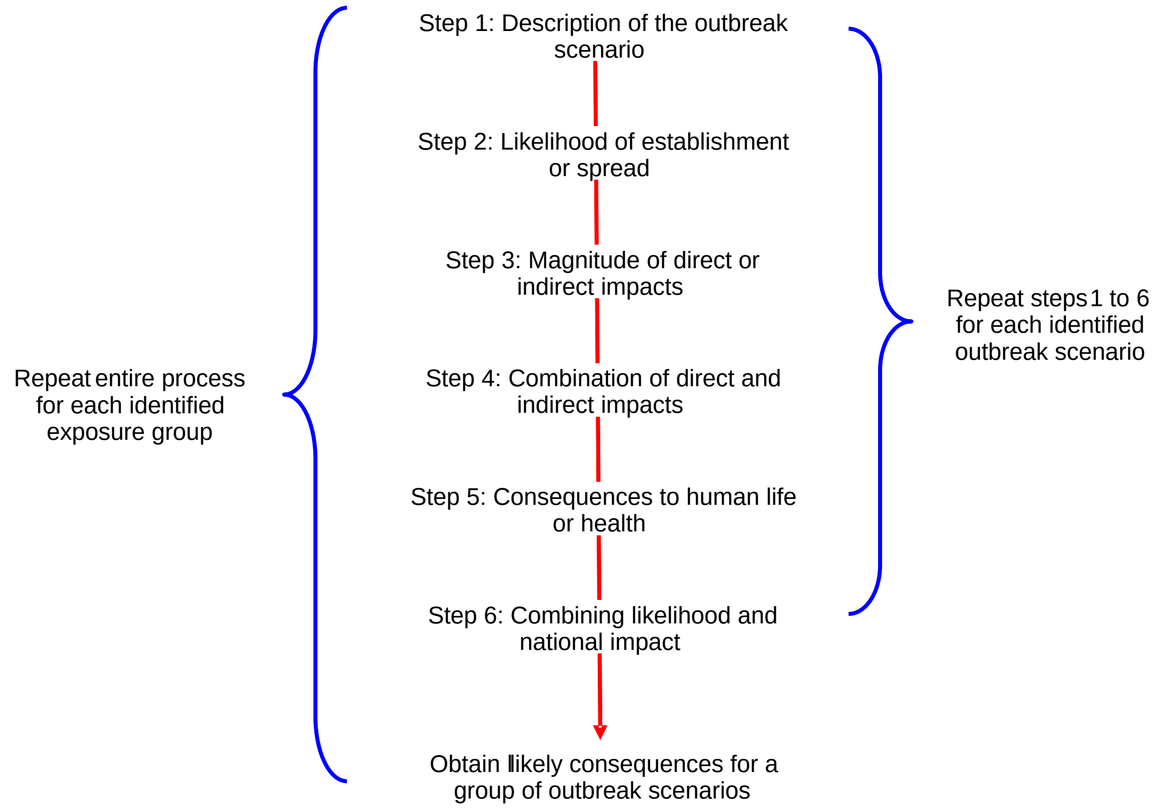
These steps are illustrated in Figure 7 and are discussed individually in the text below.

Step 1: Description of the Outbreak Scenario

Central to the clarity and transparency of the outbreak scenario construct is a careful description of each scenario. As a minimum, this includes:

– Geographic distribution of the outbreak, and whether the outbreak is likely to be unifocal or multifocal;
– Animal or plant species and industries that are directly involved;
– Animal or plant species and industries that are indirectly involved;
– Duration of the outbreak, from the exposure of susceptible animal, plant or human hosts to eradication or the establishment of an endemic state within Australia.

Figure 7: Biosecurity Australia framework for consequence assessment



Biosecurity Australia acknowledges that whilst this step is integral to Risk Analysis Team discussions, it is not always documented in any depth, and, as a result, estimation of the likelihood and impact associated with each scenario can become clouded. That said, it is a simple enough undertaking to define the characteristics of outbreak scenarios at the start of the consequence assessment, and, that done, to ensure that ensuing assessments make reference to those definitions.

Step 2: Likelihood of Establishment or Spread

The likelihood of establishment or spread for a single outbreak scenario can be estimated qualitatively or quantitatively, and may use Biosecurity Australia's system of simple probability distributions. Where there is more than a single outbreak scenario, then care should be taken to ensure that the likelihoods assigned to each sum to one.

The simplest way to ensure that this is the case is by normalising across scenarios using a simple rating system. For example, the least likely scenario is assigned a rating of one and the Risk Analysis Team or Biosecurity Australia personnel are asked to specify how much more likely the other scenarios are. The likelihood of establishment or spread for each scenario can then be calculated as a fraction of which the sum of all ratings is the denominator and the individual rating is the numerator. By definition, the set of likelihoods obtained for a group of outbreak scenarios will always sum to one. Having obtained a point estimate for the likelihood of establishment or spread, these can be retrofitted to the Biosecurity Australia qualitative likelihood descriptors. This allows the likelihood estimate to be combined with an estimate for the national impact (Table 2) associated with the outbreak scenario. Retrofitting the likelihood estimate to a qualitative descriptor also ensures that likelihoods are not reported in terms more precise than those of the underlying science.

Step 3: Magnitude of Direct or Indirect Impacts

The magnitude of impact is obtained independently for each of seven standardised direct and indirect criteria. These are:

- The direct impact on the life or health (including production effects) of production, domestic or feral animals; or the life or health (including production effects) of commercially cultivated, garden or feral plants.
- The direct impact on the environment, including the life or health of native animals and plants, and any direct impacts on the non-living environment.
- The indirect impact of new or modified eradication, control, surveillance or monitoring and compensation strategies or programs.
- The indirect impact on domestic trade or industry, including changes in consumer demand and impacts on other industries supplying inputs to, or utilising outputs from, directly affected industries.
- The indirect impact on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand.
- The indirect impact on the environment, including biodiversity, endangered species and the integrity of ecosystems.
- The indirect impact on communities, including reduced tourism, reduced rural and regional economic viability, the loss of social amenity and any 'side impacts' of control measures.

Collectively, these seven criteria encompass the 'economic', 'environmental' and 'social' impacts of pests and disease agents. They are considered mutually exclusive, in that a particular impact of a pest or disease agent is not assessed more than once.

The national cost associated with each of these seven direct and indirect impacts is estimated on a qualitative scale (A-G), using the cross-tabulation of rules shown in Table 2 (page 24). Under this system, the following qualitative descriptors are used to assess the magnitude of impact:

- An 'unlikely to be discernible' impact is not usually distinguishable from normal day-to-day variation;
- An impact of 'minor significance' is recognisable, although minor and reversible;
- A 'significant' impact is serious and substantive, although reversible and unlikely to disturb economic viability or the intrinsic value of the criterion; and
- A 'highly significant' impact is extremely serious and irreversible and likely to disturb economic viability or the intrinsic value of the criterion.

Table 2: Assessment of direct or indirect consequences on a national scale

Impact Score	National	State or Territory	District or region	Local
G	**Highly significant**[11]	-	-	-
F	**Significant**	-	-	-
E	**Minor**	-	-	-
D	Unlikely to be discernible	**Minor**	-	-
C	Unlikely to be discernible	Unlikely to be discernible	**Minor**	-
B	Unlikely to be discernible	Unlikely to be discernible	Unlikely to be discernible	**Minor**
A	Unlikely to be discernible	Unlikely to be discernible	Unlikely to be discernible	**Unlikely to be discernible**
Level				

In order to assign a rating to each direct and indirect criterion, the rules shown in Table 2 are applied systematically. Impact is estimated from top (row G) to bottom (row A), and the row that best fits the magnitude of likely impact for that criterion is selected. Under this system, the following definitions are adopted for the terms 'national', 'State or Territory', 'district or regional' and 'local':

- National: Australia-wide;
- State or Territory: An Australian State (New South Wales, Victoria, Queensland, Tasmania, South Australia or Western Australia) or Territory (the Australian Capital Territory, the Northern Territory, the Australian Antarctic Territory and other Australian Territories covered under the Act, but excluding the Cocos Islands);
- District or region: A geographically or geopolitically associated collection of aggregates, which is generally a recognised section of a state, such as the 'North West Slopes and Plains' of New South Wales or 'Far North' Queensland; and
- Local: An aggregate of households or enterprises, such as a rural community, a town or a local Government area.

This part of Biosecurity Australia's approach to consequence assessment has had some complications. These are discussed individually.

The first complication is the difficulty that can be encountered when estimating systematically the significance of direct or indirect impacts at the local, district or regional, State or Territory level. This procedure is commonly made awkward by pest or disease impacts that are not necessarily of significance at one of the sub-national levels of Government, but which are nevertheless measurable and should be included in the analysis. A lack of significance at a sub-national level of Government can arise from a pest or disease with a low magnitude of effect, or from the nature of sub-national Government jurisdiction over that effect. By extension, the system as it stands tends to accommodate well any pest or disease impacts that are likely to be accrued as Government costs, but to underestimate pest or disease impacts that are borne by communities, by individual producers or by particular industries. Importantly, costs borne by communities, individual producers or industries also have utilities that should be considered.

Another difficulty encountered when estimating a sub-national level of significance is the accommodation of multifocal outbreaks. Multifocal outbreaks are those that occur in more than one

[11] Shaded cells with bold font are those that dictate national impact scores.

locality, district or region or State or Territory, and, whilst individual *foci* of impact may be relatively less significant, the cumulative direct and indirect effects of the pest or disease may be quite different. Multifocal outbreaks are currently accommodated by scaling the rating assigned to each direct and indirect impact up one level. By way of example, a multifocal outbreak considered significant at the level of each affected district or region would, under this system, be considered significant at the State or Territory level. This system is quite coarse, and does not always result in an appropriate or transparent final rating for national significance. On balance, the system could be improved by accepting that national impact is the goal, and that estimation of impact at sub-national levels, whilst important for evaluating some Government costs, should not be carried out for all of the direct and indirect impact criteria.

A second difficulty that has been encountered in estimating the significance of direct and indirect pest or disease impacts is consideration of the period over which these impacts are likely to be accrued. The difficulty is particularly apparent for pests or diseases that are likely to require long periods for control or eradication, or for which eradication is unlikely. Also relevant are direct or indirect impacts that are not resolved with control or eradication. Examples of these include ongoing indirect effects on the environment, long-term disturbances to patterns of trade or the permanent disruption of communities or social amenities. This difficulty does not have an immediate solution, and would be faced under any qualitative or quantitative (economic) model for consequence assessment. That said, the difficulty could be ameliorated by standardising the way in which longer-term or permanent impacts are handled, and, thus, ensuring consistency within and between analyses.

The third area of difficulty concerns the qualitative definitions for assessing the magnitude of impact; that is, 'unlikely to be discernible', of 'minor significance', 'significant' and 'highly significant'. These definitions are in fact quite complicated, and contain wording that is often considered unclear or ambiguous. The upshot is that the definitions are applied essentially as a ranking system, and that consistency is maintained by way of internal comparisons or comparisons with ratings given in other import risk analyses. It has been suggested that economic analysis could be used to provide a concrete basis for the definitions, although this is made problematic by the fact that the terms are applied generically to each of the seven direct and indirect criteria, and are applied at a national and a range of sub-national levels. One further suggestion has been to assess the 'significance' of each form of direct and indirect impact in a different way. This approach is appealing, as it would enable some criteria (such as the cost of control or eradication) to be assessed on economic or quasi-economic grounds, and others (such as impact on the environment) to be assessed in terms of their key 'values'. An example of the latter, which will be discussed in greater depth in the Discussion and Analysis (page 70), is the value-based approach that DEH Approvals and Wildlife Division apply when assessing the likely consequences of an action on each of the seven areas of national environmental significance (page 37).

Step 4: Combination of Direct and Indirect Impacts

The ratings obtained for each direct and indirect impact are combined to give a measure of the 'national significance' of the outbreak scenario.

Because the individual impacts are additive and mutually exclusive they should, in theory, be summed. However, because the assessment of consequences is qualitative, true summation is not possible and a framework of qualitative rules was developed. These rules are intended to be addressed in the order that they appear in the list. Thus, if the first set of conditions does not apply, the second set should be considered; if the second set does not apply, the third set should be considered; and so forth, until one of the rules applies.

1. Where the impact of a pest with respect to any direct or indirect criterion is G, the overall impact is extreme.
2. Where the impact of a pest with respect to more than one criterion is F, the overall impact is extreme.
3. Where the impact of a pest with respect to a single criterion is F and the impact with respect to each remaining criterion is E, the overall impacts is extreme.
4. Where the impact of a pest with respect to a single criterion is F and the impact with respect to remaining criteria is not unanimously E, the overall impact is high.
5. Where the impact of a pest with respect to all criteria is E, the overall impact is high.
6. Where the impact of a pest with respect to one or more criteria is E, the overall impact is moderate.
7. Where the impact of a pest with respect to all criteria is D, the overall impact is moderate.
8. Where the impact of a pest with respect to one or more criteria is D, the overall impact is low.

9. Where the impact of a pest with respect to all criteria is C, the overall impact is low.
10. Where the impact of a pest with respect to one or more criteria is C, the overall impact is very low.
11. Where the impact of a pest with respect to all criteria is B, the overall impact is very low.
12. Where the impact of a pest with respect to one or more criteria is B, the overall impact is negligible.
13. Where the impact of a pest with respect to all criteria is A, the overall impact is negligible.

These rules imitate summation, but also recognise that the overall impact of a pest or disease will be dominated to some extent by the frequency of its most serious direct or indirect impacts. By way of example, the minor production impacts of a devastating disease of wildlife would be expected to be of relatively lesser importance than its stated devastating impact on wildlife. It was also important for the summation rules to recognise that the cumulative impact of a group of impacts of a given magnitude will tend to be greater than the magnitude of the individual impacts.

The rules are, in a sense, conservative, as they tend to allow the cumulative impact of a pest or disease to be relatively easily rated as ‘extreme’, ‘high’ or ‘moderate’. This was deliberately the case as it was important to encapsulate within the system a ‘safety net’ that accommodated any imprecision or uncertainty associated with the individual qualitative estimates. Finally, because the individual direct and indirect impacts are assessed with reference to their ‘national significance’, they can be treated in the combination rules as equivalent. In other words, there is no call to weight within the summation any particular direct or indirect impacts.

On balance, the combination rules are generally considered by Biosecurity Australia to be transparent and workable. If, however, the method for estimating national significance was altered in the manner suggested in the previous discussion, then the combination rules would also need to be revisited and any necessary changes incorporated.

Step 5: Consequences to Human Life or Health

The approach that Biosecurity Australia has adopted in recent import risk analyses has been to remove human health concerns from each assessment and to request that DHA and Food Standards Australia and New Zealand (FSANZ) evaluate the mitigation measures in place for matters of animal health and consider whether additional measures are required.

The words used to describe this process are shown below:

> *Biosecurity Australia consults with the Australian Department of Health and Ageing and Food Standards Australia and New Zealand (FSANZ), on the assessments for ‘zoonotic’ pests or diseases that may establish in Australia’s animal population… At the discretion of the Director of Human Quarantine, this may result in a requirement for biosecurity measures to manage the risk to human life or health associated with the importation of ….*

Because the measures that have been required for animal health have, to-date, been sufficient to safeguard against zoonoses, a precedent has not been set under which trade has been restricted on the grounds of human health. Notwithstanding this, a precedent is likely to arise from one or more of the currently ongoing Biosecurity Australia import risk analyses and a transparent solution will be required.

Step 6: Combining Likelihood and National Impact

The likelihood that the specified outbreak scenario will occur (Step 2), and the estimate of national impact should it occur (Step 3 to Step 5), are combined using the rules displayed in the matrix in Table 3. The outcome of this step is an estimate of the likely consequences associated with the outbreak scenario.

Because the cells in the matrix represent the product of a likelihood (or probability) and a qualitative estimate of national impact, it stands to reason that they cannot exceed the corresponding ‘raw’ estimates of national impact. Given this, the extent to which national impact will be reduced by multiplying it by a probability will be determined by the magnitude of that probability; the trend being that the smaller the probability the greater the reduction.

Table 3: Matrix for estimating 'likely consequences' for each outbreak scenario

Likelihood of observing the Outbreak Scenario	Negligible	Very low	Low	Moderate	High	Extreme
High: $0.7 \rightarrow 1$	Negligible	Very low	Low	Moderate	High	Extreme
Moderate: $0.3 \rightarrow 0.7$	Negligible	Very low	Low	Moderate	High	Extreme
Low: $0.05 \rightarrow 0.7$	Negligible	Negligible	Very low	Low	Moderate	High
V. Low: $0.001 \rightarrow 0.05$	Negligible	Negligible	Negligible	Very low	Low	Moderate
E. Low: $10^{-6} \rightarrow 0.001$	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible: $0 \rightarrow 10^{-6}$	Negligible	Negligible	Negligible	Negligible	Negligible	Very low

National impact for the Outbreak Scenario

In view of the imprecision inherent in this essentially qualitative assessment, Biosecurity Australia has conservatively assumed that probabilities greater than or equal to its definition of 'moderate' are not sufficiently small to reduce consequences within the limits of measurement. This means that the first two rows of the matrix mirror the national impact scale on the horizontal axis. For the remaining levels of probability – that is, 'low', 'very low', 'extremely low' and 'negligible' – consequences are reduced by one, two, three and four categories, respectively, or to 'negligible.

One of the dangers in adopting a matrix of rules for combining likelihood and likely consequences is that its essentially qualitative nature can be lost in over-analysis of technical characteristics. In particular, it is appealing to some readers to examine closely the likelihood axis, which is inherently more defined than the qualitative likely consequences axis, and to consider whether gradations in risk should be driven by absolute or relative differences in the magnitude of likelihood. Mathematically the question is valid, although it does deviate from the philosophy and function of the matrix; *viz* to show simply and transparently that events of any reasonable likelihood will have an 'expected loss' that can be approximated by the events' likely consequences; whilst events that are less likely to occur will have an 'expected loss' that is smaller than their likely consequences. The degree to which expected loss is reduced will be determined by the size of the likelihood, although it is clear that with only six qualitative categories in total the system is constrained inherently in its precision. Constraint by way of minimal precision is, in this context, deliberate, as Biosecurity Australia has found that few (if any) import risk assessments give likelihood estimates that are more accurate than the level of detail provided by the six qualitative descriptors.

3 Likely Consequences for a Group of Outbreak Scenarios

Where exposure of susceptible animals, or a particular group of susceptible animals, is associated with a range of outbreak scenarios, then Steps 1 to 5 described above will yield a corresponding range of likely consequences. To obtain an estimate of the overall likely consequences of exposure, each of the components is summed using the rules listed in the bullets below.

The process of summation is necessarily qualitative, but aims to replicate the concept and derivation of 'expected loss', as commonly obtained from economic analysis. Expected loss is the sum of the product of the magnitude of each possible outcome and its probability of occurring. Under the outbreak scenario construct, the magnitude of each outcome is the overall measure of national impact associated with each scenario (Steps 3 to 5), whilst the probability is the corresponding likelihood of establishment or spread (Step 2). The combination of these (Step (6) is the result of applying the rules in the matrix in Table 3. The sum of these products is then obtained from the rules in the bullets below.

The rules are mutually exclusive, and should be consulted in the order that they appear in the list. Thus, if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered; and so forth until one of the rules applies.

1. Where the likely consequences for any outbreak scenario are 'extreme', the overall likely consequences are also considered 'extreme'.
2. Where the likely consequences for more than one outbreak scenario are 'high', the overall likely consequences are considered 'extreme'.
3. Where the likely consequences for a single outbreak scenario are 'high' and the likely consequences for each of the remaining scenarios are 'moderate', the overall likely consequences are considered 'extreme'.
4. Where the likely consequences for a single outbreak scenario are 'high' and the likely consequences for the remaining outbreak scenarios are not all 'moderate', the overall likely consequences are considered 'high'.
5. Where the likely consequences for all outbreak scenarios are 'moderate', the overall likely consequences are considered 'high'.
6. Where the likely consequences for one or more outbreak scenario are 'moderate', the overall likely consequences are considered 'moderate'.
7. Where the likely consequences for all outbreak scenarios are 'low', the overall likely consequences are considered 'moderate'.
8. Where the likely consequences for one or more outbreak scenarios are 'low', the overall likely consequences are considered 'low'.
9. Where the likely consequences for all outbreak scenarios are 'very low', the overall likely consequences are considered 'low'.
10. Where the likely consequences for one or more outbreak scenarios are 'very low', the overall likely consequences are considered 'very low'.
11. Where the likely consequences for all outbreak scenarios are 'negligible', the overall likely consequences are considered 'negligible'.

The intent and structure of the rules for combining likely consequences across a group of outbreak scenarios are very similar to those used to combine the direct and indirect pest or disease impacts. The rules have not created any difficulties to-date, and would appear to provide sensible results.

5.5 Conclusions

Biosecurity Australia's approach to import risk analyses is one of the most rigorous of those used by regulatory authorities worldwide.[12]

The Biosecurity Australia method for consequence assessment has three key characteristics:

– It incorporates the direct and indirect consequences of each pest and disease;
– It is a qualitative ranking scheme in which pests and diseases are divided into categories based on their expected consequences on a national scale. To assist in describing consequences, especially for those pests and diseases where the impact will be less easily discerned on a national scale, consequences at various sub-national levels are also considered; and
– It provides an outcome relevant to the Australian community as a whole, rather than to directly affected parties.

Also central to the Biosecurity Australia method are the qualitative constructs represented by 'exposure groups' and 'outbreak scenarios'. Biosecurity Australia evaluates the likely consequences accrued to each outbreak scenario, and, where more than a single scenario has been described, combines these to give an estimate of the likely consequences of exposing the relevant exposure group. If more than a single exposure group has been identified, then the likely consequences associated with each are combined at the risk estimation step with the relevant likelihoods of pest or disease entry and exposure.

The approach is complex if all possible components (exposure groups and outbreak scenarios) have been elaborated. In simpler cases, however, the approach collapses to a straightforward evaluation of the likelihood of establishment or spread, and an estimate of direct and indirect impacts. These are considered the fundamental components of a consequence assessment, as described by OIE and IPPC.

Notwithstanding this, several difficulties have been identified in applying the method across a range of animal-, plant- and product-based import risk analyses.

The first difficulty is encountered when assessing the significance of each of direct and indirect impact at sub-national (i.e. local, district or regional and State or Territory) levels. The difficulty occurs principally because sub-national impacts are most relevant to the costs accrued by sub-national levels of Government – less meaning can generally be

[12] 'In my view, Biosecurity Australia has done a remarkable job in achieving the aims put forward by the SPS agreement and the OIE Code. I use the term "remarkable" because, as far as I am aware, no other country has produced an import risk analysis methodology that has explicitly stated how it will evaluate the consequence of a disease introduction nor matched their evaluation to a risk management action that achieves the ALOP. Most countries, if they publish their import risk assessments at all, consider only the probability of disease introduction.' Submission by David Vose to the Federal Court of Australia, Australian Pork Ltd v Director of Animal & Plant Quarantine [2005] FCA 671 (27 May 2005), quoted at paragraph 240.

attributed to ‘local’ versus ‘regional’ impacts on, for example, producers or the environment. The difficulty is compounded in the case of multifocal pest or disease outbreaks, where each outbreak focus might be small and of relatively minor impact but the collective impact of the pest or disease on the country as a whole is completely different. The simple solution is to accept that national impact is the goal, and that estimating impact at sub-national levels, whilst important for evaluating some Government costs, should not be carried out for all of the direct and indirect impact criteria.

