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PRODUCTIVITY
COMMISSION

The Role of Risk and Cost-Benefit Analysis in Determining Quarantine Measures

Staff Research Paper

Monika Binder

The views expressed in this paper are those of the staff involved and do not necessarily reflect those of the Productivity Commission. Appropriate citation is indicated overleaf.

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Key messages

- In Australia, as in other countries, quarantine measures are necessary to protect animals and plants from pests and diseases, and consequent impacts on community wellbeing.
- Such measures must conform with the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
- Import risk analysis is typically undertaken by WTO members to inform decisions about measures to reduce pest and disease risks. This usually involves scientifically assessing the risks of imports and evaluating measures to reduce those risks against a desired risk target.
- The WTO requirements and international guidelines do not provide explicitly for consideration in import risk analyses of the costs and benefits to the wider community.
  - One mooted approach is to use cost–benefit analysis. This would entail choosing measures based on the magnitude of their net benefits to the community, rather than on whether they merely reduced risks to a given target. The role of scientific risk assessment would remain fundamental.
- However, there are a number of difficulties in seeking to broaden import risk analysis in this way. They include:
  - practical and technical difficulties. Cost–benefit analysis can be demanding of data and involve complex techniques. This implies a need for expert knowledge and judgment residing in independent institutions subject to public accountability and transparency;
  - legal obstacles. Some commentators argue that the SPS Agreement precludes a broad economic perspective; and
  - perverse policy outcomes, including the scope among WTO members to misuse economic analysis for protectionist purposes.

Another option is to consider the scope to enhance import risk analyses by, among other means, using cost–effectiveness analysis of measures with comparable risk outcomes.

Overview

Importing animals, plants and their products from other countries brings the possibility that pests or diseases may be brought into a country. These can affect adversely the health of humans, animals and plants and, in turn, economic wellbeing. The quarantine regimes of countries play an important role in managing and reducing these pest and disease risks.

Quarantine regimes must conform with World Trade Organization (WTO) requirements arising from the completion of the Uruguay Round of Multilateral Trade Negotiations in 1995. A fundamental aspect of those requirements is the need for a science-based approach to setting measures which potentially restrict trade in animals, plants and their products. This approach is commonly described as import risk analysis (IRA). In some quarters, it is argued that a broad economic perspective should be incorporated in IRAs.

This paper looks at the WTO requirements and supporting international guidelines, describes in broad terms the existing IRA approach to determining quarantine measures and addresses some options for improvement and associated problems.

Legal and policy setting

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) acknowledges the legitimate use by members of measures to protect against risk to human, animal or plant life or health, whilst curbing their use in protecting domestic producers from international competition.

The Agreement provides members with the rights to take a ‘sanitary or phytosanitary’ (SPS) measure and to determine their own ‘appropriate level of protection’ (also referred to as ‘the acceptable level of risk’), which is effectively a desired risk target. In exercising these rights, however, members must meet a number of specific requirements, of which the key ones are presented in table 1.

Compared with many other WTO agreements, there is little ‘judicial interpretation’ relating to the SPS Agreement at this time. Such judicial interpretation helps to clarify the meaning of articles within the Agreement. Only three SPS disputes have been considered by dispute panels and the Appellate Body. Of these, one involved a complaint by Canada about Australia’s previous longstanding ban on imports of fresh and frozen salmon.

Concerns to ensure compliance with the SPS Agreement were largely behind two major reviews of Australia’s quarantine regime in 1996. In respect of the regulation of imports of animals, plants and their products, the Australian reviews prompted significant changes, including the introduction of a formal administrative IRA process.

What is ‘import risk analysis’?

Risk analysis, generally speaking, assembles available scientific and other relevant information, such as from the fields of epidemiology, chemistry, biology, statistics and economics, to facilitate decisions on how to deal with risk. It also involves the exercise of discretion, for example, in the choice of information to be used and in the determination of a desired risk target.

Within the context of imports of animals, plants and their products, risk analysis is frequently referred to as ‘import risk analysis’, even though the phrase does not appear in the SPS Agreement. Quarantine regulators use different terminology to describe the components or stages of IRA. Two reviews of Australia’s quarantine regime defined IRA as consisting of three components or stages: risk *assessment* (the scientific estimation of risk), risk *management* (the evaluation of options to reduce estimated risk) and risk *communication* (the interaction with, largely industry, stakeholders).

International guidance on how to undertake IRAs is contained in the International Office of Epizootics’ International Animal Health Code 2001 and the International Plant Protection Convention Guidelines for Pest Risk Analysis 2001. Although the terminology and level of detail associated with the two sets of guidelines differ, there are broad similarities between them. They:

- advocate the identification of the risk of concern, the scientific estimation of that risk, the identification of options to reduce the risk to a desired target and an evaluation of those options;
- advocate the application of a limited set of economic criteria in the evaluation of options, including ‘cost-effectiveness’, ‘trade-restrictiveness’, ‘equivalence’ and ‘non-discrimination’; and

1 Introduction

Importing animals, plants and their products can involve the likelihood that pests or diseases are brought into a country which can affect adversely the health of humans, animals and plants and, thus, economic wellbeing.[1] The quarantine regimes of countries, therefore, play an important role in managing these pest and disease risks.

As a result of the Uruguay Round of Multilateral Trade Negotiations completed in 1995, the quarantine regimes of countries became subject to new international rules governing trade, in particular, the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Whilst acknowledging the legitimate use of measures (described in the Agreement as ‘sanitary and phytosanitary measures’) to protect against risks to human, animal or plant life or health arising from pests or diseases accompanying imports, the new rules were intended to curb their use in protecting domestic producers from international competition.

Concerns to ensure compliance with the SPS Agreement were largely behind two major reviews of Australia’s quarantine regime in 1996. The first was a wide-ranging review by a committee chaired by Professor Malcolm Nairn (Nairn et al. 1996). The second review was by a National Task Force on imported fish and fish products (DPIE 1996).

A key area of Australia’s quarantine regime dealt with in both reviews was the approach taken to determining measures governing the imports of animals, plants and their products which carried pest or disease risks. An essential feature of the approach was ‘import risk analysis’ (IRA). IRA was (and still is) viewed as encompassing ‘risk assessment’, ‘risk management’ and ‘risk communication’. Boxes 1.1 and 1.2 explain these terms.

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[1] It is also possible that pests or diseases may be brought into a country through international travel and tourism.

Box 1.1 Components of import risk analysis

The Nairn Committee and the National Task Force on imported fish and fish products identified three common components in IRA: namely, 'risk assessment', 'risk management' and 'risk communication'. They defined these components in similar terms as follows:

IRA component	*Nairn Committee*	*National Task Force*
Risk assessment	The process of identifying and estimating the risks associated with an import and evaluating the consequences of taking those risks.	The process of identifying, estimating the statistical probabilities and evaluating the consequences of all risks potentially associated with the import of an animal, plant or product.
Risk management	The process of identifying, documenting and implementing measures to reduce these risks and their consequences.	Measures that can be applied before, during and after an import to reduce the risk to an acceptable and manageable level.
Risk communication	The process of interactive exchange of information and opinions concerning risk between risk managers and stakeholders.	The process of communicating the risk assessment results and the risk management decision to the regulators of import programs and to other interested parties such as industry and the public.

Sources: DPIE (1996); Nairn et al. (1996).

Box 1.2 Some key terms used in this paper

As risk analysis is a relatively young discipline, its terminology is in some turmoil, despite attempts to develop a standardised nomenclature in Australia and other countries (Nairn et al. 1996, p. 84). The terminology appearing in the SPS Agreement and relevant international guidelines, and used by quarantine regulators can differ. (However, the terminology used by Biosecurity Australia follows that set out in international guidelines.) In the context of IRA, this box sets out the terms, and their definitions, which are used frequently in the remainder of this paper. Any notable differences are identified where relevant.

As noted in box 1.1, the Nairn Committee and the National Task Force used the term 'risk analysis' to encompass three components: 'risk assessment', 'risk management' and 'risk communication'.

(Continued next page)

Box 1.2 **(continued)**

The term ‘risk’ is a combination of the probability (or frequency or likelihood) that an adverse event (or hazard) will occur and the magnitude of the consequences of the adverse event. It may be expressed qualitatively (for example, ‘high’, ‘moderate’ or ‘low’ risk of a disease infecting cattle) or quantitatively (for example, ‘a one in a million probability in 100 years of a disease causing more than $50 million damage to the cattle industry’).

Some authors distinguish the terms ‘risk’ and ‘uncertainty’. They consider that risk applies only to an event where an objective probability can be formed. An objective probability is the relative frequency of an event observed over a large number of repeated trials or experiments. In contrast, uncertainty applies to an event where there is little or no knowledge about the probability distribution; the event may yet to be observed and may be non-recurring (or unique) and, thus, only a subjective probability can be formed. In recent years, however, some authors have extended the term risk to events where ‘reasonable’ subjective probabilities can be formed, with the term uncertainty reserved for other events (noted in Hinchy and Fisher 1991, p. 46).

Another important term is the ‘acceptable level of risk’ or, in the words of the SPS Agreement, the ‘appropriate level of protection’. In essence, this can be viewed as a desired risk target. There are many different ways of describing this target. For example, it may be expressed quantitatively (for example, ‘a 99 per cent probability in 100 years of no disease causing more than $50 million damage to the cattle industry’) or qualitatively (for example, ‘an acceptably low probability of no cattle being infected by disease’).

Particular concerns about IRAs that were addressed by the Nairn Committee and the National Task Force included the standard of public consultation involved, their scope, the adequacy of resources committed to them and the lack of a formal appeal mechanism (for example, Nairn et al. 1996, pp. 86–8). Both reviewing bodies recommended actions to address these concerns, many of which were accepted by the Commonwealth Government in 1997 (box 1.3).

Box 1.3 Key Australian recommendations relating to import risk analysis and the Commonwealth Government’s response

Nairn Committee recommendations

- The Australian Quarantine and Inspection Service (AQIS) continue to use and refine scientifically-based risk analysis to develop its quarantine policies and recommendations.
- AQIS use a specified process to ensure that IRA is consultative, scientifically-based, politically independent, transparent, consistent, harmonised and subject to appeal.

(Continued next page)

Box 1.3 **(continued)**

- AQIS improve community and stakeholder understanding of IRA by, for example, developing and circulating a public handbook on its process.
- For each import access request warranting detailed risk analysis, AQIS coordinate and chair a risk analysis panel, which is to assess risks and examine appropriate risk management strategies needed to approve or reject the request.
- AQIS's IRA process and associated decisions on import access requests be subject to periodic external review.
- A key centre for quarantine-related risk analysis be established.

National Task Force on imported fish and fish products recommendations

- AQIS review existing quarantine policy and protocols for aquatic animals.
- In the context of aquatic imports, a relevant economic factor in socioeconomic impact assessment be defined as 'the direct economic impact on affected industries plus indirect effects on associated industries'.
- In an IRA, where there is a high degree of uncertainty about both the initial impact of a disease and its effect over time, an 'appropriately conservative judgment' be made.
- When an economic analysis is used to assess the effect of a policy change, all direct economic effects resulting from disease establishment, including ecosystem and amenity effects, be taken into account.
- AQIS undertake various changes to the IRA process including to develop and publish standards, guidelines and criteria for the IRA process, to develop a core risk assessment unit and to separate risk assessment from risk management.

The Commonwealth Government's response

In 1997, the Commonwealth Government accepted many of these recommendations and provided, over four years, $13.24 million for IRA generally, $3.8 million for AQIS's review of existing quarantine policy and protocols relating to aquatic animals, and another $0.44 million to the fish products policy unit to facilitate, coordinate and undertake socioeconomic and industry policy input to the IRA process.

However, some of the Nairn Committee's recommendations were rejected or modified. Recommendations to establish a key centre of quarantine-related risk analysis and to give decision-making authority to the chair of the risk analysis panel were rejected. The recommended IRA process was modified.

Some of the National Task Force recommendations relating to the IRA process were subsumed in the Commonwealth Government's response to the Nairn Committee.

Sources: DPIE (1996, 1997); Nairn et al. (1996).

As a result of the Nairn Committee and National Task Force reviews, there have been significant changes to the Australian approach to determining quarantine measures, including to IRA. The Australian Quarantine and Inspection Service (AQIS) commenced systematically reviewing IRAs of aquatic animals (as well as responding to an influx of import access requests), issued a handbook detailing a new and formal 'IRA process' — as seen in the next chapter, this policy determination process consists of initiation, risk analysis and policy determination — and revised and consolidated its earlier (and many) quarantine proclamations.

Late in 2000, prime responsibility for considering changes to existing quarantine policy in respect of imports, including for the IRA process, shifted to a new agency, Biosecurity Australia, within the Department of Agriculture, Fisheries and Forestry — Australia (AFFA 2000a). AQIS implements the policy determinations. The new agency has begun a review of the IRA process, which is expected to be completed in 2002.

Scientific assessments of pest and disease risks are clearly fundamental to determining quarantine measures governing imports of animals, plants and their products. Indeed, the SPS Agreement's requirements are likely to have reduced the scope for the disingenuous use of quarantine measures.

However, some commentators have raised the question of whether consideration should also be given to the community-wide benefits and costs of measures that inevitably restrict trade.

James and Anderson argued for a comprehensive economic review of Australia's quarantine measures which currently affect the import of more than 150 plant products, as well as most animal, bird and aquatic products and said:

> If scientific analysis reveals a significant plant or animal health risk associated with importing a product, then a quarantine restriction tends to be imposed or retained with little thought given to whether its cost to others outweighs the benefits to those lobbying for the restriction. In this sense, looking only at the direct effects and using command and control measures rather than also looking at indirect effects and using benefit-cost thinking, [sanitary and phytosanitary] policy assessment currently is about where environmental policy assessment was two or three decades ago. (1998, p. 426)

Roberts noted:

> … the balance achieved by the SPS Agreement over the first five years — curbing the most egregious uses of SPS measures as non-tariff barriers while leaving domestic regulatory regimes largely intact — is exactly what many WTO members have hoped for. It is from this perspective that these countries will judge initiatives to allow the costs and benefits of measures to factor into decisions that govern if and how agricultural products gain access to markets. Therefore, the challenge is to develop a voluntary "WTO+" policy framework for countries with the analytical capability and interest to begin to rank SPS policy options on the basis of efficiency and equity goals with sufficient transparency to permit informed judgment about compliance with the

> Agreement. A truly integrated assessment will require coordination of multiple disciplines. … It is likely that differences in paradigms, unstated assumptions, and expected end-products of analysis will make such collaboration difficult at first. But if the SPS Agreement is to fulfil its potential as serving the overarching goal of welfare enhancement through trade, such challenges must be met. (2001, p. 26)

This paper focuses on the SPS Agreement and issues relating to IRA, including whether a broad economic approach — such as reflected in a cost–benefit framework — could be effectively incorporated in the determination of quarantine measures. Chapter 2 reviews the legal and policy setting in which the determination of quarantine measures, and IRA, is undertaken in Australia. Chapter 3 examines ‘models’ of risk analysis pertinent to pest and disease risk and how, in practice, Biosecurity Australia undertakes IRAs. Chapter 4 considers quarantine measures within a cost–benefit framework. Chapter 5 examines issues in IRA, in particular relating to the appropriate level of protection and the scope for incorporating a broad economic perspective.

