
5 AUSTRALIA'S APPROPRIATE LEVEL OF PROTECTION AND IMPORT RISK ANALYSIS

5.1 Introduction

The SPS Agreement defines the concept of an ‘Appropriate Level of Protection’ as the level of protection deemed appropriate by a World Trade Organization Member when establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. When setting its Appropriate Level of Protection, a World Trade Organization Member may consider the full range of national interest considerations that reflect community expectations. However, under the SPS Agreement, World Trade Organization Members must ensure that biosecurity measures are not more trade-restrictive than required to achieve the Appropriate Level of Protection, and that the Appropriate Level of Protection is applied consistently.

The Panel’s terms of reference do not require it to consider what Australia’s Appropriate Level of Protection should be. Rather, the Panel is required to consider ‘the appropriateness, effectiveness and efficiency of current arrangements to achieve Australia’s Appropriate Level of Protection.’

Australia defines its Appropriate Level of Protection as ‘providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not to zero’ (Department of Agriculture, Fisheries and Forestry 2007). The Panel has encountered much confusion over what this qualitative statement means and how it is operationalised. As a consequence, the Panel has explored the issue in some depth. The struggle to define the Appropriate Level of Protection is not unique to Australia.

A country’s Appropriate Level of Protection is applied through its decisions on whether to allow imports, and if so, under what conditions. The Import Risk Analysis process is how Australia makes its decisions on more complex market access proposals. It has been suggested to the Panel that the Appropriate Level of Protection can be considered as ‘an emergent property of a sequence of Import Risk Analyses and decisions taken based on them’ (Prof. Mark Burgman

2008, pers. comm.). The Import Risk Analysis process is squarely within the Panel's terms of reference.

Consistency in the application of the Appropriate Level of Protection through import decisions, and associated sanitary and phytosanitary measures, is crucial. Failure to apply the Appropriate Level of Protection consistently has led to appeals to the World Trade Organization, for example, Canada's successful appeal against Australia's Import Risk Analysis for Canadian salmon.

The Import Risk Analysis process and some of the decisions made by successive Directors of Animal and Plant Quarantine, including those based on the recommendations of Import Risk Analyses, have been extensively criticised by domestic stakeholders and international trading partners alike. New Zealand's challenge in relation to import conditions of New Zealand apples is a recent example.

There are over 175 separate import requests awaiting consideration by Biosecurity Australia on the basis of current requests. The vast majority are formal market access requests received from trading partners and businesses wishing to bring products into Australia but include others, such as the Import Risk Analysis for horses recommended by Commissioner Callinan in his equine influenza report. Some of these market access requests are awaiting information sought from the applicant or initiating country. Biosecurity Australia also conducts risk assessments following requests from AQIS to review existing policy as a result of changes to scientific knowledge or levels of risk associated with particular commodities or products.

5.2 Current arrangements

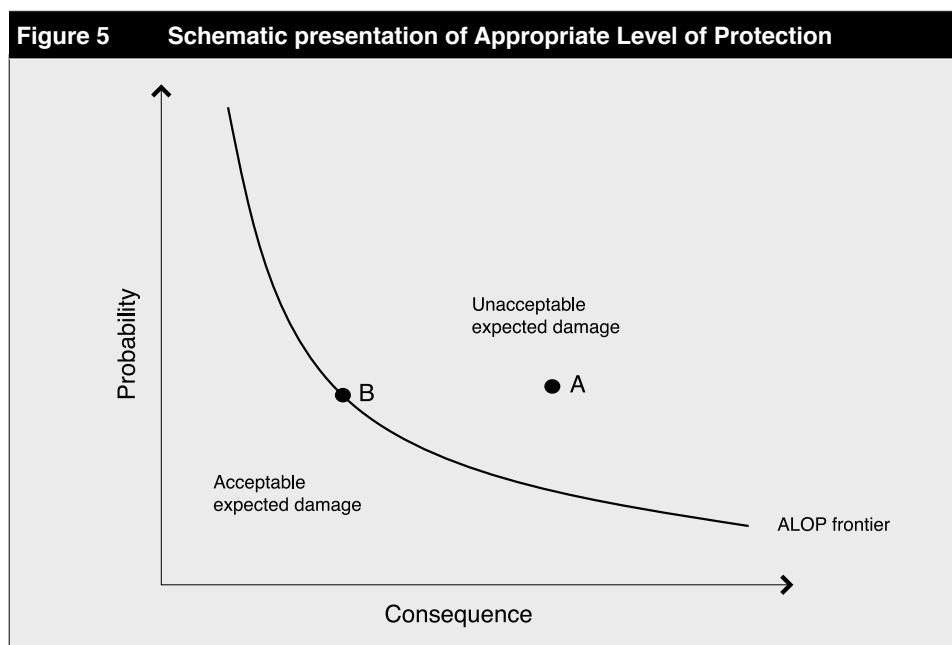
5.2.1 Australia's Appropriate Level of Protection

Australia's Appropriate Level of Protection was set by the Government following lengthy consultations through the Agriculture and Resource Management Council of Australia and New Zealand, and the Primary Industries Ministerial Council. It does not reflect a formal cabinet or ministerial decision. The definition followed a 2000 Senate Rural and Regional Affairs and Transport Legislation Committee report *An Appropriate Level of Protection?—The Importation of Salmon Products: A case study of the Administration of Australian Quarantine and the Impact of International Trade Arrangements*.

The Committee recommended that the Commonwealth Government, in consultation with the community and the states, be responsible for establishing a more explicit Appropriate Level of Protection. The Primary Industries Ministerial Council then agreed that the draft guidelines for risk analysis, developed by Biosecurity Australia and which illustrated the concept by way

of a risk estimation matrix, adequately met Australia's needs and that further definition was not a Ministerial Council priority (Primary Industries Ministerial Council 2002, Meeting 1, Resolution No. 1.3).

Figure 5 schematically, and somewhat simplistically, illustrates the Appropriate Level of Protection in the form of an indifference curve that reflects the *probability* of a pest or disease incursion combined with the anticipated *consequence* of such an event. In Figure 5, the curve, marked 'ALOP frontier', expresses the future consequences of an incursion at various probabilities of its occurrence. Point A represents a commodity that poses an unacceptable expected damage if imported in its current form. Point B represents the same commodity that, following the application of biosecurity measures, has reduced the biosecurity risk to a level consistent with the Appropriate Level of Protection. While in theory this ALOP frontier could be expressed in dollar terms—the Net Present Value over a nominated period of time of the probability adjusted consequences—in fact this has never happened. In part this is for reasons of the practical difficulty of quantifying probabilities and consequences, and measuring non-economic impacts in dollar terms.



Few, if any, other countries have a more explicit statement of their Appropriate Level of Protection than Australia, although some countries are attempting to address the ambiguity of their definition. Some examples of other definitions are shown in Box 12 (see also Section 10.2).

BOX 12 Definitions of Appropriate Level of Protection used in other countries

European Commission - 'For serious threats to human health and the rural economy, we must strive to reduce the risk to a negligible level.'

Japan - 'Its level of protection is that achieved by the import prohibition.'

United States of America - 'Reasonable certainty of no harm – that must be applied to all pesticides used on food commodities.' (Used in the context of food safety)

Source: European Commission 2007; World Trade Organization 2001;
http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_implementation.htm

5.2.2 The Import Risk Analysis process

The Appropriate Level of Protection is given practical expression through:

- Biosecurity Australia's Import Risk Analysis process;
- import policy determinations and any associated conditions determined by the Director of Animal and Plant Quarantine (or his/her delegate); and
- decisions made under delegation in relation to individual import applications.

Australia uses risk analysis to assess whether a proposed import can be brought into the country in a way that meets the Appropriate Level of Protection and under what conditions consistent with its obligations under the SPS Agreement. Risk assessments vary in complexity, from a straightforward assessment associated with minor changes to an existing import policy decision through to a full blown Import Risk Analysis following steps set out in regulations under the *Quarantine Act 1908*.

While the formal Import Risk Analysis process applies to only a small proportion of import requests considered by Australia, it attracts the bulk of criticism regarding Australia's risk assessment system. Within the formal process are a smaller number of remaining 'legacy' Import Risk Analyses being conducted—chicken meat, prawn and prawn products, and bananas from the Philippines. These have been under consideration for a long time, have consumed disproportionate resources both within government and business, and have attracted widespread media and political attention in Australia and abroad. Outside this group, many of the Import Risk Analyses conducted by Biosecurity Australia go largely unnoticed (see Box 13).

BOX 13 Import Risk Analyses and related assessments conducted by Biosecurity Australia in 2007-08.

Market access requests awaiting consideration end 2007-08: 175

Market access requests received in 2007-08: 13 (plant), 7 (animal)

Import Risk Analyses finalised in 2007-08: 0

Import Risk Analyses in progress: 13 (plants), 12 (animals)

Risk Assessments referred by AQIS: 530 (plant), 450 (animal), 337 (weeds)