The second difficulty encountered by Biosecurity Australia is accommodation of the period over which impacts might be accrued. More specifically, whilst short-duration outbreaks that lead to eradication of a pest or disease can be assessed relatively easily, the longer-term impacts or impacts accrued in the case where a pest or disease becomes endemic, are more difficult to assess. This difficulty does not have an immediate solution, and would be faced under any qualitative or quantitative (economic) model for consequence assessment. That said, the difficulty could be ameliorated by standardising the way in which longer-term or permanent impacts are handled, thus ensuring consistency within and between analyses.

A third key area of difficulty concerns the qualitative definitions for assessing the magnitude of impact; that is, ‘unlikely to be discernible’, of ‘minor significance’, ‘significant’ and ‘highly significant’. These definitions do not correlate with any concrete measure, and so tend to be applied as a qualitative ranking scheme. This difficulty could be addressed by assessing the significance of each direct and indirect impact against a different scale, or benchmark. In some cases, such scales could have a quantitative meaning, even though individual pest or disease assessments are likely, on the whole, to be qualitative. In other cases, the scales could represent community held values, or other less tangible measures.

Other parts of Biosecurity Australia’s approach to consequence assessment would need to modified if alterations were made in the directions suggested above. That said, such modifications would be relatively minor, and could be implemented in a such a way as to prevent disruption of the overall risk estimation framework.

6 REVIEW: DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY

6.1 Overview

DAFF is responsible for Australia's agricultural, fisheries, forestry and food industries. The Department works to increase the competitiveness, profitability and sustainability of these industries through:

- Sustainable use and management of the natural resource base;
- Protecting the health and safety of our plant and animal industries;
- Responsive and efficient industry;
- Improved market access and performance;
- Benefiting from new technology and practices; and
- Skilled, financially self-reliant producers.

The Department is large and diverse with around 4,200 staff working throughout Australia and overseas. Divisions within DAFF include Rural Policy and Innovation, Food and Agriculture, Market Access (MA),[13] Fisheries and Forestry, Product Integrity Animal and Plant Health (PIAPH), ABARE, Bureau of Rural Sciences (BRS), Management Services and the Australian Quarantine and Inspection Service (AQIS). Biosecurity Australia is a Prescribed Agency within DAFF.

A preliminary analysis of internet and published material showed that of these divisions and agencies, ABARE, AQIS and Biosecurity Australia carry out risk analysis or consequence assessment as a part of their core business, and have developed methods or procedures relevant to the review. Of these, AQIS was subsequently removed as its methods for risk analysis and management, whilst designed to identify hazards or hazardous processes with the minimum of data, do not provide any depth of consequence assessment. Such methods include those used to assess the riskiness of ballast water or cargo. ABARE and Biosecurity Australia were subsequently examined in depth.

[13] At the time of writing, Market Access was poised to be renamed International Division.

6.2 Australian Bureau of Agricultural and Resource Economics

Introduction

The Australian Bureau of Resource Economics has not been dealt with in this review in the manner of other Government agencies. ABARE does not carry out risk analysis or management *per se* but, rather, conducts applied economic research into a broad range of economic and social issues affecting the welfare of Australians. Key areas of expertise within the bureau are listed below.

Australian commodity forecasts and industry analysis:

- Agriculture: farm, industry and national level impacts;
- Energy: impacts of industry reforms and other developments;
- Fisheries: individual fishery and society level impacts of management policies;
- Forestry: regional and national impacts on industry and resource management;
- Natural resources: regional and national impacts of water and land use policies; and
- Minerals: assessing prospects and policy impacts.

International economic issues:

- Global climate change: Using their global trade and environment model ABARE analyse the potential economic impacts of policies intended to mitigate the global impacts of greenhouse gas emissions;
- WTO multilateral trade negotiations: ABARE spotlights the implications of reforming world trade policies; not only for the major players in world trade but for developing nations and Pacific rim countries; and
- International energy analysis: Using their databases, modelling expertise and international networks, ABARE highlights energy issues that are likely to have significant impacts on international energy markets and trade.

From this base of expertise and experience, ABARE offers a resource base in consulting, as well as access to a range of databases, surveys and economic models. Of these resources, economic models are the most directly relevant to this review and are summarised in the subsections below.

Summary

ABARE is DAFF's principal source of economic expertise for policy advice, research or survey work. ABARE is also DAFF's principal source of economic and industry data and economic models. ABARE is well placed to provide these services, with a diverse profile of completed and ongoing projects and a range of state-of-the-art tools and databases.

Of key relevance to this review is the range of economic models developed, enhanced or simply utilised by ABARE. Some of these are of peripheral interest whilst others might lend themselves directly to pest or disease consequence assessment. The latter includes the AgTrade suite of models for grains, dairy and sheep meat; the AUSTEM computable general equilibrium model of the Australian economy; the AUSTATE computable general equilibrium model of Australian State and Territory economies; the AUSREGIONAL computable general equilibrium model of an Australian region; the BEEF-BEM bio-economic model of the Australian beef cattle industry; the BEM-SBT bio-economic model of the blue-fin tuna industry; the EIM exotic incursion management model and the FISH suite of models. (PHA's Regional Economic Impact Model project has also developed a dynamic multi-regional computable general equilibrium model of a pest incursion; see Section 9.4.)

As a group, these models utilise a range of economic approaches, including econometrics, mathematical and linear programming, spatial optimisation, partial equilibrium, computable general equilibrium and neural networks. In contrast to probability models, which commonly seek to answer the same or similar questions by different methods, the different sorts of economic models address fundamentally different questions. As a result, no single approach is inherently 'better' than another, and more than one approach is commonly needed in the context of a Government policy question as complex as pest or disease consequences. Economic models also differ widely with regard to the nature and depth of the data required for parameterisation, and in their robustness to data gaps or uncertainties. For this reason, some models that are apparently well-suited to addressing particular questions may be completely unsuited to practical application in that area.

Accepting the above, it will often be desirable to augment import risk analyses with economic assessments, to complement the qualitative approach currently used and extend it where appropriate with relevant quantitative information. There are two ways this could be achieved:

- The first is the use of ad hoc economic assessment as the need arises;
- The second is the customisation of a chosen model, or a suite of models, such that larger numbers of assessments can be completed quickly and with a focus on the particular questions required in the context of import risk analysis.

The latter approach would seem preferable, both from the standpoint of efficiency for Biosecurity Australia, and in view of the overarching need for consistency amongst and within import risk analyses. It might be that one or more of ABARE's existing models is well-suited to this objective or could be modified with relatively little development effort. Alternatively, it may be that some research would be required to first establish the ideal model framework for import risk analysis, and, from this, to develop a new model or suite of models.

Economic assessment can also be used to assist in the risk treatment stage of import risk analysis; in particular, in helping decision makers choose among measures that reduce the risk of importing pests and diseases. However, as this paper is about consequence assessment the discussion about the role of economics is necessarily focussed on this task.

Detailed Analysis: Economic Models

Economic models are key research tools for applied economic analysis. Over the years, ABARE has developed a range of economic models to deal with important empirical issues and policy questions facing Australia. Some of these models are purely economic while others are integrated bioeconomic and economic-engineering models. These models are built using either a partial or computable general equilibrium approach.

With its wealth of models and accumulated knowledge and research expertise, ABARE undertakes systematic and rigorous analysis of a wide array of economic issues. These issues can be either global or domestic in nature and scale, and may relate to agriculture, energy, natural resources, forestry, fisheries, international trade, climate change or commodity forecasting.

The models identified in this review include:

- AgTrade: a suite of agricultural commodity models;
- AUSTEM: a dynamic computable general equilibrium economy-wide model of the Australian economy;
- AUSTATE: a state-based dynamic computable general equilibrium model of Australia;
- AUSREGIONAL: a dynamic computable general equilibrium model that operates at the level of an Australian region;
- BEEF-BEM: a dynamic bioeconomic model of the Australian beef cattle industry;
- BEM-SBT: a dynamic bioeconomic model of the southern blue-fin tuna fishing;
- D-Net: a discrete wavelet transform neural net model for economic forecasting;
- E4cast: a comprehensive regional projections of energy consumption, production and trade by industry and fuel type;
- EIM: an integrated bioeconomic model that integrates the biophysical aspects of disease incursion with the agricultural production system and the wider regional economy;
- FISH: a suite of models for aquaculture farms and bioeconomic models for particular regions;
- GTEM: a dynamic multi-region, multi-sector, computable general equilibrium model of the world economy;
- MARKAL: an Australian national energy system analysis;
- MOSAIC: an integrated spatial optimisation framework for exploring land use;
- SALSA: an integrated economic-hydrological model of land use and salinity processes in the Murray Darling Basin;
- SUGABARE: an economic model of world raw and refined sugar markets; and
- TRANSPLANT: a comprehensive modelling framework for key land use activities in Australia.

Each of these models is of relevance to the overarching principles of consequence assessment, and will be discussed individually.

4 AgTrade

AgTrade is a suite of agricultural commodity models known as AGM (ABARE grains model), ADM (ABARE dairy model), ASM (ABARE sheep meat model). It was developed from the OECD AgLink model and contains detailed representations of commodity markets, including prices, crop areas, livestock numbers, production, consumption, trade and stocks.

AgTrade includes all major producing, consuming and trading countries and explicitly models policies in the form of market access, export subsidy and domestic support policy in most represented countries. It covers grains such as wheat, coarse grains, oilseed meals and oilseed oils, and palm oil; dairy products such as milk, butter, cheese, skim milk powder and whole milk powder; and sheep meat products including sheep and mutton as well as live sheep.

AgTrade capabilities include:

- Medium term baseline projections of Australian prices, production, consumption, trade and stocks for the main agricultural commodities;
- Quantitative support for analysis of domestic policies in the United States and European Union;
- Quantitative underpinnings for analysis of global trade policies for grains, dairy products and sheep meat;
- Simulating the impacts of economic shocks on commodity markets and trade; and
- Quantifying the impacts of changes to supply or demand on commodity markets and trade.

5 AUSTEM

AUSTEM is ABARE's state-of-the-art dynamic computable general equilibrium model of the Australian economy. AUSTEM incorporates a range of ABARE-developed design characteristics applied across other country-specific computable general equilibrium models. These characteristics are unique amongst computable general equilibrium models and incorporate advanced methodology to better reflect real world economic behaviour.

AUSTEM has a broad range of capabilities, including a comprehensive framework for assessing climate change issues. The model includes 131 sectors and is capable of forecasting 20 years ahead and beyond. AUSTEM is able to be linked into ABARE's suite of sector specific partial equilibrium models as well as GTEM, ABARE's global model. Linking into GTEM enables a refinement of the model simulations to incorporate international impacts and developments. For Australian economic scenario analysis, ABARE is able to choose between AUSTEM or AUSTATE – ABARE's state based model of the Australian economy – according to which tool is most appropriate.

6 AUSTATE

AUSTATE is a dynamic computable general equilibrium model that depicts the Australian economy at the level of the eight states and territories. AUSTATE is an in-house ABARE development with a range of unique innovations and characteristics.

AUSTATE brings to ABARE comprehensive capability for quantitative assessments at the state level for a broad range of issues. In depicting issues facing the Australian economy, AUSTATE can be used in conjunction with its suite of sector specific partial equilibrium models as well as GTEM, ABARE's global model.

7 AUSREGIONAL

AUSREGIONAL is An in-house developed dynamic computable general equilibrium model that operates at the level of an Australian region.

8 BEEF-BEM

BEEF-BEM is a dynamic bioeconomic model of the Australian beef cattle industry. The model has to-date been used to evaluate the impacts on Australian beef producers and consumers of a foot-and-mouth disease (FMD) outbreak in Australia.

Key features of the model include the ability to analyse:

- Herd dynamics, by half yearly age cohort and sex;
- Forward-looking competitive behaviour of beef producers for decisions on turning off cattle, by age and sex;
- Competitive behaviour of traders or processors for decisions on buying or processing of cattle for domestic and export markets;
- Beef and cattle prices as well as net returns over time; and
- Overseas market closure options, by region and duration, following an FMD outbreak; and allows quarantine zoning options within Australia.

The model has been used to evaluate the impact of a hypothetical FMD outbreak on Australian beef producers and consumers under alternative management options, outbreak locations and zoning conditions and overseas market closures by region and duration; including determination of the economic impact of alternative options for controlling the disease outbreak.

9 BEM-SBT

BEM-SBT is a dynamic bio-economic model of the southern blue-fin tuna fishery, which consists of biological and economic components. The model contains fish stock composition by age cohort, as well as multiple fishing countries (Japan, Australia, New Zealand, Korea, Indonesia and Chinese Taipei).

A key feature of the model is that it determines a path for optimal fishing and associated net returns over time. It can evaluate the impact on catch stock and net returns of alternative management options, where the options include open access, catch quota, export or import tax, and combinations of management options applied in the fishing countries. The model is also used to project fish catch, stocks and net returns over time.

10 D-Net forecasting

This is an in-house developed and sophisticated forecasting methodology based on neural network programs and the discrete wavelet transform process. This methodology is being used as an input into ABARE's gold price forecasts and is also being applied to develop forecasting models for a range of other commodity and financial market variables.

Neural network models are designed to recognise patterns between explanatory variables and dependent variables, and, from these, to produce forecasts. Neural network models are also able to recognise changes in the relationship between variables for different levels of those variables, as well as changes in the strength of the relationships through time. The nonlinear nature of neural network models allows the reproduction of a range of data patterns and features, such as chaotic behaviour, which are not captured by linear models.

ABARE has devoted significant resources to investigating techniques to improve the forecast performance of neural network models. This research has found that improvements can be achieved by performing complex manipulations to the input data. In manipulating this input data, ABARE has used the discrete wavelet transform. This is a mathematical function that transforms time series data into different frequency levels. Decomposing a time series into different levels of detail provides a basis for revealing information that can be interpreted on theoretical grounds as well as being useful in improving forecast accuracy. Forecasting models like neural networks are able to extract information from the different scales of wavelets that is otherwise hidden in the aggregate time series. This dramatically improves the ability of neural network models to explain different levels of variation in dependent variables over time.

11 E_4cast

For more than 25 years ABARE (and its predecessor) has regularly published long-term projections of Australian energy consumption and production. In 2000, ABARE commenced development of the E_4cast modelling framework that is now used to generate ABARE's energy projections. The original E_4cast modelling framework was documented in Australian Energy: National and State Projections to 2019-2020.

E_4cast is a partial equilibrium model of the Australian energy sector that approximates the principal interdependencies between energy production, conversion and consumption in Australia. Consumers and producers of energy fuels are assumed to act competitively in each of the domestic, export and import markets. The model is used to project energy consumption, by fuel type and industry, and, by state, giving explicit regard to real incomes (or industry production trends) and fuel prices.

The model covers the consumption and production of crude oil and petroleum products, LPG, black and brown coal, coke and coal by-products, natural gas, electricity, and renewables – hydroelectricity, biomass, biogas, wind and solar energy – in all major conversion sectors and 20 end-use sectors. Interstate trade in electricity and natural gas is modelled explicitly as is electricity generation and gas production. In this model the Australian energy sector is divided into seven regions: New South Wales, which includes the Australian Capital Territory, Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory.

12 EIM

The EIM (Exotic Incursion Management) model is a bioeconomic model that integrates the biophysical aspects of disease incursion with the agricultural production system and the wider regional economy. The spatial and agent based nature of the model makes it possible to capture the physical process of disease transmission from a variety of different vectors, the economic impact of the spreading disease, and any resulting management to eradicate or control the incursion.

The model consists of four main components that represent the pest or disease, the farm system, the incursion management system and the regional economy. The pest or disease module captures the unique characteristics of the particular pest or disease, including transmission vectors, and estimates of the rate of movement or spread. The farm system is modelled on a weekly time-stepped basis and includes production choices and estimates of financial returns. The incursion response and management module incorporates the methods by which the pest or disease is first identified, the process by which potential incursions are investigated, and any subsequent containment and eradication measures that are put in place. A stylised representation of the regional economy is also included to enable calculation of the flow-on effects of an incursion to the wider community.

13 FISH

FISH comprises a suite of fish models – namely, aquaculture farm models (AQUA) and integrated biological and economic (bio-economic) models for a particular area (region, country or country group).

The AQUA models use production and financial data, and risk and uncertainty information collected from farmers, industry and Governments. They provide quantitative support for undertaking stochastic investment analysis. The bio-economic models integrate the biological models of fisheries, with behavioural equations representing fishing effort and estimates of fishing costs, and determine catch and effort levels and net returns to the fishery under alternative scenarios.

Recent applications include:

- Stochastic investment analysis for abalone, Murray cod, mussels, silver perch, snapper and yabbies;
- Evaluation of alternative management proposals in the northern prawn fishery; and
- Estimating the economic returns associated with alternative management options in the southern blue-fin tuna fishery for the regions Australia and New Zealand, Japan, Korea, Indonesia and Chinese Taipei.

14 GTEM

GTEM, the global trade and environment model, is a dynamic multi-region, multi-sector, computable general equilibrium model of the world economy. This model provides the basis for ABARE's international policy analysis.

GTEM was developed by ABARE to address policy issues with long term global dimensions, and was derived from the GTAP model. ABARE applies GTEM in examining issues such as climate change and the Kyoto Protocol, trade reform under the World Trade Organisation (WTO), and trends and issues in international energy markets. Recently ABARE has used GTEM to examine the impacts of the Kyoto Protocol targets set for the European Union and the most cost effective policy options; to assess the costs to Australian agriculture of United States farm bill subsidies; and to forecast the outlook for global coal markets to 2010.

GTEM captures the impact of policy changes on large numbers of economic variables in all sectors of the economy including gross domestic product, prices, consumption, production, trade, investment, efficiency, competitiveness and greenhouse gas emissions. The strength of GTEM lies in its extensive detail: the database represents 66 regions and 62 sectors across the world economy. GTEM policy analysis results are reported as deviations from a reference case. The reference case provides a ‘business as usual’ outlook for the economy in the absence of any major policy changes, which enables accurate quantification of the impacts of policies on indicators of interest.

The inter-temporal version of GTEM (GTEM-LR), currently at an advanced stage of implementation, incorporates forward looking dynamics critical to modelling the consumption and investment decisions made by economic agents. ABARE is also building the capacity of other organisations by making GTEM publicly available for academic purposes.

15 MARKAL

ABARE’s Australian MARKAL is an inter-temporal linear programming model of the Australian national energy system. It is based on a generic framework developed under the auspices of the International Energy Agency Energy Technology Systems Analysis Program. ABARE has enhanced MARKAL to improve the model’s representation of ‘real world’ markets, with applications in policy analysis.

The model is used to simulate the Australian energy systems to deal with a wide range of technical and economic issues facing the energy sector, such as least cost simulation of a wide range of policy instruments, measures and long run technology based scenario analysis.

Key features include:

– Comprehensive representation of existing and potential technologies over a long run projection period;
– A regional structure, based on the six Australian states, and representation of interstate electricity transmission and gas pipelines;
– Detailed modelling of the electricity supply sector represented by all existing and prospective generation types (within a projection period beyond 2040), with a separate treatment of each state and transmission (both existing and prospective) between state systems;
– Detailed modelling of electricity demand including separate treatment for seasonal and diurnal periods;
– Competitive energy markets simulated by minimising an objective function incorporating the costs of energy technologies and resources;
– A database containing detailed and comprehensive characterisations of existing and prospective technologies, including economic costs and engineering features such as energy efficiencies and emissions coefficients; and
– Autonomous efficiency improvements explicitly represented in the existing stock of technologies and price induced investment in higher efficiency options allowed for.

16 MOSAIC

MOSAIC is an integrated spatial optimisation framework for exploring future land use and management options at regional and landscape scales. Critical spatial interactions and linkages, such as resource use externalities, transport costs and habitat configuration, are supported explicitly. MOSAIC provides the capability to identify the social, environmental and economic trade-offs of changing the way land is managed in particular landscape contexts.

MOSAIC is currently implemented as a plug-in to the EcoPlan software developed by Environment Australia. The user interface provides GIS functionality and utilises wizards to define scenarios (which specify how landscapes are valued) and to develop allocations (which specify how each part of the landscape is managed). All the data used and generated by MOSAIC is contained in a Microsoft Access database. The actual optimisation is carried out by a C/C++ language dynamic link library that can be modified to suit different applications of the framework.

A prototype application of MOSAIC includes objectives relating to biodiversity, greenhouse emissions, dry-land and river salinity, and economic costs and returns. MOSAIC builds on past collaborative research with Environment Australia and university ecologists. This earlier work has been used for terrestrial and marine reserve design in Australia.

17 SALSA

SALSA is an integrated economic-hydrological model of land use and salinity processes in the Murray Darling Basin that explicitly models externalities in resource use. Key capabilities of the model include that it:

- Generates baseline projections for land returns, and dry-land and in-stream salinity;
- Enables scenario analysis for salinity control options and water allocation rules;
- Estimates the overall social opportunity cost; and
- Identifies winners and losers from alternative resource use scenarios

Recent uses include:

- Evaluation of salinity control options in the Murray Darling Basin;
- Estimation of the opportunity costs for environmental flows;
- Assessing externalities associated with improved water use efficiency and water trade; and
- Impact analysis of climate change on water availability and salinity outcomes

18 SUGABARE

SUGABARE is an econometric model of world raw and refined sugar markets. It contains a detailed representation of the market in terms of prices, production, consumption, trade and stocks over time, and includes all major producing, consuming, toll refining, and trading countries. The trade and domestic policies of major exporting and importing countries are explicitly modelled in SUGABARE.

The model's capabilities include:

- Medium term baseline projections of production, consumption, trade and stocks for each country or region and world raw and refined sugar prices;
- Quantitative evaluation of the impact of alternative domestic and trade policies of countries over time; and
- Quantitative evaluation of the impact of change in other factors affecting supply or demand over time – for example, the impact of drought on supply and the impact of substitution of alternative sweeteners for sugar on demand.

Examples of the model's use include assessing the impact of changes to Brazilian sugar production and fuel ethanol policies for world sugar markets, and quantifying the impact of reforms to international sugar trade policies on major sugar exporting and importing countries.

19 TRANSPLANT

TRANSPLANT is a comprehensive modelling framework for key land use activities in Australia. It was developed by ABARE to project emissions from agricultural activities, as well as to examine emission policy initiatives on Australian agricultural activities.

TRANSPLANT is a dynamic mathematical programming model that solves jointly the allocation of land and other inputs between regions, activities and time periods. A strength of TRANSPLANT is its simulation of competition for land and other inputs among competing agricultural activities.

Key features of the model include:

- Integration of agricultural activities;
- Comprehensive coverage of activities, commodities and emissions;
- Reflection of competition between activities;
- Its inter-temporal nature;
- Appropriate spatial context; and
- Consistency and compatibility with other key models or systems

TRANSPLANT is currently used to provide emissions projections to 2020 for Australian agriculture to the Australian Greenhouse Office. ABARE is further developing TRANSPLANT to link other land use activities such as forestry, plantations, revegetation and land clearing into the existing framework.

7 REVIEW: DEPARTMENT OF ENVIRONMENT AND HERITAGE

7.1 Overview

DEH[14] develops and implements national policy, programs and legislation to protect and conserve Australia's natural environment and cultural heritage. The role of the Environment and Heritage portfolio is to achieve three major outcomes for the Australian Government:

- The environment, especially those aspects that are matters of national environmental significance, is protected and conserved;
- Australia benefits from meteorological and related sciences and services; and
- Australia's interests in Antarctica are advanced.