2 Legal and policy setting

Dominating the domestic legal and policy setting in which quarantine measures are imposed on imports of animals, plants and their products are new World Trade Organization (WTO) requirements arising from the Uruguay Round of Multilateral Trade Negotiations. The WTO requirements have led members, including Australia, to reconsider their quarantine regimes.

2.1 WTO requirements

In deciding whether or not to allow imports or to vary import conditions with respect to animals, plants and their products, Australia, as a member of the WTO, must abide by requirements under the General Agreement on Tariffs and Trade (GATT) 1994 (which incorporates the original GATT) and the Agreement on the Application of Sanitary and Phytosanitary Arrangements (the SPS Agreement).

According to the GATT 1994, although members are generally required to eliminate quantitative import and export restrictions or prohibitions, they can take measures ‘necessary to protect human, animal or plant life or health’ provided that the measures are not applied in a manner which would constitute a ‘means of arbitrary or unjustifiable discrimination’ between countries where the same conditions prevail or a ‘disguised restriction on international trade’ (article XX(b)).

The SPS Agreement elaborates members’ rights and obligations in applying these measures, now described as ‘sanitary and phytosanitary’ measures (see box 2.1 for a definition of this and other key terms). This Agreement provides members the right to take a SPS measure and, moreover, the right to determine their own ‘appropriate levels of protection’. In exercising these rights, however, members must meet various requirements including requirements relating to:

- SPS measures generally;
- ‘risk assessment’; and
- the appropriate level of protection.

Box 2.1 Key terms in the SPS Agreement

SPS measure	Any measure applied to: protect animal or plant life or health within the territory of the member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; protect human or animal life or health within the territory of the member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; protect human life or health within the territory of the member from risks arising from diseases carried by animals, plants or their products, or from the entry, establishment or spread of pests; or prevent or limit other damage within the territory of the member from the entry, establishment or spread of pests. Measures include: all relevant laws, decrees, regulations, requirements and procedures including end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.
Risk assessment	The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing member according to the SPS measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.
Appropriate level of protection	The level of protection deemed appropriate by the member establishing a SPS measure to protect human, animal or plant life or health. Many members otherwise refer to this concept as the ‘acceptable level of risk’.

Source: SPS Agreement, annex A.

The general requirements relating to SPS measures include some basic obligations on members that the measures must:

- be applied ‘only to the extent necessary to protect human, animal or plant life or health’, be ‘based on scientific principles’ and not be maintained without ‘sufficient scientific evidence’ (article 2.2);

- not ‘arbitrarily or unjustifiably discriminate’ between members where ‘identical or similar conditions prevail’, and not be applied in a manner constituting a ‘disguised restriction on international trade’ (article 2.3); and
- be based on an assessment, as ‘appropriate to the circumstances’, of the risks to human, animal or plant life or health (article 5.1).

Members can be exempt from the first basic obligation. Where ‘relevant scientific evidence is insufficient’, an SPS measure may be adopted ‘provisionally’ on the basis of ‘available pertinent information’, including that from relevant international organisations as well as from SPS measures applied by other members provided that:

- additional information necessary for a more ‘objective assessment of risk’ is sought; and
- the SPS measure is reviewed accordingly within a ‘reasonable period of time’ (article 5.7).

Requirements relating to the assessment of risk (see box 2.1 for a definition of the term) include:

- taking into account risk assessment techniques developed by the ‘relevant international organizations’ (article 5.1); and
- taking into account specified factors, namely:
    - available scientific evidence, relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine and other treatment (article 5.2); and
    - ‘relevant economic factors’ in relation to animal and plant life or health: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication; and the relative cost-effectiveness of alternative approaches to limiting risks (article 5.3).

Finally, there are a number of requirements relating to the appropriate level of protection. This is defined tautologically in the Agreement as the ‘level of protection deemed appropriate’ by the member establishing an SPS measure and is equated to the ‘acceptable level of risk’ (box 2.1). This concept is distinguished in the Agreement, in the first place, from the risk evaluated in a risk assessment and, in the second place, from the SPS measure to be applied in achieving that level.

One group of requirements relates to the determination of the appropriate level of protection itself. There is little guidance in the Agreement on how to set the level, apart from requirements on members to:

- take into account the objective of 'minimizing negative trade effects' (article 5.4); and
- avoid 'arbitrary or unjustifiable distinctions' in the levels considered 'appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade' (article 5.5 or the 'consistency requirement').

In relation to the consistency requirement, the Committee on Sanitary and Phytosanitary Measures has issued guidelines to further its practical implementation (WTO 2000).

Another group of requirements applies when members are determining the SPS measure to be applied to achieve the appropriate level of protection. These requirements include:

- taking into account a list of 'relevant economic factors' (article 5.2 and see above); and
- ensuring that such measures are not more trade-restrictive than required to achieve the appropriate level of protection taking into account technical and economic feasibility (article 5.6).

Some commentators have argued that, overall, these requirements support an approach to determining quarantine measures which is centred around achieving an appropriate level of protection or desired risk target; an approach that discounts consideration of the community-wide benefits and costs of importing. Roberts has said:

> While the Agreement's emphasis on risk assessment and its elaboration of risk-related costs that 'shall' be factored into SPS policies may ease the task of judging the legimitacy of trading partners' measures, its silence on the role that benefits might play in policy choice leads to the conclusion that it is a product of what has been called the 'risk assessment paradigm'. ... The risk assessment paradigm, centred on the concept of 'acceptable level of risk' (referred to as the appropriate level of protection in the SPS Agreement), has a number of shortcomings, but its principal drawback in the context of SPS policies is that it encourages myopic focus on the direct risk-related costs of imports. In the risk assessment paradigm, regulators view their task as promulgating measures that reduce risk to negligible levels; in an economic paradigm, the normative framework would account for the benefits as well as the potential costs of imports to infer appropriate levels of protection from individual preferences. If the omission of WTO rules for factoring the benefits of imports into policy choice is interpreted as a

> prohibition of such considerations, SPS measures will continue to be biased against welfare-improving imports. (2001, pp. 10–11)

The nature of cost–benefit analysis and the legal scope for incorporating a broad economic perspective into quarantine decision-making is considered in chapters 4 and 5, respectively.

A mandated review of the SPS Agreement was conducted in 1999 by the SPS Committee (WTO 1999b). Key areas of the Agreement considered by the Committee were the transparency requirements (including notification requirements), provisions for special and differential treatment of developing and least-developed country members, and technical assistance.

In the lead up to the Qatar Ministerial Conference in 2001, members raised a number of issues about the SPS Agreement, most of which were first raised in preparations for the inconclusive Seattle Ministerial Conference in 1999. The issues included:

- how to establish that an exporting country's measures are equivalent to those used in the importing country;
- the difficulty amongst developing countries of demonstrating sufficient scientific evidence to justify their own measures or challenge those of others;
- the absence of the 'precautionary principle', particularly in article 5.7; and
- the uncertain coverage of the Agreement to genetically modified organisms and biotechnology (WTO 2001b, pp. 11–13).

A decision (WTO 2001c) on implementation-related issues in WTO agreements was made at the conclusion of the Qatar Conference. In respect of the SPS Agreement, the decision (among other things) instructed the Committee on Sanitary and Phytosanitary Measures to develop expeditiously a program to implement article 4 (which is about equivalence) and to review the operation and implementation of the Agreement once every four years.

Disputes

Compared with many other agreements under the WTO (for example, the GATT 1994), there is little 'judicial interpretation' relating to the SPS Agreement at this time. Only three disputes have reached and been reported on by dispute panels and by the Appellate Body (WTO 2001a). These are the European Communities hormones dispute (WTO 1998a), the Australian salmon dispute (WTO 1998d) and the Japanese varietal testing dispute (WTO 1999a). Nonetheless, those three disputes have provided guidance on the meaning of some of the Agreement's provisions. Basic details about the disputes, as well as the guidance they provide, are summarised in tables 2.1 and 2.2. Specific guidance on the concept of the appropriate level of protection is given in box 2.2.

Table 2.1 Disputes involving the SPS Agreement

	European Communities hormones dispute	*Australian salmon dispute*	*Japanese varietal testing dispute*
SPS measures complained of	European Communities' measures prohibiting imports of meat and meat products from cattle to which either natural or synthetic hormones had been administered.	Australian measures prohibiting the import of fresh, chilled or frozen Canadian salmon.	Japanese requirement that each variety of a United States product that may carry codling moth be tested to demonstrate the efficacy of a treatment (involving fumigation) before an import ban is lifted.
Complaining member/s	United States and Canada	Canada	United States
Date of dispute panel report[a]	18 August 1997	12 June 1998	27 October 1998
Date of Appellate Body report[a]	16 January 1998	20 October 1998	22 February 1999
Date of adoption by the Dispute Settlement Body	13 February 1998	6 November 1998	19 March 1999

[a] The date the report was circulated to members.

Source: WTO (2001a).

Box 2.2 Dispute settlement guidance on the appropriate level of protection

The Appellate Body in the Australian salmon dispute (WTO 1998d) made a number of general observations about the concept of the 'appropriate level of protection' including that:

- the appropriate level of protection is a 'prerogative' of the member concerned and not of a dispute panel or the Appellate Body (p. 99);
- the appropriate level of protection and the SPS measure to be applied in achieving that level are not one and the same thing. The first is an objective, the second is an instrument chosen to attain or implement that objective. The determination of the appropriate level of protection is an element of the decision-making process which 'logically precedes and is separate' from the establishment or maintenance of the SPS measure (p. 100);
- a member could determine its own appropriate level of protection at 'zero risk' (p. 75); and
- although there is no obligation to determine the appropriate level of protection in quantitative terms, this does not mean that a member is 'free to determine its level of protection with such vagueness or equivocation' that the application of the relevant provisions of the SPS Agreement becomes impossible (p. 101).

Table 2.2 **Dispute settlement guidance on certain articles in the SPS Agreement**

Article	*Significant WTO Appellate Body comments on the article*
2.2 — Members shall ensure that any SPS measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in article 5.7.	The article should be 'constantly read' with article 5.1 (which requires SPS measures to be based on a risk assessment) (European Communities hormones dispute, WTO 1998a, para 180). For an SPS measure to be maintained without sufficient scientific evidence, there must be a lack of a 'rational or objective' relationship between the SPS measure and the scientific evidence. Whether there is such a relationship is to be determined on a case by case basis and will depend on the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence (Japanese varietal testing dispute, WTO 1999a, paras 73, 84).
3.1 — To harmonize SPS measures on as wide a basis as possible, members shall base their SPS measures on international guidelines, where they exist, except as otherwise provided in the Agreement, and in particular in article 3.3.	The article does not mandate 'conformity or compliance' with international guidelines. 'Based on' does not mean 'conform to' (European Communities hormones dispute, WTO 1998a, paras 165–8).
3.2 — SPS measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of the Agreement and of GATT 1994.	An SPS measure which complies with the article 'enjoys' the benefit of a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the SPS Agreement and of the GATT 1994' (European Communities hormones dispute, WTO 1998a, para 170).
5.1 (and annex A.4) — Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.	The risk evaluated must be an 'ascertainable risk' and not 'theoretical uncertainty'. There is no requirement for the quantification of risk or the establishment of a minimum magnitude of risk. For an SPS measure to be 'based on' a risk assessment, it must be 'sufficiently supported or reasonably warranted' by a risk assessment (European Communities hormones dispute, WTO 1998a, para 186). A risk assessment must meet a three pronged test: it must identify the disease to be prevented and the 'potential biological and economic consequences' of the disease; it must evaluate the likelihood of the disease and associated potential biological and economic consequences; and it must evaluate this likelihood according to the SPS measures which might be applied (Australian salmon dispute, WTO 1998d, p. 73). It is not sufficient that a risk assessment conclude that there is a 'possibility' of entry, establishment or spread and associated consequences. A 'proper' risk assessment must 'evaluate' the likelihood, that is the probability of entry, establishment or spread and associated consequences as well as the likelihood of entry, establishment or spread according to the SPS measures which must be applied. The likelihood may be expressed qualitatively or quantitatively (Australian salmon dispute, WTO 1998d, p. 74).

(Continued next page)

Table 2.2 **(continued)**

Article	*Significant WTO Appellate Body comments on the article*
5.2 — In the assessment of risks, members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest – or disease – free areas; relevant ecological and environmental conditions; and quarantine or other treatment.	The list of factors is not a 'closed list' (European Communities hormones dispute, WTO 1998a, para 187).
5.5 — With the objective of achieving consistency in the application of the concept of appropriate level of SPS protection against risks to human life or health, or to animal and plant life or health, each member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. ...	For this article to be breached, three elements must be present: the member imposing the SPS measure complained of has adopted its own 'appropriate levels of protection' against risks to life or health in several different situations; those levels of protection must exhibit arbitrary or unjustifiable differences (or distinctions) in their treatment of different situations; and the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade (European Communities hormones dispute, WTO 1998a, para 214). In regard to the first element above, the situations must present some common element or elements sufficient to render them comparable (European Communities hormones dispute, WTO 1998a, para 214). In regard to the third element, there are several warning signals as well as additional factors arising from the circumstances of the dispute. The warning signals are: the arbitrary or unjustifiable character of the difference in the levels of protection; a 'rather substantial difference' in the levels of protection (for example, between import prohibition and tolerance); and a finding of inconsistency with article 5.1 (and by implication article 2.2) (Australian salmon dispute, WTO 1998d, pp. 86–93).
5.7 — In cases where relevant scientific evidence is insufficient, a member may provisionally adopt SPS measures on the basis of available pertinent information, including that from the relevant international organizations as well as from SPS 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 SPS measure accordingly within a reasonable period of time.	This article sets out four cumulative requirements which must be met in order to adopt and maintain a provision SPS measure: the measure is imposed in respect of a situation where 'relevant scientific information is insufficient'; the measure is adopted 'on the basis of available pertinent information'; the member 'seeks to obtain the additional information necessary for a more objective assessment of risk'; and the member 'reviews the ... measure accordingly within a reasonable period of time'. Whenever one of these requirements is not met, the measure at issue is inconsistent with this article (Japanese varietal testing dispute, WTO 1999a, para 89). The information sought must be 'germane' to conducting a more objective assessment of risk. What constitutes a reasonable period of time must be established on a case by case basis depending on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure (Japanese varietal testing dispute, WTO 1999a, paras 91–3).

