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Kym Anderson, Cheryl McRae and David Wilson (eds.)



# The Economics of Quarantine and the SPS Agreement

The Centre for International Economic Studies (CIES) was established at the University of Adelaide by its School of Economics in 1989. Its purpose is to strengthen teaching and research in the field of international economics and closely related disciplines. Both theoretical and empirical, policy-related studies are undertaken, with particular attention given to WTO and trade policy issues.

**Biosecurity Australia**, a group within the Department of Agriculture, Fisheries and Forestry - Australia (AFFA), is responsible for assessing the quarantine risks associated with import proposals for animals, plants and their products, through conducting import risk analyses in accordance with Australian Government policy and our international obligations. The group also negotiates with trading partners on appropriate export conditions for Australian animals and plants.

## The Economics of Quarantine and the SPS Agreement

Edited by Kym Anderson, Cheryl McRae and David Wilson







Centre for International Economic Studies and AFFA Biosecurity Australia

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#### **Acronyms**

ABARE Australian Bureau of Agricultural and Resource

**Economics** 

AFFA Agriculture, Forestry and Fisheries - Australia

ALOP Appropriate level of protection

ANZFA Australia New Zealand Food Authority

APHIS USDA Animal and Plant Health Inspection Service

AQIS Australian Quarantine and Inspection Service

CBA Cost/benefit analysis

CBD Convention on Biodiversity

EC European Community

EIS Environmental Impact Statement

EU European Union

GATT General Agreement on Tariffs and Trade

GMO Genetically modified organism

HACCP Hazard analysis and critical control points

IBD Infectious bursal disease

IPPC International Plant Protection Convention

IRA Import risk analysis

ISO International Standards Organization

OECD Organization for Economic Cooperation and

Development

OIE Office International des Epizooties

MFN Most-favoured-nation

MTN Multilateral trade negotiation

SPS Sanitary (human and animal health) and

phytosanitary (plant health)

TBT Technical barrier to trade

USDA United States Department of Agriculture

WTO World Trade Organization

#### **Preface**

This collection resulted from an international workshop funded and organised by Biosecurity Australia, the agency of government responsible for analysing Australia's quarantine import risks and for negotiating multilateral SPS rules and less restrictive access to overseas markets for Australian produce. The workshop, which was held at the Melbourne Business School on 24-25 October 2000, brought together a distinguished group of applied economists and quarantine policy analysts whose focus involves regions as disparate as Europe, North America, Africa, Asia and New Zealand, in addition to Australia.

The editors are very grateful to the authors for preparing, presenting and then revising their papers promptly following the workshop; to David Robertson for organising the venue and for summing up the workshop and the proceedings; to all the paper discussants and especially Richard Snape whose paper with David Orden (Chapter 10) was born and developed during the workshop discussion; to Jane Russell of Adelaide University's Centre for International Economic Studies for ably assisting the editors in producing this volume to a tight deadline; and to Biosecurity Australia for resourcing both the workshop and this proceedings volume.

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#### Introduction

KYM ANDERSON, CHERYL MCRAE AND DAVID WILSON

The Uruguay Round of multilateral trade negotiations, culminating in the GATT Secretariat being transformed into the World Trade Organization (WTO) on 1 January 1995, has altered forever the process of quarantine policy-making by national governments. On the one hand, WTO member countries retain the right to protect the life and health of their people, plants and animals from the risks of hazards such as pests and diseases arising from the importation of goods. On the other hand, the WTO's Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) requires that quarantine measures be determined in a manner that is transparent, consistent, scientifically based, and the least trade-restrictive.1 This tension between national sovereignty and international obligation is aggravated by the vagueness of wording in the SPS Agreement, and has led already to several contentious cases coming before the WTO's Dispute Settlement Body. It has forced national governments to review and in many cases to consider reforming their quarantine

<sup>&</sup>lt;sup>1</sup> The term quarantine measures is shorthand for sanitary (human and animal health) and phytosanitary (plant health) measures as used in the formal title of the SPS Agreement. An excellent non-technical guide to the SPS Agreement is available in WTO (1996). The legal text of the Agreement is reproduced in the Appendix to this volume, taken from WTO (1995, pp. 69-84). The SPS measures dealt with in that Agreement are a subset of the various technical barriers to trade, the rest of which are disciplined somewhat more loosely under the WTO's more generic *Agreement on Technical Barriers to Trade* (WTO 1995, pp. 138-162)

policies, and in the process to try to understand how best to implement the SPS Agreement.

Simultaneously, national governments the world over are under pressure from their constituents to bring more rational economic thinking to bear on all areas of policy making. Quarantine policy is not immune from this pressure for better economic governance. Yet the SPS Agreement seems to ignore important economic dimensions of quarantine policy, most notably the cost of those policies to consumers. Perhaps this is a reflection of the fact that quarantine agencies (who supplied the drafters of the SPS Agreement) have focused their attention on the scientific aspects of quarantine and not consulted economists, even as consultants, and, partly as a result, the economics profession has paid little attention to quarantine issues in the past.

In addition to these pressures on national governments, two others are affecting quarantine policy making. One is the ever-growing demands, as incomes and international traffic increase, from (i) food consumers for tougher import barriers to ensure food safety standards do not drop and (ii) environmental groups concerned that the natural environment not be threatened by imported pests and diseases. The other is from food-exporters abroad who worry that the long-hoped-for benefits to them from the Uruguay Round Agreement on Agriculture will be reduced by traditional farm protectionist measures being replaced by excessively protectionist SPS responses to the health and environmental lobbying.

When it is brought to their attention, economists are surprised that the SPS Agreement does not take consumer interests explicitly into account, because they are used to thinking of import barriers as equivalent to a consumption tax and a producer subsidy. However that oversight/omission is a natural consequence of quarantine policy making being a science-based process. If import risk analysis reveals an unacceptable plant, animal or human health risk associated with importing a product, then a quarantine measure is imposed or retained. Producers' (and increasingly health and environment groups') concerns about the risk of imported products carrying pests and diseases with them, and/or counter-claims by

would-be importers, are also taken into account. However little thought is given to whether the cost of quarantine measures to others outweigh the producer, environmental or food safety benefits of restricting trade. In this sense, of looking only at the direct effects and using command-and-control measures rather than also looking at indirect effects and blending cost/benefit thinking into import risk analysis and considering the efficiency of alternative prevention or mitigation strategies, it has been claimed by some economists that quarantine policy assessment is about where environmental policy assessment was two or three decades ago.<sup>2</sup>

The imperative on national governments to improve their understanding of their international obligations under the SPS Agreement, and at the same time to respond appropriately to the above range of domestic pressures on them, calls for a fresh approach to quarantine policy making. As a beginning, economists and quarantine officials need to come together to discuss their different approaches to policy analysis, with a view to seeing to what extent cost/benefit thinking can be profitably blended into quarantine policy making while honouring their SPS Agreement obligations. This volume represents the fruits of one attempt to do just that via an international workshop to explore the economics of quarantine and the SPS Agreement.

The volume begins in Part I with an in-depth discussion of the issues and challenges raised above from four different perspectives: those of a US government economist, an Australian quarantine official, a WTO official, and a pair of national government trade lawyers (one Australian, one Swiss).