The Environment and Heritage portfolio consists of: DEH, which itself is made up of twelve divisions and offices; four statutory authorities; and a single executive agency, the Bureau of Meteorology:

DEH divisions and offices are:

- Australian Antarctic Division;
- Approvals and Wildlife Division;
- Australian Greenhouse Office;
- Industry, Communities and Energy Division;
- International, Land and Analysis Division;
- Corporate Strategies Division;
- Heritage Division;
- Land, Water and Coasts Division;
- Marine Division;
- Natural Resource Management Programmes Division;
- Parks Australia Division;
- Policy Coordination and Environment Protection Division; and
- Supervising Scientist Division.

Environment and Heritage portfolio statutory authorities are:

- The Director of National Parks;
- The Great Barrier Reef Marine Park Authority;
- The Office of the Renewable Energy Regulator; and
- The Sydney Harbour Federation Trust.

[14] Now the Department of Environment and Water Resources

A preliminary analysis of internet and published material showed that of these divisions, offices and agencies, the Approvals and Wildlife Division, the Australian Greenhouse Office and the Marine Division carry out risk analysis or consequence assessment as a part of their core business and have developed methods or procedures relevant to the review. These divisions and offices were subsequently examined in depth.

7.2 Approvals and Wildlife Division

Introduction

The Approvals and Wildlife Division contributes to the protection and conservation of the environment and wildlife through the implementation of the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act).[15] It also administers the Environment Protection (Sea Dumping) Act 1981, the Sea Installations Act 1987 and the Sea Installations Levy Act 1987, and conducts assessments under the Telecommunications Code of Practice 1997.

The Division is responsible for:

- Environmental assessments and approvals;
- Regulation of wildlife trade;
- Identification and protection of nationally threatened species and ecological communities; and
- Regulation of sea dumping and sea installations.

Summary

The approach that the Approvals and Wildlife Division of DEH takes to assessing the likely consequences of an action on each of the seven areas (or 'matters') of national environmental significance is guided by the terms and conditions of its EPBC Administrative Guidelines on Significance. These guidelines outline the general issues that should be considered when assessing the significance of an action, as well as the particular criteria that will be relevant to each matter of national significance.

The guidelines, whilst drafted to assist with a very specific regulatory objective, can be taken as useful material for other assessments based on the impact

[15] Available at: http://www.deh.gov.au/epbc/about/index.html

of an event (such as a pest or a disease incursion) on, for example, wetlands in general, migratory species, threatened species and ecological communities or marine environments. In particular, the guidelines may assist Biosecurity Australia in improving its qualitative assessments of direct and indirect impacts of pest or disease incursions.

Risk Management Context

Under the EPBC Act, assessment and approval is required for actions that are likely to have a significant impact on:

- A matter of national environmental significance;
- The environment of Commonwealth land (even if taken outside Commonwealth land); or
- The environment anywhere in the world (if the action is undertaken by the Commonwealth).

An action includes a project, development, undertaking, activity, or series of activities. When a person proposes to take an action that they believe may need approval under the EPBC Act, they must refer the proposal to the Commonwealth Environment Minister.

The Act identifies seven matters of national environmental significance:

- World Heritage properties;
- National heritage places (from 1 January 2004);
- Ramsar wetlands of international significance;
- Threatened species and ecological communities;
- Migratory species;
- Commonwealth marine area; and
- Nuclear actions (including uranium mining).

The EPBC Administrative Guidelines on Significance[16] provide guidance on determining whether an action has, will have, or is likely to have a significant impact on a matter of national environmental significance. The guidelines cover each of the seven matters outlined above.

Although the Approvals and Wildlife Division of DEH is complex and multifaceted, assessment of the significance of actions carried out with regard to the seven matters of national significance was found to be the principal area in which risk management and consequence assessment were applied consistently. This was therefore considered the framework for risk management, and further review was restricted to this area of work.

Risk Management Framework

The guidelines include criteria that are intended to assist in determining whether the impact of an action on any matter of national environmental significance is itself likely to be significant. Criteria are set out for each matter of national environmental significance.

The guidelines are intended to provide general guidance on the types of actions that will require approval and the types of actions that will not require approval. They are not intended to be exhaustive or definitive. The particular facts and circumstances of a proposed action need to be taken into account in determining whether that action will have a significant impact on a matter of national environmental significance.

In order to decide whether an action is likely to have a significant impact, it is necessary to take into account the nature and magnitude of potential impacts. In determining the nature and magnitude of an action's impact, it is important to consider matters such as:

- All on-site and offsite impacts;
- All direct and indirect impacts;
- The frequency and duration of the action;
- The total impact which can be attributed to that action over the entire geographic area affected, and over time;
- The sensitivity of the receiving environment; and
- The degree of confidence with which the impacts of the action are known and understood.

The Act provides that, in deciding whether an action is likely to have a significant impact on a matter of national environmental significance, the Minister must take account of the precautionary principle. Accordingly, the fact that there is a lack of scientific certainty about the potential impacts of an action will not itself justify a decision that the action is not likely to have a significant impact on a matter of national environmental significance.

The Act provides that in deciding whether the action is a controlled action, the Minister must not consider any beneficial impacts that the action has, will have or is likely to have. Therefore, activities which will have only beneficial impacts will not be captured by the Act.

[16] Available at: http://www.deh.gov.au/epbc/assessmentsapprovals/guidelines/.

Approach to Consequence Assessment

The approach that the Approvals and Wildlife Division of DEH takes to assessing the likely consequences of an action on each of the seven areas of national environmental significance is spelt out in the guidelines. Interestingly, an approach is not provided for the assessment of actions performed in relation to national heritage places, although this appears only to have been added to the list of six others on 1 January 2004.

In each case, assessment of the nature and magnitude of an action's impact focuses on the overarching principles listed above, customised to encompass the particular attributes of each topic. Actions taken with regard to 'Ramsar wetlands', for example, will need to consider:

- Areas of the wetland being destroyed or substantially modified; or
- A substantial and measurable change in the hydrological regime of the wetland for example, a substantial change to the volume, timing, duration and frequency of ground and surface water flows to and within the wetland; or
- The habitat or lifecycle of native species dependant upon the wetland being seriously affected; or
- A substantial and measurable change in the physico-chemical status of the wetland for example, a substantial change in the level of salinity, pollutants, or nutrients in the wetland, or water temperature which may adversely impact on biodiversity, ecological integrity, social amenity or human health; or
- An invasive species that is harmful to the ecological character of the wetland being established in the wetland.

Similar lists of considerations are provided for each of the other six matters of national environmental significance.

It can be seen that these assessments are systematic and comprehensive, and primarily qualitative. No attempt is made to quantify the significance of impact on any matters of national significance, nor to incorporate the components of each part of the assessment into a rule-based decision making framework. This is not to say that quantitative data is not used, as the Division will clearly take note of any scientific evidence available to support any part of its assessments.

7.3 Australian Greenhouse Office

Introduction

The Australian Greenhouse Office delivers the majority of programmes under the Australian Government's climate change strategy.

The UN Framework Convention on Climate Change and the Kyoto Protocol arose from increasing international concern about the implications of climate change and a recognition that no one country can solve this global environmental problem. They provide the international framework for countries – especially developed countries – to undertake and implement commitments to reduce their emissions of greenhouse gases. The ultimate objective is to stabilise greenhouse gas concentrations in the atmosphere at a level that will prevent dangerous human-induced interference with the climate system.

Greenhouse abatement is a cross-cutting issue, as all sectors of the economy are implicated and all sectors have opportunities for change. The Government's climate change strategy is centred on five key areas: emissions management; international engagement; strategic policy support; impacts and adaptation; and science and measurement.

Major initiatives include:

- Boosting renewable energy actions and pursuing greater energy efficiency;
- Investing significant resources into greenhouse research and monitoring Australia's progress towards its Kyoto target through the National Greenhouse Gas Inventory;
- Studying the landscape of Australia through the National Carbon Accounting System;
- Encouraging the development and commercialisation of low emissions technologies;
- Encouraging industry, business and the community to use less greenhouse intensive transport; and
- Fostering sustainable land management practices.

To achieve these initiatives, the Australian Government is building partnerships with industry through the Greenhouse Challenge programme, which provides a framework for undertaking and reporting on actions to abate emissions. The Greenhouse Friendly initiative and Greenhouse Gas

Abatement programme encourage industry action to abate greenhouse emissions from a range of sectors. In addition, the Government is encouraging households, communities and local councils to take action to reduce greenhouse gas emissions through its Local Greenhouse Action initiative which includes the International Cities for Climate Protection programme. Action is being pursued with the energy industry through the establishment of efficiency standards.

The National Climate Change Adaptation Programme, announced in the May 2004 Budget, has the objective of commencing the preparation of Australian Governments and vulnerable industries and communities for the unavoidable impacts of climate change. Current risk management initiatives within this programme include a soon to be released report, Climate Change Risk and Vulnerability: Promoting an Efficient Adaptation Response in Australia,[17] the development of practical guidance for integrating climate change impacts into current risk management practices and the development of integrated assessment methodologies.

Issues relevant to the principles of a risk management context, a risk management framework and approaches to consequence assessment are encapsulated in the tools available for assessing impacts and vulnerability. A review of such tools has been provided by the United Nations Framework Convention on Climate Change (UNFCCC).[18]

Summary

Consequence assessment in the Australian Greenhouse Office is focussed on risk-based methods for assessing the vulnerability and adaptability of environments, communities or industries to climate change. Assessments carried out in this field do not appear to follow the conventional risk management structure, although they do enlist many analytic tools and approaches that could be adapted to the assessment of disease consequences.

The distinction between 'top down' and 'bottom up' approaches, for example, could be applied equally in the context of pest or disease consequences, where one might be interested in the seriousness of a particular establishment or spread scenario (the top-down approach), or, alternatively, might seek to focus on the vulnerability of an industry or community to harm from pests or diseases (the bottom up approach). The former has provided much of the basis for consequence assessment in import risk analysis. The latter, however, could be relevant to considerations of the indirect effects of pests or diseases on key industries or communities, where a concept of vulnerability might better inform decisions about the threat posed by exotic pests or diseases than analyses of specific outbreak scenarios.

It is also clear that some of the analytic tools might also be useful for examining pest or disease impacts. Sectoral economic models, for example, have a place in the evaluation of direct and indirect disease effects. Likewise, many of the ecological or industry focussed models could be used to examine the effect of a pest or disease shock, in the place of a shock due to climate change.

Extension of such tools from one environment (climate change) to another (pest and disease risk analysis) would require collaboration between relevant analysts, and a willingness to share project objectives, methods and outcomes. It is also likely that technical specialists in the application of particular analytic tools would be required to perform some experimental pest or disease impact analyses, or analyses of the vulnerability of ecosystems, communities or industry to pest or disease shocks. Such analyses, if promising, could be peer reviewed and published, and, if received positively by the broader community of risk analysts, could be adopted for ongoing use within the more traditional framework for consequence assessment.

Risk Management Context

The background and reasons for undertaking risk-based studies of the vulnerability and adaptive capacity of Australian industries to climate change were outlined above. In general terms, these provide the context for any ensuing risk management exercises.

Risk Management Framework

Various frameworks have been adopted in Australian and overseas initiatives to investigate vulnerability and adaptive capacity. Such frameworks, whilst generally risk-based, are not risk analyses in the sense of most other applications of risk analysis included in this review. For

[17] Unpublished Report to the Australian Greenhouse Office, DEH, by the Allen Consulting Group.
[18] Application of Methods and Tools for Assessing Impacts and Vulnerability, and Developing Adaptation Responses: Background Paper, http://unfccc.int/resource/docs/2004/sbsta/inf13.pdf.

completeness, some discussion of such frameworks is included below.

The most complete summary of frameworks for assessing the vulnerability to climate change is provided in the UNFCCC report. Specifically, this paper explores:

– The types of the approaches, methods and tools available for assessing impacts of, and vulnerability to, climate change, as well as for the development of appropriate adaptation responses;
– Experiences in applying such methods and tools in developing and developed countries;
– Limitations associated with the use of different methodologies; and
– The type of questions these methods and tools can address, as well as questions which these models are not set up to answer but for which they may be inadvertently used to supply proxy data to stakeholders or policy makers.

The review paper explains that the approach to be followed will depend on the scale of the assessment and the questions the assessment is to explore. Vulnerability and adaptation assessment can be conducted on different scales – from a global to local – and address fundamental questions, such as:

– What are the key long-term impacts of climate change?
– To what extent can the harmful effects of climate change be reduced through adaptation?
– What can a country or community do to adapt to climate change?
– How can adaptation policies best be developed and applied?

The choice of suitable approach, methods and tools depends on what question an assessment is focusing on, as well as a number of other issues, including the sector or system under consideration and the time frame. Approaches typically fall into two major categories: top-down (scenario-driven) and bottom-up (vulnerability-driven).

<u>Top-down or scenario-driven</u> approaches have been widely used to address the first two questions above. This type of approach is described in the IPCC Guidelines and elaborated in guidelines prepared for the United States Country Studies Program and the United Nations Environment Programme (UNEP) Handbook on Methods for Climate Change Impact Assessment and Adaptation Strategies.

Taken together, these guidelines and the ways they have been applied have become known as the 'standard approach' based on climate scenarios derived from general circulation models (GCMs), as well as on some consideration of socio-economic scenarios. The climate scenarios chosen were commonly applied to models of ecosystems, and to a variety of sectoral impact models designed to quantify the magnitude of the physical impacts on vulnerable sectors. Possible options to adapt to those future impacts were identified at the last stage of the assessment. Studies using this approach (referred to in a number of sources as the 'first generation' of vulnerability and adaptation assessments) have an analytical thrust that emphasises the identification and quantification of impacts.

Key methods and tools used in this approach include various downscaling techniques for developing scenarios of future climate and socio-economic conditions, sectoral impact models and tools for assessing and prioritising adaptation options. The approach and tools are strong in biophysical aspects of impacts and certain types of dynamic interactions, but do not do well in representing human interactions and local abilities to adapt. For example, crop impact modelling can yield information on the magnitude of potential impacts but sheds little light on the distribution of these impacts among local communities.

<u>Bottom-up or vulnerability-driven</u> approaches are oriented towards localised vulnerability. This type of approach (also called the 'multi-stressors' approach) is increasingly considered the most appropriate for addressing the last two questions above. It centres on assessing current vulnerability to both climate related factors (for example, climate variability, drought, flooding and extreme weather events) and non-climate factors (for example, lack of resources, inadequate institutions and poverty) and examining current practices in adaptation. It also includes evaluation of vulnerability to future climate related risks (and involves key stakeholders in the evaluation process) and eventually leads to formulation of adaptation policies that strengthen adaptive capacity. The approach also addresses longer-term vulnerability to climate change, hence contributing to sustainable development.

Studies using this approach (referred to in a number of sources as 'second generation' assessments) are more attuned to the local institutional, economic and productivity contexts, and are better able to represent local options and constraints than are scenario-driven studies. They are useful for developing specific strategies and in the implementation of policy. They are often limited, however, by lack of data (in terms of type and level of detail).

Key methods and tools used include stakeholder tools, risk assessment techniques and decision-support tools that are strong in integrating information and accounting for dynamic interactions between human and natural systems but weak in addressing scale and magnitude. For example, community-level studies can yield information on how communities have managed to adapt to multiple local stresses (drought, poverty, etc.) but shed little light on how such experiences can be 'scaled-up' or integrated over time and space.

The two approaches are not necessarily competing or exclusive. Studies using a vulnerability-driven approach can be conducted in parallel with or integrated into scenario-driven studies, and are designed to meet the needs of adaptation policy development. Moreover, no approach or type of approach is entirely adequate by itself, and most methods can be used in a variety of contexts. For instance, any discussion of the future will rely on scenarios at some stage. Also, stakeholders should be involved at some stage in all assessments, even those that are top-down.

Approach to Consequence Assessment

Methods and tools for assessing vulnerability were also reviewed by the UNFCCC. Loosely interpreted, these tools encompass the range of methods currently used to assess the consequences of climate change on environment, industries or communities. As noted above, the tools do not correlate directly with the methods for consequence assessment that are usually employed under a traditional risk management framework. The tools do, however, include some specific methods and applications, such as sectoral impact models, that could be considered in assessing the indirect effects of other kinds of 'shocks' to an economic system; most pertinently, animal or plant disease events.

The UNFCCC review explains that the list of methods and tools for vulnerability assessment encompasses a broad range of applications, from cross-cutting or multicultural (for example, climate models, scenario-building methods, stakeholder analysis, decision-making tools) to specific sectoral (for example, crop or vegetation models, methods for coastal zone vulnerability assessment). Scenario methods and tools are mainly used by climate change analysts and decision makers asked to consider vulnerability and adaptation options in the context of different possible future conditions. The IPCC–Task Group on Scenarios for Climate Impact Assessment (TGCIA) Guidelines on the Use of Scenario Data for Climate Impact and Adaptation Assessment address this application generally, discussing a wide range of issues relating to the application of both climate scenarios and socio-economic baseline scenarios.

There are several methods and tools that can be used for downscaling climate data or developing socio-economic scenarios. The downscaling techniques can be used to produce small-scale climate data of the type often required by impact models, and to develop future climate scenarios at the local and national scales. The approaches to socio-economic scenario construction are all part of larger frameworks but can be used separately. In practice, the process of developing scenarios depends on the nature of the planned assessment. None provides a 'one-size-fits-all' method or tool for developing socio-economic scenarios, but rather should be viewed as informing a necessarily *ad hoc* process.

Stakeholder analysis tools typically include a range of techniques that can be used to gain or account for on-the-ground perspectives. They can also be used in processes aimed at untangling the sometimes competing perspectives of stakeholder groups. Some of the tools available include agent-based simulation techniques, vulnerability indicators or indices, sustainable livelihood assessments, Delphi techniques, expert judgement and stakeholder thematic networks. Much of the recent literature relating to incorporating adaptation into national planning contexts, as well as recent efforts in adaptation research, places emphasis on the use of such tools. They can be readily used in bottom-up processes to identify and assess the attractiveness of adaptation options. Some of them could also be considered decision-support tools. All may be effective when used in the context of a stakeholder dialogue.

Decision-support tools encompass general analytical tools that assist analysts in making choices between adaptation options. They include cost–benefit analysis, multi-criterion analysis, project screening or prioritization, decision matrices, environmental assessments and cost-effectiveness analysis. Some of these tools rely on a single monetary metric and focus on a single decision criterion (for example, cost–benefit analysis). Others enable the user to define and incorporate more than one decision criterion (for example, multi-criterion analysis, tools for environmental assessment and management, and the adaptation decision matrix). Other tools seek to inform larger policy decision questions, taking into account the institutions involved and affected when pursuing specific adaptation options. Some are used within the context of national adaptation programs of action (NAPAs) and adaptation research processes. These kinds of tools are used in bottom-up processes to identify and assess the attractiveness of adaptation options.

Sector-specific methods and tools, and tools for integrated assessment, mostly impact models, have been used in top-down or scenario-driven studies to assess impacts from climate change. They include crop models, water system evaluation tools, coastal resource tools, human health assessment methods and terrestrial vegetation tools. Some of the more recent tools have used integrated analysis and have expanded it to provide assessments of vulnerability in multiple sectors rather than just physical estimates of sector-specific impacts. An example of integrated impact modelling is the Advanced Terrestrial Ecosystem Analysis and Modelling (ATEAM) tool for integrated assessments of vulnerability of a number of sectors.

Sectoral tools can provide a quantitative estimate of the possible harm to specific sectors or systems due to future climate change. However, they are limited by the uncertainty inherent in the models and parameters, and by the fact that they are not able to represent local conditions well. Moreover, these tools are almost entirely limited to impact evaluation and do not lend themselves to evaluation of adaptation options.

7.4 Biotechnology

DEH is concerned with the environmental applications and impacts of biotechnology including gene technology, and in particular genetically modified organisms (GMOs) and products derived from these.

DEH is a member of Biotechnology Australia, a multi-Departmental Government agency responsible for coordinating biotechnology issues for the Australian Government, including the development and implementation of the National Biotechnology Strategy. Under the Strategy, DEH is part of an Ecological Risk Assessment for GMOs project to improve our understanding of risks to the environment from GMOs. The Department also carries out work under the Strategy on access to biological and genetic resources.

DEH advises the Environment Minister (under the Gene Technology Act 2000) on risk assessment and risk management plans for GMOs released into the environment. Because not all GMOs have the same traits, the Department assesses the applications and proposed management plans on a case-by-case basis to determine whether environmental risks can be managed appropriately. It also advises on future information requirements, for example, the risks if the GMO is released for commercial production.

DEH assesses the environmental safety of biological products (including for ‘biological control’) and GMOs regulated as agricultural and veterinary chemicals by APVMA.

When developing advice for the Minster regarding GMOs and biological products, DEH generally uses criteria and processes consistent with those of the initiating agencies (OGTR and APVMA), although the DEH focus is on environmental outcomes. Much of the analysis concerns the likelihood of transfer, establishment and spread of biological agents in the environment. Where there is high uncertainty, the precautionary principle is applied.

Whilst transparent and internally consistent, there were not seen to be any elements of the Biotechnology approach that might be used to augment Biosecurity Australia’s methods for import risk analysis.

7.5 Marine Division

Introduction

DEH Marine Division provides central coordination and policy advice to the Australian Government on the marine environment, including the implementation and further development of Australia’s Oceans Policy.

Australia’s Oceans Policy aims to achieve healthy oceans: cared for, understood and used wisely for the benefit of all, now and in the future. The Policy addresses the complex issues confronting the long-term future of one of the world’s largest Exclusive Economic Zones. It focuses on an integrated and ecosystem-based approach to ensure sustainable development of Australia’s marine resources. The Policy is being implemented through a whole-of Government approach.

The Division also undertakes programs and advises on marine species conservation, marine protected areas, regional marine planning, national integrated oceans management, marine science research and the promotion and development of Australia’s international oceans environmental objectives.

The Division has three branches:

- The National Oceans Office;
- The Marine Conservation Branch; and
- The Marine Environment Branch

Of these, the National Oceans Office is the lead Australian Government agency responsible for the implementation of Australia's Oceans Policy.

Summary

DEH Marine Division has a broad scope of responsibility, including management of the cooperative development of Regional Marine Plans. Although currently under development, these plans will include multiple use risk assessments. The method to be used for these assessments, and, more specifically, the methods to be used to assess the impact or consequences of regional activities, are directly relevant to this review. In particular, such methods could assist with the development of an approach to import risk analysis that is based on a generic national (Biosecurity Australia) standard but otherwise customised to address the impacts of marine pests and diseases.

It is recommended that dialogue be established between Biosecurity Australia or the Centre of Excellence and DEH Marine Division's National Oceans Office, so that ongoing developments can be assessed.