The role of international guidelines

The SPS Agreement encourages members to harmonise their SPS measures (and risk assessment techniques) on as wide a basis as possible. The key harmonisation requirement provides that members must base their SPS measures on international guidelines (as well as standards and recommendations) where they exist, except as otherwise provided in the Agreement and GATT 1994 (article 3.1).[2] Also, when assessing risks, members must take into account risk assessment techniques given in relevant international guidelines (article 5.1). The relevant international guidelines are those developed under the auspices of the Codex Alimentarius Commission (human health), the International Office of Epizootics and the International Plant Protection Convention (annex A.3).

Should SPS measures 'conform' to international guidelines, they are 'deemed' to be 'necessary' to protect human, animal or plant life or health and, thus, consistent with the provisions of the SPS Agreement and the GATT 1994 (article 3.2).

There is allowance, however, for SPS measures which result in a higher level of protection than would be achieved if they were based on the relevant international guidelines:

- if there is 'scientific justification'; or
- as a consequence of the level of protection a member determines to be appropriate in accordance with article 5 (article 3.3).

Further discussion about international guidelines on IRAs is contained in chapter 3.

2.2 Domestic regulation of imports

Australian regulations governing imports of animals, plants and their products are contained in the *Quarantine Act 1908*, the Quarantine Proclamation 1998 and the Quarantine Regulations 2000.

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[2] Notably, the inclusion of provisions on 'relevant statistical methods, sampling procedures and methods of risk assessment' in the definition of SPS measures contained in annex A.1 (box 2.1) means that they must, under article 3.1, be 'based on' international guidelines unless there is scientific justification to do otherwise.

By and large, imports of animals, plants and their products are prohibited unless a permit has been granted.[3] In deciding whether or not to grant a permit, a ‘Director of Quarantine’ is required to consider:

- the ‘level of quarantine risk’ if the permit were granted; and
- if the permit were granted, whether the imposition of conditions to limit the risk to a level that would be ‘acceptably low’ is necessary; and
- anything else known to be relevant.[4]

The term ‘level of quarantine risk’ is defined as the:

- ‘probability of a disease or pest’:
  - being ‘introduced, established or spread’ in Australia; and
  - causing ‘harm to human beings, animals, plants, other aspects of the environment, or economic activities’; and
- ‘probable extent of the harm’.[5]

There is no domestic definition of, or guidance on, what amounts to Australia’s target level of risk to be achieved (other than it be ‘acceptably low’). In its response to the Nairn Committee’s report, the Commonwealth Government stated:

> There are many paths for pests and diseases to enter Australia, by natural routes, accidents, or breaches of quarantine regulations. We cannot eliminate all these potential means of entry so therefore a ‘zero risk’ quarantine policy is not possible. The Government accepts that there will always be an element of risk. The challenge facing us is to *manage the risks within an appropriately conservative framework.* (DPIE 1997, p. 10, emphasis added)

And in its handbook on the IRA process, the Australian Quarantine and Inspection Service (AQIS) has said:

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3 Section 13(1) of the Quarantine Act empowers the Governor General to prohibit by proclamation the importation of, amongst other things, animals and plants. Such proclamations are found in the Quarantine Proclamation 1998. For example, see sections 37 (live animals), 38 (dead animals or animal parts), 39 (meat and meat products), 40 (dairy products), 41 (eggs and egg products), 42 (honey and other bee products), 43 (specific types of fish) and 44 (fish meal and crustacean meal), 62 (living plants), 63 (seeds), 64 (fresh fruit and vegetables) and 65 (other plant parts). The status of this approach under the SPS Agreement — prohibition unless explicitly allowed — could be questioned.

4 Quarantine Proclamation 1998, section 70. The Minister has no legal power to make decisions regarding imports. In contrast, decisions by the Australian and New Zealand Food Authority, which is responsible for food safety, are subject to a vote by a Ministerial Council before they can be implemented.

5 Quarantine Act, section 5D and Quarantine Proclamation 1998, section 70 (note).

> Australia does not ... maintain a zero risk quarantine policy ... Rather, Australia's quarantine policy is based on the concept of the *management of risk to an acceptably low level.* (1998a, p. 11, emphasis added)

In its recent draft IRA guidelines, Biosecurity Australia said:

> Due to Australia's unique and diverse flora and fauna and the value of its agricultural industries, successive Australian Governments have *maintained a highly conservative but not a zero-risk* approach to the management of biosecurity risks. (2001i, p. 18, emphasis added)

Responsibility for administering the regulation of imports is shared between Biosecurity Australia, which undertakes the IRAs to determine policy on imports of animals, plants and their products, and AQIS, which implements the policy on a case by case basis.

The basic process which Biosecurity Australia follows in determining policy, and which is based on the Commonwealth Government's response to the Nairn Committee's report, distinguishes between routine and non-routine matters, involves the establishment of a risk analysis panel in non-routine matters, includes public consultation at particular stages, and includes an appeal mechanism (AQIS 1998a).

The process seeks to ensure that an IRA is:

- conducted in a consultative framework;
- a scientific process and therefore 'politically independent';
- transparent and open;
- consistent with both Government policy and Australia's international obligations;
- harmonised through taking account of international standards and guidelines; and
- subject to appeal (DPIE 1997, p. 21).

However, the process contains little detail on how Biosecurity Australia undertakes the substance of IRA itself. Such detail is contained in the IRA reports issued by that agency (and its predecessor, AQIS). Recently, Biosecurity Australia has issued draft guidelines for IRAs (2001i), which provide further clarification.

For most proposals to import animals, plants and their products, the full process does not apply. According to Biosecurity Australia:

> Most new quarantine conditions or variations to existing conditions do not require significant analysis and are assessed relatively quickly … without the use of the formal

> IRA process … Proposals involving significant variations in established policy require an IRA, which may be conducted using a routine or non-routine approach. Both approaches allow for input by stakeholders and the lodging of appeals if stakeholders are not satisfied that due process … has been followed. (AFFA 2000b, p. 1)

More than 30 IRAs have been completed under the process (AFFA 2001c, d); about 50 are currently in progress (table 2.3) and another 180 or so are awaiting action (AFFA 2001e, f).

Table 2.3 **Import risk analyses underway**
as at December 2001

Animals and animal products	*Plants and plant products*
Cattle from the United States	Allium
Dogs and cats	Apples from New Zealand
Eggs and egg products (edible)	Bananas from the Philippines
Equine semen from the European Union	Bulbs from the Netherlands, the United Kingdom, New Zealand and Israel
Ferrets	Citrus from Italy
Freshwater crayfish	Citrus from South Africa
Freshwater finfish	Citrus from the United States (Florida)
Hides and skins	Coniferous sawn timber from Canada, New Zealand and the United States
Horses from the Republic of South Africa	Limes from New Caledonia
Horses (surra)	Longans and lychees from the Peoples Republic of China
Live birds – crowned cranes	Maize from the United States
Live birds – flamingoes	Mushrooms
Live birds – psittacines	Papaya from Fiji
Live snakes	Pineapples
Non-viable bivalve molluscs	Snow peas from Africa
Pig meat	Sweetcorn seed from the United States
Pig semen	Table grapes from Chile
Prawns and prawn products	Table grapes from the United States
Uncooked chicken meat	Tomatoes from the Netherlands
Wool, animal hair and feathers	Wood packing materials from Asia
Zoo bovidae	Yam bean from Samoa
Zoo carnivores	
Zoo marsupials and monotremes	
Zoo primates	
Zoo suidae and dicotylidae from the European Union and North America	

Sources: AQIS (2001a, b).

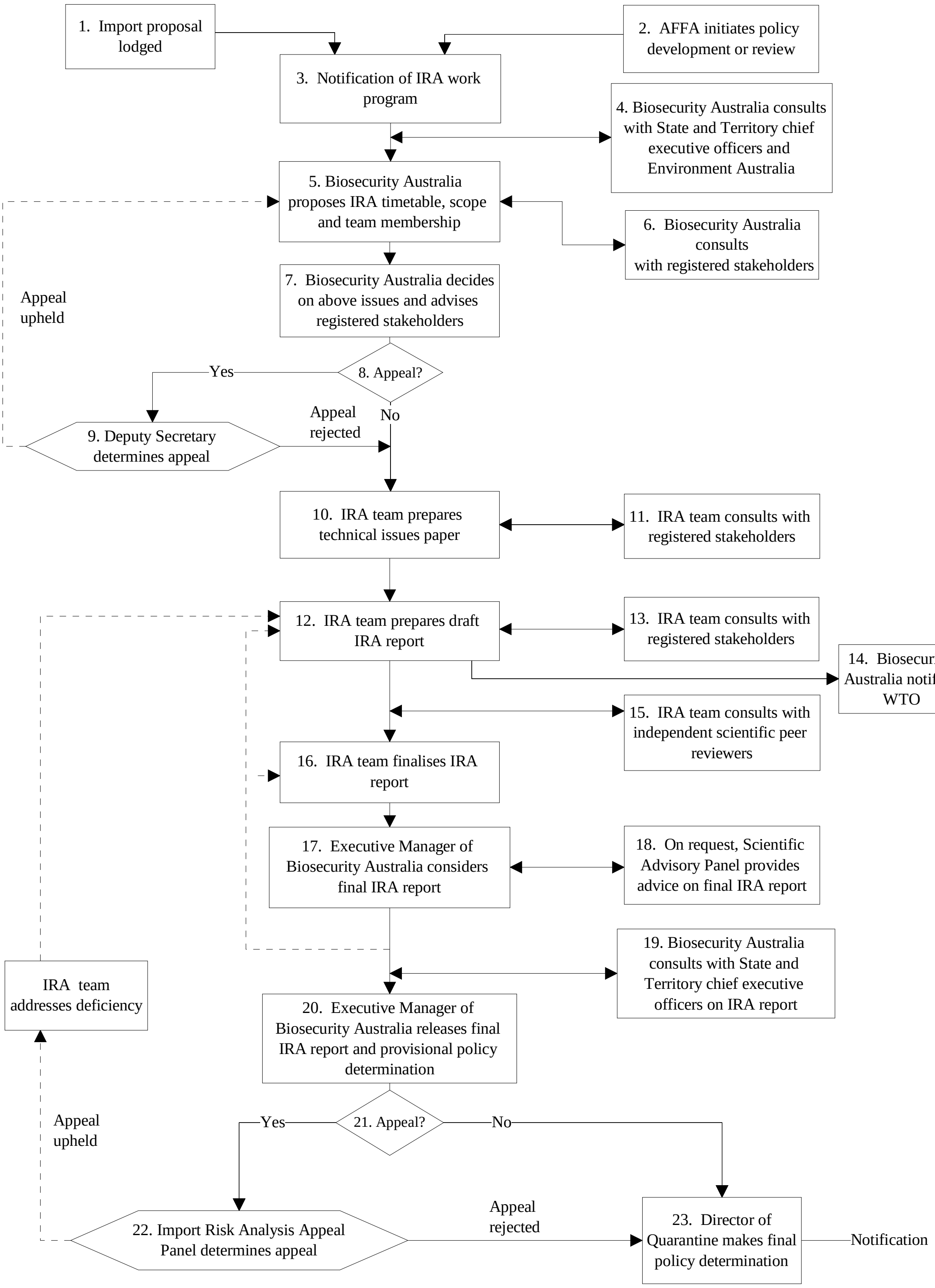
Notably, the process is distinct from that relevant to determining the Government's response to any industry adjustment effects from allowing imports. In its response to the Nairn Committee and the National Task Force, the Government decided that the then Department of Primary Industries and Energy would be responsible for determining if AQIS approval of imports is likely to have a significant effect on an Australian industry and identifying any structural adjustment measures that might be required (DPIE 1997, p. 48). The Department of Agriculture, Fisheries and Forestry — Australia has now assumed this role.

Biosecurity Australia is currently reviewing the process. It has recently proposed changes that include:

- not distinguishing between routine and non-routine matters;
- greater consultation with stakeholders on scope, timetable, approach and IRA team membership and giving stakeholders a right of appeal on these matters;
- the introduction of a technical issues paper for all IRAs;
- formalisation of independent scientific peer review;
- the establishment of a scientific advisory panel; and
- early contact with relevant State and Commonwealth authorities (AFFA 2000b, p. 2; AFFA 2001h, j).

Its proposed new process is illustrated in figure 2.1.

Figure 2.1 **A proposed new import risk analysis process**


1. Import proposal lodged
2. AFFA initiates policy development or review
3. Notification of IRA work program
4. Biosecurity Australia consults with State and Territory chief executive officers and Environment Australia
5. Biosecurity Australia proposes IRA timetable, scope and team membership
6. Biosecurity Australia consults with registered stakeholders
7. Biosecurity Australia decides on above issues and advises registered stakeholders
Appeal upheld
Yes
8. Appeal?
Appeal rejected
No
9. Deputy Secretary determines appeal
10. IRA team prepares technical issues paper
11. IRA team consults with registered stakeholders
12. IRA team prepares draft IRA report
13. IRA team consults with registered stakeholders
14. Biosecurity Australia notifies WTO
15. IRA team consults with independent scientific peer reviewers
16. IRA team finalises IRA report
17. Executive Manager of Biosecurity Australia considers final IRA report
18. On request, Scientific Advisory Panel provides advice on final IRA report
19. Biosecurity Australia consults with State and Territory chief executive officers on IRA report
IRA team addresses deficiency
20. Executive Manager of Biosecurity Australia releases final IRA report and provisional policy determination
Appeal upheld
Yes
21. Appeal?
No
22. Import Risk Analysis Appeal Panel determines appeal
Appeal rejected
23. Director of Quarantine makes final policy determination
Notification

Source: AFFA (2001k, p. 27).

3 What is import risk analysis?

Risk analysis is a discipline whose modern use dates to the early 1950s when it was applied in the United States in relation to concerns about the safety of nuclear power and weapons, occupational health and safety, and environmental degradation (Molak 1997, p. 5).

Risk analysis is applied by many different regulators. In Australia, these include not only Biosecurity Australia and the Australian Quarantine and Inspection Service (AQIS), but also the Civil Aviation Safety Authority, the Federal Office of Road Safety and the Australia New Zealand Food Authority. A survey of how some of these regulators have approached the analysis of risk is presented in a paper by the Office of Regulation Review (ORR 1995).

Although a discipline in its own right, risk analysis is not science as such, but an approach to decision-making. The method of science is to gather data and to test hypotheses. In contrast, risk analysis structures available scientific and other relevant information, such as from the fields of epidemiology, chemistry, biology, statistics and economics, to make decisions about how to deal with risk (Ahl 1998). And it also involves the use of subjective judgments, for example, in the choice of information or evidence to be used, the implementation of ‘default assumptions’ where information is incomplete, the choice of risk estimation techniques and the determination of a desired risk target.