Part II of the volume focuses very specifically on one of the most difficult parts of the SPS Agreement to understand and therefore operationalise. The SPS Agreement leaves national governments to

<sup>&</sup>lt;sup>2</sup> See e.g., James and Anderson (1998). Economic assessment of environmental policies is so mainstream in the US now that a detailed handbook for doing analyses has been published by the Environmental Protection Agency (2000) and is freely downloadable at www.epa.gov/economics.

determine their own 'appropriate level of protection' (ALOP), but requires them to provide that quarantine protection in a manner that is consistent across commodities. Three perspectives on how to do that are provided by authors from the United Kingdom, Australia, and New Zealand. The latter suggests an 'iso-risk' approach to ALOP but, as Chapter 9 points out, that still ignores the benefits to consumers from imports. Chapter 10 is an attempt to bring together the ALOP concept as it relates to the cost of imports due to risk of pests, diseases or food hazards, on the one hand, with on the other hand the other benefits from importing (e.g., lower prices for consumers). That short chapter was not a commissioned paper, but rather one that grew out of the discussion at the workshop for which the other chapters were prepared.

Part III provides four more papers by economists on the potential benefits of including more economics in import risk analysis. Among other things, Chapter 11 focuses on the requirement of the SPS Agreement that quarantine policy measures should be the least trade-restrictive available to achieve the country's ALOP. Chapters 12 and 13 focus on Australia's quarantine decision making, including the recent reforms to that process. The final chapter in this section evaluates the economic consequences of livestock disease importation, drawing primarily on US experience.

Then in Part IV some specific health and environmental issues are analysed. A group of World Bank economists examine in Chapter 15 the trade effects of the recent tightening of European Union technical standards on aflatoxin levels in cereals, dried fruits and nuts. They focus just on African exports of those products to the EU, but even that subset of economic damage to EU trading partners is estimated to be massive – and for a miniscule reduction in health risk within the EU. In Chapter 16 a Danish and an Australian economist take a global view of the economics of the adoption of genetically modified organisms (GMOs). They estimate the economic effects of some countries adopting new GM farm technologies without and then with bans by other countries on their importation of the resulting GM products. The latter bans are shown to be hugely more expensive than the alternative of just requiring labelling of GM products so that consumers in the importing

country can make a free but more informed choice. Food safety issues more broadly are the focus of Chapter 17, while Chapter 18 focuses on SPS issues of relevance to the natural environment.

The book concludes in Part V with a brief summing up by an international trade economist of what he learnt from the workshop discussion. We the editors also learnt a great deal. One important point of consensus was that while clearer language and explicit recognition of trade benefits to consumers would have been helpful, their omission from the SPS Agreement is not sufficiently serious to warrant opening up the Agreement for re-negotiation at this stage. It is not serious because most participants felt that integrating economic analysis into quarantine policy making was not prevented by the SPS Agreement. On the contrary, it was felt that the use of cost/benefit analysis might promote a greater understanding of the SPS Agreement and an economy wide approach to determining ALOP. Further, there was general agreement that cost/benefit analysis and other economic tools may help governments to better understand the gains and losses inherent in any chosen ALOP, and that this would lead to better quarantine policy making - from the economic viewpoint not only of the implementing country but, in almost all cases, also that of its trading partners. Put another way, good SPS policy from a WTO perspective is likely also to be good economic policy from a national perspective.

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### PART I

The multilateral rules under WTO

# The integration of economics into SPS risk management policies: issues and challenges DONNA ROBERTS\*

Although many governments are now committed to reducing the number and rigidity of regulations that are thought to stifle economic innovation and competition, it is widely expected that the regulatory environment for agricultural producers and processors will become more complex in the coming years (OECD 1997). growth is fuelling demand for food safety environmental amenities, and media coverage, such as reports on dioxin in European animal feed or on the effects of Bt corn on North American monarch butterfly populations, amplifies the political salience of this demand. On the 'supply side' of regulatory activity, officials who devise sanitary and phytosanitary (SPS) measures regulations that sometimes restrict imports in order to reduce risks to animal, plant, and human health - face additional challenges. These officials are now bound by the multilateral legal obligations found in the Agreement on the Application of Sanitary and Phytosanitary *Measures* (SPS Agreement) of the World Trade Organization (WTO) which came into force in January 1995. By drawing attention to policies that were generally ignored (even by trade specialists) until the Uruguay Round, the SPS Agreement has had the intended effect of prompting widespread review of SPS measures by regulators and lawyers in both importing and exporting countries, and the unintended effect of begetting policy re-evaluation by others.

<sup>\*</sup> The views expressed in this paper are not to be attributed to the USDA or the Office of the US Trade Representative.

Economists in particular have started to scrutinise SPS policies in much the same way that they previously examined other risk-reducing measures, including asbestos removal or toxic waste cleanups. Taken together, these developments have substantially changed the parameters for regulating imports of agricultural products from the time when the maxim "when in doubt, keep it out" was viewed as an appropriate decision rule.

It is clear that efforts to improve economic governance in the area of risk regulation share many goals with the SPS Agreement.<sup>1</sup> Regulatory reform initiatives and the Agreement both advocate transparency of regulatory rulemaking in order to promote symmetry of information among stakeholders, which includes agricultural producers, processors and consumers on one hand, and trading partners on the other. Both also require that a regulation be based on a careful assessment of the risks that the measure is designed to mitigate, and make provision for the inclusion of the costs of control programs as a factor in regulatory decisions.

However, in other respects, there is some ambiguity about whether the legal obligations found in the SPS Agreement are wholly congruent with the spirit of reform initiatives which have produced efficiency consideration of guidelines for economic distributional effects of measures as decision criteria. The SPS Agreement is primarily intended to aid WTO Members in the decentralised policing of regulatory protectionism in foreign markets. Regulatory protectionism or capture occurs when domestic groups with a vested interest in a particular regulatory outcome successfully lobby for overly restrictive SPS measures which, by limiting or preventing safe imports, lower net social welfare. Two requirements in the SPS Agreement - to base SPS decisions on a risk assessment and to notify trading partners of changes in SPS measures - underpin the multilateral system of pre-empting protectionism.

While the Agreement's emphasis on risk assessment and its elaboration of risk-related costs that "shall" be factored into SPS

<sup>&</sup>lt;sup>1</sup> For a review of the regulatory reform agenda see Viscusi (1998).

policies may ease the task of judging the legitimacy 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" (Kopp, Krupnick and Toman 1997). The risk assessment paradigm, centered 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.

Developments since the conclusion of the Uruguay Round highlight the need for increased attention to the issue of how economic analysis can improve the quality of SPS policies. To date, debates in the WTO SPS Committee, the international standards organisations, and public fora have largely focused on the appropriate roles of national sovereignty, consumer concerns, and risk assessment in policy formulation, reflecting legal, political, and scientific perspectives on risk management (Roberts 2000). The absence of economists at the table may be explained by the fact that they are prone to point out that absolute levels of health and safety are prohibitively expensive, and hence "often viewed as the immoral purveyors of the dismal science" (Viscusi 1992). But it is also true that with few exceptions, economists have been slow in turning their attention to SPS policies, and a great deal of work lies ahead for those who advocate a role for economics both in these multilateral debates and in individual regulatory decisions.