Risk Management Context

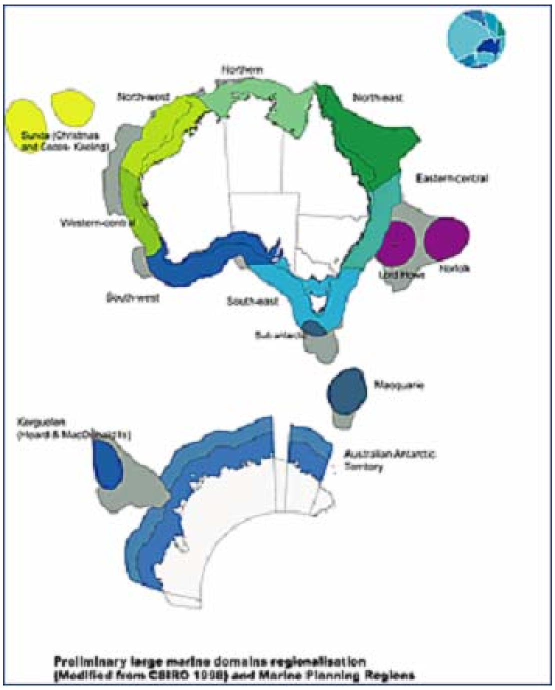
The primary means by which the National Oceans Office is implementing Australia's Oceans Policy is through regional marine planning, an integrated and ecosystem-based approach to planning and management. Regional marine planning focuses on:

- Maintaining a sustainable ecosystem;
- Generating certainty for industry;
- Involving indigenous peoples in the use, conservation and management of oceans;
- Encouraging industry and community stewardship of Australia's oceans; and
- Facilitating stakeholder participation in oceans management and planning.

The following marine plans are currently being developed (Figure 8)

- South-East Regional Marine Plan;
- North Regional Marine Plan; and
- Torres Strait Marine Plan.

Figure 8: Regional Marine Plans



Risk Management Framework

The South-East Marine Plan (2004) was the first of the Marine Plans to have been initiated and is currently the most advanced.[19] The South-East Marine Plan covers two million square kilometres of Australia's south-east ocean waters, including the ocean off Victoria, southern New South Wales, eastern South Australia, Tasmania and around Macquarie Island. It has been developed by the National Oceans Office in consultation with south-east State Governments, industry representatives, indigenous groups, marine communities and others with an interest in the marine environment. It illustrates how individual management actions by Governments, industry and community members can be brought together.

Within the South-East Marine Plan are a number of action items, signalling areas of ongoing development. One of these items (Action 4.2.3), 'Risk Assessment', describes an intent to develop and apply methods of 'multiple-use' risk assessment for threats to the marine environment, industry and communities. Of particular interest to this review is a stated objective of multiple use risk assessment, which is to "assess the cumulative, social, economic and ecological impacts of multiple uses in the Region to determine priority issues and areas for research and management".

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[19] Available at: http://www.oceans.gov.au/pdf/5063_SERMP.pdf.

Under the framework put forward in the Plan, risk assessment is characterised as a systematic and transparent analysis of information to predict and describe likely outcomes of specific events that may occur, and the magnitude of their consequences. This leads to the identification of priorities for management responses and further research. It is maintained that whilst risk assessment has been applied in many areas of environmental management, there is a need to develop a standard approach to assessing risks to all aspects of the sustainable use of broad areas of ocean.

The approach will:

- Assess risks to ecosystems, economies and communities in an integrated way;
- Simultaneously consider the cumulative impacts arising from multiple uses and threats;
- Build on rather than duplicate existing risk assessment processes;
- Be open and transparent and involve stakeholders at various stages;
- Use a staged approach to risk assessment consisting of an overview phase and subsequent more detailed investigations where appropriate; and
- Be consistent with the Australian and New Zealand environmental risk assessment standard.

Under the proposed framework, the following steps will be followed when carrying out multiple use risk assessment:

- Description of activities or processes that constitute a source or risk, including their nature, frequency and location;
- Identifying the elements of the ecosystem (ecological, economic, socio-cultural) that might be impacted and the nature and location of these elements;
- Description of the potential impacts on the selected ecosystem components;
- Analysis of the extent to which the activity and the elements might interact;
- Estimation of the likelihood of the impact occurring (where there is interaction);
- Ranking the relative levels of risk posed to the ecosystem elements;
- Ranking the relative levels of risk posed by each of the activities or processes; and
- Consideration of any risk management measures already in place in estimating risk levels.

Following from the risk assessment process would be the development of risk mitigation measures, including the ranking of possible mitigation measures that may be applied.

The multiple use risk assessment process is a work in progress. Work to date has included development of a framework and a standard method for risk assessment, building on AS/NZS 4360:2004 and the collection and publication of information on the identification of ecosystem components and the identification of ecological threats. The proposed framework and method is currently being trialled in the Otways area. The Plan explains that further work is needed to develop detailed methods for social and economic risk assessment, and to incorporate these into a full assessment of the risks to the marine environment, industries, and human communities in the area. When completed, the methods will be applied across the whole of the south-east region.

Approach to Consequence Assessment

The method for multiple use risk assessment to be trialled and applied within the South-East Marine Plan remains under development. In particular, work is needed to develop detailed methods for social and economic risk assessment and to incorporate these into a full assessment of the risks to the marine environment, industries, and human communities.

8 REVIEW: DEPARTMENT OF HEALTH AND AGING

8.1 Overview

DHA is large and multifaceted, with a complex arrangement of divisions, Government agencies (and their subsidiaries) and portfolio agencies. These are outlined below.

Divisions:

- Acute Care Division;
- Ageing and Aged Care Division;
- Audit and Fraud Control;
- Business Group;
- Health Services Improvement Division;
- Medical and Pharmaceutical Services Division;
- Office for Aboriginal and Torres Strait Islander Health;
- Primary Care Division;
- Population Health Division; and
- Portfolio Strategies Division.

Government agencies:

- CRS Australia;
- TGA; and
- National Health and Medical Research Council.

TGA structure:

- Adverse Drug Reactions Unit;
- Drug Safety and Evaluation Branch;
- Non-prescription Medicines Branch;
- Office of Chemical Safety;
- Office of Devices, Blood and Tissues;
- OGTR;
- TGA Laboratories;
- Trans-Tasman and Business Management Group; and
- Adverse Drug Reactions Unit.

DHA pursues the achievement of the portfolio outcomes in association with a number of other agencies in the portfolio. These agencies are:

- Aged Care Standards and Accreditation Agency Ltd;
- Australian Institute of Health and Welfare;
- Australian Radiation Protection and Nuclear Safety Agency;
- Food Standards Australia New Zealand (FSANZ);
- General Practice Education and Training Limited;
- Health Insurance Commission;
- National Blood Authority;
- Private Health Insurance Administration Council;
- Private Health Insurance Ombudsman; and
- Professional Services Review.

A preliminary analysis of internet and published material showed that of these divisions and agencies, TGA (and its subsidiary, OGTR) and FSANZ carry out risk analysis or consequence assessment as a part of their core business, and have developed methods or procedures relevant to the review. These divisions and agencies were subsequently examined in depth.

8.2 Food Standards Australia New Zealand

Introduction

FSANZ, until recently known as Australia New Zealand Food Authority (ANZFA), and formerly the National Food Authority (NFA), is a bi-national statutory authority operating under the Food Standards Australia New Zealand Act 1991.[20]

The Act provides a focus for cooperation between Governments, industry and the community to establish and maintain uniform food regulation in Australia and New Zealand. Australian food standards are harmonised as a result of an Inter-Government Agreement between the Commonwealth and the States and Territories. Under this agreement, the States and Territories adopt, without variation, food standards that have been approved by the Australia New Zealand Food Standards Council (ANZFSC) which is the Ministerial Council representing all jurisdictions, including New Zealand. FSANZ has offices in Canberra and Wellington, New Zealand.

The Act describes the consultative process that is followed when an application is made for a change in the Australia New Zealand Food Standards Code (the Code). Under this arrangement, FSANZ develops and approves standards, and variations to standards, then notifies the Ministerial Council for approval. The Ministerial Council may reject,

[20] Available at: http://scaleplus.law.gov.au/html/pasteact/0/31/top.htm

amend or seek a review of any standard notified to it by FSANZ. The Ministerial Council bases its decisions on advice from the Food Regulation Standing Committee, which comprises senior Government officials from the Commonwealth, New Zealand, the States and the Territories. The Ministerial Council also consults with stakeholders on the development of policy guidelines. FSANZ is an observer at the Ministerial Council meetings.

The responsibilities of FSANZ include:

– Development standards for food manufacturing, labelling, processing and primary production;
– Provision of information to consumers to enable better consumer choice;
– Coordination of national food surveillance, enforcement and food recall;
– Conduct of consumer and industry research;
– Undertaking dietary exposure modelling and scientific risk assessments; and
– Provision of risk assessment advice on imported food.

Summary

FSANZ is one of the agencies covered in this review whose functions and procedures are governed by an act of legislation. The Food Standards Australia New Zealand Act 1991 is explicit about the focus of the agency and its use of risk assessment as the means by which it establishes the severity of hazards in foods. FSANZ has produced quite detailed guidelines explaining its terminology for risk assessment and risk management, and the steps that each of these two procedures will entail. FSANZ divides risk assessment and risk management both in procedural terms, and with regard to the structure of the organisation and the tasks assigned its various branches and teams.

Although FSANZ does not use the term ‘consequence assessment’, it does assess the severity of hazards. This incorporates consideration of the extent of likely exposure of individuals, or particular groups of individuals, and the relationship between exposure and the likely extent of harm. FSANZ also handles chemical, microbiological and nutrient hazards differently, recognising that the relationship between exposure and the likely severity of harm differs markedly for each group.

In characterising hazards, and in assessing the likely severity of harm, FSANZ uses some categorical classification schemes and some less prescriptive forms of qualitative assessment. FSANZ acknowledges that lack of good quantitative data, and variance in the likely harm associated with particular hazards or foods, generally preclude the use of detailed economic analysis for the ‘consequence assessment’ component of a risk assessment. That said, FSANZ does in some cases use risk-benefit analysis or cost-benefit analysis to inform a decision about risk management strategies or approaches.

Finally, and not discussed in the FSANZ Framework, is the difficulty that might be associated with estimating quantitatively some of the less tangible effects of food-borne hazards on the health of individuals. These include, in particular, the ‘cost’ of pain or suffering or any other aspect of the quality of an individual’s life, or the ‘cost’ of a potentially shortened lifespan. In many cases, such effects would be directly relevant to the extent of harm associated with a hazard. Thus the question that could be asked in this instance is, “Would an attempt to quantify the less tangible effects of a hazard make more precise, or otherwise improve, the assessment of risk or the benefit-cost assessment of risk management?” Given the paucity of solid data to support other parts of each risk assessment, and the difficulty associated with obtaining surrogates for intangible effects and communicating quantitative analyses based on such surrogates, it is unlikely that an attempt to quantify intangibles would be successful.

It is difficult to identify a particular part of Biosecurity Australia’s approach to consequence assessment that might benefit immediately from the FSANZ methods. This partly because it specifically addresses human health, which is not one of Biosecurity Australia’s direct concerns, and partly because, whilst transparent and functional, it does not include novel techniques or approaches.

Risk Management Context

FSANZ carries out its core business within the requirements of the Food Standards Australia New Zealand Act 1991, and in compliance with Australia’s international obligations as a WTO member country.

The Food Standards Australia New Zealand Act 1991 sets out in Part III the rigorous process of consultation and analysis that must be followed in developing standards. This statutory process involves a minimum of two periods of public comment and publication of two comprehensive reports containing relevant material, analysis and consideration of the public submissions. At any stage in this process, FSANZ may release supplementary discussion papers, hold public forums, undertake stakeholder workshops, consult with expert panels, set up stakeholder working groups, seek peer review, or, following a first full assessment, may release a revised full assessment report. These additional processes serve to strengthen and improve the decision making processes and are particularly useful where the issue under consideration is contentious or technically complex.

When FSANZ develops a standard it must apply the objectives set out in section 10 of the Act. These are (in descending order of priority):

- The protection of public health and safety;
- The provision of adequate information relating to food to enable consumers to make informed choices; and
- The prevention of misleading or deceptive conduct.

Subsection 10(2) also requires that, in developing standards, FSANZ must also have regard to:

- 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; and
- The promotion of fair trading in food.

These objectives are consistent with the objectives set down in the Treaty between Australia and New Zealand for joint food standards and with the objectives of Codex for international food standards (Section 4.4). Each of these objectives and ancillary matters are considered and elaborated in FSANZ full assessment and inquiry reports.

FSANZ is also bound, on behalf of Australia and New Zealand, to uphold the requirements of the WTO Multilateral Trade Agreements.

The WTO SPS Agreement requires that members ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence. In the assessment of risks, members must take into account available scientific evidence, relevant economic factors and attempt to minimise negative trade effects.

In order to harmonise sanitary and phytosanitary measures, members must base their measures on international standards. In the case of food standards, international standards are determined through the mechanisms of Codex. Members can only depart from these standards where there are evidence-based reasons for doing so, and still must adopt the least trade restrictive measure. That said, because Codex proceeds by consensus among its 160 members, it is slow in developing and reviewing its standards, and many are out of date or inconsistent with contemporary scientific knowledge or community expectations. Therefore many countries, including Australia and New Zealand, have many standards that depart from Codex standards, but this only occurs where there is sound scientific evidence supporting the need to do so.

The TBT Agreement requires members to ensure that technical regulations are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade. This Agreement also requires application of international standards where these exist except where they would be inappropriate.

The Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) requires members to respect the intellectual property rights of other members. It has been of particular relevance to the work of FSANZ in relation to the development of standards regulating geographical indications.

Because both Australia and New Zealand are significant exporters of food and food products, both are vulnerable to retaliatory action in the event that international obligations are not upheld. FSANZ gives full consideration to these issues in considering regulatory options and also provides an opportunity for comments from other countries on proposed standards through the WTO notification process, when appropriate. These matters are discussed in its full assessment and inquiry reports.

Risk Management Framework

FSANZ has described its risk management practices in a public document, Framework for the Assessment and Management of Food-related Health Risks (the FSANZ Framework).[21] The concepts and procedures described in this document are broadly consistent with those of other

[21] Available at: http://www.foodstandards.gov.au/_srcfiles/Health-related%20Risks%20Framework%20Sept%2003.pdf.

regulatory agencies, and with principles established by Codex under the Joint Food and Agriculture Organisation of the United Nations (FAO) / World Health Organisation (WHO) Food Standards Programme and by the International Programme on Chemical Safety in cooperation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The FSANZ Framework also places the procedures of the organisation within the broader regulatory framework which operates in Australia and New Zealand to protect public health and safety in relation to food.

Within the FSANZ Framework it is explained that risk is considered to be “the probability of an undesirable outcome from a particular event”. In relation to food, this is usually interpreted as the probability of an adverse health outcome, which may occur either immediately or over the long term. It is also pointed out, however, that the concept of ‘risk’ has many dimensions, and that the probability of adverse health effects is just one of these. Other dimensions include psychological, social, ethical and economic factors, all of which contribute to the perception of risk by an individual or community. Risk assessment, as performed at FSANZ, involves the scientific assessment of health risks and is performed independently of these other dimensions of risk, although they may contribute to subsequent risk management decisions. These other dimensions of risk are not explored in detail in the FSANZ Framework.

Under the FSANZ approach, the analysis of risk is divided into two distinct parts: risk assessment and risk management. Risk assessment is the process of using available information to identify, characterise and quantify the adverse health effects of exposure to a biological, chemical or physical agent; whilst risk management is the process of integrating risk assessment results with social and economic goals and, after considering policy options, identifying a strategy to control the risks.

Risk assessment is carried out in four discrete steps – hazard identification, hazard characterisation, exposure evaluation and risk characterisation.

For chemicals, hazard identification establishes the toxicity of a substance (or the adverse effect it can cause) and may identify the inherent properties which make it capable of causing an adverse effect. When there has been no prior use in food, this is established through a consideration of:

– The structure and associated physiochemical properties;
– The metabolism and toxicokinetics of the substance; and
– The results of a series of toxicity tests conducted both in animal models or in in-vitro systems.

For microbiological agents, hazard identification consists of identifying the micro-organisms or microbial toxins of concern. The International Commission of Microbiological Specifications for Food (ICMSF) has categorised the most serious and common of the microbiological hazards according to the severity of the hazard they present. Data for classifying microbial hazards may come from animal studies, but more commonly from controlled human studies, epidemiological studies, or studies on outbreaks of food-borne diseases.

The second step in risk assessment is hazard characterisation, the qualitative or quantitative evaluation of the nature of the adverse effects associated with an agent which may be present in food.

For chemicals, hazard characterisation involves a consideration of the results obtained in the hazard identification phase in relation to the dose levels used. The outcomes should be:

– Identification of the major toxicological endpoints and the dose levels at which they occur;
– If there is a threshold, an estimate of the dose level below which the observed toxicity does not occur;
– Some understanding of the metabolism and kinetics of the substance in a mammalian system; and
– In some cases, information on the mechanism of the chemical in causing the observed toxicity.

A qualitative evaluation may be necessary when there is a paucity of data.

For microbiological agents, hazard characterisation involves a quantitative or qualitative evaluation of the nature of the agent, and the influence of the food vehicle, processing and host factors on its ability to cause food poisoning in particular circumstances. It may also include an estimate of the infective dose for a particular food vehicle taking into account at-risk groups such as the young, the elderly, and the immuno-compromised.

The third step in risk assessment is exposure evaluation, or evaluation of the magnitude and duration of actual or anticipated human exposure to an agent that may be present in food, and the number of persons affected.

For chemicals, exposure evaluation involves estimating the level of human intake of a particular substance from individual foods, the whole diet and, where applicable, other sources. When the exposure evaluation is based on estimated or anticipated exposure, the process is sometimes referred to as dietary modelling. Where survey data are available, more accurate exposure evaluations for specified population groups can be made. In general, exposure estimates are based on known or anticipated dietary information for particular foods together with an estimate of the level of the chemical in particular commodities. In some cases, if may be possible to determine the systemic levels of exposure based on gastrointestinal absorption or on direct measurement of blood or urine levels.

For microbiological agents, exposure evaluation is based firstly on the potential extent of food contamination by a particular agent, and secondly on dietary information to indicate the potential 'at risk' population. The potential for contamination is influenced by the effects of food preparation or processing and the potential for proliferation in a particular food. Identification of the 'at risk' group may depend on cultural as well as dietary considerations.

For nutrients, dietary information together with food composition data are used to estimate potential levels of nutrient intake. The systemic level of an individual nutrient does not always bear a direct relationship to dietary intake, due to interaction with other nutrients or absorption factors, and it is often desirable to measure nutrient levels in the blood or other tissues.

The final step in risk assessment is the characterisation of risk. This is the process of estimating the probable incidence of risk events associated with an agent which may be present in food for a given population, including a description of the uncertainties involved. Risk characterisation brings together information gained from previous steps and provides a practical estimate of risk for a given population. Risk management strategy is then formulated on the basis of this determination. The degree of confidence in the final estimation of risk depends on the uncertainty factors identified in previous steps.

Acceptance of a degree of uncertainty is fundamental to an estimation of risk. The basis of this uncertainty is two-fold. Firstly, there is uncertainty about the quantity and quality of the information upon which the estimate is made. Secondly, there is uncertainty about the validity of the assumptions upon which the estimation of risk is made, such as species extrapolation, dietary modelling or the degree of heterogeneity in the population. Together, these determine the degree of uncertainty of a particular risk estimation. The various sources of uncertainty in risk assessment are considered later.

For chemicals, risk characterisation might be expressed as a margin of safety between the acceptable level of intake of an additive or contaminant, based on the known hazard, and the known level of human exposure via the diet. When no threshold is evident, a more qualitative estimate of risk is necessary. For microbial agents, risk characterisation is usually a qualitative description of the circumstances under which a food may be contaminated at a level which would potentially pose a risk to human health. It may include reference to a sampling plan which should conform to the microbiological limits. For nutritional factors, risk characterisation may be a statement of the potential effect of modifying part of the diet on the overall nutritional status of a population or sub-population.

Approach to Consequence Assessment

The FSANZ Framework explains that whilst the majority of the public health and safety risks associated with foods arise from the direct effects of either microbiological or chemical hazards, indirect effects, such as alterations in the availability and balance of nutrients, should also be considered. It also explains that nutritional risks are less easily defined because less is known about those nutritional factors that adversely affect health. Poor nutrition also enhances the known risks associated with particular microbiological or chemical hazards.

In assessing the possible direct or indirect of hazards, the FSANZ Framework draws heavily on an evaluation of the likely extent to which individuals might be exposed. This evaluation includes individuals in a state of good health, as well as individuals considered to be more vulnerable. The exposure evaluation rests on a range of data sources, including periodic Australian Total Diet Surveys conducted by the Australian Bureau of Statistics and the Apparent Consumption of Foodstuffs surveys carried out by ABARE. In some cases, surveys are carried out by or on behalf of FSANZ to examine the exposure of the Australian population, or vulnerable sections of it, to particular hazards.

The general steps and principles for risk assessment are adapted to some extent to fit more closely with the characteristics of chemical hazards, microbiological hazards and nutritional hazards. In this context, adaptation is based largely on issues relevant to the exposure of individuals and to the likely outcome of exposure. Of particular importance are the different ways in which 'thresholds' relating to the amount of exposure required to elicit a harmful effect are estimated and reported for the three broad groups of hazards.

The concept of dose-response, for example, is fundamental to establishing the safety or otherwise of chemicals in food. In his context, chemicals include food ingredients, food additives or food contaminants. Dose-response relationships can be established in some cases by way of animal or human trials, which give rise to a 'no observed effect level (NOEL). This measure is given a 'safety factor' (generally 1,000 to 2,000), which provides some indication of the uncertainty surrounding its estimation. The acceptable daily intake (ADI) for the given chemical hazard can then be obtained by dividing the NOEL by the safety factor. By correlating the ADI with the amount of the chemical likely to be consumed by various categories of individuals during a day, FSANZ can obtain a measure of the likely consequences of permitting the unrestricted or unmanaged sale of the product.

The likely consequences associated with microbial hazards, on the other hand, depend on the way in which harmful effects are realised and the 'minimum infective (or intoxication) dose' (MID). In general terms, there are three ways whereby pathogenic micro-organisms cause disease:

- Ingestion of a toxin which is present in the food as a result of microbial growth (for example, Staphylococcus aureus [enterotoxin], Bacillus cereus [emetic toxin]);
- Formation of a toxin within the intestinal tract after ingestion of the organism (for example, Clostridium perfringens [enterotoxin]); or
- Infection of an organism, followed by widespread systemic effects (for example, Listeria monocytogenes and many of the enteric viruses).

With consideration to these three general modes for causing harm, the International Commission on Microbiological Specifications for Foods (ICMSF) has grouped the most common and serious of these microbiological hazards into three categories according to the severity of hazard or seriousness of disease they may cause. These categories include 'severe hazards'; 'moderate hazards, potentially extensive spread'; and 'moderate hazards, limited spread'. Foods may also be assigned categories of severity based upon the likelihood that the foodstuff will or will not be infected from source; whether or not it is able to support the growth of the pathogen concerned; whether there is substantial potential for abusive handling of the food; or whether the food will be subject to a terminal heat process after packaging or before consumption. The presence and growth of micro-organisms in food is limited by the storage environment, including the temperature of storage, the relative humidity of the environment and the gaseous composition of the atmosphere, as well as a number of parameters inherent to the foodstuff. These include pH, moisture content, nutrient content and presence of antimicrobial substances.

Notwithstanding these general classification schemes, detailed analysis of the severity of a microbiological hazard is hampered in most cases by a lack of information about MID, by know variance in the MID for different individuals or by variance in the effect of processing, handling or preparing foods on the amount of infective or toxic material that might be consumed by an individual.

Nutrients, the third group of hazards, have generally been regarded as different from chemicals and the methods based on maximum safe limits are not generally applied. This is because most nutrients have both a deficient level of intake and an upper acceptable level of intake, with a continuum in between that may vary distinctly amongst individuals in different physiologic states. Also important are interactions amongst nutrients, such that an 'optimal' level of intake of one may depend on the level of intake of anther.