It is apparent from the available literature (especially United States sources) that there are many different approaches to analysing risk, even the same type of risk. This is no different for pest and disease risks. This chapter focuses on guidelines by the International Office of Epizootics (OIE) — which deals with animal health — and the International Plant Protection Convention (IPPC) — which deals with plant health — (box 3.1). As noted in chapter 2, the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) endorses the guidelines of the OIE and IPPC, generally, as pertinent to the determination of quarantine measures. In Australia, draft guidelines on import risk analysis (IRA) have been issued recently by Biosecurity Australia (AFFA 2001i). The chapter concludes by describing how Biosecurity Australia approaches IRA in practice.

Box 3.1 **What are the International Office of Epizootics and the International Plant Protection Convention?**

The OIE is an intergovernment organisation dealing with animal health which was established in 1924 by international agreement. It has 158 member countries. It operates under the authority and control of a committee of delegates (the International Committee) designated by the governments of the member countries.

The OIE's main objectives are to:

- guarantee the transparency of animal disease status worldwide;
- collect, analyse and disseminate veterinary scientific information;
- provide expertise and promote international solidarity for the control of animal diseases; and
- guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products.

The IPPC is an international treaty dealing with plant health which was first adopted by the Food and Agriculture Organization of the United Nations (FAO) in 1951. It was amended once in 1979 and again in 1997. Although it is administered by the FAO, it is implemented primarily through the cooperation of member governments and regional plant protection organisations. It currently has 116 member governments.

The IPPC emphasises cooperation and the exchange of information towards the objective of 'global harmonisation'. In addition to describing national plant protection responsibilities, it also deals with international cooperation for the protection of plant health and the establishment and use of international standards for phytosanitary measures.

Sources: IPPC (2001b, 2001c) and OIE (2001b).

3.1 International guidelines

The OIE and IPPC guidelines on the analysis of risks to plant and animal health are contained in the International Animal Health Code 2001 (OIE 2001a, section 1.3) and Pest Risk Analysis for Quarantine Pests 2001 (IPPC 2001a), respectively.

The basic components of the guidelines are summarised in table 3.1 using the relevant OIE and IPPC terminology. Although the terminology and level of detail associated with each component differ, as the table shows, the guidelines involve the identification of the risk of concern, the estimation of that risk, the identification of options to reduce that risk to a desired risk target and an evaluation of options.

The table also identifies where a degree of economic input into the risk analysis is required — typically, in the estimation of risk (namely, the assessment of consequences) and the evaluation of options to reduce that risk.

Table 3.1 **International guidelines on risk analysis: basic components**

OIE	*IPPC*
Hazard identification	**Initiation**
	Identification of initiation points
	Identification of pest risk analysis area
	Information gathering
Risk assessment	**Pest risk assessment**
Release assessment	Pest categorisation
Exposure assessment	Assessment of the probability of introduction and spread
Consequence assessment*	Assessment of potential economic consequences (including environmental impacts)*
Risk estimation	Documentation of the degree of uncertainty
Risk management	**Pest risk management**
Risk evaluation	Deciding the acceptable level of risk
Option evaluation*	Determination of the technical information required*
Implementation	Determination of the acceptability of the assessed risk
Monitoring and review	Identification and selection of appropriate risk management options*
	Consideration of compliance procedures
Risk communication	**Documentation**

* Indicates that a degree of economic input is required in this component of risk analysis.

Sources: IPPC (2001a); OIE (2001a, section 1.3).

The guidelines advocate a number of desired features of risk analyses. For example, the OIE advocates a set of 'principles' for the different components of risk analysis (table 3.2). The IPPC too advocates that, in respect of the pest risk management component of risk analysis, the choice of measures be based on the following considerations:

- the measures are shown to be cost-effective and feasible;
- the measures should not be more trade-restrictive than necessary;
- no additional measures should be imposed if existing measures are effective;
- if different measures with the same effect are identified, they should be accepted as equivalent; and
- the measures comply with the principle of 'non-discrimination' (IPPC 2001a, pp. 19–20).

The guidelines allow a great deal of discretion in undertaking risk analysis. For example, there is discretion in whether to estimate risks qualitatively or quantitatively, in setting desired risk targets, in the handling of uncertainty about risk estimates (such as arising from poor data), and in evaluating options to reduce risks.

Further details of the guidelines are contained in appendix A.

Table 3.2 **International Office of Epizootics' principles of import risk analysis**

IRA component	*Principle*
Risk assessment	Risk assessment should be flexible to deal with the complexity of real life situations. Both qualitative and quantitative risk assessments are valid. Risk assessment should be based on the best available information that is in accord with current scientific thinking. Consistency in risk assessment methodology should be encouraged and transparency is essential. Risk assessment should document the uncertainties, the assumptions made and the effect of these on the final risk estimate. Risk increases with increasing volume of product imported. Risk assessment should be amenable to updating when additional information becomes available.
Risk management	The objective of risk management is to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import goods and fulfil its obligations under international trade agreements. The international standards of the OIE are the preferred choice of measures for risk management. The application of these measures should be in accordance with the intentions in the standards.
Risk communication	Risk communication is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout. A risk communication strategy should be put in place at the start of each risk analysis. Risk communication should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on imports. The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock providers and consumer groups. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated. Peer review is a component of risk communication to ensure that the data, information, methods and assumptions are the best available.

Source: OIE (2001a, section 1.3).

3.2 Import risk analysis in practice: New Zealand apples

The approach of countries such as the United States, New Zealand and Australia to IRAs, although varying in the detail, are broadly consistent. As an illustration of how IRAs are undertaken in practice, this section describes Biosecurity Australia's draft IRA on New Zealand apples (AFFA 2000c). This IRA is the subject of an inquiry (and interim report) by the Senate Rural and Regional Affairs and Transport Committee (2001). Biosecurity Australia has subsequently issued a final inventory of issues raised by stakeholders and is presently engaged in further public consultation on the draft IRA (AFFA 2001g).

Background

New Zealand was permitted to export apples to Australia until 1921, when a prohibition was imposed following the establishment of fire blight in Auckland. Fire blight was, and still is, absent in Australia.[6] It is a disease, caused by the bacterium *Erwinia amylovora*, of hosts such as apples, pears, cotoneasters, pyracanthas and other species of rosaceous plants.

New Zealand made two applications to regain access in the 1980s. The prohibition was maintained primarily because of 'unresolved issues relating to whether trade in apples could lead to the establishment of fire blight in Australia' (AFFA 2000c, p. 17).

In 1995, AQIS received another access application from New Zealand in which it proposed to export apples, regardless of the fire blight disease status of the orchard from which they originated, provided they were mature and free of 'trash' when packed. New Zealand claimed that mature apples free of trash are not a 'vector' for fire blight. AQIS undertook an IRA and, in its final report, rejected New Zealand's application stating that it did not consider on the basis of available evidence that the New Zealand claim that mature apple fruit free of trash is not a vector of fire blight was adequately demonstrated or that the proposal provided an equivalent level of protection required for other products imported into Australia that could carry high impact (1998b, p. 6). AQIS considered that in these respects, the New Zealand proposal was not consistent with Australia's appropriate level of protection and therefore could not be accepted.

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[6] The only recorded incident of fire blight in Australia was in the Melbourne botanic gardens in 1997. The disease was detected in a few plants and eradicated (AFFA 1998b, p. 8).

New Zealand submitted a new application in 1999 requesting a review of available risk management options with a view to ‘establishing phytosanitary measures that are the least [trade] restrictive in respect of the New Zealand apple exports while ensuring the level of protection deemed appropriate by Australia’ (AFFA 2000c, p. 19). The request was agreed to and an IRA commenced. A draft report was released by Biosecurity Australia in October 2000 (AFFA 2000c).

The draft 1999 import risk analysis

In undertaking the IRA, Biosecurity Australia followed its own guidelines, which in turn reflected IPPC guidelines on pest risk analysis.

Risk assessment

Risk estimates associated with 17 quarantine pests of concern were made (table 3.3). The estimates consisted of the combination of the likelihood and the economic consequences of incursion by each pest.

Table 3.3 **Risk assessment and management summary**

Pest (common name)	*Probability of entry, establishment and spread*	*Economic consequences*	*‘Unrestricted’ risk*[a]	*‘Restricted’ risk*[a]
	P	C	R = P x C	
Black lyre moth	Low	Moderate	Very low	not applicable
Dried fruit beetle	Low	Moderate	Very low	not applicable
Brown-headed leafroller[b]	High	Moderate	Moderate	Very low
Apple leaf-curling midge	Low	High	Low	Very low
Apple blister mite	Moderate	Moderate	Low	Very low
Fire blight	Low	Extreme[c]	Moderate	Very low
Cutworm[b]	Low	Moderate	Very low	not applicable
European canker	Low	High	Low	Very low
Green-headed leafroller[b]	High	Moderate	Moderate	Very low
Mealybugs	Moderate	Moderate	Low	Very low
Native leafroller	Low	Low	Negligible	not applicable
Oecophorid moth	Low	Moderate	Very low	not applicable
New Zealand flower thrips	Moderate	Moderate	Low	Very low
Leafrollers	High	Moderate	Moderate	Very low

[a] ‘Unrestricted’ risk is the risk in the absence of risk management measures. ‘Restricted’ risk is the risk where risk management measures are applied. [b] There are two species of this pest. [c] Includes economic consequences to the pear industry.

Source: AFFA (2000c, pp. 97–8, 131).

Both likelihood and economic consequences were described qualitatively using the nomenclature in box 3.2. The economic consequences considered included crop losses; the costs of control and surveillance measures; environmental effects; effects on domestic and export markets; changes to producer costs or input demands; and changes to domestic or foreign consumer demand resulting from quality changes.

Box 3.2 Nomenclature

Likelihoods

Extreme. The event would be virtually certain to occur.

High. The event would be likely to occur.

Moderate. The event would occur with an even probability.

Low. The event would be unlikely to occur.

Very low. The event would be very unlikely to occur.

Negligible. The event would almost certainly not occur.

Economic consequences

Extreme. The impact is likely to be highly significant at the national level. This classification implies that the impact would be of significant national concern. Economic stability, societal values or social wellbeing would be seriously affected in more than one geographic region.

High. The impact is likely to be significant at the national level and highly significant within affected geographic regions. This classification implies that the impact would be of national concern. However, the serious effect on economic stability, societal values or social wellbeing would be limited to a given geographic region.

Moderate. The impact is likely to be recognised at the national level and significant within affected geographic regions. The impact is likely to be highly significant to directly affected parties.

Low. The impact is likely to be recognised within an affected geographic region and significant to directly affected parties. It is not likely that the impact will be recognised at the national level.

Very low. The impact on a given criterion is likely to be minor to directly affected parties. The impact is unlikely to be discernible at any other level.

Negligible. The impact is unlikely to be recognised by directly affected parties.

Source: AFFA (2000c, pp. 39, 46).

Risk estimates were also described qualitatively and were drawn from the 'risk estimation matrix' in figure 3.1.

Figure 3.1 **Risk estimation matrix**

		Consequence					
		Negligible	*Very low*	*Low*	*Moderate*	*High*	*Extreme*
Likelihood	*Extreme*	Negligible	Very low	Low	Moderate	High	Extreme
	High	Negligible	Very low	Low	Moderate	High	Extreme
	Moderate	Negligible	Negligible	Very low	Low	Moderate	High
	Low	Negligible	Negligible	Negligible	Very low	Low	Moderate
	Very low	Negligible	Negligible	Negligible	Negligible	Very low	Low
	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low

Source: AFFA (2000c, p.48).

Risk management

Australia's 'appropriate level of protection'. Biosecurity Australia noted that Australia's appropriate level of protection as consistent with a 'very low' or 'negligible' level of risk (AFFA 2000c, p. 49). This is depicted as the shaded band in figure 3.1.

Identifying and choosing amongst risk management measures. Biosecurity Australia noted that Australia's 'preferred policy' for products imported for consumption is to 'manage risks offshore' (AFFA 2000c, p. 101). Accordingly, it identified general risk management measures in relation to each stage of importation to reduce the probability of *entry* of quarantine pests. For example, some general measures included: at the orchard, registration of growers and inspection for fire blight disease symptoms; in the packinghouse, disinfestation treatment; during transport, cool storage and disinfestation treatment; and on arrival, inspection of a sample per consignment.

Also identified were measures for each quarantine pest which required risk management in order to meet Australia's appropriate level of protection (see box 3.3 in relation to the risk management of fire blight disease). The estimated 'restricted' risks when these measures were put in place are given in the last column of table 3.3.

Box 3.3 **Risk management of fire blight disease**

An approach consisting of the following strategies was proposed by Biosecurity Australia to reduce the risk of fire blight disease to a level consistent with Australia's appropriate level of protection:

- establishment of registered export blocks free from fire blight disease, based on inspections at critical growth stages in the current and previous growing seasons;
- establishment of detection zones and inspections as in the above strategy;
- disinfestation of harvesting bins;
- disinfestation of fruit;
- sanitation of packing line;
- sorting, grading and packing;
- phytosanitary inspection and certification;
- registration of exporters and packinghouses;
- maintenance of fruit security;
- AQIS audits of New Zealand apple production and packing house systems; and
- on-arrival inspection.

Source: AFFA (2000c, p. 129).

Notably, the choice of risk management measures was not based expressly on an assessment of cost-effectiveness (for example, do the measures achieve Australia's appropriate level of protection at least cost to Australia) or, for that matter, a comparison between total benefits and costs to Australia (which would have required consideration of the benefits to Australian consumers of permitting trade). Instead, the measures were chosen according to whether they brought the risks of the different quarantine pests to a very low level.

Biosecurity Australia's preliminary determination

Biosecurity Australia's preliminary view was that the risks associated with the importation of apples from New Zealand can be effectively managed by employing a series of phytosanitary measures.

> These measures would reduce the quarantine risks to a very low level consistent with Australia's highly conservative approach to quarantine risk management. (AFFA 2000c, p. 13)

3.3 Concluding remarks

IRA is a decision-making framework. It structures available and relevant information about pest and disease risks so that decisions can be made about how to deal with those risks.

International guidelines on IRAs and the current approach of Biosecurity Australia, exemplified by its draft IRA on New Zealand apples, focus on reducing pest and disease risks to a level consistent with an ‘appropriate level of protection’ or desired risk target. A broader decision-making framework to that of IRAs — cost–benefit analysis — is reviewed in the next chapter.

4 A cost–benefit framework

As illustrated by recent outbreaks of foot and mouth disease and ‘mad cow’ disease in the United Kingdom and other European countries, pest and disease risks associated with imports of animals, plants and their products can be of acute national concern.

Nevertheless, quarantine measures to reduce the pest and disease risks associated with imports of animals, plants and their products involve various tradeoffs — or costs and benefits — within the whole community (including producers and consumers). A fundamental tradeoff in an import ban is between the benefit of reducing a particular pest or disease risk — which in many cases will be substantial — and the cost of being denied cheaper or different products.