Examining if or how the SPS Agreement purposefully or inadvertently constrains the use of economics in SPS policymaking is a logical first step for this agenda. This chapter provides an

overview of the "rules of the game" from an economic perspective, and, equally important, examines how major regulatory actors might be expected to interpret these rules as they implement the Agreement. The first section describes the origins of the SPS Agreement and examines the provisions most relevant to risk management practices. The following section turns to a brief review of the use of cost/benefit analysis in regulatory decision making. This review sets the stage for an assessment of the status of economic criteria in the multilateral rules for SPS measures. This is intended to flag a number of issues and challenges that could arise regulators seek manage trade-related health as to environmental risks more efficiently. The final section presents some brief concluding remarks about the potential role for economics in risk management policies. This discussion notes that at this stage in advance of extensive SPS jurisprudence - the development of principles for efficient regulatory decision-making could make a substantial contribution to domestic economies as well as the international trading system.

#### The SPS Agreement: origin and principle provisions

The consensus view that emerged in the decade following the Tokyo Round of trade negotiations was that multilateral rules had failed to stem disruptions of trade in agricultural products caused by proliferating technical restrictions. Not one SPS measure was successfully challenged before a GATT dispute settlement panel after the Tokyo Round, and several prominent disagreements over SPS measures in the 1980s (most notably the US-EU beef dispute over hormone-treated beef) remained unresolved (Stanton 1997). Meanwhile, the commitment to negotiate an Agriculture Agreement during the Uruguay Round which would discipline the use of agricultural non-tariff barriers for the first time heightened concerns that governments would resort to regulatory compensation, in the form of SPS barriers, to appease domestic producers in this politically sensitive sector (Josling, Tangerman, and Warley 1996).

#### Origins of the SPS Agreement

The Punta del Este Ministerial Declaration which launched the Uruguay Round in 1986 stated that one objective of the negotiations would be to create disciplines which would minimise the "adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture". Initial negotiations targeted perceived defects in the Tokyo Round Technical Barriers to Trade (TBT) Agreement which had impeded resolution of some SPS disputes.<sup>2</sup> But despite progress on closing some loopholes in early drafts of a revised TBT Agreement, support for the negotiation of a separate SPS Agreement emerged during the negotiations. It was recognised that SPS measures mitigate risks that may vary by the source and the destination of the traded product; as a result, such measures often violate (or apparently violate) the GATT Most-Favoured-Nation (MFN) and national treatment principles.<sup>3</sup> Negotiators therefore concurred that the elaboration of multilateral rules for these measures could not be conveniently incorporated into the revised TBT Agreement which reiterates the GATT principles.

In 1988, a Working Party was created to draft a separate agreement for SPS measures. Consensus formed around an agreement which consisted of a preamble stating the objectives of the Agreement in broad terms; fourteen Articles which stipulate both procedural and substantive disciplines; and three annexes which set forth definitions and elaborate on procedural requirements (GATT, 1994). The provisions in two of these Articles indicate what the scope for

<sup>&</sup>lt;sup>2</sup> For example, one loophole had been created by the TBT Agreement's definition of a measure that would be subject to the disciplines in the Agreement. The definition omitted explicit reference to production and processing methods. This omission provided the legal rationale for the European Community (EC) when it blocked the US request for a technical expert group to review the scientific basis of the EC's ban on hormone-treated beef.

<sup>&</sup>lt;sup>3</sup> The MFN principle (found in Article I of the GATT) stipulates that concessions offered to one trading partner must be offered to all; the national treatment principle (codified in GATT Article III) holds that imported products must be "accorded treatment no less favourable than that accorded to like products of national origin".

integrating economics into risk management decisions is under the SPS Agreement.

#### Relevant provisions of the SPS Agreement

To provide a substantive basis for judging the legitimacy of SPS risk mitigation measures, the SPS Agreement sets out a number of criteria in Article 2 (Basic Rights and Obligations) and Article 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection). Article 2 broadly states the scientific requirements: measures must be "based on scientific principles," and "not maintained without sufficient scientific evidence" (Article 2.2). Article 5.1 expands on these general obligations, requiring Members to base SPS measures on a risk assessment, defined as an evaluation of the likelihood and economic and biological consequences of the hazards specified in the Agreement.<sup>4</sup> Article 5.2 elaborates on factors, such as disease prevalence or relevant testing methods, to be included in a risk assessment. Article 5.3 shifts from scientific factors to economic factors, but the focus remains on the potential adverse consequences of imports. Potential production or sales losses and potential eradication or control costs are the "relevant economic factors" to be taken into account in assessing and managing risks to animal and plant health, according to Article 5.3. The Agreement is silent on economic decision criteria for human health measures.

Articles 2 and 5 also set forth consistency tests for judging whether SPS measures are discriminatory or disguised restrictions on trade which rest on comparisons of potential risk-related costs of imports. Article 2.3 states that Members must ensure that their measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, which includes

<sup>&</sup>lt;sup>4</sup> The relevant hazards are identified in the definition of an SPS measure in Annex A: those measures that protect human, animal, or plant life and health within the territory of the Member from risks related to diseases, pests, and disease-carrying or -causing organisms, as well as additives, contaminants, toxins, or disease-causing organisms in food, beverages, or feedstuffs.

between their own territory and that of other Members.<sup>5</sup> Thus if the commodity risk is thought to be the same for imports from Country X and Y, the language of the Agreement suggests that the importing country should adopt the same import measure for both countries. Comparisons of the risks of Commodity X with Commodity Y are indicated in Article 5.5, which enjoins Members to avoid "arbitrary or unjustified variation" in protection against risks. The Article states that avoiding such variation is necessary "to achieve the objective of consistency in the application of the concept of appropriate level of protection" (ALOP). An ALOP is tautologically defined in the Agreement as the level of protection deemed appropriate by the Member establishing SPS measures to protect human, animal, or plant life or health: an explanatory note states that many Members otherwise refer to this concept as the "acceptable level of risk."

These disciplines, in addition to the frequent reference to the ALOP throughout the entire Agreement<sup>6</sup>, sustain the perception that it is a product of a paradigm which endorses risk-related costs as a normative basis for SPS regulatory decision-making. Within this decision framework, authorities choose measures which reduce risk to negligible levels rather than measures whose benefits at the margin equal their costs, as in the economic paradigm. The role of economics in an SPS risk assessment paradigm is primarily relegated to the calculation of the quantity of imports to help the risk assessors with their job of calculating the likelihood and consequences of disease or pest introduction.

Policy analysis and choice within the risk paradigm can be illustrated by a recent response to a US request to export poultry meat to New Zealand (Ministry of Agriculture and Forestry 2000).

<sup>&</sup>lt;sup>5</sup> These disciplines are simply variants of the aforementioned GATT MFN and national treatment principles.

<sup>&</sup>lt;sup>6</sup> For example, the Agreement states that Members may adopt measures that do not conform to international standards if these standards do not provide the chosen ALOP (Article 3), and that Members shall accept the SPS measures of other Members as equivalent if the exporting country objectively demonstrates that its measures achieves the importing country's ALOP (Article 4).

One of the concerns of NZ regulators was that importing poultry meat from the United States could introduce infectious bursal disease (IBD).7 NZ authorities determined that if US exports of bonein chicken cuts equaled 1 percent of total NZ consumption, the estimated risk of IBD being introduced into back yard flocks evaluated at the 95th percentile was three introductions per 100 importation years (assuming that the flocks were fed cooked scraps from the imported chicken) which was considered too high. The same quantity of boneless cuts was estimated to present a risk of less than one introduction per 1,000 importation years, again at the 95th percentile of the risk estimate, which was considered acceptable. However, the report notes, should US exports equal 10 percent of current NZ consumption, the risk of boneless cuts would increase to 6 introductions per 100 importation years, which again would be considered to be unacceptably high. It is apparent that the gains from trade could be exceptionally modest and still outweigh the potential costs of allowing imports, but a further implication of the risk paradigm is that, because risk monotonically increases with quantity, judgments based on the levels of risk alone will logically be conditional on the amount imported. The prospect of SPS quotas in international trade should cause enough concern to prompt at least some re-consideration of this decision framework.