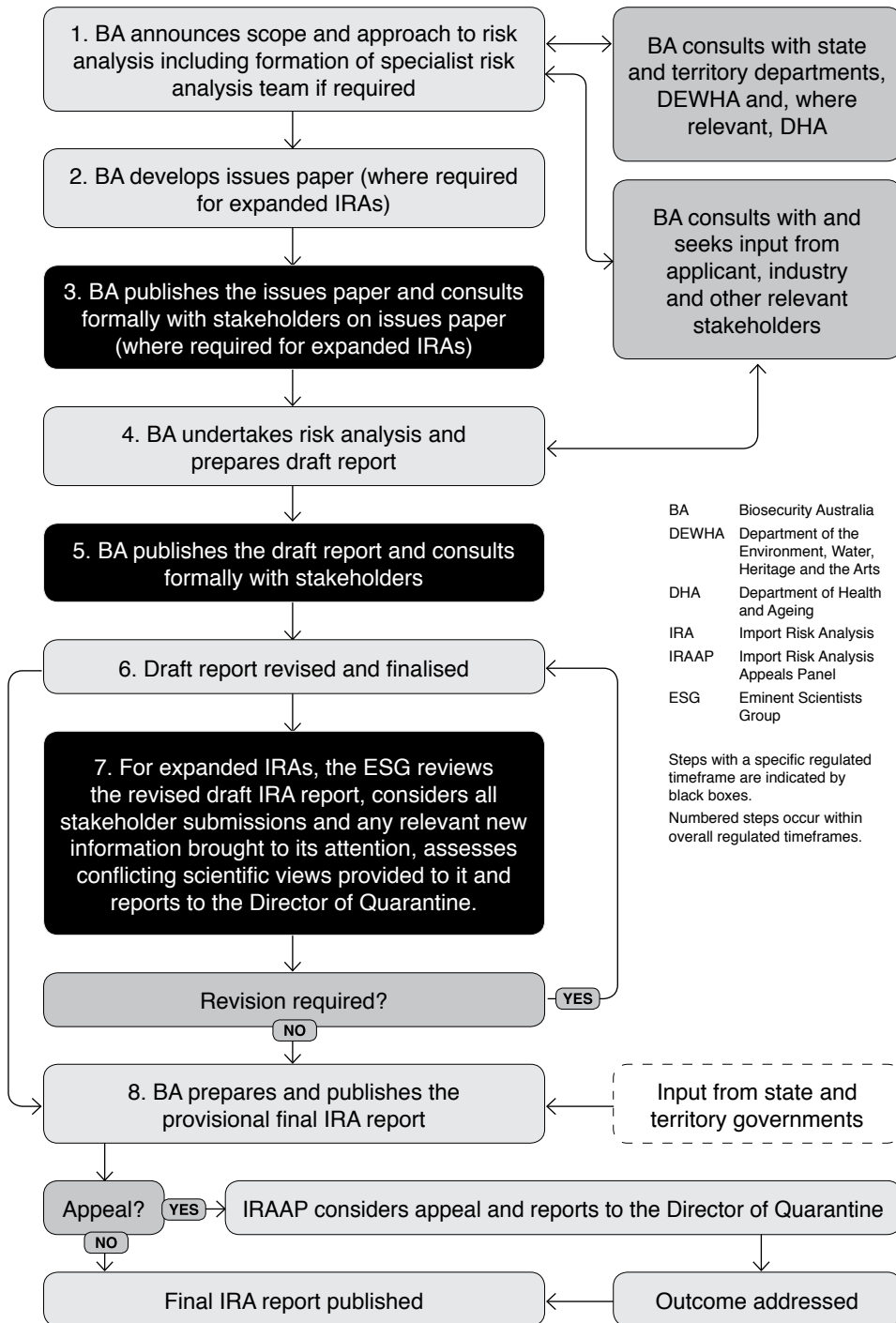
Biosecurity Australia also conducts risk assessments following requests for policy advice from AQIS on a range of routine import permit decisions. This generally occurs in relation to imported products for which AQIS has identified a biosecurity risk and requires clarification of import policy related to that product.

A fundamental requirement of the SPS Agreement is that risk management measures be based upon a risk assessment and not maintained without sufficient scientific evidence. Risk assessment is defined in Annex 5 of the SPS Agreement as ‘the evaluation of the likelihood of entry, establishment or spread of a pest or disease and of the “associated” biological and economic consequences’. This is a definition that falls short of a conventional national interest assessment. Only biological and economic consequences that are ‘associated’ with the entry, establishment and spread of the pest or disease are deemed to be relevant. Importantly, Import Risk Analyses do not involve consideration of the broader economic and social issues arising from the impact of competition between imported and domestic products that may be taken into account in a full national interest test (for example, the beneficial effect on consumer prices or choice of import competition or the loss of jobs in rural communities as a result of imports).

The *Import Risk Analysis Handbook 2007* outlines the steps in the Import Risk Analysis process (see Figure 6). Australia’s process is consistent with the SPS Agreement, and with international guidelines and standards on risk assessment developed under the Codex Alimentarius Commission, the International Plant Protection Convention and the OIE. Once the Import Risk Analysis Report is finalised, the Chief Executive of Biosecurity Australia provides it, and a recommendation for a policy determination, to the Director of Animal and Plant Quarantine.

The Australian Centre of Excellence for Risk Analysis was established in the School of Botany at the University of Melbourne in 2006, as a Commonwealth Government election commitment. Funding is managed by the Department

Figure 6 Import Risk Analysis Flowchart



of Agriculture, Fisheries and Forestry. Its purpose is to develop risk analysis methods and communicate its findings to governments and others engaged in risk analysis.

In September 2007, significant changes to the Import Risk Analysis process were implemented when regulations made under the *Quarantine Act 1908* formally took effect. These changes were made in response to domestic and international criticisms. The changes enhanced the scientific scrutiny and transparency of Import Risk Analyses, improved timeliness, and formalised consultation arrangements for stakeholders. They:

- specified timeframes for the Import Risk Analysis process;
- established an Import Market Access Advisory Group to determine priorities for considering import proposals; and
- established a stronger role for the Eminent Scientists Group.

The Import Market Access Advisory Group is chaired by a Deputy Secretary of the Department of Agriculture, Fisheries and Forestry, and comprises the Chief Executive of Biosecurity Australia, the Executive Director of AQIS, and the Executive Managers of Trade and Market Access Division and PIAPH. It formulates its views on priorities based on the national interest, export country considerations and practicalities such as availability of technical information.

The Eminent Scientists Group existed prior to the 2007 reforms. Its role was to examine final drafts of Import Risk Analysis reports prior to their release and consider whether Biosecurity Australia had properly taken account of all technical issues in submissions received. This role has now been enhanced to include consideration of whether the conclusions of Import Risk Analysis reports are scientifically reasonable, based on the material presented. To this end, the Eminent Scientists Group is able to co-opt additional expertise, for example in economics, statistics or specialised scientific disciplines.

Under its terms of reference, the Eminent Scientists Group is only involved in what are termed 'expanded' Import Risk Analyses. An expanded Import Risk Analysis is used for those import proposals that the Chief Executive of Biosecurity Australia considers will raise significant differences in scientific opinion or the possibility of significant harm to people, animals, plants or the environment were they to be approved.

The Eminent Scientists Group provides scientific review but it does not constitute an appeal mechanism. Appeal options arise once a provisional final Import Risk Analysis report has been published, but then only in relation to the process rather than the final decision. This non-judicial review is conducted by an Import Risk Analysis Appeals Panel which provides its report to the Director of Animal and Plant Quarantine. The Import Risk Analysis Appeals Panel

may offer advice to the Chief Executive of Biosecurity Australia on ways of overcoming any identified deficiencies.

Because an Import Risk Analysis is not an administrative decision in relation to a specific import, it is not subject to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*.

5.2.3 Dealing with the environment and human health

Under current arrangements, permits for all imports are issued by the Director of Animal and Plant Quarantine, who in the process considers the likelihood and consequence to human health and the environment that could be caused by issuing the permit.

When assessing the risks of an import that may have implications for human health or the environment, Biosecurity Australia and/or AQIS consults the relevant Commonwealth agencies—the Department of Health and Ageing, via the Chief Medical Officer (who holds the position of Director of Human Quarantine under the *Quarantine Act 1908*), or the Department of the Environment, Water, Heritage and the Arts in the case of the import of live species which may fall under the *Environment Protection and Biodiversity Conservation Act 1999*.

The arrangement by which Biosecurity Australia and/or AQIS considers human health risks varies according to the nature of the item that is proposed for import whether it be a biological material, including human therapeutics, human remains, or food commodities.

5.2.4 Food risk assessments

Food Standards Australia New Zealand conducts all food risk assessments for Australia. These are not in the scope of Biosecurity Australia's Import Risk Analysis process. The process is triggered by an application for an amendment to the Australia New Zealand Food Standards Code, which can be made by Food Standards Australia New Zealand itself, individuals, businesses or governments. The process, stipulated in the *Food Standards Australia New Zealand Act 1991*, is transparent with opportunities for comment at several points in the risk assessment process as well as the subsequent separate development of risk management options.

Very few food risk assessments have dealt specifically with issues related to imported food—examples are raw milk cheeses (Roquefort and some Swiss varieties) and beef and beef products that may contain the BSE agent that causes variant Creutzfeldt-Jakob disease in humans.

5.3 Current debates and views in submissions

5.3.1 Appropriate Level of Protection

The Panel has found that there is no agreed understanding of the practical implications—as distinct from the simple verbal description—of Australia’s Appropriate Level of Protection among governments, businesses and the wider community. In 2005, Australian Pork Limited and a pork producer challenged the policy determination made by the Director of Animal and Plant Quarantine and the subsequent issuance of an import permit for pork from the United States. During the course of this case, the Federal Court of Australia referred to the Appropriate Level of Protection as ‘the imponderable standard of acceptable lowness’ (*Director of Animal and Plant Quarantine vs Australian Pork Limited (2005)*).

The complexity underlying the Appropriate Level of Protection was noted by Plant Health Australia in its submission to the Panel:

‘Defining the ALOP for Australia is undoubtedly a complex and dynamic task. The interests of Australia’s agricultural industries must be taken into account, as must considerations about national, jurisdictional and regional post-border risk mitigation and emergency plant pest response capability. Balanced against this, consideration must also be given to international and bilateral trading rules, especially adherence to standards governing acceptable quarantine restrictions and controls.’ (Plant Health Australia submission, p. 9)

Equally, the Panel found that regardless of views that Australia’s Appropriate Level of Protection may be set too high or too low, there exists almost universal confusion about what the Appropriate Level of Protection actually is as distinct from what it is not—zero, that is, it is ‘not zero risk’.

A number of submissions, particularly those from private individuals, argued that it would be preferable to have a zero risk tolerance as the *aim*. AgForce representatives told the Panel that there should be a zero risk approach to compensate for what they perceive as a lack of confidence in the regulator. Some submissions argued that the public expects an Appropriate Level of Protection that is close to zero, whereas others acknowledged that some level of risk is unavoidable. Many submissions stressed that the Appropriate Level of Protection was poorly understood by officials, businesses and the public.

‘The logical conclusion is that while Australia may not always be able to maintain zero quarantine risk with tourists, it has the power to establish zero disease risk from international trade by a total blockage of suspect imports.’ (P Phillips submission, p. 1)

‘While we cannot have zero risk with tourists, we can have zero risk with trade by blocking imports. This not only protects local plants and animals it also protects local producers.’ (B Bowtell submission, p. 1)

In 1995, the Agriculture and Resource Management Council of Australia and New Zealand considered the issue. It concluded that quarantine decisions cannot be based on a zero risk policy, nor can decisions be influenced by the desire to keep out competition (ARMCANZ 1995, Meeting No.6, Resolution 2D).

The Department of Foreign Affairs and Trade and others highlighted that a zero risk policy is neither achievable nor desirable.

‘... a zero risk stance is impractical, as it would mean no tourists, no international travel and no imports.’ (Department of Foreign Affairs and Trade submission, p. 5)

Animal Health Australia argued that the purpose and focus of Australia’s biosecurity system should be to allow the safe passage of animals, plants and people across Australia’s borders.

‘The primary role of quarantine is to allow the safe import of commodities (live animals, animal and plant genetic material, animal and plant products, food) and the safe movement of people for the benefit of the country.’ (Animal Health Australia submission, p. 11)

The Panel heard from some stakeholders that the Appropriate Level of Protection was not adequate to protect Australia from biosecurity threats, while others, including the Australian Food and Grocery Council, were satisfied with the current setting.