All tradeoffs may not necessarily be captured in an import risk analysis (IRA). As apparent from chapter 3, a feature of the international guidelines for IRA, reflected in the Biosecurity Australia approach, is that they do not provide for a consideration of the costs and benefits to the wider community of quarantine measures (such as higher prices to consumers or increased profits to producers from restricted import competition).

A formal economic approach which can determine the full extent of the tradeoffs of quarantine measures to reduce pest or disease risk is cost–benefit analysis (CBA). In principle, it could allow quarantine regulators to determine whether a measure would enhance or reduce the wellbeing of the community. It is being increasingly applied to assess various government policies and programs and, indeed, underpins the Commonwealth Government’s regulatory impact statement requirements (see ORR 1998).

This chapter looks at what is involved in a CBA of quarantine measures and how scientific risk estimates as well as community risk preferences (or attitudes to risk), such as risk aversion, could be encompassed. It is useful to begin by reviewing the main economic rationale for imposing quarantine measures on imports.

4.1 An economic rationale for quarantine measures

Although individuals confront and manage many risks, there are some risks which may warrant government involvement. These risks generally involve an 'externality' or unpriced impact on the community. This arises when individuals who engage in activities expose others to the risks and, moreover, do not bear the full consequences when those risks are realised. (Risk analysts frequently describe these risks as 'involuntary risks'.)

Pest and disease risks involve externalities of this kind. In many instances, importers of animals, plants or their products would not have sufficient incentive (due to an absence of market price signals) to reduce the pest or disease risks associated with their imports. This is because, if pests or diseases entered and spread, the associated costs would often not be borne fully, or at all, by importers, but by others in the community — including the producers and consumers of products affected by the pests or diseases. Little recourse is available to producers and consumers to recover the costs from importers.

However, notwithstanding the strong prima facie economic rationale for governments to reduce pest and disease risks, community wellbeing may not be enhanced if the costs of such intervention are such as to outweigh the benefits.

4.2 Cost–benefit analysis of quarantine measures

The aim of CBA in this context would be to determine whether, and to what extent, the wide range of quarantine measures available to reduce the pest and disease risks of imports (such as import bans or various import protocols) would enhance community wellbeing or, in other words, ensure that the community's limited resources are being used in the best possible way.[7] (For a theoretical framework underpinning CBA, see appendix B.)

CBA could be undertaken at different levels of complexity. For example, it could incorporate scientific risk estimates, focus on particular markets or a range of markets, and incorporate community risk preferences. However, the application of CBA involves several practical and technical difficulties — not the least of which are that it can be demanding of data and involve complex techniques — and, importantly, it may face some legal and policy obstacles under the World Trade

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[7] A limited version of CBA is cost–effectiveness analysis which focuses on the costs of achieving a particular target. Compared with CBA, this type of analysis does not consider the full range of tradeoffs involved in particular measures. Cost–effectiveness analysis is examined further in chapter 5.

Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). These difficulties are considered in more detail in chapter 5.

In simple terms, CBA involves:

- identifying and measuring all the costs and benefits of a measure in reducing a pest or disease risk to particular community groups relative to a situation of unrestricted trade;[8]
- determining the extent of net benefits (or net costs) to the community as a whole from implementing the measure;
- ranking the measure against alternatives according to the relative magnitude of their net benefits (or net costs); and
- choosing the measure with the highest net benefit.

Nature of benefits and costs

Where CBA is undertaken in a 'partial equilibrium' fashion, the key benefits of a measure to reduce pest and disease risks from imports (relative to a situation of unrestricted trade) are:

- a reduction in output losses and other adverse effects (for example, such as to human health and on the environment) on the community due to pest or disease entry, establishment and spread (or incursion);[9]
- a reduction in the domestic cost of pest or disease control; and
- the maintenance of Australia's pest or disease free status (which promotes access to overseas markets).

The costs of a quarantine measure would include the cost to consumers arising from reduced import availability or increased import prices and the cost to government (net of charges) of administering the measure. Assuming comparable products, the extent of the cost to consumers of restricting trade will depend on the level of the import parity price (that would occur if trade were unrestricted) relative to domestic prices that arise because of the measure in place, as well as the extent to which consumers are responsive to price changes.

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[8] Here, the costs and benefits are measured by 'opportunity costs' and 'willingness to pay', respectively.

[9] A pest or disease incursion need not destroy a local industry. Moreover, the costs of controlling pest or disease incursions need not be high.

There is scope for incorporating scientific risk estimates in a CBA to yield benefits and costs with ‘expected’ values — reflecting the probabilities of certain outcomes occurring. For example, one possible outcome is that pests or diseases do not enter, establish and spread, in which case there would be no change in costs of production and output levels or other effects (and, thus, no benefits from a measure to reduce pest and disease risk). An alternative outcome is that pests or diseases do enter, establish and spread and, thus, substantially reduce output and access to overseas markets and/or have other deleterious effects, in which case the benefits of measures could be very substantial. A way in which scientific risk estimates can be incorporated in CBA is explored below in the section on net benefit (or cost) outcomes.

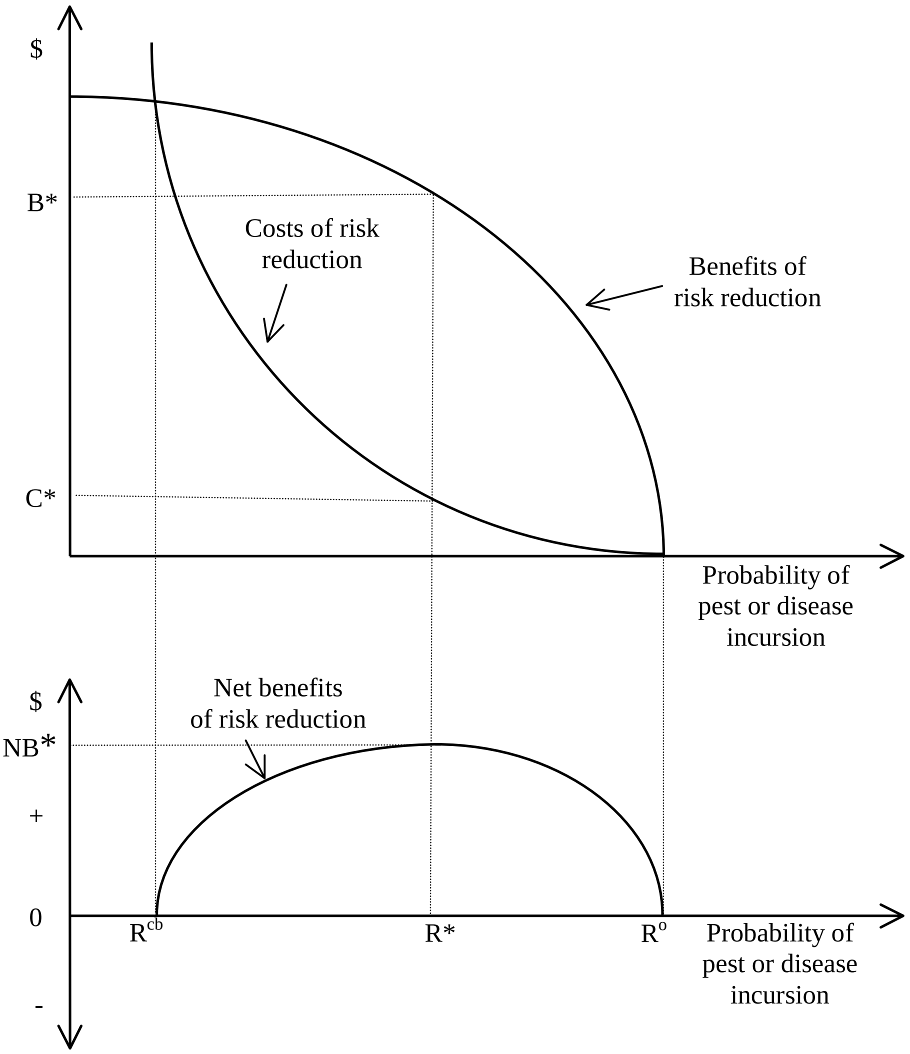
‘Acceptable’ level of risk

A notable aspect of CBA is that it does not involve specifying desired risk targets explicitly. Underlying a measure with the highest net benefit to the community as a whole is a level of risk which, if the measure is chosen, the community ‘accepts’ — zero is only one of a range of accepted risk levels. In this sense, from a community-wide perspective, the acceptable level of risk is ‘optimal’. As will be seen in chapter 5, this is very different to the meaning of acceptable level of risk or ‘appropriate level of protection’ given in the WTO SPS Agreement and by quarantine regulators.

One way of visualising this is given in figure 4.1. The top panel shows the community benefits and costs of reducing pest and disease risk for a particular product below R^o — the level of pest and disease risk in the absence of any risk-reducing measures. Associated with each level of risk below R^o is a particular measure. The shape of the benefits curve assumes that there are decreasing marginal (or incremental) benefits to the community from reducing pest and disease risk below R^o. The costs curve assumes that the marginal costs of reducing risks below R^o increase as the level of risk approaches zero. The level of risk associated with the highest net benefit to the community of a risk-reducing measure is given by R*, the benefits of reducing risk to this level is B* and the costs are C*. The lower panel, which derives a net benefits curve, shows this result more clearly.

The acceptable level of risk which emerges from a CBA will typically vary between products, including products with the same pest and disease risk. This variation arises largely because of underlying demand and supply characteristics of the product. Whether such differences might be interpreted under the SPS Agreement as involving discrimination or inconsistency is considered in chapter 5.

Figure 4.1 **An example: benefits and costs of pest and disease risk reduction**


$
B*
C*
Costs of risk reduction
Benefits of risk reduction
Probability of pest or disease incursion
$
NB*
+
0
-
Net benefits of risk reduction
R^cb
R*
R^o
Probability of pest or disease incursion

Source: Hinchy and Fisher (1991).

Net benefit (or cost) outcomes

A number of different net benefit or cost outcomes may arise from a CBA of pest and disease risk-reducing measures: indeed, a matrix of outcomes could be envisaged.

Table 4.1 provides a stylised example of what this might look like for three pest or disease events for the same product and three measures. The data used assume that the net benefit to the community increases as the measure becomes more restrictive (with import protocol B being more restrictive than import protocol A) and also as the degree of pest or disease incursion decreases. The data used do not reflect real cases. In this example, nine net benefit outcomes (specified in $ million units) are envisaged.

Table 4.1 **A stylised matrix of net benefit outcomes from quarantine measures**

Measure	*Net benefit if:*						*Expected net benefit for each measure*
	No pest or disease entry		*Pest or disease entry but no establishment and spread*		*Pest or disease entry, establishment and spread*		
	$m	probability	$m	probability	$m	probability	$m
Import protocol B	100	0.9	70	0.075	60	0.025	97
Import protocol A	80	0.8	65	0.150	50	0.050	76
Allow imports without restrictions	30	0.7	20	0.200	5	0.100	26

Whether or not probabilities could be assigned to these outcomes would depend crucially on whether it was possible to scientifically estimate risk.

If probability estimates could not be assigned, various decision rules such as ‘maximin’ or ‘minimax regret’ could be used to assist in the choice of a measure. Box 4.1 provides an illustration of the application of such rules. As will be seen below, a rule could be designed which reflects the community’s attitude to risk.

If probability estimates could be assigned, then expected values could be estimated for each measure. For example, table 4.1 gives indicative probabilities for the three pest or disease events that comply with the following conditions:

- the probability of no pest or disease entry increases as the measure becomes more restrictive;
- the probability of an adverse event (that is, an event involving pest or disease incursion) decreases as the measure becomes more restrictive; and
- for a particular measure, the probabilities of the three events equal one.

Thus, using the indicative probabilities in the table, the expected net benefit of allowing imports subject to the most restrictive protocol B is: 100 x 0.9 + 70 x 0.075+ 60 x 0.025 = $97 million.

If the community's attitude to risk is 'neutral', the measure to be applied would then be the one yielding the highest expected net benefit (import protocol B). However, as will be seen later, this might not be an appropriate rule where the community is risk averse.

4.3 Accommodating risk aversion in cost–benefit analysis

Biosecurity Australia has been charged by the Commonwealth Government to take a conservative approach to the management of pest and disease risk arising from imports (see chapter 2). This suggests an attitude of risk aversion (which may well be appropriate for Australia). As will be seen below, risk aversion implies that a measure to reduce pest and disease risk which yields an expected net cost to the community might nonetheless be accepted. This is because a lower but more certain level of community wellbeing (or wealth) is preferred to a higher, but uncertain, level.

The results of CBA could be extended in various ways to accommodate community risk preferences such as risk aversion as well as other risk attitudes. One approach where probability estimates are absent is to apply particular decision rules which emphasise worst case outcomes. (Such decision rules could also be used in an IRA during the risk management stage.) Another approach where probability estimates are available is discounting. These approaches, and their main limitations, are reviewed below.

Before reviewing them, it is worth noting that risk aversion could also be encompassed during the risk assessment stage of IRAs. This could arise, for example, where a quarantine regulator estimates pest and disease risks using worst case (rather than likely) scenarios, or applies a 'safety margin' to its risk estimates. In this situation, the use of any of the techniques reviewed below could lead to a 'double counting' of risk aversion if these risk estimates were to be used in CBA. The issue of conservatism in IRAs is discussed further in chapter 5.

Decision rules (where probability estimates are unavailable)

Where probability estimates are unavailable, decision rules which embody risk aversion could be used to choose among measures. Two such rules are maximin and minimax regret (box 4.1). The maximin rule involves focusing on the minimum possible net benefit for each measure and then choosing the highest of those minimum values.[10] The minimax regret rule focuses on minimising the cost of regret from making a mistake.

Box 4.1 Decision-making in the absence of information about pest and disease risk

A number of decision rules could be applied to help choose amongst measures with different net benefit or cost outcomes in the absence of probability estimates.

The application of some of these rules is illustrated using the stylised ‘payoffs matrix’ in table 4.1. The matrix is duplicated below.

Stylised payoffs matrix ($ million)

Measure	*Net benefit if:*			*Minimum payoffs*	*Maximum payoffs*
	No pest or disease entry	*Pest or disease entry but no establishment and spread*	*Pest or disease entry, establishment and spread*		
Import protocol B	100	70	60	60	100
Import protocol A	80	65	50	50	80
Allow imports without restriction	30	20	5	5	30

Using this payoffs matrix, at least two rules could be applied to select a measure. These are as follows:

- Determine the lowest payoff outcome for each measure, then choose the measure which maximises these lowest payoffs. According to this rule (frequently referred to as ‘maximin’), import protocol B would be chosen.
- Determine the highest payoff outcome for each measure, then choose the measure which maximises these highest payoffs. According to this rule, import protocol B would be chosen.

Another decision rule is called ‘minimax regret’. This rule requires minimising the cost of regretting a mistake. A mistake might arise, for example, from choosing to impose an import ban when the pest and disease risk from imports is negligible. In this case, a major component of the cost of regret is the forgone net gains from trade.