Fortunately, other language in Article 5 alludes to a larger role for economics in SPS policy choice. Article 5.6 states that measures must not be more trade-restrictive than necessary to achieve the ALOP, taking into account technical and economic feasibility. While such language takes the ALOP – no matter how conservative – as a given, it does require importers to choose the least trade-restrictive means to achieve it. Language which directly addresses the choice of the *level* of risk reduction is more tentative: Article 5.4 states that when

<sup>&</sup>lt;sup>7</sup> The International Office des Epizooties (OIE) classifies transmissible animal diseases onto a "List A" of those most harmful "diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence," and a "List B" of those less harmful "diseases which are considered to be of socio-economic and/or public health importance within countries." IBD has been classified as a List B disease.

determining the ALOP, Members should (not "shall" which indicates a legal obligation) "take into account the objective of minimizing negative trade effects." These two provisions clearly do not require SPS measures to be justified by the economic welfare effects on producers, consumers, taxpayers, and industries which use the regulated product as an input, but at least envision consideration of economic factors that extend beyond the potential risk-related costs of imports.

#### **Economic analysis of SPS regulations**

Officially mandated reviews related to improvement in the content and process for regulations over the past 25 years reflect policymakers' increasing interest in the use of cost/benefit analysis (CBA) as a tool for regulatory assessment (Antle 1995; Viscusi 1998). The intellectual foundations of cost/benefit analysis are found in welfare economics, which provides a theoretical framework within which policies can be ranked on the basis of how much they improve social well-being. Social well-being or welfare is the yardstick used by economists to provide a single metric that captures the relevant features of well-being that might be affected by a policy. The metric employed in CBA is a monetary measure of the aggregate change in individual well-being resulting from a policy decision. In the economic paradigm, individual welfare is assumed to depend on the satisfaction of individual preferences, and monetary measures of welfare change are derived from the measurement of how much individuals are willing to pay or to be compensated to live in a world with the policy in force. Within this paradigm, a policy that improved social welfare as indicated by the metric would be preferred to a policy that would reduce welfare, and a policy that would increase welfare more would be preferred to a policy that would increase welfare less. CBA can be simply described as a study to determine what effect proposed alternative policies would have on the value of this social-welfare metric. The principal merits of CBA include transparency; a consistent framework for data collection and characterisation of information

gaps; and the ability to aggregate dissimilar effects into one measure (Kopp, Krupnick, and Toman 1997).8

Net social welfare, or net benefits, produced by alternative SPS measures can most easily be described in the context of a singlecommodity, partial equilibrium model to evaluate a proposed change in a measure that protects crops or livestock. In this simple framework, SPS policy evaluation would entail calculation of changes in the welfare of producers and consumers of the regulated product. As quarantine policy prohibits agricultural products from foreign sources unless a government has specifically determined if and under what conditions a product may enter, CBA-based decisions would require evaluation of whether the benefits of lowerpriced imports (to consumers) would outweigh the potential costs (to producers) associated with these same imports. The net benefits of a proposed measure would be calculated from changes in producer and consumer surplus.9 Producer losses would stem from two sources in this open-economy framework: lower product prices and the expected value of losses resulting from exotic pests or diseases.

Scientists and regulatory officials may judge that the probability of importing a disease along with the product is essentially zero -- for example, if a disease had never been known to exist in the exporting country. This "zero risk" scenario is identical to the standard trade liberalisation scenario wherein a country decides to eliminate a prohibitive tariff. However, evaluation of a change in an SPS measure to allow imports differs from the evaluation of removing a tariff if there is some probability, however small, that a disease will be imported along with the product. In addition to the producer and consumer surplus changes that result from a decrease in price in the

<sup>&</sup>lt;sup>8</sup> Multi-attribute decision analysis tools, which likewise reflect an economic perspective on risk management, can be used when aggregation of dissimilar effects into one measure is impossible or deemed to be inappropriate. See, for example, Keeney and Raiffa (1993).

<sup>&</sup>lt;sup>9</sup> Producer surplus is defined as producers' revenue beyond variable costs which provides a measure of returns to fixed investment. Consumer surplus is a measure of consumers' willingness to pay for a product beyond its actual price.

domestic market, potential production losses from a disease must be evaluated as well. Actual empirical estimates of the effect of a change in a quarantine measure poses substantial challenges. The analyst must have a means for assessing the probability of introduction of a disease (a likelihood model) together with a means of assessing different disease outcomes (an epidemiological model) to use as inputs into an economic model to estimate (i) the expected value and standard errors of changes in producer surplus stemming from disease-related production and sales losses; (ii) producer surplus losses resulting from lower prices; and (iii) consumer gains from lower prices. Model results could then provide input into the calculation of costs not included in a partial equilibrium commodity model, including the administrative/enforcement costs of the disease-eradication import protocol potential public and expenditures.

## Is the SPS Agreement congruent with economic policy prescription?

From the previous discussion, what can be said about the apparent congruency or incongruence of the SPS Agreement with regulatory reform initiatives? Examination of this issue is made somewhat difficult by the fact that in aiming to avoid being overly prescriptive, the Agreement provides latitude for alternative interpretations. The following discussion should be understood as only an attempt to flag potentially important issues for further discussion as governments consider how best to integrate economics into SPS policy evaluation. Some issues pertaining to costs, benefits and distributional effects of changes in SPS policies that increase market access are considered in turn. It is argued here that the language of the SPS Agreement is clearest with respect to the risk-related costs associated with imports. How the benefits of imports may factor

<sup>&</sup>lt;sup>10</sup> Some reasonable interpretations of the individual provisions of the SPS Agreement can lead one to conclude that the Agreement is internally inconsistent. In the words of the Appellate Body, some parts of the Agreement are "not a model of clarity in drafting and communication" (WTO 1998a, p. 66).

into decisions is decidedly ambiguous - an ambiguity that is the root of most disagreements about how economics can inform SPS policy choice. Distributional effects are not explicitly addressed in the Agreement (with one exception, noted below) but, since policy makers are often more concerned with equity than efficiency, inclusion of such influences on SPS policies is examined as well.

#### Costs

Article 5.3 is reprised here to facilitate comparison of costs that are recognised by the SPS Agreement and costs as they are routinely calculated in a CBA. The Article states:

"In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a cost 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."

The cost components of a standard CBA for measure that protects crops or livestock were identified in the previous section as: (i) the expected value of changes in producer surplus stemming from disease-related production and sales losses; (ii) producer surplus losses resulting from lower prices; (iii) government expenditures to administer the import protocol; and (iv) the expected value of public-financed disease eradication expenditures.

With respect to the first item, the Agreement seems to neither endorse or prohibit the translation of the expected value of revenue (production and sales) losses estimated during the course of a risk assessment into the expected value of producer surplus losses in a CBA framework. The Agreement explicitly requires the third and fourth components to factor into risk management decisions. Consideration of the second component would likely be regarded by SPS authorities as a violation of the spirit of the SPS Agreement.