‘The AFGC considers that Australian’s Quarantine and Biosecurity systems appropriate to maintain its ALOP, providing a considered balance of what is a reasonable risk while taking into account the necessary impediments to trade.’ (Australian Food and Grocery Council submission, p. 5).

5.3.2 Views about Import Risk Analyses

In practice it is difficult to talk about the meaning of the Appropriate Level of Protection without considering decisions made to implement it. Australia’s system is judged domestically and internationally by the measures used to operationalise the Appropriate Level of Protection. While conceptually the Appropriate Level of Protection can be distinguished from a measure,¹ many

¹ ‘Appropriate Level of Protection’ can be described as the ‘objective’ (what you are aiming for) and the ‘measure’ as the way in which you achieve that objective.

argue that it is best observed by examining the accumulation of import policy decisions taken after the conduct of Import Risk Analyses.

In the Panel's view, there is an inconsistency in an argument that the Appropriate Level of Protection is passively determined by the accumulation of Import Risk Analyses and related decisions. This lies in the factors which are taken into account in considering the Appropriate Level of Protection on the one hand, and the Import Risk Analysis on the other.

As noted earlier, under the SPS Agreement a full range of national interest factors can be taken into account in setting the Appropriate Level of Protection—including the benefits of trade and travel. Conversely, advice to the Panel by the Australian Government Solicitor indicates that the factors appropriately considered in an Import Risk Analysis and related decisions are limited to 'evaluation of the likelihood of entry, establishment and spread of a pest or disease and of the associated biological and economic consequences'. Some submissions recognised this limitation and argued that to the extent a 'national interest' test is excluded from an Import Risk Analysis, it results in poor policy and if constrained by the SPS Agreement, means that this Agreement is flawed.

One of the dominant themes in comments received by the Panel concerned the way Australia conducts its Import Risk Analyses. The Panel heard a range of views including that Import Risk Analyses:

- advantage export focused agricultural industries at the expense of domestic industry interests;
- result in the fast-tracking of market access requests to the detriment of biosecurity—a concern that was expressed in most cases by businesses who see Free Trade Agreements as providing such a trade-off;
- are subject to political interference (argued by New Zealand in its appeal to the World Trade Organization in relation to measures affecting the importation of apples);
- are subject to lengthy delays;
- do not provide adequate review processes;
- fail to address genuine regional differences in pest and disease status within Australia; and
- do not adequately address the broader issues of human health and the environment.

Without doubt, some elements of agriculture and the wider community are convinced Australia should be taking a more conservative approach

to biosecurity, with accusations that risk management measures proposed in some Import Risk Analyses fail to meet Australia's Appropriate Level of Protection.

Conversely, other agricultural interests, especially those more export focused, plus some of Australia's trading partners and importers, openly complain about a process they see as being overly trade restrictive and inconsistent with international obligations. For example, trading partners have accused Australia of failing to conduct Import Risk Analyses in a timely and transparent manner, introducing measures that are 'more trade restrictive than required', failing to reflect international standards in import conditions, and using Import Risk Analyses as a means of protecting domestic industries from import competition.

'The United States' perspective is that Australia has occasionally adopted measures that are significantly more trade-restrictive than required to achieve the ALOP.' (United States Department of Agriculture submission, p. 3)

'There is a clear perception that the conservative interpretation [of the Appropriate Level of Protection] is increased for products where there is a vocal domestic industry opposed to imports, while the interpretation appears to be less rigorous for products that Australia wishes to import and which may suffer from the same threat from pests or diseases.' (European Commission submission, p. 10)

The Panel notes that unlike the Australian Competition and Consumer Commission authorisation and notification process, and the Australian Energy Market Commission's rule change process, draft determinations are not released for public comment.

5.3.3 Debate about Import Risk Analysis methodology

Both before and after the September 2007 reforms, Australia has gone further than many countries in setting out its Import Risk Analysis process in the public arena. However, while the steps in the process are clear, there is still uncertainty and debate surrounding the risk analysis methodology used by Biosecurity Australia.

Guidelines have been prepared by Biosecurity Australia to take officers through the steps and issues involved in determining the likelihood and consequences of a pest or disease entering, establishing and spreading in Australia. The guidelines amplify the risk analysis methodology—beyond the broad information available publicly in the *Import Risk Analysis Handbook 2007*. The guidelines are not made public. The Panel is concerned that while these guidelines are updated

periodically, they have never been finalised as a single agreed set of instructions. Currently there are several sets of draft guidelines extant and being used by Biosecurity Australia to conduct various Import Risk Analyses. Conceivably, this could affect Biosecurity Australia's ability to be consistent across Import Risk Analyses. It almost inevitably adds to uncertainty about methodologies used. None of these draft guidelines have been submitted to the Minister for consideration and approval, unlike the Import Risk Analysis Handbook.

Biosecurity Australia's consequence estimation, which appears to place significant emphasis on the national impact of the pest or disease, has attracted considerable comment from those making submissions to the Panel. For example, if the *probability* of entry, establishment or spread and relative impact on unit production costs is the same for a pest that might affect a small industry as a large industry, the *consequence* for the large industry will, by definition, be higher than for the small industry, and so therefore will the overall *risk* estimate. Many domestic agricultural groups are unhappy with this approach because they claim the assessment process means their (smaller) industries receive less biosecurity protection.

Similar concerns were also expressed in regard to highly regionalised or specialised industries.

‘In order to assess the level of impact of the establishment of a disease, Biosecurity Australia discounts the effects of diseases which impact on industries that are concentrated in one state only ... It is a direct consequence of this matrix that even a significant impact on a state-based industry sector would not register as significant on a national scale. Thus the wipe-out of the Australian salmonid farming sector based almost entirely in Tasmania, or the Southern Bluefin Tuna farming sector based almost entirely in South Australia, would not register as significant enough on a national scale to contravene Australia's ALOP.’ (Tasmanian Salmonid Growers Association submission, p. 4)

Conversely, other groups thought that too much attention might be given to industries where the economic impact was marginal—either a significant impact on a very small industry, or a broader but very modest impact. The Productivity Commission proposed to the Panel that one way of giving Import Risk Analyses a quantitative anchor would be to use an expected cost threshold (effectively a quantification of the ALOP indifference curve), below which measures would not be considered.

‘For example, where an imported product is assessed in an import risk analysis to have “a high likelihood of a \$X million cost arising from a

pest or disease incursion”, then quarantine measures would apply ... Using an expected cost threshold for the determination of (measures to maintain the) ALOP would demand quality economic consequence studies to be incorporated in import risk analyses, performed by institutions with credibility.’ (Productivity Commission, correspondence to the Panel, 2008).

Biosecurity Australia uses a range of methods for its risk analysis, from qualitative to quantitative assessments, depending on the circumstances, such as data availability. A number of industry organisations expressed a preference for quantitative analysis on the basis that qualitative analysis lacked the required rigour. For example, Seafood Services Australia argued that:

‘... the current model of applying qualitative definitions in risk assessments is being increasingly questioned by the Australian seafood industry ... it is evident to SSA that there is justification in moving to a more scientifically based quantitative risk management model.’ (Seafood Services Australia submission, p. 4)

Australian Pork Limited also expressed a preference for quantitative analysis.

‘The methodology applied in assessing risk management procedures and unavailability of necessary scientific knowledge underpin APL’s ongoing concerns with the Pigmear IRA, including the preference for quantitative risk assessment over a qualitative risk assessment.’ (Australia Pork Limited submission, p. 21)

Over recent years, Biosecurity Australia’s risk analysts have concluded that in some cases the lack or inconclusiveness of fundamental science, or the lack of data, or where data reliability is questionable, means that quantitative risk analyses cannot be sensibly undertaken. Where this is the case, expert opinion is used, combining knowledge of trade with other countries, knowledge of the biology of the pests and diseases of concern, and experience with similar products and pests and diseases. Biosecurity Australia argues that this approach has proven much more useful than attempting to provide numerical estimates for the many parameters needed for quantitative risk analyses in a way that might give rise to spurious accuracy.

Similarly, Biosecurity New Zealand explored the issue to the point of adopting a quantitative approach to risk analysis. However, recognising the same difficulties, it has now reverted to a more qualitative approach. The Panel was also told by the Department of Foreign Affairs and Trade that the World Trade Organization Appellate Body in considering the *European – Hormones* case clarified that both qualitative and quantitative approaches were acceptable.

5.3.4 Addressing regional differences

As noted earlier, a concern was expressed by several state governments and business groups about the way in which regional differences in pest and disease status are accounted for in the Import Risk Analysis process. The Tasmanian Government's submission argued this issue particularly strongly.

‘It is the Tasmanian Government's view, based on experience of the last five years, that in dealings of risk analysis, there has been a less than consistent approach shown by other jurisdictions, including the Australian Government, in acknowledging and addressing regional differences issues ...

If regional differences in pest status, likelihood and consequence were to be reflected more comprehensively in Biosecurity Australia risk analysis and the subsequent determinations by the Australian Director of Plant and Animal Quarantine, then most of the quarantine disputes between the Australian and State and Territory Governments would fall away.’ (Tasmanian Government submission, p. 7)

As noted in Chapter 2, the *Memorandum of Understanding on Animal and Plant Quarantine Measures*, signed by the Commonwealth and the states, was amended in 2002 to require the Commonwealth to address regional differences in pest and disease status and risk, and the consequent introductions of appropriate SPS measures as part of risk analysis.

The Western Australian Government advised the Panel that Biosecurity Australia has improved its recognition of regional differences in recent Import Risk Analyses but that further collaborative work would be beneficial. It argued that the routine entry into the Import Conditions database (also known as ICON) of regional differences in pest status and associated controls on imports was essential.

5.3.5 Conduct of Import Risk Analyses, backlogs and delays

As noted earlier, one of the major complaints by Australia's trading partners is the time taken for Import Risk Analyses (see also Chapter 10). For example, the Philippines complained to the Panel about delays in completing the Import Risk Analysis for bananas from the Philippines which commenced over 8 years ago. Similar views were expressed by Thailand and the United States.

‘As the record shows, it is occurred to our consideration that the timeframe for Import Risk Analysis (IRA) conducting is extensive and not appropriate. This is reflected in the case of Chicken Meat and Prawn and

Prawn Products IRA, which to date have lasted for more than 10 years.’
(Royal Thai Embassy, correspondence to the Panel)

‘Timeliness has been of concern to the United States regarding both plant and animal market access issues. Key examples of our longstanding market access issues include access for U.S. stone fruit, which first was discussed in 1993, and access for U.S. apples, first discussed in 1989.’
(United States Department of Agriculture submission, p. 5)

While these Import Risk Analyses may have involved complex scientific assessments, the Panel’s judgement is that the time taken is difficult to justify. The Panel notes that in other equally complex areas such as therapeutic goods and major project approvals involving environmental issues, the time for assessments has been much less than in the biosecurity context. The Panel also notes that the time taken by trading partners to assess Australia’s market access requests could also be considered to be excessive in some cases (see Chapter 10).