Accepting these constraints, recommended daily intakes (RDI) for nutrients have been developed to assess the adequacy of the total diet of groups in the population. Dietary modelling techniques are used to compare estimated nutrient intakes determined from food consumption and composition data with the RDIs. Nutrient RDIs have been set by firstly establishing the mean nutrient requirement for a group of healthy people, and then applying a safety margin, often two standard deviations above this mean. RDIs are defined by gender, age and physiological status (for example, pregnancy) and are expected to meet the needs of nearly all healthy people in a group. The minimum intake (usually the mean requirement minus two standard deviations) is the intake below which nearly all people will be unable to maintain metabolic integrity according to the adequacy criterion chosen.

A single value RDI can be misinterpreted as the mean requirement or as the lowest acceptable intake. It can also be misused by being applied to individuals, to only part of the diet, or to individual foods. It is now common to set a 'safe range' of intakes as reference values for each nutrient, based on an assessment of the range of the individual requirements for each nutrient.

The impact of nutrient deficiency on public health is generally cumulative and long term. There have been no internationally accepted methods of determining upper safe levels for nutrients, although several have been suggested. There is currently debate as to whether RDIs should be revised upwards to provide optimum benefits rather than be based on levels which prevent deficiencies. Harmful effects may occur at high exposure levels for minerals, trace elements and fat soluble vitamins. For some minerals and trace elements, the differences between adequate and harmful levels of intake are small, so that both upper as well as lower limits of intake must be established. For some vitamins e.g. vitamin A, harmful effects may be observed in the short term and long term.

The FSANZ Framework acknowledges that regardless of whether an assessment is in reference to a chemical, microbiological or nutrient hazard, quantification or economic analysis is generally 'very difficult'. It is pointed out that difficulty arises largely from a lack of quantitative data about the specific effects of hazards. In some cases there is also a lack of data about the extent of likely exposure of individuals, and the period over which harmful effects might be observed. Variance in the effects of hazards is also acknowledged. Notwithstanding this, FSANZ is developing ways in which risk-benefit analysis and cost-benefit analysis can be used to inform decisions about alternative risk management strategies. In this context, a deficiency in data to support some parts of the assessment may be less problematic as the analyst will generally be interested in the relative or comparative efficiency of different strategies.

8.3 Therapeutic Goods Administration

Introduction

TGA is a unit of DHA. TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

TGA, on behalf of DHA, has responsibility for administering the Therapeutic Goods Act 1989 (the TG Act). The objective of the TG Act is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices.

Under this arrangement, therapeutic goods must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. The ARTG is a computer database of information about therapeutic goods for human use approved for supply in, or exported from, Australia. The TG Act 1989 Regulations and Orders set out the requirements for inclusion of therapeutic goods in the ARTG, including advertising, labelling, product appearance and appeal guidelines. Some provisions such as the scheduling of substances and the safe storage of therapeutic goods, are covered by the relevant State or Territory legislation.

Summary

TGA is similar to FSANZ (Section 8.2) in that its functions and procedures are legislated under a dedicated act and regulations. Within this framework, TGA uses a risk management approach to regulate the licensing of medicines, of the manufacture of medicines, of medical devices and of blood and tissues. This approach is based explicitly on the Australian and New Zealand standard for risk management, AS/NZS 4360, and follows precisely the steps, terms and definitions laid down in the standard.

TGA carries out a different form of risk assessment for the regulation of different classes of therapeutic goods. Amongst these, registrable medicines receive the most detailed and conventional risk assessment. This assessment framework is in fact replicated for chemical hazards, quality control and laboratory hazards, pharmacological and toxicological hazards and hazards apparent from clinical trials or epidemiological investigations. The consequence assessment component of each sub-assessment includes qualitative and quantitative information about the likely severity of hazards, but does not seek to provide a quantitative estimate of consequences *per se*. This applies both to tangible and intangible effects.

There is a major difference between TGA's framework and that used by Biosecurity Australia and most of the other agencies included in this review: TGA explicitly considers the 'benefits' component of risk management, and the risk management exercises carried out by TGA for manufacturing, and for each category of therapeutic good, include consideration of the likely benefits of licensing. This is important, as most therapeutic goods have negative effects, and a decision to register or not must consider these in the context of the potential for such goods to treat or prevent medical disorders. Although comparing benefits and costs is standard practice in some areas of risk management, much of that which is carried out in the context of regulatory decision making concentrates on assessing and managing the 'costs' of a decision, with the assumption being that such costs when managed are not greater than the community considers to be acceptable.

As was the case for FSANZ, it is difficult to identify a particular part of Biosecurity Australia's approach to consequence assessment that might benefit immediately from the TGA methods or approach to consequence assessment. Again, this is due in part to the focus on matters of human health, and in part to the fact that, whilst transparent and functional, the TGA method does not include novel techniques or approaches.

Risk Management Context

TGA adopts a risk management approach to regulating registration of therapeutic goods. In essence, this means that the TGA:

– Identifies, assesses and evaluates the risks posed by therapeutic goods;
– Applies any measures necessary for treating the risks posed; and
– Monitors and reviews the risks over time.

The TGA has detailed the approach that it follows in the management of risks associated with the registration of therapeutic goods in a public document, The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods (henceforth the TGA Approach).[22]

The TGA Approach explains that the TGA operates in an environment where there are clear expectations about the quality, safety, efficacy and availability of therapeutic goods supplied in Australia. There is a range of potential risks associated with the supply and use of therapeutic goods that may impact on these expectations. Examples include:

– The product itself – for example, ingredients in the product, dosage form of the product, strength of a product, side effects, toxicity, potential harm through prolonged use;
– The way that the product is manufactured – for example, poor manufacturing processes can mean that the product does not contain the ingredients that it should, contains contaminants etc;
– The way the product is prescribed by a medical practitioner – for example, if a doctor has insufficient information about the product or the patient or if the doctor misinterprets the patient's symptoms or the circumstances under which the product should or shouldn't be prescribed; and
– The way the product is used by the patient – for example, if information for use is not sufficient (labelling), if the patient does not sufficiently understand how to use the product or if the patient inappropriately self-diagnoses and mistreats.

All participants in the development and delivery of therapeutic goods have a role to play in maintaining a benefit-risk balance by making sure that products are developed, tested, manufactured, labelled, prescribed, dispensed and used in a way that maximises benefit and minimises risk, when used as intended. Risk assessment and management occurs at each of these levels and by all participants in the system:

– Sponsors of therapeutic goods, identify and evaluate risks (including through animal studies and clinical trials and in vitro work) before approaching the TGA for clearance to market products;
– Manufacturers of therapeutic goods build quality assurance mechanisms into the manufacturing processes and test every batch of product to ensure that it meets the quality standards determined by the TGA – these manufacturing processes are subject to TGA approval and audit;
– TGA evaluates the risks of individual therapeutic goods and the ingredients used in them, for the population they are intended for;
– The healthcare provider evaluates risks for the individual patient; and
– The consumer evaluates risks in terms of their personal values, based on information provided about the product.

Crucial to understanding the risk assessment and management approach adopted by the TGA is understanding this broader context in which the TGA operates. The TGA plays a role in the

[22] Available at: http://www.tga.gov.au/about/tgariskmnt.pdf.

management of risks associated with therapeutic goods by:

- Identifying, analysing and evaluating the risks posed by a product before it can be approved for supply in Australia (pre-market product assessment or evaluation);
- Identifying, analysing and evaluating the risks posed by manufacturing processes before a manufacturer is issued with a licence to manufacture therapeutic goods (licensing of manufacturers); and
- Identifying, analysing and evaluating any risks that may arise following approval of the product and licensing of the manufacturer (post market surveillance).

This broad risk management framework is established in the therapeutic goods legislation which sets out the TGA's legislated responsibilities. Different areas within the agency are responsible for different aspects of the overall risk management strategy. These areas develop risk management strategies, consistent with the overall risk management approach described in the legislation, to guide their work.

Risk Management Framework

The framework for risk management outlined in the TGA Approach rests explicitly on the Australian New Zealand Standard for Risk Management, AS/NZS 4360. Accordingly, the TGA Approach explains that the process of risk management generally follows seven steps:

1. Establishing the context – for example, defining the relationship between the organisation and its environment, understanding the organisation's capabilities and identifying the internal and external stakeholders of the organisation.
2. Risk Identification – identifying the risks that need to be managed.
3. Risk Analysis – separation of minor acceptable risks from the major risks and providing data to assist in the evaluation and treatment of risks. Risk analysis involves consideration of the sources of risk, their consequences and the likelihood that those consequences may occur.
4. Risk Evaluation – comparing the level of risk found during the analysis process with previously established risk criteria.
5. Risk Treatment – identifying the range of options for treating risk, assessing those options, preparing risk treatment plans and implementing them.
6. Monitoring and Review – monitoring risks, the effectiveness of the risk treatment plan, strategies and the management system which is set up to control implementation. Risks and the effectiveness of control measures need to be monitored to ensure changing circumstances do not alter priorities.
7. Communication and Consultation – an integral part of all aspects of the risk management process.

Approach to Consequence Assessment

The TGA adopts a slightly different approach to risk assessment, and, thus, consequence assessment, when addressing the licensing of medicines (listed and registrable), the manufacture of medicines, medical devices and blood and tissues.

Medicines are first classified as listed or registrable, based on the following risk evaluation criteria:

- The ingredients, including whether the medicine contains a substance scheduled in the Standard for the Uniform Scheduling of Drugs and Poisons;
- The dosage and dosage form of the product;
- The promotional or therapeutic claims made for the product;
- Whether the medicines use can result in significant side effects;
- Whether the medicine is used to treat life-threatening or very serious illness; and
- Whether there are any adverse effects from prolonged use or inappropriate self-medication.

All medicines classified as registrable must undergo a detailed pre-market risk assessment. This assessment is divided amongst experts within and outside the TGA, so as to encompass separate sub-assessments for chemical hazards, quality control and laboratory hazards, pharmacological and toxicological hazards and hazards apparent from clinical trials or epidemiological investigations. The assessments are based on available data, but are qualitative constructs aimed at determining whether a medicine is safe with regard to each of these groups of potential hazards. In particular, no attempt is made to quantify the magnitude of possible harm that might be associated with the medicine; whether in relation to the medicine's tangible and in some sense quantifiable effects, or its less tangible effects on quality or duration of life.

Risk evaluation considers both the likelihood and consequences of identified risks, as well as the benefits attributed to the medicine. It is important that risk management in this context is about risk-benefit, as few medicines are completely free from potential hazards and yet most have measurable benefit to the treatment or prevention of human illness. Risk treatment is also noteworthy as the range of possible treatment options is legislated within the TG Act and Regulations.

By contrast, listed medicines are considered by definition to be of low risk and are not subject to the detailed process of risk assessment and evaluation.

Risk assessment and evaluation for the manufacture of medicines is based largely on a process of quality control and audit, and is less relevant to this review.

Risk assessment for medical devices is interesting, as it employ a qualitative classification system to determine the risk posed by different kinds of medical devices. Categories include, Class I, Class IIa, Class IIb and Active Implantable Medical Devices. The criteria employed in assigning a medical device to one of these categories are:

- Manufacturer's intended use;
- Degree of invasiveness in the human body;
- Location of use;
- Duration of use; and
- Use in conjunction with a power supply.

Each criterion has established thresholds. As thresholds are exceeded a higher class is assigned. An assessment is made to ensure that the design, manufacture and performance of the device conforms with the essential principles of safety and performance, ensuring that any risks of using the product are outweighed by the benefits gained. As was the case for registrable medicines, the risk assessment for medical devices considers all available quantitative and qualitative data, but does not seek to provide a quantitative estimate of the consequences associated with any identified hazards. The assessment also considers a range of manufacturing, quality control and audit issues.

Risk assessment for blood is multifaceted as some blood plasma derivatives are considered medicines, and some blood or blood components are exempt from TGA oversight under the TG Act and Regulations. The regulation of the use of whole organs and tissues is also complex, and is not subject to routine detailed risk assessment under the TG Act and Regulations.

8.4 Office of the Gene Technology Regulator

Introduction

In 2001, the legislative scheme for the regulation of genetically-modified organisms (GMOs) in Australia[23] commenced with the Gene Technology Act 2000 (the Act) and the Gene Technology Regulations 2001 (the Regulations). This also established the basis for corresponding State laws. Of specific relevance to this review is Section 3 of the Act, which states its objective to be:

> *to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.*

The Act establishes an independent statutory office holder – the Gene Technology Regulator (the Regulator) – who is charged with making decisions about the use of GMOs in accordance with the legislation.

The implementation of the regulatory system is overseen by the Gene Technology Ministerial Council (GTMC) comprising representatives from all Australian jurisdictions. The Act establishes three committees to give advice to the Regulator on matters relating to gene technology. These are the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).

The Act is a prohibitory scheme that prevents all dealings with GMOs unless they are expressly allowed. Dealings are allowed if they meet specific criteria (schedules 1 and 2 of the Regulations) or if a licence is granted by the Regulator. Under this terminology, a 'dealing' may either involve intentional release (DIR) or may not involve intentional release (DNIR).

Summary

OGTR legislation describes the context and process for the analysis of risks associated with GMOs, and exhaustive documentation of the method that is used. Risk analysis comprises risk assessment, risk management and risk communication. Risk assessment, in turn, comprises hazard identification, the assessment of likelihood and consequences and the estimation of risk. Although

[23] Available at: http://www.ogtr.gov.au/pubform/legislation.htm

there are some differences in terms and definition, the structure and components correspond to those described in the Australian and New Zealand Standard for risk management, AS/NZS 4360.

One of the interesting elements of the risk analysis framework, as described in the OGTR Risk Analysis Framework,[24] is the specification of a risk estimation matrix. This matrix explains how the likelihood and consequences components are combined to give a risk estimate. The matrix rests on standardised terms and descriptions for likelihood, consequences and risk, and illustrates how the risk estimate can be interpreted in terms of a baseline level of acceptable risk. OGTR explains that the matrix is designed to be used as a tool in arriving at the risk estimate; that is, it is not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome or on the necessity for management conditions to be imposed.

Whilst the OGTR Risk Analysis Framework provides additional detail about the identification of hazards and the evaluation of likelihood, this review has focussed on consequences and reported only on that part of the Framework. Consequences are assessed by OGTR in several ways, each of which provides a different form or depth of insight.

- The 'adverse outcomes' of an intentional or unintentional release of a GMO are examined, and the extent of such outcomes is assessed against 'measurable properties' (Table 5). This exercise is valuable, as it identifies the different ways that a GMO might directly impact on humans or the environment.
- The second perspective on consequences is the need to consider the different 'levels' of impact; where these might range from impacts on individuals to impacts on populations or ecosystems. This part of the exercise is also valuable, as enables OGTR to determine whether release of the GMO under consideration is likely to have the substantive 'flow-on' indirect impacts that typically arise from broader scale effects.
- The third form of assessment is classification of the 'significance' of the impact. This is more complex, but seeks to combine information obtained from the first two steps to categorise the impact of the GMO according to one of the four descriptors on the risk estimation matrix. To do this, five separate criteria are used. Collectively, these criteria cover the severity, spatial extent, temporal extent, cumulative effect and reversibility of impact; in other words, the likely scale of the problem.

The OGTR Risk Analysis Framework makes a point of explaining the role and indications for qualitative (versus quantitative) likelihood evaluation, and, whilst not explicitly stated, the same principles are likely to apply to their consequence assessment. This assessment, whilst qualitative, will make use of any quantitative data that might be available to inform estimates of direct or indirect impacts. Given this, one element that is not described is the rationale or logic required to combine the components of the consequence assessment and obtain a single qualitative score for use in the risk estimation matrix. This omission is likely to be deliberate, and to reflect the principle that steps, lists and tabulated considerations within a qualitative consequence assessment are only guidelines. Each part may be used *in toto*, or may be added to or subtracted from as relevant to each individual assessment.

OGTR's qualitative categorical system for assessing and evaluating risk might augment Biosecurity Australia's experiences with a similar system, within a similarly adversarial operating environment. Biosecurity Australia and the Centre of Excellence should consider dialogue with OGTR with a view to discussing the practicability of adapting its approach to import risk analyses.

Risk Management Context

The risk management context includes, in this case, the scope and boundaries of the risk analysis as determined by the Act, the Regulations and OGTR's approach to their implementation, the proposed 'dealings' (that is, whether or not the proposal is for intentional release of the modified organism) and the nature of the genetic modification.

Under his arrangement, the Act specifies that all licensed dealings require case-by-case assessment by the Regulator and the preparation of a Risk Assessment and Risk Management Plan (RARMP). The RARMP must take account of any risks to human health and safety and the environment posed by the dealing and address how these risks can be managed. The RARMP documents and communicates the Regulator's assessment of risks arising from the dealing and the management strategies that have been identified to ensure the risks are controlled.

[24] Available at:
http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf

OGTR can only consider risks posed by or as a result of gene technology. Therefore risks posed by a particular GMO need to be considered in the context of the risks posed by the unmodified parental organism in the receiving environment. For dealings involving intentional release this may be considered by examining whether the GMO would cause an adverse outcome over and above that which would occur if the status quo were maintained; that is, if the GMO was not deployed in the environment. For dealings not involving intentional release the containment facilities prevent exposure to the environment although the potential for unintentional release must be considered.

In order to establish a comparison between the properties and characteristics of the GMO and those of the unmodified organism, an appropriate baseline is needed. For example, many crop plants are elite cultivars and the cultivar that the GM crop plant was derived from would usually provide the appropriate comparator. Such a plant will have a similar genetic background to the GM plant with the exception of the GM trait. It should be noted that conventional breeding can result in changes in the genetic background of cultivars.

In the context of contained dealings, the parent organism itself can be pathogenic and the risks arising as a result of the genetic modification need to be considered against that baseline.

The environment in which the GMO is deployed is also relevant for intentional releases and it is important that an appropriate receiving environment is used as a baseline for comparison. For example, many of the GM plants approved for release to date are designed to function in an agricultural context that employs current growing and management practices. Standards such as Good Agricultural Practice may provide a benchmark for acceptable practices although it must be recognised that such practices may evolve and change over time.

An example where agricultural practice has changed as a result of deployment of GMOs is in the use of insecticidal cotton. At the time of initial release of GM insecticidal cotton, normal agricultural practice necessitated a heavy chemical regime. Initially a 60/30 distribution was mandated between non-GM and GM cotton. This ratio altered significantly with the approved uptake of new GM varieties, so the most appropriate baseline environment for comparison may change.

Where the conventional variety is the most widely grown cultivar it is relatively easy to establish the appropriate baseline for comparison. However, in some instances it may be that multiple baselines for comparison are necessary. This is increasingly likely with the deployment of new cultivars, both GM and non-GM. For instance, in the case of canola the existence of two herbicide tolerant varieties bred by conventional means that are widely grown across Australia had to be considered in assessing applications for the commercial release of herbicide tolerant GM varieties.

The receiving environment also may not be static over time and such change will be considered in the assessment. For instance, changes in agricultural practices in relation to cropping or chemical use patterns may affect the environment in which the GMO is to be deployed. There are several considerations that have some bearing in this context including: the dynamic nature of ecosystems; the process of natural succession in the evolution of ecosystems; and the inherent resilience of ecosystems because of their ability to accommodate change. Such factors are important in assessing the consequence component of risk estimation. In the first instance the appropriate time frame will be the proposed length of the application. This does not exclude the consideration of long term effects.

The Act requires a case by case assessment of applications for intentional environmental release and the selection of appropriate baselines will form part of that process.

Risk Management Framework

The approach the OGTR adopts in carrying out risk analysis under the Act and Regulations is described in its Risk Analysis Framework document. The stated purpose of the Risk Analysis Framework is to:

- Provide a guide to the rationale and approach to risk analysis used by the Regulator;
- Enable the application of a consistent risk analysis approach to evaluating licence applications;
- Provide a clear guide to the provisions of the legislation that relate to risk assessment and risk management; and
- Ensure that the risk analysis and decision-making processes are transparent to both applicants and the broader community.

The Risk Analysis Framework describes three major elements of risk analysis. These are risk assessment, risk management and risk communication, and each is considered integral to the overall process. Risk assessment is further described as 'the overall process of hazard identification and risk estimation (likelihood and consequence assessments)'.

The Risk Analysis Framework explains that risk analysis is an iterative or looping process, as outlined in Figure 9.

Although there are some differences in terminology, the overall framework for risk analysis is broadly similar to that described in the Australian and New Zealand Standard, AS/NZS 4360.

The risk analysis process gives rise to a risk estimation matrix, as shown in Table 4. The aim of the matrix is to provide a format for thinking about the relationship between the consequences and the likelihood of particular hazards. It is explained in the Risk Analysis Framework that uncertainty about either or both of these components will affect the risk estimate. It is also explained that the matrix is designed to be used as a tool in arriving at the risk estimate. It is not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome or on the necessity for management conditions to be imposed, although risks estimated as 'High' or 'Moderate' will require management.

Figure 9: OGTR risk assessment loop

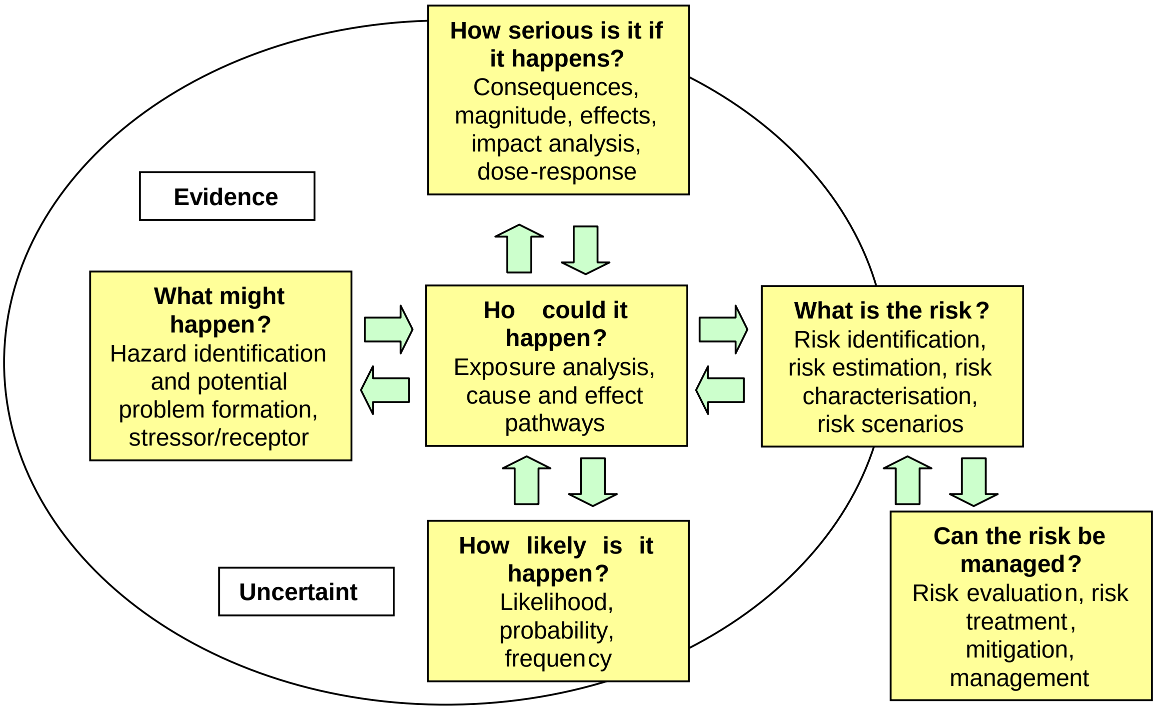


Table 4: OGTR risk estimation matrix

LIKELIHOOD	**Highly likely**	Low	Moderate	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly likely	Negligible	Negligible	Low	Moderate
		Marginal	**Minor**	**Intermediate**	**Major**
		CONSEQUENCES			

To reduce ambiguity of terminology used in qualitative risk assessments, the OGTR applies a set of distinct descriptors to the likelihood assessment, consequence assessment and the estimation of risk. The definitions are intended to cover the entire range of possible licence applications and should be regarded as relative. For instance, the consequences of a risk relating to human health will be very different from the consequences of a risk to the environment.