The Agreement is predicated on the idea that countries should not factor lower product prices resulting from imports into SPS decisions. Such producer surplus costs would likely be regarded as costs related to commercial activity, unrelated to health or environmental protection. However, trading partner's concern over this point could be mitigated by the fact that the use of cost/benefit analysis to inform SPS policies will generally result in policies that are *less* trade restrictive than current approaches to risk management, even if *all* costs are factored into policy choice. However, this conclusion hinges on whether the benefits of imports can be recognised as a legitimate factor in SPS policy choice, an issue taken up in the following section.

#### **Benefits**

It is interesting to note that the word *benefits* (in reference to trade or anything else) does not appear in the Agreement. One's interpretation of this omission is likely to depend on how one views the GATT/WTO. One view is that the recognition of the benefits of trade liberalisation is so universal, it merits no further emphasis. A less magnanimous view is that the trading system built around the GATT over the past fifty years is the product of enlightened mercantilism, rather than the ideology of free trade.<sup>11</sup> Statements found in the Agreement such as "Members shall ensure that any sanitary of phytosanitary measure is applied only to the extent necessary" (Article 2.1) are broad enough to accommodate both views.

In view of the lack of explicit disciplines on if and how the gains from trade can factor into SPS regulatory decisions, what conclusions can regulators draw? An example can best illustrate the Agreement's ambiguity about the standing that benefits have in SPS regulatory decisions. Consider the situation where the United

<sup>&</sup>lt;sup>11</sup> Krugman (1991) observes that GATT-think (i.e., exports are good; imports are bad; other things equal, an equal increase in imports and exports is good) sees trade policy as a Prisoners' Dilemma: individually, governments have an incentive to be protectionist, yet collectively they benefit from free trade.

States decides to allows imports of beef, but not poultry, because although the expected value of disease-related losses are the same for the two products, the benefits to consumers of importing beef outweigh those costs while the benefits of importing poultry do not (i.e., relative to foreign competitors, the US is a more efficient producer of poultry than of beef). Although the choice to allow only imports of beef might be efficient regulatory policy from a CBA perspective, some in the WTO community (and most certainly the country whose import request for poultry was turned down) could well view these choices as evidence of "arbitrary and unjustifiable distinctions" in the levels of protection that had resulted in discrimination or a disguised restriction on trade, in violation of Article 5.5. It is also conceivable that in some cases consideration of benefits could lead to an apparent violation of Article 2.3, the other consistency discipline, which holds that Members must ensure that their measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail.

The omission of explicit disciplines on benefits in the Agreement need not be interpreted as a prohibition on the inclusion of trade benefits as a factor in SPS regulatory decisions. It should be remembered that the Agreement is an international trade treaty whose purpose is to limit the use of the putative scientific claims for protectionist purposes, and not to establish templates for risk management decisions. More elastic interpretations of the Agreement could view the incorporation of trade benefits in regulatory decisions as congruent with the objectives of "minimizing negative trade effects" and adopting "least trade restrictive" policies, which are enunciated in Articles 5.4 and 5.6. However it is clear that decision criteria must be sufficiently explicit to support a finding that any potential variation in the ALOP is "unarbitrary and justifiable".

The long debate in the WTO SPS Committee over guidelines for implementing Article 5.5 indicates that a shift from a risk assessment paradigm to an economic paradigm is not imminent. Adopted in June 2000, five years after the SPS Agreement came into force, the guidelines faithfully reflect the decision framework implicitly endorsed by the Agreement, which in turn faithfully

reflects the decision framework of most (and certainly the most influential) WTO Members (WTO 2000). In the most generous interpretation of the guidelines, consumer or processor gains from trade could be viewed as falling in the same category as producer losses that result from decreases in domestic prices brought about by imports -- as *commercial* considerations that might somehow be integrated into a country's choice of its overall ALOP, but which should not be used as decision criteria for individual health or environmental measures. This view stems from both philosophical objections as well as pragmatic concerns that CBA-based import protocols would complicate the effective decentralised policing of SPS measures by WTO Members.

#### Distributional issues

Regulatory reform initiatives, reflecting the current mainstream view, state that while net social benefits should be an important factor in regulatory decisions, it need not be the only one. For example, USDA's Departmental Regulation on Regulatory Decision-making (DR-1512-1) encourages regulators to consider a broad range of qualitative factors such as equity, quality of life, and distributions of benefits and costs (USDA 1996). These guidelines reflect societal concerns over a strictly utilitarian approach to policy-making, e.g., adopting a policy that results in substantial benefits for the wealthy while impoverishing the poor.

Nothing in the Agreement would seem to preclude a Member from, for example, maintaining extremely conservative import protocols to protect crops and livestock that favour producers over consumers, as long as any variation in the weights does not appear to be connected to creating discriminatory or disguised restrictions on trade. In fact, the Agreement can be read as explicitly protecting the right of Members to do so in the language regarding the choice of an ALOP. According to the US Statement of Administrative Action (SAA) to Congress, the Agreement "explicitly affirms the rights of each government to choose its levels of protection including a 'zero risk' level if it so chooses" (President of the United States 1994, p. 745). The SAA also notes that "In the end, the choice of the appropriate level of protection is a societal value judgment."

The SAA was intended to assure Congress that the SPS Agreement did not jeopardise the Delaney Clause, and hence may have somewhat overstated the case, but the Agreement seems to place no constraints on a government's choice of weights for producer and consumer welfare in a CBA framework, as long as the consistency tests set forth in Articles 2 and 5 are met. These consistency requirements may, in fact, be a tall hurdle. But whether a government would actually want to explicitly adopt such weights within an economic decision framework – in contrast to current practices which fuse distributional considerations together with other factors to yield an ALOP – remains to be seen.

The use of some other distributional effects as SPS decision criteria – say to adopt more conservative import protocols for agricultural commodities produced by poorer farmers – may be judged to violate the Agreement. However, potential conflict between the SPS Agreement and guidelines for consideration of distributional impacts in regulatory decisions is limited by the obvious fact that governments usually rely on other types of policies to remedy social ills.

The Agreement does, however, allow the use of distributional considerations to override consistency criteria to aid developing countries. Article 10.2 states that WTO Members may allow longer phase-in periods for compliance with new regulations on "products of interest to developing country Members". However, these countries report that such allowances have in fact been exceedingly rare (WTO 1998b), corroborating the observation that SPS measures are not generally the instruments of choice to redress income inequalities.

#### Conclusion

The foregoing discussion highlights some issues that multidisciplinary teams will need to consider as governments judge how best to incorporate efficiency and equity criteria into its regulatory decision-making process. One issue, the valuation of non-market goods, emerges within the risk assessment paradigm as well as the economic paradigm. Another, the issue of how

policymakers should weigh the effects of a decision on different groups in society, is implicit in the determination of the appropriate level of protection in the risk assessment paradigm, and explicit in the economic paradigm. Perhaps the most important issue is examination of the circumstances where using net benefits as a decision criterion (as recommended in the economic paradigm) might run afoul of provisions of the Agreement that hinge on comparisons of risk-related costs (the end product envisioned in the risk assessment paradigm).