The 2007 changes to the regulations governing Import Risk Analyses require that assessments are handled within much tighter timelines. Biosecurity Australia is now required to complete a standard Import Risk Analysis within 24 months and an expanded Import Risk Analysis within 30 months. These timeframes start with an announcement by the Chief Executive of Biosecurity Australia of the commencement of an Import Risk Analysis.

While the Panel noted support for these changes by Australia’s trading partners, residual scepticism remained based on the possibility of the ‘bottleneck’ being transferred to the commencement of the process. In other words, if Biosecurity Australia continues to conduct the bulk of assessment work in-house and its resources are not significantly increased, there will be considerable delays in ‘getting onto the queue’ for an Import Risk Analysis. This in turn will transfer lobbying effort to ensuring that the Import Market Access Advisory Group recommends a high priority for a proposed import application.

5.3.6 Review of Import Risk Analyses and consequent decisions

Despite the provision for procedural review since 1998, and the more recent strengthening of the Eminent Scientists Group’s role, a number of submissions questioned the adequacy of existing review mechanisms.

‘The ESG needs to be given the responsibility to review all available science in order to assure the Australian government and people that full range of science that could impact on the outcome of an IRA has been taken into account. To do this it should also be given freedom to delve into

the science independently to decide if anything of significance has been overlooked by BA or the industry. The ESG should also have a significant say in whether or not the available science is an appropriate base upon which to make any decision to permit importation and, if it is not, to make recommendations on further research that needs to be carried out to achieve an appropriate level of scientific confidence.’ (Apple and Pear Australia Limited submission, p. 6)

Some submissions criticised the Import Risk Analysis Appeals Panel in terms of its independence and limited terms of reference. For example, Apple and Pear Australia Limited argued that it was time for a truly independent appeal process and a real judgment on whether or not Biosecurity Australia had followed its own processes and policies. A similar argument was also put by Australian Pork Limited who expressed frustration about the fact that the final Import Risk Analysis is not challengeable in the courts.

‘Of great concern to APL is the lack of opportunity in the appeals process to legitimately challenge the veracity of the scientific data used by BA in the IRA process. Under the current IRA process there is no body at all to adjudicate on the quality of the work done in the IRA (outside of the ESG), unlike other segments of the law involving regulations determined by public agencies. In other fields involving complex science, such as decisions on the registration of medicines by the Therapeutic Goods Administration or regulations from the Fisheries Management Authority, decisions can be questioned in the Administrative Appeals Tribunal.’ (Australian Pork Limited submission, p. 30)

The 2005 Federal Court case *Director of Animal and Plant Quarantine v Australian Pork Limited* highlighted the difficulties in challenging the Import Risk Analysis process. The Import Risk Analysis is an internal administrative exercise that is not taken under statute. While it might make a recommendation on a proposed import policy determination, an Import Risk Analysis does not of itself constitute a decision that affects the rights or interests of a party and therefore there is no provision for challenging it under Administrative Decisions Judicial Review. For similar reasons, an import policy determination by the Director of Animal and Plant Quarantine might not be reviewable. However, specific decisions by the Director of Animal and Plant Quarantine to issue/not issue an import permit, informed by a risk assessment and in accordance with an import policy determination, are subject to judicial review.

Australian Pork Limited also commented on the apparent discrepancy between the appeal opportunities afforded to international stakeholders through World Trade Organization dispute mechanisms and the opportunities for domestic challenge.

‘Australia’s trading partners have recourse to challenge the import protocols through the IRA process and via the WTO. However, following the ruling of the High Court (sic), no such challenges are available to domestic industries through law ...

On the other hand, each of the successful WTO challenges under the SPS agreement has been on the basis of some aspect of the content of quarantine measures – so trading partners can challenge on content, but domestic industries cannot.’ (Australian Pork Limited submission, p. 29)

Concern about review mechanisms was also expressed by Professor Kearney, in relation to his experience with the process used for the Import Risk Analysis for the importation of prawns and prawn products. He argued:

‘The inference ... that the Import Risk Analysis Appeals Panel is an active part of the process again demonstrates the discrepancy between perception and reality. This Panel does not play any part until the Draft IRA is finalized and has been considered by the Eminent Scientists Group. In the case of the prawn IRA management measures which have totally destroyed all trade in prawns with some countries have already been introduced (and several smaller importers have already been put out of business) and there are not even dates for completion of the draft IRA, let alone involvement of the Eminent Scientists Group, which are both required before any appeals are allowed. The delays are interminable and appear part of deliberate intent to restrain trade.’ (Professor R Kearney submission, p. 10)

To date, the use of the Import Risk Analysis Appeals Panel and the Federal Court as mechanisms for challenging Import Risk Analyses and import permit decisions has been limited. The most recent Import Risk Analysis Appeals Panel was convened in early 2007 to consider appeals made in relation to the provisional final Import Risk Analysis for apples from New Zealand. Previously, Panels have also been convened to consider appeals in relation to policy determinations on pig meat imports, durian from Thailand, and California table grapes from the United States. The pigmeat case is the only occasion to date where a quarantine decision has been challenged in the Federal Court.

5.3.7 Consideration of environmental and human health concerns

When issuing import permits the Director of Animal and Plant Quarantine (or his/her delegate) is required to consider the likelihood and consequence of impacts on human health and the environment. To help in doing this, the Director consults with other Commonwealth Government agencies.

Mechanisms exist in the Import Risk Analysis process to assess risks to the environment. This includes consultation between Biosecurity Australia and the Department of Environment, Water, Heritage and the Arts codified in a Memorandum of Understanding. However, the effectiveness of these mechanisms has been questioned by a number of stakeholders.

‘There has long been a strong bias in biosecurity and quarantine towards invasive species of potential harm to agriculture over environmental weeds and pests. There is still insufficient focus on environmental risks and inadequate competency within Biosecurity Australia to assess and manage these risks.’ (Invasive Species Council submission, p. 1)

CSIRO provided the Panel with its analysis in relation to assessment of biosecurity risks to the environment, concluding that environmental biosecurity capacity lagged well behind business-related capacity across the biosecurity continuum. It acknowledged the complexity in predicting the impact on natural ecosystems and argued that capacity in this area needed to be built.

‘Globally, invasive species are regarded as a major threat to biodiversity, along with climate change and habitat destruction. Our national capacity to assess and manage biological threats to biodiversity will need to grow as global trade increases the rate of movement of species ... In parallel we suggest there is merit in DEWHA and BA building their joint capacity for analysing the environmental risks of biosecurity threats.’ (CSIRO submission, p. 8)

It was suggested to the Panel that the Commission should use the precautionary principle in assessing biosecurity risks to the environment, similar to the approach taken under the *Environmental Protection and Biodiversity Conservation Act 1999*.

While Biosecurity Australia seeks information from the Department of Health and Ageing in relation to human health risks that should be taken into account during an Import Risk Analysis, the Panel observes that there is no equivalent Memorandum of Understanding to the one that exists with the Department of Environment, Water, Heritage and the Arts in relation to the conduct of risk assessments. As the Department of Health and Ageing does not have Biosecurity Australia’s expertise in biological risk assessment, nor the scope of health expertise at times to respond to particular Import Risk Analyses, it seeks input from expert advisers or committees.

5.4 Panel's consideration

5.4.1 The role of Ministers and the Parliament

As described earlier, the Appropriate Level of Protection in principle balances the costs and benefits of travel, trade and consumer interests arising from the movement of people and goods with the risk to human health, businesses and the environment resulting from the introduction of pests and diseases. Inherent in the Appropriate Level of Protection concept are human health, economic, social, and environmental gains and losses.

The Panel believes it is important for the community to understand that not only is an Appropriate Level of Protection of 'zero' unachievable, it is also undesirable. For example, current arrangements provide businesses with access to improved genetic material that is crucial to Australia's agricultural productivity and allow consumers access to a range of products not readily or economically available domestically. They can also impose costs on consumers and the economy. This message was confirmed in the recent Australian Competition and Consumer Commission report on grocery prices which found that:

'While quarantine laws are important for protecting Australia's economic wellbeing, there are a number of tradeoffs for both producers and consumers. For example, an obvious trade-off with an import ban is between the benefits of reducing a particular pest or disease risk and the benefits from obtaining cheaper or different products.' (Australian Competition and Consumer Commission 2008, p. 38)

Indeed it is appropriate to remind ourselves that the foundations of Australian agriculture—and the national economic and consumer benefits they confer—rest on genetic material that was at one stage imported from elsewhere in the world.

Against that background, setting Australia's Appropriate Level of Protection is quintessentially a Government responsibility. It is not primarily a technical or scientific matter. Rather, it is a matter of values, which involves considering and articulating the Australian community's interests and thereby the national interest. It is critical that the democratically elected Government, and in particular the Minister responsible to Parliament, makes this decision which underpins biosecurity administration.

The Panel notes that the practical achievement of Australia's Appropriate Level of Protection is based on a sequence of Import Risk Analyses and decisions based on them. The framework for decisions is set out in the *Quarantine Act 1908* (see Box 14).

BOX 14 Import decision framework under the *Quarantine Act 1908*

Section 5D of the *Quarantine Act 1908* states that:

‘A reference in this Act to a *level of quarantine risk* is a reference to:

- (a) the probability of:
 - (i) a disease or pest being introduced, established or spread in Australia, the Cocos Islands or Christmas Island; and
 - (ii) the disease or pest causing harm to human beings, animals, plants, other aspects of the environment, or economic activities; and
- (b) the probable extent of the harm.’

The *Quarantine Regulations 2000* define *import risk analysis* and *risk analysis* as follows.

‘*Import risk analysis*, or *IRA*, means a risk analysis conducted under this Part.’

‘*Risk analysis* means the assessment of the level of quarantine risk associated with the importation, or the proposed importation, of animals, plants or other goods and, where necessary, the identification of risk management options to limit the level of quarantine risk to one that is acceptably low.’

The *Quarantine Proclamation 1998* provides that:

‘In deciding whether to grant a permit to import a thing into Australia ... a Director of Quarantine:

- (a) must consider the level of quarantine risk if the permit were granted; and
- (b) must consider whether, if the permit were granted, the imposition of conditions on it would be necessary to limit the level of quarantine risk to one that is acceptably low; and
- (ba) for a permit to import a seed of a kind of plant that was produced by genetic manipulation — must take into account any risk assessment prepared, and any decision made, in relation to the seed under the Gene Technology Act; and
- (c) may take into account anything else that he or she knows that is relevant.’