The descriptors for likelihood are expressed in very general terms. So too are the descriptors for consequence, which need to encompass adverse consequences of events relating to both human health and safety and the environment. They are relatively simple, in order to cover the range of different factors (severity, space, time, cumulative, reversibility) that may contribute to the significance of adverse consequences. The risk estimate is derived from the combined consideration of both likelihood and consequence (Table 4).

Likelihood assessment

- Highly likely: is expected to occur in most circumstances
- Likely: could occur in many circumstances
- Unlikely: could occur in some circumstances
- Highly unlikely: may occur only in very rare circumstances

Consequence assessment

- Marginal: there is minimal or no negative impact
- Minor: there is some negative impact
- Intermediate: the negative impact is substantial
- Major: the negative impact is severe

Risk estimate

- Negligible: risk is insubstantial and there is no present need to invoke actions for mitigation
- Low: risk is minimal, but may invoke actions for mitigation beyond normal practices
- Moderate: risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective
- High: risk is unacceptable unless actions for mitigation are highly feasible and effective

Approach to Consequence Assessment

The legislation specifies matters that the Regulator *must* consider in preparing the risk assessment. These include:

- Previous assessments;
- The potential of the GMO to be harmful to humans and other organisms;
- The potential of the GMO to adversely affect any ecosystems;
- Transfer of genetic material to another organism;
- The spread or persistence of the GMO in the environment;
- Whether the GMO may have a selective advantage in the environment; and
- Whether the GMO is toxic, allergenic or pathogenic to other organisms.

Adverse outcomes or harm arising from GMOs can be grouped into categories. Types of adverse outcomes that could potentially arise, along with attributes that could be used to measure that harm, are listed in Table 5. It is important that observable, measurable properties are identified in order to accurately assess that harm has occurred.

The generic criteria for specifying harm to human health and the environment listed in Table 5 are described in the Risk Analysis Framework as ‘illustrative’, and are ‘intended neither as a requirement for all risk assessments nor as precluding the use of other criteria’. They are considered a starting point for determining how to assess harm, and describe the types of data that could be used as evidence for measuring potential adverse impacts. It is reiterated within the Risk Analysis Framework that it will be important to differentiate between adverse impacts and natural change due to the dynamic nature of biological systems. It is also stressed that no list of generic criteria would be sufficient for all cases. Therefore the properties of the GMO, its locations, the types of dealings and the management conditions employed will all be important in deciding which people and what particular local environmental attributes are most susceptible.

Table 5: OGTR generic criteria for harm to health, safety or the environment

Adverse Outcomes	Measurable Properties
Harm to human health and safety, including toxicity (acute effects such as irritation and sensitisation and chronic effects such as mutagenicity), carcinogenicity, teratogenicity, allergenicity, pathogenicity, endocrine and reproductive effects	Biochemical, physiological, physical or developmental abnormalities; frequency and age of morbidity; frequency of infection; age/weight ratio; mortality
Harm to protected species (including secondary impacts at different trophic levels)	Numbers and density (abundance); sites where present; mortality; frequency and age of morbidity; survival, fecundity, age/weight ratio; properties of habitat where it occurs
Harm to non-target species (including secondary impacts at different trophic levels)	Population morbidity; genotype frequency; abundance; yield/production
Irreparable loss of species diversity or genetic diversity within a species	Presence and abundance of species; genotype frequency; yield/production
Creating a new or more vigorous weed, pest or pathogen	Occurrence and biological properties, for example invasiveness or pathogenicity
Exacerbating the effects of an existing weed, pest or pathogen	Occurrence in new environment, new population or species of host; size/frequency of attack or invasion; intensity of disease symptoms; yield/production; species richness of the community where the weed, pest or pathogen occurs
Disruptive effects on biotic communities and ecosystems (including transient and permanent changes)	Species richness; diversity indices; extent and area; production; indices of food web structure; carbon, nitrogen and phosphorous fluxes
Disruption of rare, endangered or highly valued ecosystems (e.g. aquatic and alpine environments, coral reefs, wetlands)	Extent and area; species richness; structure
Harm to the abiotic environment	Frequency of floods, low flows and fire; pollutant concentrations; physical damage

The Risk Analysis Framework also explains that the consequences of an adverse outcome or event need to be examined on different 'levels'. For instance, harm to humans is usually considered on the level of an individual whereas harm to the environment is usually considered on the level of populations, species or communities. Consequences may also have dimensions of distribution and severity. For example, if a genetic modification resulted in the production of a protein with allergenic properties, some people may have no reaction to that protein, others may react mildly while others may be affected seriously. That is, there may be a range of consequences from an adverse outcome and some people may be more sensitive to a toxin than others, so the response may range from mild ill-health in one individual to serious illness in another, with the most common response falling between these two extremes. It will also be important to account for variation and distribution in the severity of the consequences.

In view of these considerations, the Risk Analysis Framework describes the significance of an adverse impact in terms of five primary factors:

– The severity of impact including the number, magnitude and probable severity, in the sense of degree, extensiveness or scale;
    - How serious is the impact?
    - Does it cause a large change over baseline conditions?
    - Does it cause a rapid rate of change, or large changes over a short time period?
    - Does it have long-term effects?
    - Is the change it creates unacceptable?
– The spatial extent to which the impact may eventually extend (local, regional, national and global) as well as to other organisms;
– The temporal extent of the impact, that is the duration and frequency;
    - The length of time (day, year, decade) for which an impact may be discernible

  - The nature of that impact over time
  - Is the impact intermittent or repetitive?
  - If repetitive, then how often and how frequently?
- The cumulative adverse impact;
  - The potential impact that is achieved when the particular project's impacts are added to impacts of other dealings or activities that have been or will be carried out
- The reversibility of the impact.
  - How long will it take to mitigate the adverse impact?
  - Is it reversible and, if so, can it be reversed in the short or long-term?

Table 6 provides some examples of descriptions relating to a scale of adverse consequences related to human health and separate ones related to the environment. The explanations for consequences to human health focus on injury as the adverse outcome but could equally focus on the number of people affected or the spatial scale (local, regional, national) of the adverse impact. Adverse consequences to the environment encompass a wide range of effects and the descriptions include some of elements from the factors listed above.

Table 6: OGTR descriptors for consequences to human health and environment

Descriptor	Consequences
Marginal	Minimal or no injury except to a few individuals that may require first aid Minimal or no degradation of the environment
Minor	Slight injury of some people that may require medical treatment Disruption to biological communities that is reversible and limited in time and space or number of individuals/populations affected
Intermediate	Injury to some people that requires significant medical treatment Disruption to biological communities that is widespread but reversible or of limited severity
Major	Severe injury to some people that may require hospitalisation or may result in death Extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible

9 REVIEW: OTHER DEPARTMENTS, AGENCIES AND ORGANISATIONS

9.1 Geoscience Australia

Introduction

DITR develops and administers programs and services designed to advance Australia's innovation and technology capabilities in manufacturing, resources and service industries. Of the Department's many divisions and agencies, Geoscience Australia is one with clear leadership and expertise in the field of risk analysis.

Geoscience Australia is Australia's national agency for geoscience research and geospatial information. Research and information provided by Geoscience Australia contributes to enhanced economic, social and environmental benefits to the community by providing input for decisions that impact upon resource use, management of the environment and the safety and well-being of Australians.

In 2004-05, Geoscience Australia's key business priorities (as documented in the agency's workplan) included:

- Promoting opportunities for mineral exploration through new pre-competitive geoscience information for the Gawler, Paterson and Tanami provinces;
- Improving access to pre-competitive geoscience information and compilations by accelerating development of Internet-based delivery systems;
- Promoting extended applications of geoscience through completion of the collaborative Burdekin-Fitzroy project which is designed to demonstrate applications of geoscience information for natural resource management;
- Establishing a spatial information, risk analysis, and modelling capability to support national initiatives in counter terrorism and critical infrastructure protection;
- Developing a national risk assessment framework for risk assessment models, methods and databases in support of the Disaster Mitigation Australia Package;
- Acquiring and interpreting seismic data to build new investment opportunities in south western and northern Australia in support of the 2005 offshore petroleum acreage release, and in the quest for a new oil province for Australia;
- Completing phase II of the preservation of deteriorating seismic records in the national archive of petroleum industry data;
- Providing geoscientific advice supporting the follow-up to Australia's 2004 submission to the United Nations Commission on the Limits of the Continental Shelf (UNCLCS);
- Assisting the development of geological sequestration of carbon dioxide, through the Greenhouse Gas Technologies Cooperative Research Centre (CO2CRC);
- Beginning a 1:100,000 pilot mapping program to address areas of high bushfire risk; and
- Commencing development of a Marine Spatial Information System for the Australian Marine Jurisdiction.

Summary

Geoscience Australia is one of the most highly and diversely skilled of the agencies carrying out risk management exercises. This level of expertise is illustrated in the scope and depth of ongoing projects and cooperative development or guidance initiatives. Most relevant of these are the Critical Infrastructure Project, the National Risk Assessment Project and the Risk Assessment Methods Project. Also of key relevance to this review, and to the overarching Centre of Excellence, is the establishment of TRAAC and the development a National Risk Assessment Framework, which, collectively, will seek to establish a consistent approach to disaster risk assessment at all levels of Government.

Geoscience Australia employs a simple conceptual model for risk analysis that, whilst differing in terminology, is broadly compatible with the Australian and New Zealand Standard, AS/NZS 4360. The model rests on the identification of risk events and scenarios, the assessment of exposure and the assessment of the vulnerability of human and economic communities and individuals. Aspects of this model – in particular, the concepts of community level or individual level vulnerability – could be adopted in the analysis of pest or disease risk as there is a strong analogy between the 'shock' (in its economic and social sense) produced by a natural disaster and that which is produced by a pest or disease outbreak. Importantly, this would apply to animal and plant pests and diseases, as well as to human or zoonotic diseases.

On balance, dialog between Biosecurity Australia, the Centre of Excellence, Geoscience Australia, and, specifically, the TRAAC, will promote beneficial sharing of ideas about methods, models and tools for risk analysis and greater within-Government consistency.

Risk Management Context

The breadth of topics listed above illustrate the diversity of research and policy support activities carried out by Geoscience Australia. Notwithstanding this, it is the fourth and fifth of the topics that are of particular relevance to this review and the focus of the remaining discussion. These topics are the responsibility of the Risk Research Group (RRG) within Geoscience Australia. This group of approximately 40 people encompasses technical expertise in the geosciences, civil engineering, mathematics, socio-economics, computer programming, GIS and database engineering.

More specifically, the RRG is developing risk models and innovative approaches to assess the potential losses to Australian communities from a range of sudden impact natural hazards. In this context, hazard events include earthquakes, floods (riverine and storm surge), severe wind (tropical cyclone and severe storm), landslides and, more recently, bushfires. The models are being developed to assist planners and decision makers in assessing community risk and the effectiveness of various mitigation strategies. Of these hazards, the RRG conducts basic research into the origin and consequences of earthquakes and landslides; whereas for other hazards the Group relies in part on basic data and hazard parameters from other agencies (e.g. the Bureau of Meteorology) for input to hazard and risk model development.

Two key drivers for RRG activities are:

- The endorsement of the Council of Australian Governments (COAG) review of natural disaster management arrangements and the new Disaster Mitigation Australia Package; and
- The National Research Priority, Safeguarding Australia, and, specifically, the provision of spatial information and development of risk assessment methods.

These two key drivers are discussed individually.

In September 2000 two reports were commissioned to estimate the economic cost of natural disasters in Australia and to scope a national picture of hazards and risks in Australia. From these reports, a National Mitigation Working Party coordinated by the Department of Transport and Regional Services identified the strengths and weaknesses of current arrangements for managing natural disasters. It determined that they needed to be improved to ensure Australia has a world-class national framework for natural disaster management.

The preliminary findings of the scoping study instigated a wide-ranging review of Australia's approach to dealing with natural disaster mitigation, response during a disaster event and post disaster relief and recovery. This review was commissioned by the COAG on 8 June 2001 and was carried out by a high level group of officials representing Australian Government, State and Territory Governments and the Australian Local Government Association. The review, entitled Natural Disasters in Australia: Reforming Mitigation, Relief and Recovery Arrangements, received an out of session endorsement by the COAG in December 2003, and concluded a new approach to natural disasters in Australia was needed. The approach would aim at safer, more sustainable Australian communities in addition to achieving a reduction in risk, damage and losses from natural disasters in the future.

The new approach involves a fundamental shift in focus beyond relief and recovery towards cost-effective, evidence-based disaster mitigation. Consequently, there is a move away from disaster response and reaction, towards anticipation and mitigation against natural hazards.

Many of the 66 recommendations in this review are being implemented through the Disaster Mitigation Australia Package which incorporates:

- The new Natural Disaster Mitigation Programme; and
- Modernisation and enhancement of the Natural Disaster Relief Arrangements, and related activities.

The second key driver for RRG activities in the area of risk research is the Safeguarding Australia report. This report highlighted five key 'priority goals', one of which was research to better inform the protection of Australia's critical infrastructure.

In order to support these two drivers, the RRG is managing the following new and ongoing projects:

- Critical Infrastructure Project;
- Earthquake Hazard and Neotectonics Project;
- National Risk Assessment Project; and
- Risk Assessment Methods Project.

Of the projects, the first, third and fourth are of key relevance to this review, and will be discussed in more detail.

The protection of critical infrastructure has become a major national issue in recent times, the security of which is being addressed not only by the owners and operators of critical infrastructure, but also all levels of Government. As the national agency for geospatial information, Geoscience Australia has had a strong interest in critical infrastructure protection for a number of years through its ongoing natural hazard risk research program. Geoscience Australia has been identified to work with a range of agencies to develop, maintain and refine our ability to model and analyse consequences of critical infrastructure failure and interdependencies across sectors, including banking and finance, communications and energy.

The Critical Infrastructure Project will also fulfil the National Counter Terrorism Committee (NCTC) recommendation that Geoscience Australia provide risk assessment methods and spatial information expertise at a national level. The project will focus on critical infrastructure protection, hazard and vulnerability issues and the provision of spatial data, modelling, risk analysis and advice to the Australian Government and State and Territory Government agencies. The responsibility for developing national hazard, exposure and vulnerability databases will be shared with the National Risk Assessments Project. Considerable synergies exist between the Critical Infrastructure Project and the National Risk Assessments Project.

On 1 July 2004, the National Risk Assessments Project superseded the ‘cities and critical infrastructure’ project. The new project represents a significant and logical move towards investigating and assessing the national risk from natural disasters, effectively replacing the previous emphasis on individual major cities and specific regions, such as Perth, Mackay, Newcastle, Cairns, Gladstone and south-east Queensland.

The National Risk Assessments Project will provide risk assessment methods, models and data for the Disaster Mitigation Australia Package and in particular the Natural Disaster Mitigation Programme. Addressing rapid onset hazards with the potential to cause serious disruption to a community or region is of foremost importance. Therefore priority hazards for the National Risk Assessments Project include severe storms with their associated threats (floods, winds, hail, storm tide), earthquakes and bushfires.

The Perth cities project is a major risk assessment project based in metropolitan Perth and the final output of Geoscience Australia’s cities project. For more than three years the project has assessed the risk and hazard from earthquakes, flood and severe storms to metropolitan Perth. Major datasets such as a Perth building database have also been assembled. This project provided a test bed for new risk models, including data gathering and analysis techniques that can be applied elsewhere in Australia. The final reports and databases for the Perth project are included in National Risk Assessments Project.

There are two anticipated National Risk Assessments Project outputs:

– A ‘national risk assessment framework’ developed in conjunction with all levels of Government; and
– Initial reports on national assessments of risk from major, sudden impact natural hazards.

This project aims to provide accurate and timely information so that decision makers and practitioners involved in all aspects of disaster risk management can make informed and effective policy, funding and mitigation decisions. For such an approach, it is necessary to have a long term commitment to developing nationally consistent hazard and risk modelling capabilities including vulnerability and economic loss estimates and data collection. A nationally consistent approach will highlight areas which are in need of further risk assessments, and areas which may have not previously been recognised as hazardous.

The Risk Assessment Methods Project aims to define the economic and social threat posed by a range of rapid onset hazards through a combined study of natural hazard research methods and risk assessment models. These hazards include earthquakes, cyclones, floods, landslides, severe winds and storm surge. This all-hazard approach will provide risk assessment models, methods and tools to support funding and mitigation decisions across all level of Government in support of risk mitigation initiatives such as the Disaster Mitigation Australia Package.

The project will develop fully integrated multi-hazard risk assessment tools, methods and visualisations that will support the longer term requirements of State and Local Governments. The main research areas for Risk Assessment Methods Project are:

- National Risk Model Development: Develop models and methods for the estimation of national risk from rapid onset natural hazards including earthquakes, cyclones, floods, landslides, severe winds and storm surge.
- Computational Framework for Risk Assessments: Develop a computational framework for integrated multi-hazard risk assessments, visualisation techniques and computational capacity that support the comparison of risks from an array of sudden impact hazards.
- Loss and Vulnerability Model Development: Develop models and methods to estimate the social, economic and infrastructure vulnerability of a range of sudden impact natural hazards. A proposed methodology for measuring aspects of social vulnerability to natural hazards has been published as a Geoscience Australia record.

The Risk Assessment Methods Project will continue to provide modelling capabilities to the National Risk Assessments Project and the Critical Infrastructure Project. Additionally, the project has the potential to extend its work on rapid onset risk-assessment methods by including slow-onset hazards such as urban salinity, water quality and urban coastal impacts.

A final key element of the risk management context within Geoscience Australia is the establishment of TRAAC to advise on the implementation of reform commitments within recommendations put forward in the COAG-endorsed review titled Natural Disasters in Australia: Reforming Mitigation, Relief and Recovery Arrangements. Specifically, the reform commitments under Recommendation 4 are to:

- Develop and implement a five year national programme of systematic and rigorous disaster risk assessments; and
- Establish a nationally consistent system of data collection, research and analysis to ensure a sound knowledge base on natural disasters and disaster mitigation.

The second of these objectives has given rise to the concept of a National Risk Assessment Framework, with the aim of developing a consistent approach to risk assessment at all levels of Government. The concept is of particular interest to this review as it echoes to some extent the purpose and function of the Centre of Excellence under whose auspices the review is being carried out.

Collectively, implementing an agreed National Risk Assessment Framework as part of the Disaster Mitigation Australia Package (DMAP) requires the development of national databases and standardised methods and models for assessing risk. The methods need to be applied across a wide range of natural hazards, while being sufficiently accurate to allow risks to be compared and contrasted between different hazards and regions of potential impact. Hazards identified by the TRAAC include bushfire, flood, tropical cyclone and storm surge, severe wind, and earthquake; it is clear that pest or disease emergencies (including human health emergencies) could be added to this list.

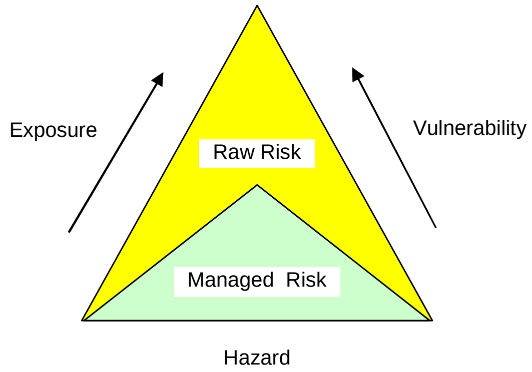
It is proposed that the initial development of a national picture of risk across these hazards and the development of a National Risk Assessment Framework will be guided by TRAAC, and by a series of focused workshops and working groups. Subsequent years of DMAP will benefit from the ability to focus on improved risk methods and associated decision-support tools for application to risk assessments and risk mitigation. In this period, and as models and databases improve, focus will be able to shift to implementation of models, training and risk communication.

Risk Management Framework

Geoscience Australia applies a simple conceptual model to studies of the risk posed by natural disasters to Australian urban population centres, illustrated in Figure 10. The model describes three fundamental elements of risk, namely, hazard, exposure and vulnerability. Under this arrangement, the hazard analysis identifies the risk events and scenarios of interest; the exposure assessment determines the likelihood associated with each event and scenario, and the vulnerability assessment determines the likely magnitude of impact and the ability of the community (human and economic) to sustain impact of that magnitude. The model shows that risk (the area of each triangle) can be reduced by reducing the hazard, the exposure or the vulnerability of communities. Hazard is, in practice, difficult to reduce in the context of natural disasters as these are generally beyond the control of Government or the community. Exposure, however, and the vulnerability of communities can generally be managed by way of the analysis and prioritisation of risks and the programmed allocation of resources. This is the principal objective of the Critical Infrastructure Project.

It is also of note that risk analysis carried out by Geoscience Australia typically leads to the concept of ‘expected loss’; where this is the sum of the product of a series of possible impacts and their associated likelihoods. In an analysis of the risks posed by natural hazards to south-east Queensland, Geoscience Australia explains that risk can be defined as "the expected number of lives lost, persons injured, damage to property and disruption of economic activity due to a particular natural phenomenon". Expected loss is an econometric concept that lends itself to qualitative, quantitative and hybrid assessment, and can often lead to a more rigorous process of risk prioritisation.

Figure 10: Geoscience Australia conceptual risk model



It is likely that the general conceptual model for risk analysis will be applied within the National Risk Assessment Project and the Risk Assessment Methods Project, and under the auspices of the TRAAC and the development of the National Risk Assessment Framework. Within each of these initiatives, however, specific methods and models for exposure assessment and for the assessment of human and economic vulnerability will continue to be developed.

Approach to Consequence Assessment

Although particular methods and models continue to be developed by way of the various projects and initiatives noted above, Geoscience Australia applies, in general terms, an expected loss model to the assessment of consequences. The framework for this model has been outlined above, but, in brief, it involves identifying a range of possible scenarios relating to a given hazardous natural phenomenon, and, for each scenario, estimating the probability of occurrence, the degree of community exposure and the vulnerability of the community. This approach results in an expected loss model for risk, which can be conceptualised as the sum of a series of products of (not necessarily quantitative) exposure likelihoods and consequence estimates.

Under this arrangement, vulnerability models tend to be complex and specific to particular forms of natural disaster. Earthquake prediction models, for example, differ from wind and storm models, which in turn differ from bushfire models. In each case, the relevant models are sophisticated, and, as relevant, make use of GIS and computer simulation. Some of the models have been developed by Geoscience Australia, and some have been developed by or in partnership with other agencies, such the Bureau of Meteorology. Ongoing development of vulnerability models will remain a focus of the various projects and cooperative initiatives.