To date, international debate over SPS measures has generally ignored the economic dimensions of risk management. Perhaps the conclusion to be drawn from discussion in the SPS Committee and elsewhere is that it is inaccurate to portray the SPS Agreement as a binding constraint which prevents regulators from using economic efficiency criteria as guideposts in SPS policy formulation. It would appear that such criteria have not systematically factored into SPS regulatory decisions in many WTO Member countries, either before or after the Uruguay Round. One economist, for example, has argued that the system of food safety regulation in the United States, arguably among the most scientific in the world, "represents a wildly inefficient allocation of public funds" (Antle 1995). It may therefore be more accurate to view the SPS Agreement as a mirror, rather than a yoke, for contemporary approaches to SPS risk management. So although the integration of economics into SPS risk management decisions will generally result in increased market access, advocates of a more expansive interpretation of the Agreement to allow this integration can expect to encounter resistance even in net exporting countries if a challenge to the domestic *status quo* decision framework is perceived.

Concerns that advocacy for a greater role for economics in SPS policy formulation could weaken the Agreement itself can also be expected to surface. Despite differences between what economists would recommend and what the Agreement might allow or proscribe, the risk assessment paradigm of the SPS Agreement has clearly reduced the degrees of freedom for the disingenuous use of SPS measures to restrict imports in response to narrow interest group pressures. Because the past five years have been witness to a

number of unilateral, negotiated, and adjudicated decisions to ease SPS trade restrictions, the principles and mechanisms established by the Agreement are credited with being an important institutional innovation that has increased market access opportunities (Roberts 1998). WTO Members will therefore be wary of any initiatives that could appear to weaken literal interpretations of the Agreement, especially Articles 2 and 5 which have been important in SPS jurisprudence. The measures challenged in the three SPS cases to advance to the Appellate Body over the past five years have failed the tests set forth in one or both of these Articles.

In short, 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 had 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 judgement about compliance with the Agreement. integrated assessment will require coordination of multiple disciplines. As James and Anderson (1999) note, "...economists and biological scientists have a symbiotic relationship in the sharing of knowledge about how to effectively reduce society's exposure to unwanted health risks in the most efficient manner, bearing in mind all the costs involved". 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.

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# The analytical foundation of quarantine risk analysis

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Although people have always made decisions in the face of uncertainty, the ability to appreciate risk by specifically assessing probability and consequences is a particular characteristic of modern times. The ability to consider what may happen in the future and to choose rationally between options is essentially a modern phenomenon that has its historical roots in the mathematics of risk-taking, particularly of gambling, insurance and financial investment (Bernstein 1997). The understanding of risk and rational risk-taking that has developed from these roots through risk analysis underpins the modern market economy, including international trade. This paper explores the analytical foundation of the analysis of risks associated with importing animals and plants or their products<sup>1</sup> as used by quarantine authorities to develop sanitary and phytosanitary measures to mitigate the spread of disease<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup> In animal quarantine, this process is called 'import risk analysis' (IRA); in plant quarantine, the same process tends to be termed 'pest risk analysis' (PRA). In this chapter, the former term is used for the generic process, regardless of what is being imported.

<sup>&</sup>lt;sup>2</sup> In animal (and human) quarantine, 'disease' is used generically to include any harmful condition caused by a transmissible agent, whether a microbe, parasite or insect. In plant quarantine, the term 'pest' tends to be used in this way, often as in the term 'quarantine pest' which includes weeds. The SPS Agreement refers to 'diseases, pests, and disease-carrying or -causing organisms, as well as additives, contaminants toxins or disease-carrying

Risk analysis has been recognised only recently as a formal discipline in its own right and there is still some confusion in both scientific and popular literature about the precise definition of each of its elements (Krewski and Birkwood 1987; Covello and Merkhofer 1993; Byrd and Cothern 2000). Several attempts have been made to develop a standardised nomenclature in a range of disciplines food animal health, plant health, safety, environmental science (Nunn 1997). However, some authorities use 'risk management' rather than 'risk analysis' for the overall term (e.g. SA/SNZ 1999) and others restrict 'risk analysis' to include elements such as risk identification, assessment and evaluation but not risk management and risk communication. Still others (including OIE define hazard identification as separate from 'risk assessment', resulting in four elements of risk analysis (hazard identification, risk assessment, risk management communication). The only difficulty arising from these variations in terminology is that one needs to be conscious of which set of terms is being used in any particular publication or discipline. Despite variations in terminology and details of application, the basic principles and analytical foundation are the same across a wide range of disciplines in which risk analysis is applied.

In this chapter, risk analysis is used as the term for the overall process comprising three elements — risk assessment, risk management and risk communication. Risk assessment is the process of identifying and estimating the risk associated with an option, including evaluation of the likelihood of an event and of the consequences if that event were to occur. Risk management is the process of identifying, documenting and implementing measures to reduce risk (either the likelihood of occurrence or the consequences). Risk communication is the process of interactive exchange of information and opinions concerning risk between risk analysts and stakeholders.

organisms in food, beverages or feedstuffs'. For the purpose of this chapter, the term 'disease' is in the broadest sense to include all of the hazards covered by the SPS Agreement.

#### Risk communication

Although usually listed last of the three elements of risk analysis, risk communication needs to be practised throughout a risk analysis. If this is not done, risk analysis is easily perceived as a process of 'expert' risk analysts advising stakeholders of the result of their risk assessment and their proposed risk management strategies. Such a limited approach implies that communication is primarily one-way and occurs only after the risk assessment and management steps have been completed, ignoring the need for two-way communication and consultation throughout the whole process, which is fundamentally iterative in nature. Such an approach also invites conflict, particularly in complex risk analysis by regulatory authorities on potentially controversial by issues. In these cases, which can occur in quarantine risk analysis, poor communication acts as critical factor in provoking outrage among stakeholders, particularly those directly involved.

Perceptions of risk by stakeholders or the general public often align poorly with those of 'experts', and a rapidly growing body of work on risk perception and communication (e.g. Slovic et al. 1985; Covello 1991; Margolis 1996) has defined a number of key factors that determine individual and group perceptions of risk. For example, factor analysis has shown that hazards that are perceived as unfamiliar or provoke dread are assigned a higher risk than can be demonstrated statistically (Slovic 1987). 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 (e.g. Ebola or Nipah viruses) or the introduction of a known disease that might decimate one or more native species. Risk analysts working in quarantine need to be cognisant of such reactions to risks and take account of them in their communication with stakeholders. Similarly, they should also appreciate the effects of trust, fear (Slovic 1993; Purchase and Slovic 1999) and outrage (Sandman 1993) on how stakeholders feel and behave.

The results of poor risk communication have been documented in a number of case studies such as the epidemic of bovine spongiform encephalopathy or 'mad cow disease' (Powell and Leiss 1997). Risk analysts, particularly those working on highly technical risk assessments, tend to focus on the technical detail of their particular problem and may be surprised to find their dedicated work on a risk assessment and carefully reasoned recommendations for risk management provokes strong and vocal opposition. 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 such unfavourable reactions.

In quarantine risk analysis<sup>3</sup>, it is critical that stakeholders understand the international framework in which import risk assessment and risk management operate. Although technical specialists practising these disciplines in regulatory agencies (such as national quarantine services) appreciate this framework and the obligations and principles associated with it, there may be only limited understanding of it among stakeholders in the industries that might be affected by their recommendations and decisions. Indeed, there may be relatively limited understanding of the international framework among some of their policy colleagues and the politicians they serve, despite the fact that these politicians or their predecessors committed their countries to this international framework. Keeping stakeholders (including, in the case of quarantine import risk analysis, affected industries as well as relevant policy makers and politicians) informed of why and how a risk assessment is being done and of the risk management options (and inviting their comments) will help them to understand the risk analysis framework. It may also help to achieve some

<sup>&</sup>lt;sup>3</sup> Risk analysis in quarantine can be applied both to imports or to exports. The former application (import risk analysis) is the more common and tends to dominate discussion of quarantine risk analysis. The latter application may be undertaken by a country to help it gain market access or on behalf of a another country (e.g. as 'technical assistance' under Article 9 of the SPS Agreement as discussed below in the fourth secion of this chapter).

understanding of, if not always agreement with and ownership of, the final decision.