The Panel notes there is no reference in the legislation, regulations or proclamation to the Appropriate Level of Protection as it has been defined by successive governments. The legislative guidance given to officials is sparse. It is therefore logical, given the importance of consistency in decisions, and the importance of those decisions, that officials have attempted to develop more detailed guidelines (of which there are several drafts extant, but none finalised).

These guidelines attempt to explain how to establish the probability of a pest or disease being introduced, established or spread in Australia, causing harm to humans, animals, plants, other aspects of the environment, or economic

activities, and the probable extent of the harm. The guidelines also explain how those probabilities can be used to develop a draft Import Risk Analysis report—including any measures to reduce risk to an acceptable level.

The Panel's view is that the guidelines need to explain how probability will be described (such as quantitatively or qualitatively, or probability 'intervals' associated with different qualitative descriptions) and how harm from a pest or disease to human beings, animals, plants, and other aspects of the environment and economic activities will be described and estimated (quantitatively or qualitatively, what dimensions of the harm to human beings, the environment and economic activity will be estimated, and whether the estimates are in gross or net terms).

More fundamentally, the guidelines should provide rules about how these estimates are to be combined to reach a decision. For example, it needs to be decided how much weight should be given to the impact on an endangered species compared with the impact on economic activity or human health. Similarly, guidance needs to be provided on the weight to be given to a concentrated regional economic impact against one of a similar size that is spread across the nation.

The analysis and consequent decisions on measures are usually taken in a climate of uncertainty. Uncertainty can arise from many factors, including a lack of understanding of the science, the complexity of natural systems, or simply a lack of data. There are many ways of making decisions under uncertainty—different decision rules may lead to different and material practical effects on decisions as to whether to allow an import, and if so what if any measures should be applied to reduce risk. It is important that the same approach is taken to dealing with uncertainty in successive assessments in order to maintain consistency. These issues are among those that should be covered in the guidelines.

These issues are complex and involve describing the science and risk estimation techniques that are used to underpin decisions, and requires important judgements about values. The Panel believes that if the guidelines were finalised (as opposed to remaining in draft) and made public, it would enhance consistency in Import Risk Analyses and import permit decisions, and reduce the scope for controversy and dispute between parties, whether domestic or international.

The Panel has concluded that the Government and the Parliament should set Australia's Appropriate Level of Protection and the principles that underpin import risk assessment. In the Panel's judgement, the Government should have the capacity in legislation to determine the Appropriate Level

of Protection and make Guidelines for the conduct of Biosecurity Import Risk Analyses, Biosecurity Import Permit Determinations (see Section 5.4.5) and import permit decisions. The determination and Guidelines would best take the form of a legislative instrument under the *Legislative Instruments Act 2003*, but should not be disallowable. This means that they will be transparent to the Parliament and can be the subject of review and debate, but the Parliament has no capacity to stop them coming into effect, other than by persuading the Government of the day that some amendment would be appropriate.

This approach recognises that fundamental policy settings are appropriately determined at a political level with the opportunity for Parliamentary discussion and debate. In the lead-up to the discussion, the responsible Commonwealth Minister would have the opportunity to consult the states—and more widely—to build an agreed national understanding underpinning the fundamentals of the Commonwealth’s approach. This would provide the basis for a genuinely national commitment to biosecurity. The outcome would be clearer guidance for the non-political science-based decision making processes in relation to individual Import Risk Analyses and import permits. It would reduce the scope for inter-governmental, business, political and diplomatic disputes.

Recommendation

- 31 The biosecurity legislation should:
- a define the concept of ‘biosecurity risk’ in a manner analogous to, but broader than, section 5D of the *Quarantine Act 1908*;
 - b provide that the basis for a decision whether to authorise, under the legislation, an import of goods should be that the level of biosecurity risk associated with the import is acceptably low;
 - c provide that the Minister may determine what level of biosecurity risk is acceptably low (that is, Australia’s Appropriate Level of Protection), and may make Guidelines for Biosecurity Import Risk Analyses, Biosecurity Import Policy Determinations and import permit decisions. The determination and Guidelines should be legislative instruments for the purposes of the *Legislative Instruments Act 2003*, and should not be disallowable; and
 - d require that decision makers under the legislation (the National Biosecurity Commission in relation to Biosecurity Import Policy Determinations and the Director of Biosecurity in making import permit decisions) should be required to apply the Determination, and act in accordance with the Guidelines.

5.4.2 Import Risk Analyses and the national interest

As discussed in Section 5.3.2, some submissions to the Panel suggested that Import Risk Analyses should be based on a full national interest test, allowing them to consider trade and consumer benefits and costs as well as the potential harm arising from pests or diseases. The Panel has instinctive sympathy for this view. It would allow a more complete analysis—leading to a more informed view—of the costs and benefits of an import proposal, analogous to the approach taken in other regulatory areas such as the *Environment Protection and Biodiversity Conservation Act 1999*, the *Foreign Acquisitions and Takeovers Act 1975* and the *Productivity Commission Act 1998*.

However, the Panel notes that such an approach would not be consistent with Australia's obligations under the SPS Agreement, which limits the factors that can be taken into account in imposing measures on imports. Perhaps paradoxically, but quite intentionally, the SPS Agreement excludes consideration of economic losses or gains arising from the import itself as distinct from the potential harm from pests or diseases. This, together with the requirement that any measures should not be more trade restrictive than required, ensures that trade issues are not brought to bear in a way that increases the risk of SPS measures being used as non-tariff barriers.

Given Australia's strong interest in a less restrictive agricultural trade environment and the risk that any move to amend the SPS Agreement could result in a more restrictive approach, the Panel has concluded that it does not support an Import Risk Analysis approach that includes a national interest test. Of course, as discussed previously, a full national interest test is integral to the determination of Australia's Appropriate Level of Protection.

5.4.3 Content of the Import Risk Analysis Guidelines

The Panel has been surprised by the heavy emphasis in both the Import Risk Analysis guidelines and the actual Import Risk Analyses it has reviewed on the estimates of the *likelihood* of entry and establishment or spread of pests and diseases relative to their consideration of the *consequences* of entry.

It is also perplexed by the lack of use of formal economic analysis, including Computable General Equilibrium analysis, to quantify the likely consequence of a pest and disease incursion. This is despite the considerable use of such analysis in Australia in determining the economic consequences of incursions of exotic pests and diseases, including whether or not to

attempt eradication and in choosing between management options where an incursion has actually occurred. For example, the Australian Bureau of Agricultural and Resource Economics has utilised such analysis in determining the feasibility of eradicating papaya fruit fly from north Queensland (Bhati *et al.* 1996), alternatives for managing outbreaks of foot and mouth disease (Abdalla *et al.* 2005) and the economic impacts of an incursion of Karnal bunt (Elliston *et al.* 2004). The Panel also notes regular use of these tools to assist decisions even in areas where estimates have to be made of the monetary value of non-market commodities (for example Integrated Assessment Modelling to assist climate change policy analysis, cost-benefit analysis as part of environmental impact assessment and project approvals) or where economic values are integrated into multi-attribute analysis.

It is important that the Guidelines deal with real economic consequences, not merely transfer payments. Estimates of consequences should take into account alternative enterprises or other adjustment options available to producers in the event that they were affected by a pest or disease incursion. By focusing on the gross rather than net consequences, there would be an inbuilt bias to overestimate pest or disease consequences and hence favour more conservative decisions in relation to import approvals than may be appropriate.

Similarly, it is important that a uniform approach to scaling the economic impact of potential pest and disease incursions is applied.

A decision needs to be taken and consistently followed as to whether Import Risk Analyses emphasise the absolute net value of production at risk against the setting of the national economy, or the relative impact on a particular industry. On balance, the Panel would favour looking at the absolute net value of production at risk. As noted earlier, the Productivity Commission has raised the possibility of providing a quantitative anchor in the form of an absolute expected cost threshold below which measures would not be considered.

The Panel further notes that while Biosecurity Australia and the Eminent Scientists Group possess high-level scientific skills, neither group has significant skills in economic analysis or direct access to a reputable and relevant economic model. In the Panel's view this should be remedied by ensuring that the National Biosecurity Commission encompasses high level economic skills and by expanding the Eminent Scientists Group to include an eminent economist. In addition, the National Biosecurity Commission should develop a relationship with the Productivity Commission, the Australian

Bureau of Agricultural and Resource Economics or other suitable public or private sector agencies, to assist in the estimation of the economic costs of potential pest and disease incursions.

Recommendations

- 32 The Guidelines should:
 - a include a clear statement of the approach to be taken to the economic assessment of potential biosecurity threats including the appropriate use of formal economic analysis; and
 - b require estimation of net rather than gross costs, allowing for best practice management methods, substitution to alternative crops or husbandry techniques.
- 33 The National Biosecurity Commission should:
 - a include high level economic skills (see Recommendation 13); and
 - b develop a close working relationship with the Productivity Commission, the Australian Bureau of Agricultural and Resource Economics or other suitable agencies.
- 34 The Eminent Scientists Group should be expanded to include an economist.

5.4.4 Recognising regional differences

Consideration of regional differences in pest and disease status and risk can enable greater flexibility in allowing imports, while preserving the biosecurity status of regions at a relatively lower cost, and in a less trade restrictive way than via other measures.

The Panel's view is that an assessment of regional differences should be explicit in the Import Risk Analysis process. Establishing regional differences will require close cooperation between the National Biosecurity Commission and the states, particularly given the more explicit timeframes for Import Risk Analyses. It would be assisted by improved state-based surveillance and monitoring to ensure that states have the data to support their claims. This approach would be consistent with Australia's treaty obligations, especially Article 6 of the SPS Agreement.

Recognising domestic differences in pest and disease status will also facilitate improved access to export markets.

Recommendation

- 35 The:
- a Guidelines should include a requirement for the assessment of any relevant regional differences in biosecurity status and risk;
 - b states and territories should be consulted on the terms of this requirement before it is included in the Guidelines; and
 - c Commonwealth and the states and territories should develop a protocol on the collection and timely provision of the scientific evidence necessary to demonstrate biosecurity threat status to support both the Biosecurity Import Risk Analysis process and improved access to export markets for Australian products.

5.4.5 Import permit applications

The Panel is conscious that under the approach outlined in Chapter 3, the National Biosecurity Commission will be making decisions that have an important influence on subsequent decisions by the Director of Biosecurity in relation to import permit applications. The Commission’s decisions—to be referred to as Biosecurity Import Policy Determinations—will provide the framework within which specific import permit decisions will be made. This approach combines the current role of Biosecurity Australia in undertaking Import Risk Analyses and the Director of Animal and Plant Quarantine’s role in making import policy determinations.