Before applying the rule, it is necessary to derive a ‘regrets matrix’ using the payoffs matrix above. The highest possible net benefit outcome for each pest or disease event is chosen (these are $100 million, $70 million and $60 million) and then the cost of regret is estimated for each measure. For example, in relation to the event of no pest or disease incursion, the highest possible net benefit is $100 million, which occurs if import protocol B was imposed. Thus, if the measure was implemented, the cost of

(Continued next page)

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[10] An analogous rule where payoffs are in terms of net costs is minimax, which looks at the maximum possible net cost for each measure and then chooses the measure which yields the lowest of these maximum costs.

Box 4.1 **(continued)**

regret is 0 (that is, $100 million – $100 million). However, if protocol A is applied, the cost of regret is $20 million (that is, $100 million – $80 million). Similarly, if imports were allowed without restriction, the cost of regret is $70 million (that is, $100 million – $30 million).

Once the regrets matrix is derived (see below), it is then possible to determine the highest regret cost for each measure and choose the measure which minimises these maximum regret costs. In this example, this means imposing import protocol B.

Regrets matrix ($ million)

Measure	*Net benefit if:*			*Maximum regret for each measure*
	No disease or pest entry	*Pest or disease entry but no establishment and spread*	*Pest or disease entry, establishment and spread*	
Import protocol B	0	0	0	0
Import protocol A	20	15	10	20
Allow imports without restriction	70	50	55	70

There are two observations to make about the use of these decision rules. First, given that the SPS Agreement provides that measures must be based on 'risk assessments' (as defined by the Agreement), an issue arises as to whether the rules can be legitimately used. To apply the rules, it is not necessary to assess or estimate pest and disease risk; the rules can be applied without this information. A second observation is the choice of decision rule is subjective; no one rule is objectively superior to the other.

Source: Neter, Wasserman and Whitmore (1978, pp. 555–65).

However, as the rules do not depend on probability estimates, an issue arises as to whether they can be legitimately used given that the SPS Agreement provides that measures must be based on 'risk assessments' (as defined in the Agreement).

Discounting

Where probability estimates are available, a rough approach for taking account of risk aversion is to apply a simple discount factor to the results of CBA. For example, an expected net cost (or benefit) for a measure could be deflated by particular dollar amounts or by a percentage.

Although this approach is simple to use and makes transparent an assumed degree of risk aversion, the size of the discount is inevitably a matter of judgment.

4.4 Concluding remarks

CBA is an approach which could assist in deciding amongst quarantine measures with respect to the imports of animals, plants and their products which have associated pest and disease risks. It involves evaluating, from a community-wide perspective, all the expected costs and benefits of alternative measures and choosing that measure with the highest expected net benefit. It can be undertaken at increasing levels of complexity and accommodate community attitudes towards risk. However, like many analytical tools, it is dependent on the availability of (substantial) data and on the underlying assumptions.

In contrast, IRA is an approach which emphasises different, yet similar factors in the determination of quarantine measures. It focuses on scientifically assessing (that is, identifying and estimating) a risk. And it involves evaluating measures to reduce that risk to a level consistent with a country's 'appropriate level of protection'. Accordingly, IRA focuses on the costs of imports. Even so, as seen in chapter 3, it is not necessarily the case that an IRA will involve choosing measures which are the most cost-effective in reducing risk to a given level. This limitation is discussed further in chapter 5.

5 Issues in import risk analysis

This chapter looks at key issues arising from the current international approach to import risk analysis (IRA). These issues relate to:

- the ‘appropriate level of protection’;
- the use of cost–effectiveness analysis;
- conservatism in estimating risks;
- quantitative and qualitative risk estimation;
- information gaps;
- community understanding about risks; and
- the scope for incorporating a broad economic perspective.

5.1 The ‘appropriate level of protection’

Many countries, including Australia, take an approach to determining quarantine measures centred on the concept of an appropriate level of protection. This approach involves, in the first instance, the determination or identification of a desired risk target and, in the second instance, an evaluation of measures to reduce pest and disease risk to that target. These elements, particularly the second, typically are associated with the risk management stage of IRAs.[11]

As noted in chapter 2, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) gives World Trade Organization (WTO) members a right to determine their own appropriate levels of protection provided they:

- take into account the objective of ‘minimizing negative trade effects’; and

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[11] According to Biosecurity Australia, however, the determination of Australia’s appropriate level of protection is not made during an IRA, but before it is undertaken. It said the appropriate level of protection is ‘an issue for government in consultation with the community’ and is a ‘societal value judgement to which AFFA contributes by providing technical information and advice’ (AFFA 2001k, p. 2).

- avoid ‘arbitrary or unjustifiable distinctions’ in the levels considered ‘appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade’ (the ‘consistency requirement’).

Although it is not clear from the SPS Agreement what the ‘appropriate level of protection’ means — it is tautologically defined — the Appellate Body has provided some guidance. In the Australian salmon dispute, the Appellate Body said that:

- it is a prerogative of the member concerned;
- it is an ‘objective’ and its determination is an element in decision-making which ‘logically precedes and is separate’ from the establishment or maintenance of a measure;
- it could be zero risk; and
- while it need not be quantitative, it should not be vague or equivocal (see box 2.2 in chapter 2).

Within Australia, the appropriate level of protection has been expressed as being consistent with an acceptable level of risk that is low, but not zero. The Australian Government acknowledged that ‘there will always be an element of risk’ with imports (DPIE 1997, p. 10). The Australian Quarantine and Inspection Service (AQIS) has said that ‘quarantine policies are based on the concept of the management of risk to an acceptably low level’ (AQIS 1998a, p. 11). As noted in chapter 3, Biosecurity Australia said in its IRA on New Zealand apples that:

> Australia has traditionally maintained a ‘very conservative’ attitude to quarantine risk. Given this, a risk that was either *very low* or *negligible* was considered sufficiently conservative to meet Australia’s [appropriate level of protection]. (AFFA 2000c, p. 49)

An issue concerning the appropriate level of protection of a country is whether it could be expressed more precisely. For example, is it sufficient to express the appropriate level of protection as consistent with a ‘very low or negligible’ target level of risk? Or could it be expressed, for example, in terms of a specific expected cost of pest or disease incursion (say $50 000 per annum) or in probabilistic terms (say one in a million probability in 100 years of a cost of pest or disease incursion of $50 000 per annum)?

An argument for greater precision is that it would impose greater transparency and consistency on quarantine decision-making. The more vague or ambiguous the desired risk target, the more difficult it is for a regulator to be consistent in its evaluation across cases, and the more vulnerable is a regulator to the charge of being susceptible to other influences.

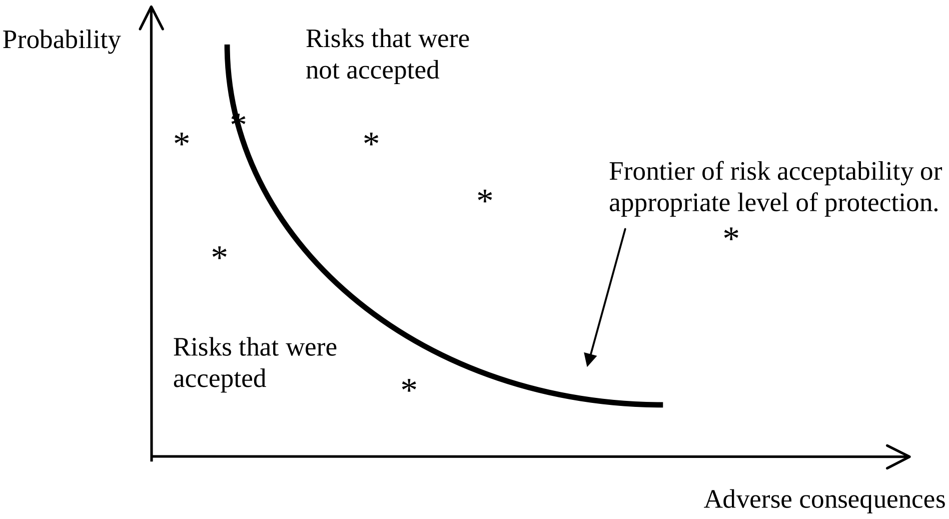
Box 5.1 **Determining and modelling the appropriate level of protection**

One approach to determining whether an assessed pest and disease risk is consistent with a country's appropriate level of protection is to compare it with the pest and disease risks associated with other situations (such as previous quarantine decisions) and to identify whether they were accepted or not in those situations. Bigsby had put the approach in the following terms:

> The problem of arriving at an [appropriate level of protection] which adequately describes a regulatory agency's perception of acceptable pest risk in an iso-risk framework can be approached by starting with a country's current regulatory treatment of pests and commodities. To establish an [appropriate level of protection], a sufficient sample of pests would first need to be evaluated for probability of entry and potential economic impacts after post-quarantine treatment. [The appropriate level of protection] should emerge from the pattern of plotted results, being represented by a line above which there would be no plots. An [appropriate level of protection] for commodities could be determined by a similar process. A value for [the appropriate level of protection] implicit in existing quarantine regulations should emerge from the analysis. (2001, p. 159)

The diagram below, which focuses on risk as a function of probability and adverse consequences, is one way of conceiving what this involves. It plots risks in different situations and identifies which risks have been accepted and which have not. Indeed, an imaginary frontier of appropriate level of protection could be drawn.

Although this approach ensures consistency in decision-making, it depends on a country having a stable attitude to risk over time and it does not of itself explain all the factors relevant in determining whether or not a risk is acceptable. Moreover, as Bigsby notes, it may show 'inconsistencies in existing policies' (2001, p. 159).


Probability
Risks that were not accepted
Frontier of risk acceptability or appropriate level of protection.
Risks that were accepted
Adverse consequences

Sources: AFFA (2000c); Bigsby (2001); Gascoine (2001).

One technique for achieving greater precision might be to model the curve in box 5.1. This could be done by examining previous quarantine decisions and by mapping the pest and disease risks involved in those decisions according to whether they were accepted or not. Such mapping may allow one to determine where the appropriate level of protection lies for a new case.

A difficulty with this technique is that it assumes that the appropriate level of protection of a country remains unchanged over time, when in fact it may change (for example, as a community's understanding and perceptions about risks improve). Also, as Bigsby (2001, p. 159) noted, 'such an analysis may show inconsistencies in existing quarantine policies' thus making it difficult to identify what the appropriate level of protection really is. Finally, and most importantly, the technique does not explain all the factors relevant to determining the appropriate level of protection in the previous decisions.

That said, the technique could be a useful step towards inserting objectivity into the expression of the appropriate level of protection.

A second issue is whether the SPS Agreement permits different appropriate levels of protection for animals and for plants, or for broad product groupings. As noted later in section 5.6, the interpretation of the consistency requirement contained in article 5.5, which potentially affects a regulator's ability to do this, continues to be debatable.

A final issue of a distributional nature is that, if the SPS Agreement permits only a single appropriate level of protection, some industries may be comparatively worse off. For example, small industries (in terms of their output values) may be less capable than large industries of absorbing an expected cost of pest or disease incursion of (say) $1 million per annum.

5.2 The use of cost–effectiveness analysis

As chapter 2 noted, article 5.3 of the SPS Agreement requires that, in determining the SPS measure to be applied to achieve a country's appropriate level of protection, account must be taken of a range of 'relevant economic factors'. One of these factors includes the 'relative cost-effectiveness of alternative approaches to limiting risk'.

Cost–effectiveness analysis is a more limited approach to evaluating quarantine measures than cost–benefit analysis (CBA). It involves an evaluation of the relative costs of different measures in addressing a particular benefit. A measure is chosen on the basis that it involves the least aggregated cost.

Although falling short of a broad economic perspective such as CBA, the application by regulators of cost–effectiveness analysis could facilitate the selection of measures which are consistent with a desired risk target at low cost.

It is possible that the cost-effectiveness of measures could be interpreted by regulators in a narrow way. For example, a regulator could prefer ‘offshore’ measures (such as a requirement for the disinfestation of fruit grown in the orchards of the exporting country) over ‘onshore’ measures that could be imposed upon or after entry and release into the importing country. The basis for this preference may be a perception that offshore measures involve fewer costs for the importing country; in other words, the measures may be perceived to ‘shift’ the costs of reducing the pest or disease risk from the importing to the exporting country. However, such an argument may be spurious. Depending upon market circumstances, it is possible that the costs of a measure would be incorporated in the export price of the product.

A preference by regulators for offshore measures can pose problems for the importing country. First, if the cost of an offshore measure is higher than need be, then the export price may also be commensurably higher. The importing country may thus be worse off by the imposition of offshore measures compared with (say) an onshore measure which is equivalent in its impact on risk. A second problem is that an offshore measure could distort trade between the exporting country and other countries which do not impose offshore measures. The reason for this is that producers in the exporting country may have to operate with higher cost structures than otherwise would be the case.

5.3 Conservatism in import risk analysis

Conservatism or risk aversion in IRAs can be incorporated in the risk assessment stage (for example, in the choice of data, assumptions and risk estimation techniques) and, again, in the risk management stage (for example, in the desired risk target).

Although a cautious attitude to risk by a community is not called into question, nor indeed is a country’s prerogative right to determine its own appropriate level of protection, the ‘double counting’ of risk attitudes by regulators — whereby caution is incorporated in both risk assessment and risk management stages of IRAs — is. Such double counting may bias decision-making towards measures which are needlessly trade-restrictive.

In principle, the scientific assessment of risks should involve, as far as possible, an objective appraisal of data and information. This means avoiding the incorporation of particular risk attitudes in the risk assessment stage of IRAs. However, a range of risk estimates from worst to best case scenarios could still be provided. The incorporation of risk attitudes could then be confined to the risk management stage; that is, in deciding amongst quarantine measures. For example, risk attitudes could be incorporated in the desired risk target or, if a broad economic perspective were applied, in the specific risk aversion factor or decision rule (see chapter 4). Such an approach could make the various stages of IRAs more transparent and enhance the integrity of the risk estimates.

5.4 Quantitative versus qualitative risk estimation

At the risk assessment stage of IRAs, risk estimates can either be quantitative or qualitative (or even semi-quantitative). Neither the SPS Agreement nor international guidelines on risk analysis require that risk be quantified. Indeed, regulators vary in their approach to the quantification of risks. For example, the quantification of risk is regularly undertaken in New Zealand and the United States, but not in Australia.