Another element of risk communication in quarantine risk analysis is the need for risk analysts working in this area to communicate to both specialists in other disciplines and with their colleagues in other countries. The latter need is particularly acute with complex quarantine import risk assessments, for which greater exchange of ideas and experience can only improve the quality of analysis undertaken in a rapidly developing and difficult area.

## Principles of risk analysis

In 1996, a major review of Australian quarantine (the 'Nairn Review', Nairn et al. 1996) reported on the process then used for quarantine import risk analysis in Australia (AQIS 1991) and recommended changes designed to increase consultation while continuing to meet international obligations. Its recommendations were largely adopted (DPIE 1997) and are now in operation (AQIS 1998, Tanner and Nunn 1998). The Nairn Review identified a number of fundamental principles that apply to risk analysis in a range of disciplines and recommended that they should also apply to quarantine import risk analysis. The review recommended that risk should be consultative, scientifically analysis transparent, harmonised, and subject to appeal on process.

#### Consultation

Risk analysis should include early and ongoing consultation with key stakeholders to help obtain consensus on matters such as priorities, the scope and type of risk assessment, and the risk management strategies required to ensure any proposed import does not jeopardise the importing country's animal and plant health status or have a negative effect on its natural environment.

## Scientific basis

Risk analysis should fundamentally be a scientific process. In particular, risk assessment should be 'essentially a scientific

endeavour based on experimentation and observation' (ANZFA 1996, p. 2). However, it is acknowledged that 'risk management involves policy decisions based on a balance of scientific, social and economic considerations' (ANZFA 1996, p. 2). In recognition of this distinction, some countries separate the regulatory application of risk analysis by assigning official responsibility to different agencies for risk assessment (its scientific or technical component) and for risk management (which is deemed to comprise its policy or political component).

#### Transparency

Risk analysis should be transparent and open. Details of the risk assessment undertaken and any risk management options examined should be readily available for both peer review and public scrutiny.

#### Consistency and harmonisation

From a regulatory perspective, risk analysis should be consistent with both government policy and international obligations. Consistency should be achieved by reference to existing policies and procedures, by reference to relevant international standards, guidelines and recommendations, and through the contribution of participants experienced in risk analysis.

## Subject to appeal on process

The process of risk analysis should be subject to appeal to ensure natural justice. Both the Nairn Review of Australian quarantine (Nairn *et al.* 1996) and a report on the use of risk analysis in a wide range of regulatory agencies in the United States (CRARM 1996) confirmed the need for provision to appeal.

## Subject to periodic external review

Within any organisation, the risk analysis process and associated decisions should be subject to periodic external review, which is consistent with the principles of transparency and harmonisation.

## The international policy framework for quarantine risk analysis

The Uruguay Round of the General Agreement on Tariffs and Trade culminated in the formation in January 1995 of the World Trade Organization (WTO). The role of WTO is defined in an agreement, of which two annexes have particular relevance to quarantine and trade - the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) and the *Agreement on Technical Barriers to Trade* (TBT Agreement). The SPS Agreement defines the basic rights and obligations of WTO member countries with respect to taking 'sanitary and phytosanitary measures' to protect human, animal or plant life or health. The TBT Agreement covers food standards such as labelling and nutritional requirements. The following sections summarise key points in the SPS and TBT Agreements. The discussion is drawn from the actual text of the Agreements, but the full text should be consulted for detailed and definitive information.

#### The SPS Agreement

The SPS Agreement defines the basic rights and obligations of countries respect to taking "sanitary member with phytosanitary measures" to protect human, animal or plant life or health. WTO member countries ('Members') shall ensure their measures are based on an assessment of the risks to human, animal or plant life or health "taking into account risk assessment techniques developed by the relevant international organizations" the Office International des Epizooties (OIE) and the International Plant Protection Convention (IPPC) and the Codex Alimentarius Commission (Codex) for animal quarantine, plant quarantine and food safety, respectively. The SPS Agreement defines nine principles governing sanitary and phytosanitary measures that may affect international trade (in Articles 2 to 10). Similar principles apply to risk analysis in related areas such as food (ANZFA 1996; safety Randell and Whitehead biotechnology (Doyle and Persley 1996).

#### *Basic rights and obligations (Article 2)*

Article 2 states that Members "have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health", provided that such measures are "not inconsistent with" the Agreement. Members shall ensure that any 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 where "relevant scientific evidence is insufficient" (in which case Members "shall seek to obtain the additional information necessary for a more assessment of risk and review the sanitary phytosanitary measure accordingly within a reasonable period of time", as provided in Article 5, on risk assessment). In addition, "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members" and such "measures shall not be applied in a manner which would constitute a disguised restriction on international trade".

#### *Harmonisation (Article 3)*

Under Article 3, Members "shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations" but "may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary and phytosanitary protection ... if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5" (on risk assessment).

## Equivalence (Article 4)

Article 4 states that Members "shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates ... that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection".

#### Risk assessment (Article 5)

Article 5 (entitled "assessment of risk and determination of the appropriate level of sanitary and phytosanitary protection") outlines Members' obligations with respect to risk assessment. Members "shall ensure that their sanitary or phytosanitary 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". Members shall take into account relevant scientific evidence and relevant economic factors, and "when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects". In addition, to help achieve "consistency in the application of the concept of appropriate level of sanitary or phytosanitary 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". Members shall ensure that "measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility".

"In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and test methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment". In addition, "in assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of lost 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 costeffectiveness of alternative approaches to limiting risks".

Paragraph 7 of Article 5 states that "in cases where relevant scientific information is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

#### Regionalisation (Article 6)

Article 6 (entitled "adaptation to regional conditions, including pestor disease-free areas and areas of low pest or disease prevalence"), outlines Members' obligations with respect to regionalisation. Members "shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether of all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined". Members shall "recognise the concepts of pest- or disease-free areas and areas of low pest or disease prevalence", and "determination of such areas shall be based factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls". In addition, "exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively".

## *Transparency (Article 7)*

Under Article 7, Members "shall notify changes in their sanitary or phytosanitary measures" and shall provide information on them promptly through a designated "enquiry point".

#### Control, inspection and approval procedures (Article 8)

Under Article 8, Members shall observe specified provisions "in the operation of control, inspection and approval procedures ... and ensure that their procedures are not inconsistent" with the provisions of this agreement.

#### *Technical assistance (Article 9)*

Article 9 states that Members shall "agree to facilitate the provision of technical assistance to other Members, especially developing country Members ... to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets". In addition, "where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved".

## Special and differential treatment (Article 10)

Article 10 states that "in the preparation and application of sanitary and phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members", including phased introduction of measures where possible. In addition, developing country Members, "upon request", may be granted "specified, timelimited exemptions in whole or in part" from obligations under the agreement, "taking into account their financial, trade and development needs".

## The TBT Agreement

The TBT Agreement covers food standards that are not related to the protection of human health and safety against risks arising from additives, contaminants, toxins, disease-causing organisms, or diseases carried by animals. It thus encompasses rules intended to provide relevant information and to protect consumers against deception and fraud. Labelling and nutritional requirements come within the scope of the TBT Agreement.