Vulnerability models are also complex, and appear to rest on two forms of analysis. The first is the assessment of the vulnerability of human communities. This has traditionally been carried out by examining five criteria:

– Setting: basic regional topics including the physical environment (climate, vegetation, geology, soils, land use, topography, elevation, etc), access (external links by major road, rail, air, marine and telecommunications infrastructures), population and administrative arrangements (local Government, suburb and other administrative boundaries).
– Shelter: the buildings that provide shelter to the community at home, at work and at play. Access to shelter is also significant, so information on mobility within the community is included here. Particular attention is paid to the capacity and vulnerability of the road network and the availability of vehicles.
– Sustenance: modern urban communities are highly reliant on their utility and service infrastructures such as water supply, sewerage, power supply and telecommunications. These lifelines are significantly dependent on each other and on other logistic resources such as fuel supply. The community is also dependent on the availability of food supplies, clothing, medical supplies and other personal items.
– Security: the security of the community in terms of its health and wealth and by the forms of protection that are provided. Physically, these may be assessed by the availability of facilities such as hospitals, nursing homes, industries, commercial premises, agricultural land use, ambulance stations, fire stations, police stations and works such as flood retention basins and levees. Also important are socio-demographic and economic issues related to the elderly, the very young, the disabled, household income, unemployment, home ownership and the resources available at the fire and police stations.

– Society: these are more intangible measures, such as language, ethnicity, religion, nationality, community and welfare groups, education, awareness, meeting places and cultural activities. Some of these may be measured in terms of the facilities that they use, such as churches, meeting halls, sporting clubs and libraries. However, the more meaningful measures, such as education, relate specifically to the individuals, families and households that make up the community.

The assessment provided against each of these criteria tends to be qualitative, although supported by quantitative data. One of the preliminary outcomes of the Risk Assessment Methods Project has been the development of a decision analysis framework for identifying social determinants of household-level vulnerability. This work is exploratory, but may provide a useful template for ongoing research in this area.

The second form of vulnerability assessment is economic assessment of the vulnerability of local and regional economic communities to natural disasters. This part of the assessment is less well documented, and, because many studies have focussed explicitly on community level personal or infrastructural risk, may not be always be included.

9.2 Australian Pesticides and Veterinary Medicines Authority

Introduction

APVMA is the Australian agency responsible for regulating pesticides and veterinary medicines up to and including the point of retail sale. APVMA administers the National Registration Scheme for Agricultural and Veterinary Chemicals in partnership with the States and Territories and with the active involvement of other Australian Government agencies. APVMA evaluates and registers pesticides and veterinary medicines and manages quality assurance programs that monitor the ongoing safety and performance of registered products.

Any changes to a product that is already on the market must also be referred to APVMA. Under the National Registration Scheme, companies must supply APVMA with extensive data about the product. These are independently evaluated to ensure the product is safe for people, animals and the environment and that it won't pose any unacceptable risk to trade with other nations. If the product meets APVMA's standards it may be registered for use in Australia.

APVMA also reviews products that have been on the market for many years to ensure they meet contemporary standards. It manages a national compliance program to ensure that products supplied in Australia continue to meet the conditions of registration.

Summary

Whilst transparent and internally consistent, there were not seen to be any elements of the APVMA approach that might be used to augment Biosecurity Australia's methods for import risk analysis.

Risk Management Context

APVMA's functions fall into two major categories:

– Risk assessment and marketing authorisation;
– Management of quality assurance and compliance programs to ensure the ongoing safety and performance of registered products.

APVMA sees independent and science-based risk assessment as a major strength of its approach.

Major areas of focus include the setting and monitoring of:

– Maximum residue limits (MRLs): the maximum concentration of a chemical residue that is legally permitted in or on a food or food commodity, also known as tolerances in some countries with which Australia trades;
– Withholding periods: the minimum periods that need to elapse between the last use of the product in relation to a crop, pasture or animal and the harvesting or cutting of, or the grazing of animals on, the crop or pasture, the shearing or slaughter of the animal, or the collection of milk or eggs from the animal for human consumption, as the case may be, in order to ensure that the product's residues fall to or below the Australian MRL; and
– Export intervals: advisory times, corresponding to withholding periods, that should be observed to allow exporters of food commodities to meet the residues standards of a trading partner.

APVMA notifies Food Standards Australia and New Zealand (FSANZ) of proposed changes to Australian MRLs, which then considers the proposed amendments for incorporation into the Food Standards Code at section 1.4.2.

Risk Management Framework

Part of the governing legislation for APVMA[25], the Agricultural and Veterinary Chemicals Code Act 1994 [Act No. 47 of 1994 as amended], specifies in Clause 14 (3) (e) the criteria to be considered when assessing applications for registration of chemical products:

(i) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
(ii) would not be likely to have an effect that is harmful to human beings; and
(iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
(iv) would not unduly prejudice trade or commerce between Australia and places outside Australia.

When preparing a standard for a chemical product APVMA must take into account additional criteria (Clause 56E (1)):

(e) would be effective according to criteria determined by APVMA for the product; and
(f) would contain, or would require a label for containers for the product to contain, adequate instructions …

Clauses 14 (4), (5) and (6) and 56E (2) and (3) indicate the matters APVMA must consider when making determinations about active constituents or chemical products or preparing standards for chemical products:

- The toxicity of the constituent or product and its residues in relation to relevant organisms and ecosystems, including human beings;
- The method by which the constituent is, or is proposed to be, manufactured;
- The extent to which the constituent will contain impurities;
- Whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis;
- The relevant poison classification of the product under the law in force in this jurisdiction;
- How the product is formulated;
- The composition and form of the constituents of the product;
- The acceptable daily intake of each active constituent contained in the product;
- Whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that APVMA has approved or approves;
- The stability of the product;
- The specifications for containers for the product;
- Whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.

Approach to Consequence Assessment

APVMA's Manual of Requirements and Guidelines (MORAG) specifies the data requirements for registration of agricultural and veterinary products.[26] The requirements are specific and detailed, and linked to the criteria noted above.

9.3 Productivity Commission

The Productivity Commission has not been dealt with in this review in the manner of other Government agencies. The Productivity Commission does not carry out risk analysis or management per se, but rather conducts public inquiries and research into a broad range of economic and social issues affecting the welfare of Australians. Typically, these issues include competition policy, productivity, the environment, economic infrastructure, labour markets, trade and assistance, structural adjustment and microeconomic reform.

A brief analysis of material published by the Productivity Commission suggests that a key area in which it might be of particular value to the Centre of Excellence is in undertaking quantitative economic assessments of the potential impact of particular pests or diseases. An example can be found in the Productivity Commission publication, Impact of Foot-and-Mouth Disease on Australia. This work, commissioned by the Australian Government, assesses the economic, social and environmental impacts of a range of hypothetical outbreak scenarios on the agricultural sector, rural and regional Australia and the national economy. It also assesses how those potential impacts would

[25] Available at: http://www.apvma.gov.au/about_us/legislat.shtml

[26] Available at: http://www.apvma.gov.au/MORAG_ag/MORAG_ag_home.shtml and http://www.apvma.gov.au/MORAG_vet/MORAG_vet_home.shtml

change if a vaccination policy were in place, or FMD-free geographic zones were established. The report uses a comparatively simple cost-flow model, with some adjustment for price effects. The report also looks at the flow-on effects to the rest of the economy.

Another area in which the Commission might be of value to the Centre of Excellence is in providing an independent and public review of economic models pertinent to Biosecurity Australia's import risk analyses. Such a review should include a brief précis of the questions answered by each group of models and a synopsis of the general application. For each of the individual models the summary should include: an outline of the data required, the particular sectors and linkages contained, the model's prior application in similar fields and any other core information that is likely to assist the Centre of Excellence in making a recommendation about the model's use. Although left to the discretion of the Productivity Commission, model groups that might be included in the review would include partial equilibrium models, computable general equilibrium models, input-output models and social accounting matrices and linear and mathematical programming models.

From such a review, it might be possible to identify a model, or group of models, that can be customised for ongoing use by or on behalf of Biosecurity Australia. Customisation might in this context mean tailoring of the sectors and linkages included in the model, standardisation of data requirements and standardisation of the output format. In this way, an economic model or group of models could serve as a component of a consistent approach to import risk analysis, rather than as a sporadic embellishment to particular high-profile assessments or analyses.

9.4 Plant Health Australia

Introduction

A joint industry-government workshop in late 1998 recommended the creation of an industry-government company limited by guarantee under Corporations Law. An intensive period of consultation, followed by an industry-government workshop held in 1999, led to the registration of PHA in April 2000.

PHA is the national coordinating body that identifies and commissions projects and coordinates policy development at the national level to protect Australia's plant industries and related resources from the risks posed by organisms, through the implementation of exclusion, eradication and control measures.

It has 20 industry, nine government and six associate member organisations, including the Australian Government. As PHA members include most major agricultural industries, the Australian Government and all state and territory governments, PHA provides a unique, effective and coordinated means of contributing to policy making and direction setting on major plant health issues.

Summary

Quantitative models to be developed under PHA's Regional Economic Impact Model project, of which one has been completed, are relevant to the assessment of consequences of a plant pest incursion.

Biosecurity Australia and the Centre of Excellence should consider dialogue with PHA, with a view to maintaining awareness of the Regional Economic Impact Model project and its implications for Biosecurity Australia's import risk analyses.

Regional Economic Impact Model Project

The Regional Economic Impact Model project[27] has developed an economic model which will be used to determine the impact of pest incursions specifically on regional economies (which may at times be highly significant). The completion of this model will lead to the development of a broad-based decision support system that will assist in pest categorisation and provide benefits in terms of a framework for making decisions on resource prioritisation and allocation in regard to exotic pest risks.

The Regional Economic Model will also be used for completing several specific case studies for PHA, based on emergency plant pests specific to a given industry. A case study for the grains industry has already been completed, using an incursion of karnal bunt as the scenario.[28] The model is a dynamic multi-regional computable general equilibrium model that estimates the micro- and macroeconomic effects of a hypothetical karnal bunt incursion in wheat in Western Australia.

[27] Available at: http://www.planthealthaustralia.com.au/our_projects/display_project.asp?ID=191&Category=2
[28] Available at: http://www.planthealthaustralia.com.au/project_documents/uploads/041214_%20KB%20economic%20model%20case%20study.pdf

10 DISCUSSION AND ANALYSIS

10.1 Introduction

In this part of the document, we draw together discussion about the approaches and methods used by each of the divisions and agencies included in the review and examine how these methods and approaches might be used to augment that which is currently used by Biosecurity Australia.

10.2 Biosecurity Australia

The overarching objective of Biosecurity Australia's method for consequence assessment, as discussed in Section 5 of this report, is to provide a structured and transparent analysis of the 'likely consequences', or likely impact, of each pest or disease agent considered in an import risk analysis. In this context, the term 'likely consequences' is used to draw attention to the fact that Biosecurity Australia does not base its assessment of consequences solely on worst case scenarios. The assessment is predicated on the assumption that the pest or disease agent has entered Australia and gained access to a suitable host or environment.

The Biosecurity Australia method has three key characteristics:

- It incorporates the direct and indirect consequences of each pest and disease;
- It is a qualitative ranking scheme in which pests and diseases are divided into categories based on their expected consequences on a national scale. To assist in describing consequences, especially for those pests and diseases where the impact will be less easily discerned on a national scale, consequences at various sub-national levels are also considered; and
- It provides an outcome relevant to the Australian community as a whole, rather than to directly affected parties.

Implicit in each of these three characteristics is the fact that Biosecurity Australia does not consider the 'benefits' of trade when carrying out import risk analysis – the consequence assessment is focussed entirely on adverse outcomes. This is unusual within the broader field of risk management, where the benefits and costs of a decision, action or event are generally included in the estimation and evaluation of risk.[29]

Central to the Biosecurity Australia method are the qualitative constructs represented by 'exposure groups' and 'outbreak scenarios'. Biosecurity Australia evaluates the likely consequences accrued to each outbreak scenario, and, where more than a single scenario has been described, combines these to give an estimate of the likely consequences of exposing the relevant exposure group. If more than a single exposure group has been identified, then the likely consequences associated with each are combined at the risk estimation step with the relevant likelihoods of pest or disease entry and exposure.

The approach, as summarised in Figure 7, is complex if all possible components (exposure groups and outbreak scenarios) have been elaborated. In simpler cases, however, the approach can be shown to collapse to a straightforward evaluation of the likelihood of establishment or spread, and an estimate of direct and indirect impacts. These are considered the fundamental components of a consequence assessment, as described by OIE and IPPC.

Three key difficulties have been identified when applying the method across a range of animal-, plant- and product-based import risk analyses. It is important that the objective in identifying and discussing these difficulties is not to criticise the method, which remains one of the most rigorous of those used by regulatory authorities worldwide, but to highlight areas where methods used by other Australian Government divisions or agencies might be most helpful.

- The first key difficulty is that which is encountered when assessing the significance of each of the direct and indirect impact at sub-national (i.e. local, district or regional and State or Territory) levels. The difficulty occurs principally because sub-national impacts are most relevant to the costs accrued by sub-national levels of Government; relatively less meaning can generally be attributed to 'local' versus 'regional' impacts on, for example, producers or the environment. The problem is compounded in the case of multi-focal pest or

[29] For example, see the discussion of TGA's approach, Section 8.3.

disease outbreaks, where each outbreak focus might be small and of relatively minor impact but the collective impact of the pest or disease on the country as a whole might be completely different.

– The second key difficulty is that it is currently difficult to estimate consistently the impacts of pests and diseases that cannot be eradicated quickly, or are likely to be become endemic. It is also difficult to estimate consistently those impacts that continue to be accrued after eradication of a pest or disease, or its containment in a controlled zone.

– The third key difficulty concerns the qualitative definitions for assessing the magnitude of impact; that is, 'unlikely to be discernible', of 'minor significance', 'significant' and 'highly significant'. Here it was pointed out that because the terms and definitions do not correlate with any concrete measure, they tend to be applied as a qualitative ranking scheme.

Possible solutions for each of these three key difficulties were considered in the review. These are summarised below.

The first key difficulty could be solved by altering the structure of the consequence assessment so that estimates of sub-national (local, district or regional, State or Territory) impact are not mandatory for each of the seven standardised direct and indirect criteria. This is a simple change, and would require only minor alteration to the overall assessment framework. The tabulation of sub-national impacts (Table 2) would be removed, but an estimate of the overall 'national impact' would still be obtained for each criterion and used in the decision rules that follow this step in the assessment. We note that some novel or sophisticated methods for obtaining economic estimates for national impact have been developed by the agencies included in this review, and are discussed in the text below.

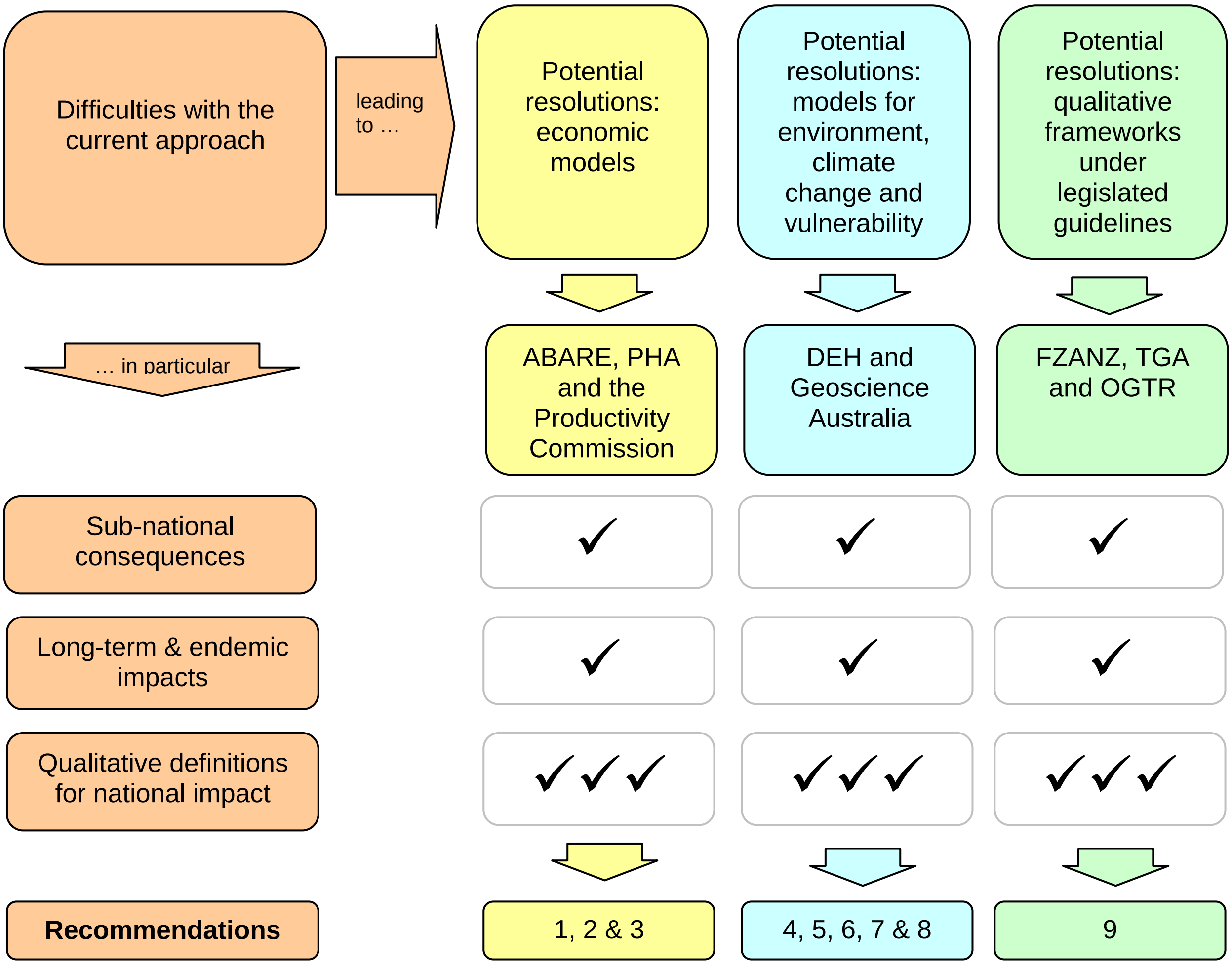
The second difficulty is complex, as it requires some standardisation of the approach Biosecurity Australia takes to the assessment of long-term pest or disease impacts. We note here that economic and qualitative methods for assessing such impacts have also been developed by some of the agencies included in this review, and will be discussed below. What is required to solve this particular problem, however, is an adaptation of the Biosecurity Australia framework, such that long-term impacts are always considered; and are always considered in the same (or a broadly similar) manner. How Biosecurity Australia chooses to standardise the consideration of long-term effects – that is, the period over which such effects are considered or the approach to effects that continue to be accrued after a pest or disease is eradicated – is a policy consideration as it has direct implications about the benchmark for acceptable risk, or ALOP.

The third key difficulty is also complex, but might be addressed by assessing the significance of each direct and indirect impact against a different scale or benchmark. It was noted in the review that the current Biosecurity Australia framework includes a single set of qualitative terms which are applied to each of the seven standardised direct and indirect consequence criteria. We suggest that this approach be revised, and separate scales be developed for each of the seven criteria. The scales for some criteria – such as the cost of control or eradication – might have a quantitative meaning, even though individual pest or disease assessments are likely, on the whole, to be qualitative. The scales for some other criteria might be qualitative, representing less tangible or readily quantifiable effects such as environmental impacts or community held values.

We stress here that the development of suitable 'scales' for assessing direct and indirect impacts is a separate objective to the development of methods for assessing impacts *per se*. Scales should be transparent, and should equate to a measure or quantity that analysts and readers can readily relate to. Once developed, such scales can be adopted as the benchmarks against which the significance of direct and indirect impacts will be assessed. Individual pest or disease assessments, which can utilise a range of analytic or descriptive tools, methods and approaches, can then be compared with each of the scales and rated accordingly. Under the current system the single qualitative scale is not adequately defined, and this crucial step of the consequence assessment is made difficult and relatively non-transparent.

In the balance of this discussion, we seek to correlate the strengths of each of the agency approaches with the three key difficulties associated with the current Biosecurity Australia approach. We have approached this by grouping the agencies as shown in the bullets below. Under this arrangement, the first group of agencies provides strength in economic analysis; the second in the assessment of environmental impacts, climate change and vulnerability; and the third in qualitative assessments under legislated guidelines.

Figure 11: Agency strengths and the current Biosecurity Australia framework



– Economic analysis: ABARE, PHA and the Productivity Commission;
– Environmental impacts, climate change and vulnerability: DEH and Geoscience Australia; and
– Qualitative assessments: FSANZ, TGA and OGTR.

Figure 11 shows how the three difficulties noted in the Biosecurity Australia link with the three groups of agencies and the recommendations that follow in Sections 1.1, 10.4 and 10.5.

10.3 Economic Analysis: ABARE, PHA and the Productivity Commission

ABARE is considered DAFF's principal source of economic expertise for policy advice, research or survey work (Section 6.2). ABARE is also the principal source of economic and industry data and economic models. Economic models have a potential role in consequence assessment for import risk analyses in assisting to put a dollar measure on adverse outcomes associated with a pest or disease outbreak.

In the context of the review, a range of economic models developed, enhanced or simply utilised by ABARE are relevant. Of these, some are of peripheral interest whilst others might lend themselves directly to pest or disease consequence assessment. The latter group includes the AgTrade suite of models for grains, dairy and sheep meat; the AUSTEM computable general equilibrium model of the Australian economy; the AUSTATE computable general equilibrium model of Australian State and Territory economies; the AUSREGIONAL computable general equilibrium model of an Australian region; the BEEF-BEM bioeconomic model of the Australian beef cattle industry; the BEM-SBT bioeconomic model of the blue-fin tuna industry; the EIM exotic incursion management model and the FISH suite of models. Models to be developed under PHA's Regional Economic Impact Model project, of which one has been completed, are also relevant (Section 9.4).

As a group, these models utilise a range of economic approaches, including econometrics, mathematical and linear programming, spatial optimisation, partial equilibrium, computable general equilibrium and neural networks. In contrast to probability models, which commonly seek to answer the same or similar questions by different methods, the different kinds of economic models address fundamentally different questions. As a result, no single approach is inherently 'better' than another, and more than one approach is commonly needed in the context of a Government policy question as complex as assessing pest or disease consequences. Economic models also differ widely with regard to the nature and depth of the data required for parameterisation and in their robustness to data gaps or uncertainties. For this reason, some models that are intuitively well-suited to addressing particular questions may be completely unsuited to practical application in that area.

The importance of economic modelling to Biosecurity Australia needs to be considered in the context of import risk analyses carried out in a broadly qualitative framework, where the overarching objective of consistency across import risk analyses needs to be preserved. It is necessary to consider the potential for economic models to customised so as to be adaptable across a range of import risk analyses, in a way that would provide information that supports the qualitative judgements required within Biosecurity Australia's overall framework for consequence assessment. The outcome would be analogous to the situation with likelihood models, where elements can be quantified as required, or where data permits, and where quantification of specific components does not alter the overall framework of the analysis. It is also important to note that it is likely to be impracticable to do complete economic studies for every pest or disease in every import risk analysis, and that import risk analyses may not require detailed economic studies if simpler and more cost-effective qualitative approaches are sufficient for making sound decisions.

Accepting the above, economic models could be used in two ways to augment import risk analyses:

- The first is the use of *ad hoc* economic assessments as the need arises;
- The second is the customisation of a chosen model, or a suite of models, so that larger numbers of assessments could be completed quickly and with a focus on the particular questions in the context of a specific import risk analysis.