In Australia, the Nairn Committee reviewed the question of whether risk estimates should be quantified. It observed an international trend amongst quarantine regulators in the quantitative estimation of risk (1996, p. 105). Nonetheless, it said:

> The perception held in some quarters that quantitative approaches are inherently ‘better’ or ‘more scientific’ than qualitative approaches is misguided — a poor quantitative risk assessment (eg one using poor data or using inappropriate quantitative techniques) can be quite misleading and far less scientific than a good semi-quantitative or qualitative assessment. (1996, p. 106)

After pointing to the resource intensiveness of quantification and the difficulties posed by information gaps, it concluded that:

> ... although quantitative approaches to risk analysis have some application in evaluating selected import access requests, semi-quantitative and qualitative approaches are most appropriate for the vast majority of import risk analyses. (1996, p. 108)

However, in its review of the Australia salmon decision, the Senate Rural and Regional Affairs and Transport Committee expressed concerns about the use by AQIS of qualitative risk assessment in that case. It considered quantitative risk assessment was a ‘more objective tool’ (2000, p. 186). It also said that while:

> The judgment on quantitative/qualitative risk analysis was one for AQIS to make … there would be less risk of a challenge were more use to be made of quantitative risk analysis methodology or if the terminology used was explicit and unambiguous. (2000, p. 187)

This view was confirmed by the Committee in its interim report on the proposed importation of apples from New Zealand (2001, pp. 76–7). Since the Australian salmon decision, a nomenclature to describe assessed risks qualitatively in IRAs has been developed (see box 3.2 in chapter 3).

In its recent draft guidelines for IRA, Biosecurity Australia provides for a range of approaches to the evaluation of risk. It noted that ‘there is no single “best approach” and, indeed, it will occasionally be sensible to combine approaches in a given assessment’ (AFFA 2001k, p. 50).

In principle, there is merit in regulators providing quantitative risk estimates in certain circumstances. For example, quantification could be undertaken if risks are initially assessed in descriptive or qualitative terms as ‘moderate’ or ‘extreme’, or where a dispute is judged to be highly likely. Dr Marion Wooldridge, an expert in risk analysis, said during the Australian salmon dispute that, where there is likely to be controversy or lack of agreement over qualitative estimates of risk (and about the decision that ensues), it would be useful to ‘proceed down the route of attempting a quantitative risk assessment’ (WTO 1998c, Annex 2, p. 220).

It is recognised, however, that deficiencies or gaps in data can make it very difficult for regulators to provide quantitative risk estimates. Some ways of handling this problem are considered next.

5.5 Information gaps

Gaps in available information can occur which limit the extent to which risks can be quantitatively estimated during the risk assessment stage of IRAs. For example, there may be a lack of knowledge about the pathways necessary for imports to introduce pests or diseases into a particular environment or about the (biological) effects on animals and plants of specified levels of exposure to pest or diseases.

There are various techniques for dealing with such gaps in order to proceed with risk estimation. For example, some approaches in deriving a single point risk estimate include:

- deriving a ‘best guess’ risk estimate (for a particular element of the pathway or for the whole pathway) from a number of experts (known as the Delphi technique); and
- using an extreme value for missing data points and running a computer simulation.

However, it is not clear whether such techniques are extensively used by quarantine regulators.

If risks are to be quantified where there are information gaps, it would be preferable that a distribution of risk estimates be presented. Sensitivity analysis is one approach that could yield such a distribution. This involves estimating risks under different scenarios including (say) a 'most likely' or 'average' scenario and a 'worst case' scenario. Another approach is using stochastic analysis (through computer simulations) to generate 'confidence intervals' of risk estimates (for example, an estimate of risk falls between one in one million and one in two million with 95 per cent level of confidence). Either approach would improve the integrity of risk estimates as well as the information content of IRAs overall.

Notably, in deciding amongst measures in the face of information gaps, the SPS Agreement provides for the provisional adoption of measures. Article 5.7 provides that, where 'relevant scientific evidence is insufficient', a measure may be adopted provisionally on the basis of 'available pertinent information'. However, in doing so a member must:

- seek the additional information necessary for a 'more objective assessment' of risk; and
- review the measure accordingly within a 'reasonable period of time'.

5.6 Community understanding about risk

Lack of understanding within the community about scientific estimates of pest and disease risk can make it difficult for a regulator to 'sell' the outcomes of IRAs (or their preferred measures). If the community overestimates risk, this could lead to excessive demand for restrictive measures. As Nunn noted:

> ... factor analysis has shown that hazards that are perceived as unfamiliar or provoke dread are assigned a higher risk than can be demonstrated statistically. ... Unfamiliar or unknown hazards, even with a low probability, that are regarded as having potentially catastrophic effects are perceived as high risk and provoke strong public demands for government to regulate and protect against them. Examples include hazards such as a nuclear accident or the introduction of an unfamiliar disease that might be a zoonosis (eg Ebola or Nipah viruses). (2001, p. 31)

This points to the ongoing need for the community to be informed about scientific risk estimates, in order to be able to more adequately interpret the outcomes of an IRA. Again, Nunn said:

> Leaving consideration of risk communication until late in the risk analysis process rather than informing and involving stakeholders or the general public early and often

> throughout the process only increases the likelihood of ... unfavourable reactions. (2001, p. 32).

Within Australia, Biosecurity Australia is undertaking work towards an understanding of public perceptions of risk and, hence, improving risk communication.

If a broad economic perspective were incorporated into the risk management stage of IRAs (see next), clear communication of what that involves, as well as the results, would be even more necessary.

5.7 The scope for incorporating a broad economic perspective

A broad economic perspective, such as provided by CBA, has not played a role in quarantine decision-making by regulators such as the United States Animal and Plant Health Inspection Service, the New Zealand Ministry of Agriculture and Fisheries, Biosecurity Australia or its predecessor AQIS.

As noted earlier, IRAs tend to be centred around achieving a desired risk target; consideration of, and even information about, the benefits that imports could bring to a community are generally not addressed, or are implicitly assumed to be of lesser importance.

The economic analysis which typically feeds into IRAs is of a limited or partial nature. This is true of all countries. For example, in Australia's case, AQIS has said in its handbook on the IRA process:

> The social and economic considerations arising from the potential impact of pests and diseases that could enter and establish in Australia as a result of importation are taken into account, but the potential competitive economic impact of prospective imports on domestic industries is not within the scope of AQIS's import risk analysis. Relevant economic considerations in quarantine risk analysis include the cost of programs required to manage disease and pest outbreaks, the cost to industry of an outbreak and the cost to industry of loss of markets due to an outbreak [of pests or diseases]. (1998a, p. 11)

Further, AQIS said of considerations such as the effect of exposing domestic industries to substantially greater import competition and consequent structural adjustment pressure:

> The Government may in such circumstances seek relevant economic analysis and consider options available for an appropriate response. Such considerations may occur

> in parallel with, but will in no way influence, the import risk analysis performed in accordance with the procedures described in [the] Handbook. (1998a, p. 11)

An Australian illustration of the way in which economic analysis has been used in quarantine decision-making is given by the approach to Canada's request to export salmon to Australia. As part of its IRA, AQIS commissioned the Australian Bureau of Agricultural and Resource Economics to provide research on the economic effects on the industry of the introduction and establishment of disease. Effects on the profitability of the industry from import competition or effects extending beyond the industry such as to consumers or user industries were not considered. At the same time as the IRA was being conducted, the Industry Commission was asked by the Government to examine the economic effects of Canadian salmon imports assuming the absence of disease introduction and establishment (IC 1996). The objective of that work was not to assist AQIS in deciding whether or not imports of Canadian salmon should be allowed, but to provide information that would assist the Government in assessing potential competitive effects on the local industry of imports.

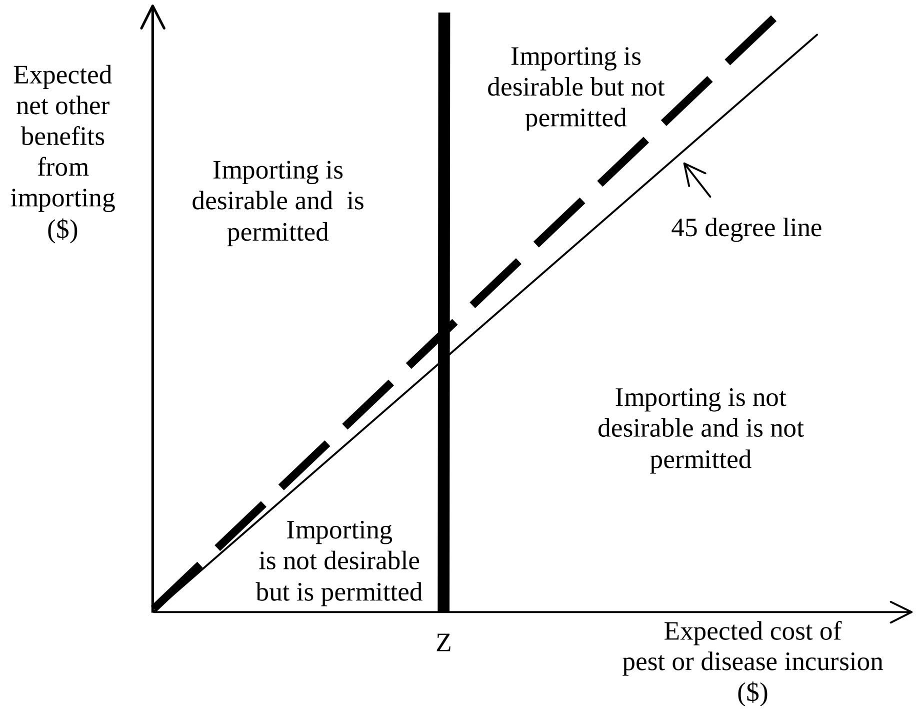
An issue thus arises as to whether there is scope for incorporating a broad economic perspective in IRAs. The potential place within IRAs for doing so is the risk management stage — that is, the stage involving an evaluation of measures to reduce pest and disease risks.

Potential payoffs

At least conceptually, there is the potential for gains in incorporating a broad economic approach such as CBA in IRAs. How these can arise is depicted in figure 5.1, based on Snape and Orden (2001, p. 176). The horizontal axis represents the expected cost of pest or disease incursion; effectively the pest or disease risk of importing animals, plants and their products in dollar terms. The vertical axis represents the benefits to a country of importing those products in dollar terms net of any costs other than those associated with pest and diseases (called net other benefits).

Under a broad economic approach, and assuming a country was neutral in its attitude to risk, imports would be desirable above the 45 degree line (this line may be conceived as the boundary whereby the net other benefits of importing animals, plants and their products equals the expected costs of pest or disease incursion). (If a country were risk averse, such as arguably applies to Australia, the boundary of tradeoffs would be steeper than the 45 degree line, for example, the dashed line.)

Figure 5.1 **A comparison of two approaches**


Expected net other benefits from importing ($)
Importing is desirable and is permitted
Importing is desirable but not permitted
45 degree line
Importing is not desirable and is not permitted
Importing is not desirable but is permitted
Z
Expected cost of pest or disease incursion ($)

Source: Snape and Orden (2001).

In contrast, under an approach focused on an appropriate level of protection, only imports occurring to the left of the Z line would be permitted; the Z line represents a country's target level of risk (which in turn is consistent with its appropriate level of protection). The costs of this approach are depicted by two areas: where imports would be desirable under a broad economic approach, but are not permitted because it would exceed the country's target level of risk; and where imports would not be desirable under a broad economic approach but would be permitted because it is within the country's target level of risk.

Potential problems

Against the potential payoffs involved in incorporating a broad economic approach in IRAs are a number of potential problems.

Practical and technical difficulties

There are a some practical and technical difficulties. CBA can be demanding of data and involve complex techniques requiring not only expert knowledge but also judgment. This implies a need for independent institutions subject to a high level of public accountability and transparency. Otherwise, there is a danger that the results of CBAs could lack rigour, objectivity and credibility. Such difficulties would need to be tested through trials and further research within relevant existing institutions.

Legal arguments

Some commentators have argued that incorporating a broad economic perspective would lead to breaches of the SPS Agreement.[12]

Perhaps the most compelling legal argument is that a broad economic approach as given in CBAs could lead to ‘distinctions’ in the levels of acceptable risk in ‘different situations’ and thus breach article 5.5 (the ‘consistency requirement’). It is this article that is pointed to frequently as justifying an approach to quarantine decision-making centred on an appropriate level of protection. It provides that:

> With the objective of achieving consistency in the application of the concept of appropriate level of [SPS] protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

The Appellate Body in both the European Communities hormones dispute (WTO 1998a) and the Australian salmon dispute (WTO 1998d) provided guidance on the interpretation of this article (see table 2.2 in chapter 2). For the article to be breached, the Appellate Body presented a three prong test:

- the member imposing the measure complained of has adopted its own appropriate levels of protection in several different (but comparable) situations;
- those appropriate levels of protection must exhibit arbitrary or unjustifiable differences in their treatment of different situations; and
- the arbitrary or unjustifiable differences result in discrimination or a disguised restriction on international trade.

On the surface, the test does appear to present a significant argument against the use of a broad economic approach. As chapter 4 has shown, differing appropriate levels of protection could certainly emerge in different situations from the use of CBAs. However, it is not clear whether these differences would be seen as ‘arbitrary’ or ‘unjustifiable’ if they were the outcomes of the consistent application of a transparent and objective analytical framework. Indeed, one could argue that the use of CBAs could, in principle, avoid the emergence of arbitrary or unjustifiable differences in appropriate levels of protection.

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[12] For a review of the key legal arguments, see Sinner (1999).

A second possible legal obstacle to incorporating a broad economic perspective in IRAs is that article 2.3 could be breached. This article provides that measures must not ‘arbitrarily or unjustifiably’ discriminate between members where ‘identical or similar conditions prevail’ and not be applied in a manner constituting a ‘disguised restriction on international trade’. The concern here is that a broad economic perspective might lead to divergent results for members where identical or similar conditions prevail, thus leading to complaints about arbitrary or unjustifiable discrimination. Divergent results could arise, for example, in relation to two products from two countries with similar pest and disease risks which face different demand and supply conditions in Australia. It is conceivable that one CBA could suggest that the preferred measure is to restrict imports, while the second CBA suggested that imports be allowed.

A third argument that has been raised is that, in deciding amongst measures to be applied to reduce pest and disease risk, article 5.3 excludes consideration of the competition or trade-related impacts of allowing or restricting imports on consumers, producers or others in a community. This article provides that:

> In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of [SPS] protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Although the language in this article is clearest with respect to the costs of pests or diseases, it simply does not address the competition or trade-related impacts on consumers, producers or others of allowing or restricting imports. There is nothing in the article to suggest that only specified factors must be taken into account in choosing amongst measures to reduce risk.

A fourth argument is that incorporating a broad economic perspective is limited by article 3.1 which provides that members must ‘base’ their measures on international guidelines (as well as standards and recommendations) where they exist, except as otherwise provided in the Agreement. This is because a broad economic perspective may not be applied in determining the guidelines themselves. Nonetheless, as the Appellate Body noted in the European Communities hormones dispute, the article does not necessarily mean that compliance with international guidelines is mandatory; merely, that they be considered in the establishment of the measures to be applied (see table 2.2 in chapter 2).