The Panel recommends that the biosecurity legislation provide that when the Director of Biosecurity (or delegate) considers an import permit application for which a relevant Biosecurity Import Policy Determination is in place, the Director of Biosecurity should have primary regard to that Determination in deciding whether to grant the permit. This requirement would apply unless the Director of Biosecurity has reason to believe that granting the permit would lead to a biosecurity risk that is not acceptably low. If an import permit is denied on these grounds, the Director must immediately inform the National Biosecurity Commission of the reasons. Circumstances in which the Director of Biosecurity could reach a decision not to grant a permit in accordance with a Biosecurity Import Policy Determination would include notification of a change in the disease or pest status on which the Biosecurity Import Policy Determination was based—for example, new science, or new information on the effectiveness of the biosecurity measures required under it.

In the absence of a Biosecurity Import Policy Determination, the Panel recommends that the Director of Biosecurity have two options for dealing with

market access and import permit applications. If the Director of Biosecurity is satisfied that the biosecurity risk involved is acceptably low, the Director should authorise importation, with or without conditions. This decision may also be informed by experience and policies in relation to analogous goods. Alternatively, if the Director is not satisfied that the biosecurity risk is acceptably low, the Director should refuse to issue an import permit and ensure that a Biosecurity Import Risk Analysis is conducted and a Biosecurity Import Policy Determination made before an import permit is granted.

Recommendation

- 36 The biosecurity legislation should provide:
- a that when an import permit application is made for which a relevant Biosecurity Import Policy Determination exists, the Director of Biosecurity should have primary regard to that Determination in deciding whether to grant the permit, unless the Director has reason to believe that granting the permit would lead to a biosecurity risk that is not acceptably low. If the Director of Biosecurity denies an import permit on these grounds he/she must immediately inform the National Biosecurity Commission of the reasons; and
 - b that the Director of Biosecurity have two options for dealing with market access and import permit applications for which there is no specific Biosecurity Import Policy Determination already in place:
 - if the Director is satisfied that the biosecurity risk involved is acceptably low, he/she should authorise importation, with or without conditions; and
 - if the Director is not satisfied that the biosecurity risk would be, or could be through imposing conditions, acceptably low, he/she should not grant a permit and should not provide market access, until the National Biosecurity Commission has made a Biosecurity Import Policy Determination following a Biosecurity Import Risk Analysis.

5.4.6 Backlogs and delays

In the past Australia’s Import Risk Analysis process has been criticised for extensive delays. The Panel agrees that these delays have been extraordinary compared to equally complex science-based decisions in other regulatory fields, but also notes that Import Risk Analyses conducted by some of Australia’s trading partners occur over similar timeframes. The Panel also notes that, responding to these concerns, the regulations under the *Quarantine Act 1908* now require that Import Risk Analyses are completed within 24 – 30 months depending on whether they are considered as a standard or expanded Import Risk Analysis. However, the regulated timeframe does not start until an Import

Risk Analysis has formally commenced—applications might still wait for many months or years until Biosecurity Australia is ready to commence an Analysis.

Regardless of the type of Import Risk Analysis, the current process imposes significant resource demands on Biosecurity Australia. The agency is currently faced with a backlog of import market access requests, some dating back decades. Again the Panel notes that Australia is not alone in this regard with many countries struggling to process market access requests in a time of ever expanding global trade. Australia's agricultural exporters are familiar with the frustration of having to wait in a long queue before access to new markets is granted by Australia's trading partners.

A situation in which access can be effectively denied for decades because of resource constraints on the Government agency may well invite disputes with trading partners and the risk of the World Trade Organization dispute resolution processes being invoked. Neither is desirable nor in Australia's interests.

The Panel examined the risk analysis task in other science-based, or otherwise technical, regulatory areas to see if they offered alternative approaches. The regimes examined included the *Environmental Protection and Biodiversity Conservation Act 1999*, the *Food Standards Australia New Zealand Act 1991*, the *Therapeutic Goods Act 1989* and the Australian Energy Regulator. Under each of these processes, the regulator retains a significant analytic capacity, but it is usual to place a considerable responsibility (and hence a heavier resource demand) on the proponent to conduct or assemble required scientific analysis. Some of these regimes have graduated assessment processes with an ascending degree of 'in house' involvement by the regulator.

The Therapeutic Goods Administration model for listing of goods in the Australian Register of Therapeutic Goods involves a mix of responsibility between the regulator and applicant. In other instances, the majority of the responsibility rests with the applicant. For example, under the *Environment Protection and Biodiversity Conservation Act 1999*, the onus is placed on the applicant to provide the information needed to assess its application. Similarly, under the *Food Standards Australia New Zealand Act 1991*, applications to vary the Australia New Zealand Food Standards Code rest primarily with the applicant.

The Panel believes that the National Biosecurity Commission should similarly have an approach available to it which would place greater obligations on the proponent to prepare the major risk assessment material to an appropriate standard and to meet any Guidelines made by the Minister to govern the risk assessment process. This would free up resources, reduce the assessment burden and enable the Commission to address the large backlog of market access requests.

This approach would not be available as of right. When an application is made the proponent would be required to furnish the Commission with its proposed scope and planned methodology for developing what the Panel has referred to as a Biosecurity Import Risk Statement. The Commission would be empowered to assess within set timeframes whether it believed that the proponent's scope of review and proposed methodology was acceptable, and whether the Commission had the resources to carry out its associated supervisory and assessment task. If the Commission approves the use of this avenue, it will inform the proponent of the terms of reference for the review covering matters such as pests and diseases and other biosecurity risks of concern, their ecology and epidemiology, and proposed risk management measures with evidence supporting their efficacy. It will advise the proponent of any specific requirements in relation to methodology for preparation of the draft Biosecurity Import Risk Statement. The Commission would also be obliged to publish the Biosecurity Import Risk Statement for the information of domestic and other stakeholders.

The intention is that the Biosecurity Import Risk Statement should provide the National Biosecurity Commission with the information required to complete a Biosecurity Import Risk Analysis and a draft Biosecurity Import Policy Determination.

In preparing a Biosecurity Import Risk Statement, the proponent would bear the responsibility for, and meet the costs of, providing material to meet requirements specified by the National Biosecurity Commission. The time taken to prepare a Biosecurity Import Risk Statement would be entirely in the hands of the proponent. Once satisfied with its Statement, the proponent would submit it for consideration by the Commission. Once approved by the Commission as meeting the Guidelines, the Biosecurity Import Risk Statement would be released for public comment at a stage analogous to the release of an issues paper by the Commission. This marks the start of the regulated timeframe and the point at which the application is referred from the proponent to the National Biosecurity Commission for preparation of a draft Biosecurity Import Risk Analysis.

Having received comments from the public on the Biosecurity Import Risk Statement, and a final Statement from the proponent responding to those comments, the National Biosecurity Commission would be required to prepare and post its draft Biosecurity Import Risk Analysis and draft Biosecurity Import Policy Determination for a further round of public comment before finalising its decision. Each step involving decisions by the National Biosecurity Commission or periods for public comment and submission would be subject to statutory timelines—where appropriate the opportunity should be taken to bring the steps and timelines under the Biosecurity Act and the *Environment Protection and Biodiversity Conservation Act 1999* into consistency, so that to the greatest

extent possible Biosecurity Import Risk Analyses can meet all the requirements for an acceptable assessment for decisions taken under the *Environment Protection and Biodiversity Conservation Act 1999*.

This approach would allow more strategic use of the available scientific expertise within the Authority, with process management directed to staff with more general skills. It would also expedite lower priority and less complex risk analyses—including those from the veterinary medicine sector whose ability to bring products into Australia has often been hampered by Biosecurity Australia's lack of sufficient technical staff with experience in specific scientific disciplines.

5.4.7 A power to conduct public hearings and take evidence on oath

Under the various regulatory regimes—environmental, therapeutic goods and economic—reviewed by the Panel, the regulator has considerable choice about the type of assessment process they employ, ranging from assessing the application based on the 'referral information' through to assessment by a Public Inquiry. They have a capacity to take evidence on oath. The regulator can require the production of relevant material and it is usually an offence to supply misleading or false information knowingly.

The Panel believes that the National Biosecurity Commission should have these options available to it. It should have the capacity to hold hearings, require the production of material and documents, require sworn evidence and qualify and examine witnesses (typically expert witnesses) under oath. The Commission should be given the power to summons a person to appear before a Public Inquiry similar to provisions granted to the Australian Competition and Consumer Commission under the *Trade Practices Act 1974*.

Interested parties and technical experts would be invited to make statements, and then be questioned directly by Commissioners, in a formal and open environment, similar to the process adopted by the New Zealand Commerce Commission. The Panel envisages that this process would only be utilised in circumstances where the Commission is of the view that it would be a useful way to clarify or obtain further information.

The decision to establish a Public Inquiry should be at the Commission's discretion. There should also be appropriate provisions to enable the National Biosecurity Commission to determine whether material provided to it is to be held in confidence and in relation to this material to place on the Commission an obligation to protect its confidentiality. Such material could relate to matters of commercial value or issues relevant to Australia's foreign relations.