The latter approach would seem to be preferable, both from the standpoint of efficiency and in view of the overarching need for consistency amongst and within import risk analyses. One or more of ABARE's existing models might be well-suited to this objective or could be modified with relatively little development. Alternatively, some research might be required first to establish the ideal model framework for import risk analysis, and from this to develop a new model or suite of models. One approach might be for an ABARE economic modeller to be seconded to Biosecurity Australia for the purpose of coordinating such studies.

If economic models might be customised to meet Biosecurity Australia's needs for import risk analysis, then the next question is precisely how the information might be helpful. Although the response to this would require some ongoing dialogue between Biosecurity Australia, the Centre of Excellence and ABARE, economic modelling might, in principle, be used to develop a basis for the qualitative descriptors used to represent the national significance of some inherently quantifiable impacts. It was pointed out earlier in this discussion that one immediate solution to the difficulty inherent in the current generic qualitative descriptors would be to develop separate scales for each of the direct and indirect impacts. Of these, the direct effect of a pest or disease on animal or plant life or health (including production effects), the cost of control or eradication strategies, the cost of lost domestic and international trade and some parts of the indirect impact on communities would all be immediately amenable to assessment against a quantitative value or distribution. By this it is meant that if economic modelling was used across a range of pests and diseases to establish what is meant in quantified terms by an agreed set of qualitative descriptors, then such descriptors could be applied more transparently in a qualitative context to ensuing assessments. Where data were available, and the depth of an assessment warranted it, the same models could also be used to quantify these direct and indirect impacts. This approach would preserve consistency within and amongst analyses, and would enable the less-quantifiable (intangible) direct and indirect impacts to be assessed against other more suitable metrics.

The Productivity Commission (Section 9.3) was seen by the reviewers to be another key resource for Biosecurity Australia for third party economic models and modelling. Whilst individual studies are of benefit, and could be carried out by the Productivity Commission, a more substantive and strategic benefit might arise from a systematic review of available economic models. This review would include, but not be limited to, models used by the Productivity Commission and ABARE, as well as other organisations like PHA, and might include partial equilibrium models, computable general equilibrium models, input-output models and social accounting matrices and linear and mathematical programming models.

The benefit of such a review might be the identification of a model or group of models that could be customised for ongoing use by or on behalf of Biosecurity Australia. Customisation might in this context mean tailoring of the sectors and linkages included in the model, standardisation of data requirements and standardisation of the output format. In this way, a model or group of models could serve as a component of a consistent approach to import risk analysis, rather than as a sporadic embellishment to particular high-profile assessments or analyses.

The role of economic measures in the cost/benefit analysis of specific risk treatment options has been noted, although it is outside the scope of this report.

Recommendation 1

Economic methods have a potential role in consequence assessment for import risk analyses in assisting to put a dollar measure on adverse outcomes associated with a pest or disease outbreak. Such methods should be capable of generating a quantitative basis for the scales against which Biosecurity Australia's estimates the national significance of:

– The direct impact on the life or health (including production effects) of production, domestic or feral animals; or the life or health (including production effects) of commercially cultivated, garden or feral plants;
– The indirect impact of new or modified eradication, control, surveillance or monitoring and compensation strategies or programs;
– The indirect impact on domestic trade or industry, including changes in consumer demand and impacts on other industries supplying inputs to, or utilising outputs from, directly affected industries;
– The indirect impact on international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand; and some aspects of
– The indirect impact on communities, including reduced tourism, reduced rural and regional economic viability, the loss of social amenity and any 'side impacts' of control measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with ABARE with a view to developing quantitative scales for the national significance of these five direct and indirect impacts. Such scales could then be used as a transparent benchmark for ongoing routine qualitative assessments.

Biosecurity Australia and the Centre of Excellence should also investigate the development of a generic model, or suite of models, that could be used routinely to quantify relevant parts of individual pest or disease risk assessments.

Recommendation 2

Biosecurity Australia and the Centre of Excellence should consider dialogue with PHA, with a view to maintaining awareness of the Regional Economic Impact Model project and its implications for Biosecurity Australia's import risk analyses.

Recommendation 3

A systematic review of available economic models that might add value to Biosecurity Australia's consequence assessments would augment work undertaken in collaboration with ABARE, and provide Biosecurity Australia and other interested parties with a clearer understanding of the breadth and focus of economic modelling in Australia.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Government Treasury with a view to commissioning a review by the Productivity Commission of economic models from Government, academic and private sources relevant to Biosecurity Australia's import risk analyses.

10.4 Environmental Impacts, Climate Change and Vulnerability Assessments: DEH and Geoscience Australia

In this part of the discussion, we correlate the strengths or methods and approaches used by the DEH agencies and Geoscience Australia with the three key weaknesses in the current Biosecurity Australia framework for consequence assessment.

Approvals and Wildlife Division

The approach the Approvals and Wildlife Division of DEH takes to assessing the likely consequences of an action on each of seven 'matters of national environmental significance' is guided by the terms and conditions of its EPBC Administrative Guidelines on Significance (Section 7.2). Whilst these matters are quite specific, the principles set out in the guidelines provide useful background for assessing environmental impacts. These principles include assessment of:

- All on-site and offsite impacts;
- All direct and indirect impacts;
- The frequency and duration of the action;
- The total impact that can be attributed to that action over the entire geographic area affected, and over time;
- The sensitivity of the receiving environment; and
- The degree of confidence with which the impacts of the action are known and understood.

In addition to the generic assessment principles above, specific detail is provided about assessments for each of the seven matters of national significance.

Although these considerations are guidelines only, and are not claimed to be exhaustive, they do provide some additional perspective on the assessment of direct and indirect environmental impacts.

Given this, it might be sensible if Biosecurity Australia and the Centre of Excellence were to develop (from these criteria or otherwise) a qualitative ranking system for determining the significance of direct and indirect environmental impacts of pests and diseases. Such a system would complement the development of quantitative metrics (as described above), and thus would help to circumvent the third of the key difficulties with Biosecurity Australia's existing method for consequence assessment.

Recommendation 4

DEH Approvals and Wildlife Division has guidelines for assessing direct and indirect environmental consequences that are relevant to Biosecurity Australia. Aspects of the approach have the potential for adaptation for use in import risk analyses, and would complement the development of quantitative models and measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with DEH Approvals and Wildlife Division, with a view to developing a qualitative ranking system for assessing the significance of direct and indirect terrestrial environmental impacts.

Australian Greenhouse Office

The review of methods used by the Australian Greenhouse Office focussed on risk-based approaches to assessing the 'vulnerability' and 'adaptability' of environments, communities or industries to climate change. Assessments carried out in this field do not appear to follow the conventional risk analysis or risk management structure, although they do utilise analytic tools and approaches that could be adapted in some cases to the assessment of pest or disease consequences.

The distinction between 'top down' and 'bottom up' approaches, for example, could be applied equally in the context of pest or disease consequences where interest might lie in the seriousness of a particular establishment or spread scenario (the top-down approach), or the vulnerability of an industry or community to harm from pests or diseases (the bottom up approach). Whilst the former is the more traditional approach, the concept of vulnerability could be helpful when assessing the indirect impact of a pest or disease on key industries or communities. Indeed, it might be that a metric based on vulnerability is the most appropriate means by which to benchmark the significance of this form of pest or disease impact.

Also of relevance was the range of analytic tools used to investigate the magnitude of impact due to climate change. Sectoral economic models, for example, have a place in the evaluation of direct and indirect disease effects. Likewise, many of the ecological or industry-focussed economic and simulation models could be used to examine the effect of a pest or disease shock, in the place of a shock due to climate change.

Extension of such tools from one environment (climate change) to another (pest and disease risk analysis) would require collaboration between the relevant analysts and a willingness to share project objectives, methods and outcomes. It is also likely that technical specialists in the application of particular analytic tools would be required to perform experimental pest or disease impact analyses, or analyses of the vulnerability of ecosystems, communities or industry to pest or disease shocks, to test the approach. Such analyses, if promising, could be peer reviewed and published, and, if received positively by the broader community of risk analysts, could be adopted for ongoing use within the more traditional framework for pest and disease consequence assessment.

Specific recommendations about Australian Greenhouse Office methods for assessing vulnerability and the impacts of climate change are detailed in the discussion of Geoscience Australia (below).

Marine Division

DEH Marine Division has a broad scope of responsibility, including management of the cooperative development of Regional Marine Plans. Although currently under development, these plans will include multiple use risk assessments.

The method to be adopted for these multiple use assessments, and, more specifically, the methods to be used to assess the impacts or consequences of regional activities, could assist with the development of a metric against which to assess the direct and indirect impacts of marine pests and diseases.

Recommendation 5

The multiple use risk assessments to be included in DEH Marine Division's Regional Marine Plans could assist with the development of approaches for assessing the consequences of marine pests and diseases. Such approaches would complement the development of quantitative models and measures.

Biosecurity Australia and the Centre of Excellence should consider dialogue with DEH Marine Division, with a view to developing a qualitative ranking system for assessing the significance of direct and indirect impacts on the marine environment.

Geoscience Australia

Geoscience Australia was seen by the reviewers as one of the more highly and diversely skilled of the agencies carrying out risk management exercises. This level of expertise is illustrated in the scope and depth of ongoing projects and cooperative development or guidance initiatives. Most relevant of these are TRAAC and the development of a National Risk Assessment Framework, which, collectively, will seek to establish a consistent approach to disaster risk assessment at all levels of Government.

Geoscience Australia generally employs a simple conceptual model for risk analysis that, whilst differing in terminology, is broadly compatible with the Australian and New Zealand Standard, AS/NZS 4360. The model rests on the identification of risk events and scenarios, assessment of exposure and assessment of the vulnerability of human and economic communities and individuals. In this respect, it is not dissimilar to the model used by the Australian Greenhouse Office, with which there are close links.

Aspects of the Geoscience Australia model – in particular, the concepts of community level or individual level vulnerability – could be adopted to the analysis of pest or disease risk as there is a strong analogy between the 'shock' (in its economic and social sense) produced by a natural disaster and that which is produced by a pest or disease outbreak.

Recommendation 6

Qualitative methods for estimating the vulnerability of Australia to pest and disease incursions would provide a different perspective from which to approach import risk analysis from that currently used by Biosecurity Australia. Such methods would complement the current approach.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Greenhouse Office and Geoscience Australia, with a view to developing a qualitative method for estimating the vulnerability of Australian communities to pest and disease incursions.

Recommendation 7

Quantitative models for examining the effects of long-term changes or shocks due to climate change or natural disasters may provide a different approach to examining the impacts of pest and disease incursions. Such models might be adapted to augment qualitative or quantitative aspects of consequence assessments for import risk analyses.

Biosecurity Australia and the Centre of Excellence should consider dialogue with the Australian Greenhouse Office and Geoscience Australia, with a view to reviewing practical aspects of quantitative analytic tools used in the fields of climate change and natural disasters.

Recommendation 8

Geoscience Australia's initiatives with the TRAAC and the development of a National Risk Assessment Framework both draw on its substantial technical skills base and corporate experience in estimating and evaluating the components of risk. Exposure to this skills base is likely to be of benefit to the Centre of Excellence as well as to Biosecurity Australia.

Biosecurity Australia and the Centre of Excellence should consider dialogue with Geoscience Australia, with a view to establishing links to TRAAC and the National Risk Assessment Framework.

10.5 Qualitative Assessment: FSANZ, TGA and OGTR

In this part of the discussion, we correlate the strengths or methods and approaches used by the FSANZ, TGA and OGTR with the three key weaknesses in the current Biosecurity Australia framework for consequence assessment. (The agencies discussed in Section 10.4 also use qualitative approaches that have the potential to add value to Biosecurity Australia's framework, as noted in Recommendations 4, 5 and 6.)

FSANZ

FSANZ has produced detailed guidelines explaining its terminology for risk assessment and risk management and the steps that each of these two procedures entail. FSANZ divides risk assessment and risk management in procedural terms and with regard to the structure of the organisation and the tasks assigned its various branches and teams. Although FSANZ does not use the term 'consequence assessment', it does assess the severity of hazards. This incorporates consideration of the extent of likely exposure of individuals, or particular groups of individuals, and the relationship between exposure and the likely extent of harm. FSANZ handles chemical, microbiological and nutrient hazards differently, recognising that the relationship between exposure and the likely severity of harm differs markedly for each group.

In characterising hazards, and in assessing the likely severity of harm, FSANZ uses some categorical classification schemes and some less prescriptive forms of qualitative assessment. FSANZ acknowledges that a lack of good quantitative data, and variance in the likely harm associated with particular hazards or foods, generally preclude the use of detailed economic analysis for the 'consequence assessment' component of a risk assessment. That said, FSANZ does in some cases use risk-benefit analysis or cost-benefit analysis to inform a decision about risk management strategies or approaches.

It is difficult to identify a particular part of Biosecurity Australia's approach to consequence assessment that might benefit immediately from the FSANZ methods. This partly because it specifically addresses human health, which is not one of Biosecurity Australia's direct concerns, and partly because, whilst transparent and functional, it does not include novel techniques or approaches.

TGA

TGA uses a risk management approach to regulate the licensing of medicines, the manufacture of medicines, medical devices and blood and tissues. This approach is based explicitly on the Australian and New Zealand standard for risk management, AS/NZS 4360, and follows precisely the steps, terms and definitions in the standard. The difference between TGA's framework and that used by Biosecurity Australia and most of the other agencies included in this review is that TGA explicitly considers the 'benefits' component of the risk management question. This is important, as most therapeutic goods have negative effects, and a decision to register or not must consider these in the context of the potential for such goods to treat or prevent medical disorders.

TGA carries out different forms of risk assessment for the regulation of different classes therapeutic goods. Amongst these, registrable medicines receive the most detailed and conventional analysis, with separate assessments for chemical hazards, quality control and laboratory hazards, pharmacological and toxicological hazards and hazards apparent from clinical trials or epidemiological investigations. The consequence assessment component of each sub-assessment includes qualitative and quantitative information about the likely severity of hazards, but does not seek to provide a quantitative estimate of consequences *per se*. This applies both to tangible and intangible effects.

As was the case for FSANZ, it is difficult to identify a particular part of Biosecurity Australia's approach to consequence assessment that might benefit immediately from the TGA methods or approach to consequence assessment. Again, this is due in part to the focus on matters of human health, and in part to the fact that, whilst transparent and functional, the TGA method does not include novel techniques or approaches.

OGTR

OGTR includes a risk estimation matrix within its Risk Analysis Framework (Section 8.4). This matrix explains how the likelihood and consequences components are combined to give a risk estimate. The matrix rests on standardised terms and descriptions for likelihood, consequences and risk, and illustrates how the risk estimate can be interpreted in terms of a baseline level of acceptable risk. OGTR explains that the matrix is designed to be used as a tool in arriving at the risk estimate; that is, it is not a prescriptive solution for deciding on the appropriate risk estimate for any given adverse outcome or on the necessity for management conditions to be imposed.

Consequences are assessed by OGTR in several ways, each of which provides a different form or depth of insight. The 'adverse outcomes' of an intentional or unintentional release of a GMO are examined, and the extent of such outcomes are assessed against 'measurable properties' (Table 5). This exercise is valuable, as it identifies the different ways that a GMO might directly impact on humans or the environment. The second perspective on consequences is the need to consider the different 'levels' of impact; where these might range from impacts on individuals, to impacts on populations or ecosystems. This part of the exercise is also valuable, as enables OGTR to determine whether the GMO under consideration is likely to have the substantive 'flow-on' indirect impacts that typically arise from broader scale effects. The third form of assessment is classification of the 'significance' of the impact. This is more complex, but seeks to combine information obtained from the first two steps to categorise the impact of the GMO according to one of the four descriptors on the risk estimation matrix. To do this, five separate criteria are used. Collectively, these criteria cover the severity, spatial extent, temporal extent, cumulative effect and reversibility of impact; in other words, the likely scale of the problem.

One aspect of the OGTR approach that is not described is the method, rationale or logic required to combine the components of the consequence assessment to obtain a single qualitative score for use in the risk estimation matrix. This omission is likely to be deliberate, and to reflect the principle that steps, lists and tabulated considerations within a qualitative consequence assessment are only guidelines. Each part may be used *in toto*, or may be added to or subtracted from as relevant to each individual assessment.

On balance, the OGTR approach to risk analysis, and, more specifically, to consequence assessment, is interesting as it most closely resembles Biosecurity Australia's prescriptive ranking approach. That said, the most tangible benefit that might be drawn from this review would be dialogue between the two agencies with regard to the advantages of each approach and their perceived drawbacks, as well as a more general discussion about the value of prescriptive ranking systems. Aside from this, the particular issues considered by OGTR, or the terms and definitions of their ranking system, were not seen to be sufficiently novel or inventive to be of immediate benefit to Biosecurity Australia.

Recommendation 9	
OGTR's qualitative ranking system for assessing and evaluating risk has some similarities to Biosecurity Australia's approach, although it differs in detail, and both agencies operate in an environment often characterised by powerful stakeholders and competing interests.	Biosecurity Australia and the Centre of Excellence should consider dialogue with OGTR with a view to sharing experiences and augmenting the qualitative approaches they each use for consequence assessment.

11 APPENDIX: AGENCY WORKSHOP

11.1 Background

On July 19th an interactive workshop was held with representatives from the agencies that participated in the project. The objective of the workshop was to discuss the outcomes of the review, as documented in the Draft Project Report, and to provide an opportunity for agency representatives to clarify or otherwise correct the report's content or conclusions. It was also hoped that the workshop would provide a forum for contact between the agencies, and thus pave the way for ongoing discussion about the project outcomes.

Invitations to the workshop were distributed to the agency representatives that had participated in the interviews. In some cases these representatives were not available on the chosen day, and others attended in their stead. The names and email addresses for review and workshop participants are provided in Table 7.

The workshop contained two parts. The first was a presentation about the fundamental elements of risk management, and about how the terminology for risk management differs amongst the various standards and guidelines. The presentation concluded with an overview of the project and an opportunity for group discussion about core issues. The second part of the workshop was structured around the Draft Project Report. Here Broadleaf provided some summary talking points, but otherwise offered each agency representative the opportunity to explain the context in which risk management is carried out, the broad approach taken to risk management and the specific approach taken to the assessment of consequences. Agency representatives were encouraged to frame their descriptions of consequence assessment around: (a) the criteria against which impact is generally assessed; (b) how impact is 'measured' or estimated; and (c) how the agency incorporates the scale of the event concerned. The presentations were spontaneous and informal, and in each case included iterative discussion amongst the workshop participants.

Feedback from the workshop has indicated that the participants enjoyed the interaction and appreciated the opportunity to meet with and listen to colleagues from the different departments, divisions and agencies. The workshop concluded with a request to participants to re-read the relevant sections of the Draft Project Report, and to provide comments about technical accuracy and interpretation. Comments were received from all participating agencies, and were incorporated into this Final Project Report.

11.2 Specific Comments from the Workshop

The following notes provide a summary of the main discussion points from the workshop.

ABARE uses a range of different models. Relevant characteristics are:

- Data needs are high, particularly for establishing the models.
- Experimental economic models are an emerging area, e.g. for ascribing value to aspects of the environment that are hard to value. The Productivity Commission is starting to do some work in this area, but ABARE is just looking at the moment.
- There are many other economic models in the market place, and there is a lot of interaction between agencies for specific purposes (e.g. the Productivity Commission used a model from ABARE to examine the effects of foot and mouth disease for the Treasury).
- It is difficult to develop a single model for all purposes. The conceptual framework needs to be clarified before models are developed, and the availability of data may impose constraints.
- Caveats associated with models are related to their sensitivity, assumptions, accuracy and variability.
- Economic models can assist in identifying the risk treatment measures and policies that are most cost-effective (compared with the measures that are most effective purely in reducing risk). This is different from their use in consequence analysis.

The Biosecurity Australia approach is complicated by the presence of multiple criteria, multiple susceptible target populations and the range from local to national effects.

Australian Greenhouse Office:

- Risk management has not been a core area of interest of the AGO until recently.

- A national climate change adaptation programme is in progress. Sectors of interest have been identified.
- Risk management process guidelines are being developed for examining risks associated with regional climate change and adaptation.
- Likelihoods of scenarios are difficult to estimate, which imposes a constraint of top-down approaches. Sensitivity analyses of thresholds allows bottom-up vulnerabilities to be identified.
- AGO works closely with other groups (e.g. CSIRO, Bureau of Meteorology).
- AGO is developing a web-based tool-kit, including regional projections of potential climate changes and effects.

FSANZ undertakes risk assessments that are largely straightforward, focussing on the health of the Australian population. There are three distinct areas of interest:

- Chemical assessment is well-structured and uses accepted approaches. There are good data bases and good dose-response information from laboratory and other studies.
- Microbiological assessments are constrained by absence and variability of data.
- Nutritional assessments must include the impacts of both too little and too much of a particular item.

Other aspects of the FSANZ approach:

- There are major challenges in acquiring data.
- FSANZ looks at benefits as well as adverse consequences. Benefit-cost analyses are undertaken for new standards and regulations.
- More or less susceptible sub-populations are treated differently in terms of setting regulatory levels (e.g. the frail or elderly, the very young).

OGTR's mandate is to look at adverse consequences to human health and the environment.

- Benefits are not considered explicitly.
- There is a challenge in identifying the risks associated with a modified organism compared with a non-modified organism.
- A body of case study experience with the new process is being developed and included on the OGTR web site: see the decision on bovine herpes virus; Bulgar 2 cotton; roundup ready canola.
- Clarity of descriptors for consequence levels is important.

Geoscience Australia

- There are some changes to the structure of Geoscience Australia and the projects from those described in the draft report. Otherwise the report summarises activities and processes well.
- The Risk Assessment Methods Project is focused on model and technique development.
- The Critical Infrastructure Project is reporting to DOTARS.
- There has bee good buy-in to the National Risk Assessments Project, with good involvement from State Governments as an on-going activity.
- Geoscience Australia is also undertaking modelling work aimed at direct and indirect economic loss and socio-economic effects.

APVMA:

- The draft report talks about the three functions, which are actually the functions of the national agvet regulatory system, with DEH and the States and Territories. Not all functions are done by APVMA.
- No modelling is done at all.
- Methods for examining the export trade effects of residues are most relevant to the discussion here.
- Size is one criterion for determining which industries and products are considered. The limit is set currently at $100 million turnover.

The Productivity Commission does no risk assessment. It only conducts studies commissioned through Treasury, which may limit the way in which dialogue is initiated. Reviewing economic models would be a feasible task (as noted in the recommendation), but there would be practical difficulties in getting approval for this to start.

Table 7: Review and workshop participants

Agency	Participant	Review	Workshop
ABARE	Lisa Elliston	✓	✓
Australian Greenhouse Office	Jean Douglass	✓	
	Matthew Walker	✓	✓
APVMA	Phil Reeves	✓	✓
Biosecurity Australia	Bill Roberts	✓	
	Robyn Martin	✓	
	Steve Prothero		✓
	Brian Stynes		✓
	Peter Beers	✓	
	David Buckley	✓	✓
	Sharan Singh		✓
Biotechnology Australia	Kevin Gale	✓	✓
Bureau of Rural Sciences	Jean Chesson	✓	
	Mellissa Wood	✓	✓
	Liona May	✓	✓
	Simon Barry	✓	✓
	Simon Knapp		✓
FSANZ	Marion Healy	✓	
	Hikmat Hayder	✓	
	Deon Mahoney		✓
Geoscience Australia	John Schneider	✓	
OGTR	Peter Thygesen	✓	✓
	Robyn Cleland	✓	✓
	Paul Kleese	✓	✓
	Phil Cummins	✓	
	Ken Dale	✓	✓
Productivity Commission	Monika Binder	✓	✓