Although each of these legal arguments appears to have some merit, they must be considered debatable until further WTO guidance is given (through its dispute settlement system), or there is an explicit change in the rules.

Policy difficulties

A final potential problem is that, if members agreed to change the SPS Agreement to explicitly allow the incorporation of a broad economic approach in IRAs, some might misuse — either intentionally or unintentionally — this facility. Snape and Orden argued:

> ... the purpose of the SPS Agreement is simply to prevent countries from making egregious arbitrary and unjustifiable distinctions between products on quarantine grounds, and that if it achieves this it will have achieved a great deal. Taking into account other net benefits of trade could backfire, and open the door to protection against economic competition for particular producers or socio-economic groups in a country. This could undermine what was intended to be achieved under the WTO Agreement on Agriculture. In such event, the alternative decision rule [that is, given by a CBA approach] could facilitate what many observers feared: that as other forms of protection are wound back, economic protection through quarantine provisions could be increased. The best could be the enemy of the good. (2001, pp. 179–80)

Such a perverse policy outcome could arise because, as CBAs are demanding of data and expertise, their quality is likely to vary from country to country. Not all countries may be able to resource an independent and transparent institution capable of generating good quality CBAs. Without additional safeguards in the SPS Agreement, the likelihood of poor decisions or, worse, strategic use for protectionist ends, is high.

In conclusion, while adopting a broad economic framework in quarantine decision-making has merit at a conceptual level, in practice there are significant informational and institutional obstacles that would first need to be addressed. A greater payoff in the short term could come from improving the quality of IRAs and, in particular, ensuring that the quarantine measures proposed are as cost-effective as possible.

5.8 Concluding remarks

Quarantine measures play an important role in helping countries to deal with risks of pest or disease incursions.

Tightening the rules in relation to the imposition of quarantine measures under the SPS Agreement has proved a positive step towards limiting the egregious use of quarantine measures.

There is scope, however, for some further improvement in the following aspects of IRAs:

- the specification of the appropriate level of protection applying to a member country;
- the application of cost–effectiveness analysis to quarantine measures;
- the handling of risk attitudes;
- the quantification of pest and disease risks; and
- the handling of information gaps.

While adopting a broad economic perspective in IRAs has conceptual merit, there are significant information and institutional obstacles that would first need to be addressed.

A International guidelines on import risk analysis

This appendix reviews international guidelines on risk analysis pertinent to pest and disease risk in some detail. The terminology used is specific to the particular guidelines described.

A.1 International Office of Epizootics

The International Office of Epizootics' (OIE's) guidelines on import risk analysis (IRA) in respect of animal health is contained in section 1.3 of the International Animal Health Code 2001 (OIE 2001a).

The guidelines divide IRA into four stages:

- hazard identification;
- risk assessment;
- risk management; and
- risk communication.

Hazard identification

This stage involves identifying pathogenic agents which could potentially produce adverse consequences associated with the importation of a product. The potential hazards identified would be those 'appropriate' to the species being imported, or from which the product is derived, and which may be present in the exporting country.

Risk assessment

This stage involves the evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country in qualitative or quantitative terms. It includes the following steps:

- release assessment — describing the biological pathway/s necessary for an importation activity to release pathogenic agents into a particular environment and estimating the probability of that occurring;
- exposure assessment — describing the biological pathway/s necessary for exposure of animals and humans in the importing country to the hazards released from a given risk source and estimating the probability of the exposure/s occurring;
- consequence assessment — describing the relationship between specified exposures to a biological agent and the consequences of those exposures and estimating the probability of the consequences occurring; and
- risk estimation — integrating the results from the release, exposure and consequence assessments to produce overall measures of the risks associated with the identified hazard.

The OIE guidelines list principles of risk assessment which include that:

- risk assessment should be flexible to deal with the complexity of real life situations;
- both qualitative and quantitative risk assessments are valid;
- risk assessment should be based on the best available information that is in accord with current scientific thinking;
- consistency in risk assessment methodology should be encouraged and transparency is essential;
- risk assessment should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate;
- risk increases with increasing volumes of product imported; and
- risk assessment should be amenable to updating when additional information becomes available.

Risk management

This stage involves deciding upon and implementing measures to achieve a country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. It includes the following steps:

- risk evaluation — comparing the estimated risk with a country's appropriate level of protection;

- option evaluation — identifying, evaluating the efficacy and feasibility of different measures, and selecting measures in order to reduce the risk associated with an importation in line with a country's appropriate level of protection;
- implementation — following through with the risk management decision and ensuring that the risk management measures are in place; and
- monitoring and review — continuously auditing risk management measures to ensure that they are achieving the results intended.

The OIE lists principles of risk management. These are that:

- the objective of risk management is to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import products and fulfil its obligations under international trade agreements; and
- the international standards of the OIE are the preferred choice of measures for risk management.

Risk communication

During risk communication, information and opinions regarding hazards and risks are gathered from potentially affected and interested parties prior to and during a risk analysis, and the results of the risk assessment and proposed measures are communicated to the decision-makers and interested parties in the importing and exporting countries.

The OIE guidelines lists principles on risk communication. These are that:

- risk communication is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout;
- a risk communication strategy should be put in place at the start of each risk analysis;
- risk communication should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on imports;
- the principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups;
- the assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated; and
- peer review is a component of risk communication to ensure that the data, information, methods and assumptions are the best available.

A.2 International Plant Protection Convention

The International Plant Protection Convention (IPPC) guidelines on Pest Risk Analysis for Quarantine Pests were adopted by the Interim Commission on Phytosanitary Measures of the United Nations in April 2001 (IPPC 2001a).

The guidelines divide pest risk analysis into four components or stages:

- initiation;
- pest risk assessment;
- pest risk management; and
- documentation

Initiation

This involves identifying the pest(s) and pathways that are of quarantine concern and should be considered for risk analysis in relation to an identified pest risk analysis area. Specific steps during initiation include specification of initiation points, identification of the pest risk analysis area and the gathering of information.

Pest risk assessment

Pest risk assessment is the evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences. Steps involved in pest risk assessment are:

- pest categorisation — determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest;
- assessment of the probability of introduction and spread of the pest;
- assessment of potential economic consequences (including environmental impacts); and
- documentation of the degree of uncertainty.

The IPPC guidelines notes that pest risk assessment need only be as complex as is technically justified by the circumstances:

> This standard allows a specific [pest risk assessment] to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination … (2001a, pp. 9–10)

Pest risk management

This is the evaluation and selection of options to reduce the risk of introduction and spread of a pest. Steps include:

- deciding the level of acceptable risk;
- collecting relevant technical information;
- determining whether the assessed risk is acceptable;
- identifying and selecting appropriate risk management options; and
- considering appropriate compliance procedures such as export certification.

The IPPC guidelines advocates the following desirable features of pest risk management:

- the measures chosen should be shown to be cost-effective and feasible;
- the measures should not be more trade-restrictive than necessary and should be applied to the minimum area necessary for the effective protection of the endangered area;
- no additional measures should be imposed if existing measures are effective;
- if different measures with the same effect are identified, they should be accepted as equivalent;
- if the pest under consideration is established in the area of concern but of limited distribution and under official control, the measures in relation to import should not be more stringent than those applied within the area of concern; and
- the measures should not discriminate between exporting countries of the same phytosanitary status.

Documentation

This involves the documentation of the process from initiation to risk management stages. The objective is to ensure the risk analysis is transparent and, in particular, when a review or a dispute arises, the sources of information and rationales used can be ‘clearly demonstrated’.

B A partial equilibrium framework

Examining the economic effects of measures that are intended to reduce disease and pest risks of imports can be done by using a standard comparative static partial equilibrium model of a single product market.[13] This is illustrated in figure B.1. Being partial, the model does not trace income and second round economic effects of the measures throughout the economy, or dynamic adjustment within the industry.

Several assumptions underlie the model:

- there is a homogenous product in the market and the product's world price is lower than the domestic market price under no trade (autarchy);
- the import price, the exchange rate and the domestic markets for other products are unchanged for all possible changes in this product's market;
- the domestic market is perfectly competitive;
- society is risk neutral;
- any pests or diseases imported are host-specific such that they raise the costs for import competing domestic producers in this industry, but do not affect the costs of producers in other industries, nor do they affect consumers of this or other products or the natural environment; and
- technology, disease resistance and consumer tastes do not change.

Figure B.1 shows that initially the domestic industry supplies the entire domestic market with quantity Q^o at price P^o, where S and D are the domestic supply and demand curves. Consumer surplus (or the value of the willingness of consumers to pay in excess of what the market price requires them to pay) is the area P^oAE, and producer surplus (or profit) is the area P^oAB. The sum of consumer surplus and producer surplus reflects the net economic welfare from buying and selling the product.

Under full liberalisation, the economy moves from no trade (that is, a total import ban) to free trade (no restriction) in a product which is assumed at first to be disease free. After lifting the import ban, the world supply curve becomes relevant and, for this small economy, is completely elastic at the world price P^w. The domestic industry then supplies Q^s at this price and consumers demand quantity Q^d, so imports are Q^sQ^d. Consumer surplus is now equal to P^wDE and producer surplus P^wCB. The change in net economic welfare in moving from no trade to full liberalisation is the sum of the change in producer surplus ($-P^o$ACP^w) and the change in consumer surplus (P^oADP^w). There is thus a net gain in economic welfare of ACD from full liberalisation and assuming the absence of disease.

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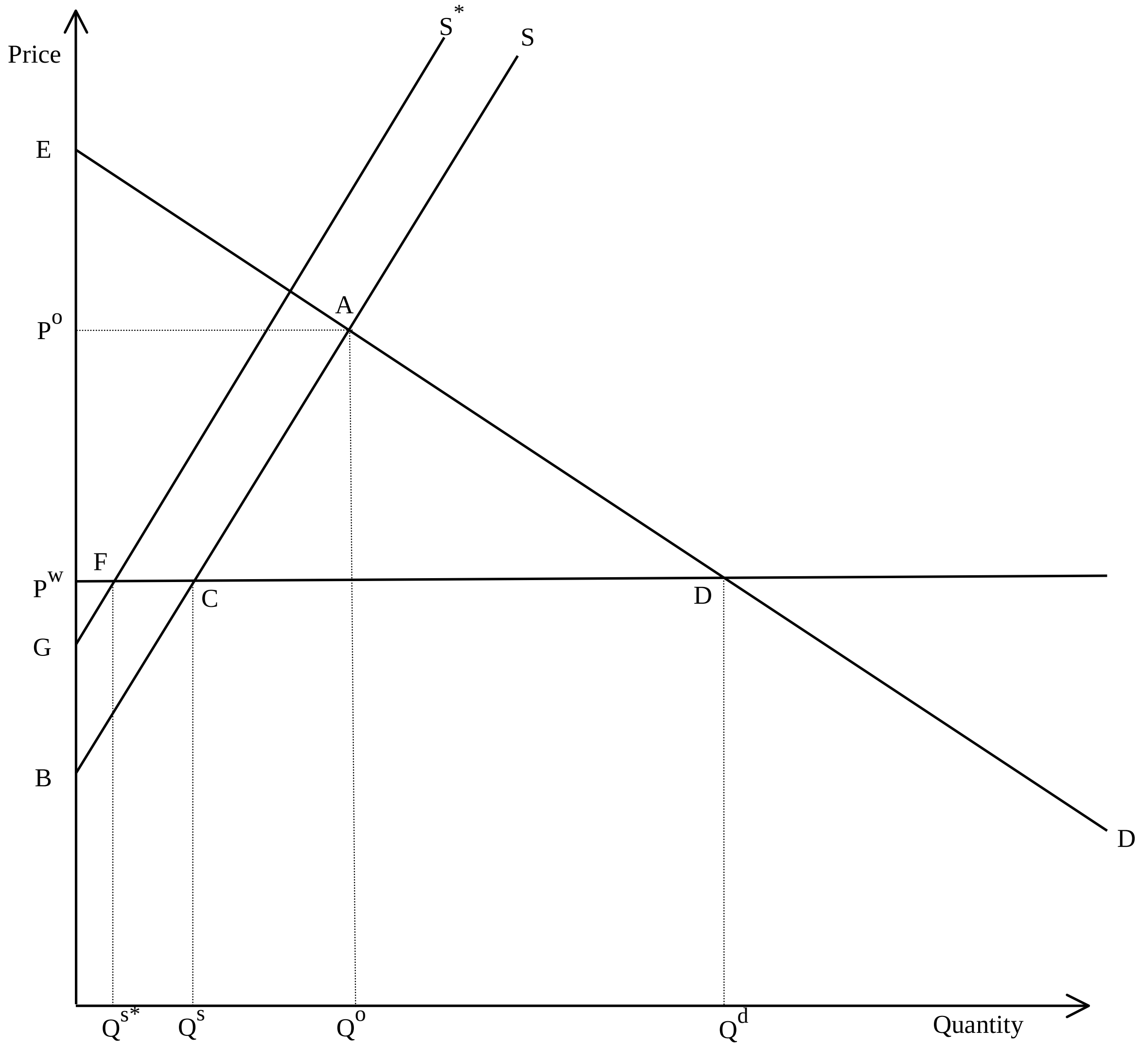
[13] This appendix is based on James and Anderson (1998).

Figure B.1 **Economic effects of measures to reduce pest and disease risks of imports**



If disease is imported, the costs of domestic production of this product would be raised (for example, because disease control strategies would need to be implemented) and, thus, the domestic supply curve would shift upwards from S to S^*. The price facing domestic producers and consumers, and consumer surplus, would still be the same as under liberalisation, but production would be less at Q^{s*} and, hence, imports greater at $Q^{s*}Q^{d}$. Producer surplus, would be reduced to P^{w}FG (rather than P^{w}CB). In the presence of disease, it is not clear whether or not there is a net gain in economic welfare from removing the import ban. Further information about the increase in marginal costs when disease is imported would be required.

Allowing for the risk of disease complicates the analysis further. If the risk of disease entry is π, which is less than 1, there are now two possible changes in economic welfare under full liberalisation:

- ACD with probability $1-\pi$; and
- ACD-GFCB with probability π.

The expected change in net economic welfare is thus:

$(1-\pi)$ ACD + π (ACD-GFCB) = ACD – π (GFCB)

Although it is not clear what the change of welfare would be in moving to full liberalisation where there is a risk of disease, there could be a net loss to society:

- the more internationally competitive are domestic producers (that is, the lower is P^{w} relative to P^{o});
- the less price elastic are the demand and supply curves below point A;
- the larger are losses from any disease importation (that is, the larger the shift in the supply curve from S to S^{*}; and
- the higher is π, the probability of disease entry in the absence of any quarantine restrictions.

The above analysis could be extended to the case where imports are permitted, albeit under certain conditions (or import protocols). Further details of this partial liberalisation case are contained in James and Anderson 1998.

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