5.4.8 Setting priorities for Biosecurity Import Risk Analysis

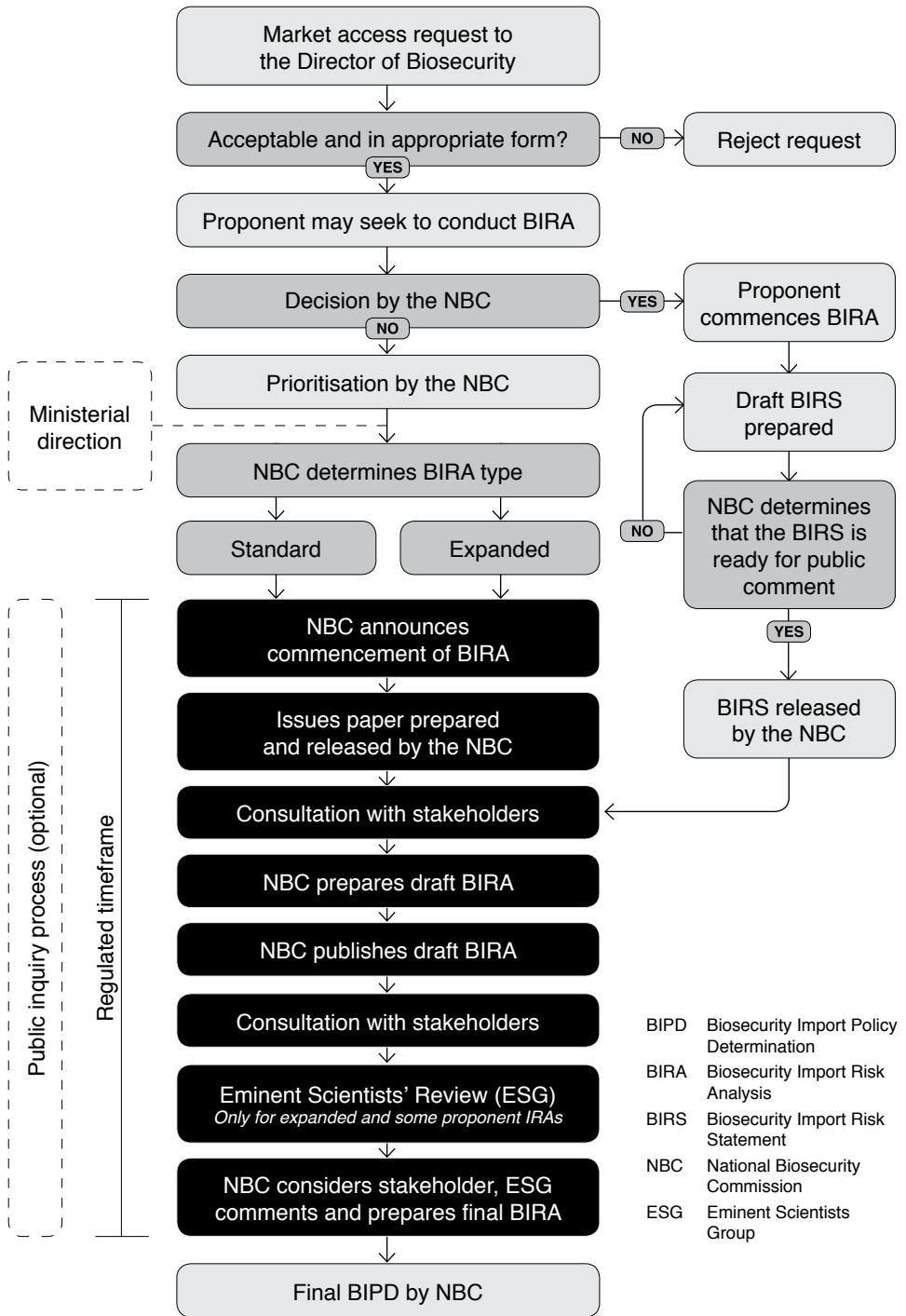
Even with these changes, the National Biosecurity Commission is likely to face a demand for Biosecurity Import Risk Analysis that will exceed its resource capacity. This is regrettable, but by no means unusual in many other countries around the world. This means that before it starts the clock by formally announcing the commencement of a Biosecurity Import Risk Analysis it needs to have carefully considered priorities and resources. The Panel believes that in addition to placing greater emphasis on the proponent to conduct Biosecurity Import Risk Analyses, the Authority should be provided with more resources (see Chapter 9) to help the Commission deal with the backlog of Import Risk Analyses and market access requests.

The prioritisation function of the existing Import Market Access Advisory Group should be performed by the National Biosecurity Commission. In determining its priorities, the Commission should consult with Commonwealth Government's agriculture, health, environment, foreign affairs and trade departments, with the states and with appropriate stakeholders relevant to import access proposals. Consultations with overseas governments should continue to be handled by the relevant departments.

The legislation should provide the Minister with a power to direct the National Biosecurity Commission to commence a Biosecurity Import Risk Analysis. This will provide the Minister with an avenue to ensure that undertakings given to trading partners under Free Trade Agreements or as a result of other bilateral negotiations are met. It will also enable matters which the Minister believes require a Biosecurity Import Risk Analysis to be referred to the Commission. This could include matters where the Minister has independently received advice of a change in biosecurity risk conditions. In no way would this provide the Minister with the capacity to prevent the commencement of a Biosecurity Import Risk Analysis or influence the priorities assigned by the Commission. Any direction by the Minister to commence a Biosecurity Import Risk Analysis should be tabled in Parliament. The Panel's recommended Biosecurity Import Risk Analysis process is illustrated in Figure 7.

In relation to proponent-based Biosecurity Import Risk Analyses, the Panel notes that some developing country proponents may not have the capacity to carry out analysis to the same standard as those in developed countries. Under Article 9 of the SPS Agreement, Australia is obliged to provide technical assistance to permit developing countries to maintain or expand market access. The Panel also notes the extensive program of technical assistance the Australian Government provides to developing countries in relation to SPS capacity building and Import Risk Analysis worth over \$1.2 million in 2007-08. Consideration should be given to expanding regional assistance programs to ensure that developing countries can develop the capability to access this mechanism.

Figure 7 Proposed Biosecurity Import Risk Analysis process



Recommendation

- 37 The biosecurity legislation should provide:
- a for three broad Biosecurity Import Risk Analysis processes—the existing standard and expanded Import Risk Analyses and a new process under which a greater obligation to prepare detailed information about relevant biosecurity risks would be placed on the proponent / applicant;
 - b that, in conducting a Biosecurity Import Risk Analysis, the National Biosecurity Commission should have the power to compel the production of any relevant documents, the power to require relevant evidence to be given to it under oath and to hold public hearings;
 - c that in deciding priorities for Biosecurity Import Risk Analyses, the National Biosecurity Commission should consult with relevant Australian Government agencies, including the departments having responsibility for agriculture, health, environment and foreign affairs and trade, with the states and territories and with other appropriate stakeholders relevant to import access proposals; and
 - d the Minister with the power to direct the National Biosecurity Commission to commence a Biosecurity Import Risk Analysis, with such a direction to be tabled in Parliament.

5.4.9 Review mechanisms

In a democratic society, governments must be accountable to the public for the way they exercise their powers. Providing appropriate review mechanisms aims to improve the way that decisions are made and generate public confidence in government administration (Administrative Review Council 2007). As it currently stands, the Import Risk Analysis process includes several points of potential review. These include:

- peer review during the Import Risk Analysis, including by external experts included on the risk analysis panel;
- formal consultation with stakeholders on the draft Import Risk Analysis report and other technical documents;
- external scientific review of a revised draft Import Risk Analysis report by the Eminent Scientists Group; and
- review of the Import Risk Analysis process by the Import Risk Analysis Appeals Panel.

Apart from the potential for prerogative writs under section 77(v) of the Constitution, review by the courts is only available in relation to the individual import permit decisions taken by the Director of Animal and Plant Quarantine (or delegate). In those cases, for example the *Director of Animal and Plant*

Quarantine v Australian Pork Limited, the decision is subject to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*. There is no opportunity for merits review to determine whether the ‘right’ decision was made.

In the context of its overall recommendations, the Panel has considered what review mechanisms should be provided and what should be subject to review.

The Administrative Review Council states that as a principle, where an administrative decision will, or is likely to, affect the interests of a person, it should be subject to merits review (Administrative Review Council 2005). The objective of allowing merits review is to ensure that administrative decisions are correct. More broadly, merits review can improve the quality and consistency of decisions over the longer-term, enhancing the openness and accountability of governments.

Conversely, merits review processes can impose significant time delays and costs for the parties and the regulator. Specialist topics—as are involved here—require a review body with relevant skills. Moreover, history suggests that unless care is taken, applicants will treat the appeal panel as an alternative regulator and seek to ‘game’ the process by withholding crucial information until the appeal stage. Stringent requirements—such as restricting the information that can be considered by an appeals panel and specifying tight statutory time constraints—may help, but merits review inevitably involves costs and time. The hope is that these costs are justified by more rigorous decision making and a process seen by all parties to be manifestly fair.

The Eminent Scientists Group provides one form of reassurance of the quality and independence of a Biosecurity Import Risk Analysis. The Eminent Scientists Group provides scientific, external peer review during the Import Risk Analysis process—and it is proposed that this role would be preserved in the Biosecurity Import Risk Analysis process. Its continuation would enhance confidence in the Biosecurity Import Policy Determinations made by the National Biosecurity Commission.

The Panel also sees value in strengthening the Eminent Scientists Group. Expansion to include an eminent economist has already been recommended. In addition, the Eminent Scientists Group should be empowered to draw on both domestic and international experts by appointing them as Associate Members for particular cases (much as the Productivity Commission does). The Eminent Scientists Group should be apolitical, expert and appointed by the Minister after consultation with the states.

Merits review is generally available for administrative decisions which grant rights or impose costs. Biosecurity Import Policy Determinations set a policy

framework and would not of themselves grant rights or impose costs. They would therefore fall outside the limits of what would normally be regarded as administrative decisions for the purpose of merits review. The provision of an open process, with clear guidelines, an expanded and clearly independent Eminent Scientists Group to provide high level comment on the quality of material, and the provision for the final decision to be taken by an independent Commission provide ample avenues to all stakeholders to ensure that their views and evidence are considered. In the judgement of the Panel, this makes Biosecurity Import Policy Determinations analogous to the decisions of the Australian Energy Markets Commission and other independent authorities which make policy determinations. Accordingly, the Panel is not persuaded that these Determinations should be subject to merits review.

Similarly, the expanded Eminent Scientists Group and the National Biosecurity Commission, both of which are independent, allied with open processes requiring the publication of draft Biosecurity Import Risk Analyses, would remove the need for the purely procedural review provided by the current Import Risk Analysis Appeals Panel process. The Panel recommends that it should be removed.

Biosecurity Import Policy Determinations have to be applied through import permit decisions made by the Director of Biosecurity. The Panel considers that it would be desirable to provide an option for merits review of a restricted class of import permit decisions taken by the Director of Biosecurity. Merits review should only be available where the Director had made a decision to refuse to issue an import permit on the grounds that to do so would not be consistent with the existing Biosecurity Import Policy Determination. The applicant must be able to demonstrate that there is an existing Biosecurity Import Policy Determination relevant to that commodity from that location. The Panel believes it is important that merits review is restricted to permit decisions made pursuant to an existing Biosecurity Import Policy Determination to avoid the possibility of merits review being used to accelerate consideration of a Biosecurity Import Risk Analysis. The legislation should make it clear that a Biosecurity Import Policy Determination is not the subject of review, only its application through an import permit decision.

In addition:

- standing should be limited to the permit applicant;
- provisions should be established to guard against vexatious appeals; and
- there should be strict timeframes around the lodgement of appeals.

These merits appeals would be considered by the Administrative Appeals Tribunal. The Tribunal would need to appoint additional panel members with relevant expertise for this purpose.

Some import permit decisions may be taken by the Director of Biosecurity in the absence of a Biosecurity Import Policy Determination. These decisions should not be subject to merits review.

Recommendations

- 38 The:
- a Import Risk Analysis Appeals Panel should cease to exist as the review mechanism for determining whether a Biosecurity Import Risk Analysis has followed due process;
 - b Biosecurity Import Policy Determination should be a non-reviewable instrument;
 - c Eminent Scientists Group should be empowered to co-opt one or more Associate Members; and
 - d Eminent Scientists Group should be appointed by the Minister after consultation with the states and territories.
- 39 Merits review of import permit decisions should only be available where the Director of Biosecurity has made a decision to refuse to issue an import permit on the grounds that to do so would not be consistent with a Biosecurity Import Policy Determination. In addition, access to merits review should be subject to the following requirements:
- a standing should be limited to the applicant for the permit;
 - b provisions should be established to guard against vexatious appeals; and
 - c there should be strict timeframes around the lodgement of appeals.

5.4.10 Improving the consultative process

Consultation and communication are built into the risk analysis process at a number of stages, both informally and formally. For example, there is consultation prior to the announcement of the commencement of an Import Risk Analysis, with the release of an issues paper (for an expanded Import Risk Analysis) and with the release of a draft Import Risk Analysis report. Communication occurs through a number of channels, including notifications to registered stakeholders, media releases, newsletters, web publications, and stakeholder meetings.

Those involved in the process generally acknowledge that Biosecurity Australia disseminates information well but complain they have limited time to provide views and that their views are not always taken into account. While it is inevitable that some stakeholders will be dissatisfied with decisions, it is important they believe that their concerns have been fairly considered.

Several stakeholders expressed frustration about large Import Risk Analysis documents being released with no prior notice and limited time to respond. Some business groups told the Panel that given the scientific complexity of these documents, it is necessary for them to engage experts (who may not be instantly available) to assist them in the preparation of responses and that the short notice jeopardised their capacity to respond adequately. The Horticulture Australia Council submission commented that an Import Risk Analysis can take up to two years to produce, while only 60 days is available to respond to it. The Council cited the experience with the New Zealand apple Import Risk Analysis, where it was unable to bring together input from relevant experts in the time allowed.

Balancing consultation needs and timely decision making is difficult—a fact that the Horticulture Australia Council acknowledged in its submission. The current Import Risk Analysis process attempts to reconcile these two objectives by setting the 60 day timeframe, but also providing for a 60 day extension where the Chief Executive of Biosecurity Australia considers that stakeholders may not have had reasonable opportunity to comment within the normal consultation period. In addition, for expanded Import Risk Analyses, the regulated process provides for the release of an issues paper which should start preparing stakeholders for the likely issues associated with the Import Risk Analysis.

The Australian National Audit Office, in a 2005-06 report *Managing for Quarantine Effectiveness—Follow-up*, recommended that Biosecurity Australia incorporate a period of notice to be given prior to the release of Import Risk Analysis reports (Australian National Audit Office 2005-06). The recommendation was accepted by Biosecurity Australia, but does not appear to have been fully implemented.

The Panel's view is that the time limits set in the regulations achieve a reasonable balance between the opportunity for consultation and timeliness. However, improvements could be made to help stakeholders prepare to meet the consultation deadlines. For example, more use could be made of issues papers and, as recommended by the Australian National Audit Office, greater effort should be made to provide advance notice of draft document release dates. This would allow stakeholders to start consulting with members and engage experts required. Similarly, consultation needs to go beyond affected domestic businesses to include market access proponents and importers.

The hearings process proposed by the Panel would also allow parties to examine and comment on other evidence.

The Panel proposes that the National Biosecurity Commission be subject to similar consultation requirements as other major regulators in making Biosecurity Import Policy Determinations. To achieve this the Commission should be required to include a draft Biosecurity Import

Policy Determination with the draft Biosecurity Import Risk Analysis when it is released for public comment.

Recommendation

- 40 The National Biosecurity Commission should:
- a provide stakeholders with advance notice of the release of draft Biosecurity Import Risk Analyses and issues papers to allow sufficient time to prepare responses; and
 - b include a draft Biosecurity Import Policy Determination with the draft Biosecurity Import Risk Analysis when it is released for public comment.

5.4.11 Environmental risks

The Panel considers that the current biosecurity framework is not being effectively used to analyse and manage the risks to the Australian environment. A Memorandum of Understanding has been established between Biosecurity Australia and the Department of Environment and Heritage (now the Department of the Environment, Water, Heritage and the Arts) to facilitate communication between the two groups. However, to some extent this seems to have led to a greater reliance on environmental agencies to assess risks than they are capable of delivering, rather than supporting the development of competence to deal with these issues within Biosecurity Australia. In addition, current arrangements do not appear to be achieving a coordinated approach in relation to import assessments for live animals or plants under the *Environmental Protection and Biodiversity Conservation Act 1999* and the *Quarantine Act 1908*.

To improve this situation, the Panel recommends that the Biosecurity Import Risk Analysis Guidelines should require that assessments are adequate to meet the requirements, including timelines and consultation, of the *Environmental Protection and Biodiversity Conservation Act 1999*. As part of this, and as part of the broader biosecurity approach recommended by the Panel, the National Biosecurity Commission will need the capacity to assess environmental risks as part of a Biosecurity Import Risk Analysis. The Director of Biosecurity will need to ensure that the staff assisting the Commission have skills in this area. This will have resourcing implications, as discussed in Chapter 9. In addition, once the National Biosecurity Commission commences a Biosecurity Import Risk Analysis, it should advise the agriculture, environment and health Ministers of the terms of reference and coverage.

It was also suggested to the Panel that the Commission should use the precautionary principle in assessing biosecurity risks in the terms in which it

is set out in section 391(2) of the *Environmental Protection and Biodiversity Conservation Act 1999*: ‘the precautionary principle is that lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage’. It was suggested to the Panel that this would enable a full harmonisation of approvals under the *Quarantine Act 1908* and the *Environmental Protection and Biodiversity Conservation Act 1999*.

While the Panel is sympathetic to this suggestion, using the precautionary principle as it is set out in the *Environmental Protection and Biodiversity Conservation Act 1999* to justify SPS measures is unlikely to be consistent with the requirements of the SPS Agreement.

Article 5.7 of the SPS Agreement sets out an explicit statement of the manner in which scientific uncertainty is to be managed by Parties to the Agreement: ‘in cases where scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary and phytosanitary measure accordingly within a reasonable period of time’.

The Panel is of the view that to the extent that adopting in the Biosecurity Act the definition of the precautionary principle in the *Environmental Protection and Biodiversity Conservation Act 1999* led to different outcomes to those that would arise from applying Article 5.7 of the SPS Agreement, there is a risk that Australia would be in breach of its obligations under that Agreement and hence would be open to challenge through the World Trade Organization dispute settlement procedures.

This will mean that there will still be some differences in the decision criteria that apply to some matters covered by the *Environmental Protection and Biodiversity Conservation Act 1999* in addition to the *Quarantine Act 1908*.

5.4.12 Human health risks

The Panel considers that the roles and responsibilities for collaboration on Biosecurity Import Risk Analyses that involve human health elements should be formally defined between the Commission and the Department of Health and Ageing. The Commission should consult the Department of Health and Ageing with respect to proposed biosecurity measures to protect human health. These issues are most likely to arise from concerns about transmission of zoonotic diseases.

Recommendations

- 41 A memorandum of understanding should be developed between the National Biosecurity Commission and the Department of Health and Ageing to cover human health aspects of Biosecurity Import Risk Analyses.
- 42 The National Biosecurity Commission should have the professional capacity to assess risks to the environment and human health in a Biosecurity Import Risk Analysis to the same quality as agricultural assessments.

5.4.13 ‘Legacy’ Import Risk Analyses

The majority of risk analyses and assessments are completed without controversy, and trade is able to be facilitated whilst meeting Australia’s Appropriate Level of Protection.

As discussed earlier, there are, however, a relatively small number of Import Risk Analyses that have generated a lot of public and political scrutiny over the last decade or more, detracting from Australia’s reputation for science-based risk analysis and consuming a disproportionate amount of the resources available for assessing import access proposals. These are termed ‘legacy’ Import Risk Analyses and include import proposals for bananas from the Philippines, as well as chicken meat, and prawns and prawn products. The Import Risk Analysis relating to the import of apples from New Zealand did fall within this category until relatively recently. This small group of Import Risk Analyses has done much to generate international perceptions of trade restrictiveness, unreasonable delays and questionable science.

In six cases² the concerns of trading partners have advanced to the point of a World Trade Organization SPS dispute. Each of these disputes has challenged the scientific basis of Australia’s biosecurity measures and some have alleged that Australia’s measures were more trade-restrictive than required. The dispute over measures affecting the importation of salmon is the only one that has been finalised by the World Trade Organization Appellate Body to date. The other disputes have either been settled by mutual agreement or could be reactivated

2 DS18 - Measures Affecting the Importation of Salmon (Complainant: Canada); DS21 - Measures Affecting the Importation of Salmonids (Complainant: Canada); DS270 – Certain Measures Affecting the Importation of Fresh Fruit and Vegetables (Complainant: Philippines); DS271 – Certain Measures Affecting the Importation of Fresh Pineapple (Complainant: Philippines); DS287 – Quarantine Regime for Imports (Complainant: European Communities); and DS367 – Measures Affecting the Importation of Apples from New Zealand (Complainant: New Zealand).

at any time. In the *Australia-Salmon* dispute, the Appellate Body found Australia's import restrictions violated SPS Agreement requirements (Department of Foreign Affairs and Trade submission, p. 11).

Not only are these disputes damaging to Australia's reputation, they tie up extensive resources in defensive, reactive activities. This point is made in the Department of Foreign Affairs and Trade's submission.

'Defending Australia's position in WTO disputes is a significant responsibility which engages the Government's limited international trade law and scientific resources for lengthy periods of time. For example, there are currently three [Department of Foreign Affairs and Trade] lawyers plus one administrative officer working full time preparing Australia's defence to New Zealand's WTO challenge on apples ...

This also means fewer resources can be devoted to prosecuting Australia's offensive interests either by providing scientific muscle to our own market access requests, or in bringing forward WTO disputes where our own trade is adversely affected by measures imposed by our trading partners.' (Department of Foreign Affairs and Trade submission, p. 11)

The legacy Import Risk Analyses have also been extremely contentious for the domestic industries involved, and relationships between these groups and Biosecurity Australia have been strained by disagreements over science, Import Risk Analysis methodology and consultative processes. There can be no doubt that over time, this has had an impact on the outlook of the organisation and the Australian government more broadly.

The Panel's view is that until the legacy Import Risk Analyses are completed, they will continue to be a thorn in the side of Biosecurity Australia. It is important that they be completed as soon as possible. The new regulated process recommended by the Panel will go a long way to avoiding the creation of future 'legacy' Import Risk Analyses.