Under the TBT Agreement, Members shall ensure that products imported from one country are accorded treatment no less favourable than accorded to like products of national origin and to like products originating in any other country. Members shall also ensure that technical regulations are "not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade". Technical regulations shall be no more trade-restrictive than necessary to fulfil a legitimate objective, taking into account the risks non-fulfilment would create. Legitimate objectives specifically include national security requirements; the prevention of deceptive practices; and the protection of human safety, animal or plant health or safety, or the environment.

#### Risk assessment

The fundamental steps in risk assessment are the identification of the risks or hazards of concern, the assignment of a probability of the occurrence of each risk, and the estimation of the consequences resulting from the occurrence of each risk. There are several published reviews of methods used in import risk assessment (e.g. Sutmoller (1997) for animal quarantine) and such papers and individual assessments should be examined for discussion of the details of specific approaches.

In summary, the initial step in quarantine import risk assessment is to determine which diseases in the country of origin of a proposed import do not occur in the importing country and are of sufficient concern to warrant measures to exclude them. The assessment establishes a scenario tree or outline of the pathway or pathways of entry and establishment of unwanted diseases that might be associated with a proposed import. In qualitative approaches, emphasis focuses on the key points in the pathway where risk management factors can be applied to eliminate (e.g. by heat treatment of a product) or reduce (e.g. by vaccinating or testing live animals) the risk of importing diseases of concern. In semi-

quantitative approaches, numerical values (e.g. the prevalence of the disease of concern) are applied at each point for which data are available. In fully quantitative approaches, such data are applied at all points of the pathway of entry and establishment. Data used in the assessment are extrapolated from information on the biology and pathology of the disease of concern in countries where it occurs. Such information may be readily available in published scientific literature, may require specific investigation with the assistance of countries where the disease occurs, or in some cases may not be available and must be obtained by additional field or laboratory studies.

#### Quantification

In many disciplines, there has been a marked trend towards the use of more quantitative methods of risk assessment over recent years. engineering and related disciplines, fully quantitative assessments are feasible and widely undertaken. However, in biological and natural resource disciplines the lack of basic data is often a limiting factor to attempting quantitative risk assessments. It is only in relatively simple cases that reliable quantitative data are available for all steps in quarantine import risk assessment (i.e. for all points in the pathway of entry and establishment of a disease). There has been a tendency to consider that more quantitative approaches are necessarily 'better' or 'more scientific' than less quantitative approaches. Such a view is misguided, for a quantitative risk assessment that uses poor data or inappropriate quantitative techniques can far less scientific than a good semiquantitative or qualitative assessment.

At present, methods used in risk assessment range from fully qualitative approaches to fully quantitative approaches (in which numbers are used for all stages or steps in a scenario tree) — with many actual assessments using both approaches (i.e. using quantitative data where these are available and qualitative assessment where quantitative data are not readily available). All degrees of quantification are acceptable under the SPS Agreement and WTO recognises the validity of qualitative risk assessments. However, as in other areas of application of risk analysis, there is a

trend towards increasing use of more quantitative approaches to quarantine import risk assessment and a number of developed countries devoting significant resources to more quantitative approaches. From a practical perspective, it should also be appreciated that even when they are possible, more quantitative approaches are extremely resource-intensive, requiring skilled staff, large amounts of data, sophisticated computing resources, and a large investment of time.

The vast majority of quarantine decisions on import access requests do not require complex risk assessments, whether qualitative or quantitative. In such cases, importing countries can meet their appropriate level of protection by basing their risk analysis on the application of well tried and proven risk management measures that are adopted as or consistent with international guidelines and standards. This is reflected in the huge quantity and high value of animals, plants and their products that are traded internationally without spreading disease. Thus although quantitative approaches to risk analysis have some application in evaluating selected import access requests, semi-quantitative and qualitative approaches are more appropriate for the vast majority of quarantine import risk analyses.

In a minority of cases, which tend to occupy the majority of effort and raise the most policy and economic concern, import access requests do not require complex and resource-intensive risk analysis. These cases tend to involve the proposed import for the first time of a commodity from a country or region that has a number of diseases that do not occur in the proposed importing country and for which there are significant gaps in knowledge (e.g. of epidemiology and pathogenesis) and no internationally agreed risk management measures. Risk assessment in such cases is extremely difficult because of their inherent complexity, which also frequently makes them unamenable to a more quantitative approach but inevitably leads to differences in interpretation of the judgements made by adopting a more qualitative approach. The proposal to import salmon meat into Australia was an example of such a case and led to an appeal by Canada and ultimately use of the WTO dispute settlement procedures (Pauwelyn 1999).

#### Deterministic and stochastic approaches

Semi-quantitative or quantitative approaches to risk assessment can be either deterministic or stochastic. The deterministic approach assigns a single number (e.g. an amount or a probability) to each point in a scenario tree so that assessment leads to a single value, ignoring the fact that variation is an integral component in all natural systems. In contrast, the stochastic approach assigns a probability distribution to each point and determines a net probability density distribution by using techniques such as Monte Carlo simulation (Cohen et al. 1996; Thompson and Graham 1996; Vose 2000). For example, in considering disease risks associated with an import access request, a risk assessment using a deterministic approach might assign a value of 10per cent for the prevalence of a particular disease in the population of origin. In contrast, a stochastic approach might assign this a value determined by a normal distribution with a mean of 10per cent and a standard deviation of perhaps 2per cent, thus approximating the real range of values encountered in the population. The stochastic approach uses computer simulation, which can now be undertaken through a range of software packages that can be run on personal computers. Such simulations lead not to a single value for the overall assessment but to a range of values defined as a probability density distribution. A stochastic approach provides a more realistic estimate than does deterministic analysis because it takes account of natural variation.

## Sensitivity analysis

For most quarantine risk assessments there are - and are likely to continue to be - data gaps that preclude the use of a fully quantitative approach. In such cases, simple scenario trees can be analysed in a semi-quantitative or quantitative manner even where there are some gaps in data. For example, an extreme value may be assumed for data missing at a particular point (e.g. that the prevalence of a pathogen in the population of origin is 100 per cent) and the simulation run. Alternatively, expert opinion can be used to provide a 'best guess' of the value for a particular data point (e.g. using the Delphi technique). Other approaches that are likely to be

used increasingly include applications from new computing developments (e.g. of fuzzy logic or agent-based modelling) to help fill data gaps. Such approaches enable the analyst to conduct sensitivity analyses to determine whether or not the particular parameter for which data are not available has a major impact on the overall risk.

Such analysis often shows that there are only a few critical points in the pathway that have a significant effect on the overall probability, and if good data are available on these points, the analyst can be confident that the assessment is robust. However, if good data are not available on these critical points, the analyst can report that robust quantitative risk analysis is not possible until further information is available to fill these gaps. Risk analysts reaching this conclusion might encourage research providers to commission or conduct appropriate research to fill the gaps identified, use a less quantitative approach, or focus on appropriate risk management options to reduce the risk.

## Applying the international policy framework for quarantine risk analysis

Aside from the technical issues associated with risk assessment methods, three issues dominate the application of the current international framework for quarantine risk analysis — the use of the 'precautionary' approaches, determining the appropriate level of protection, and the need for multidisciplinary input.

## The 'precautionary principle'

In some cases, a risk analysis may determine that there are significant gaps in information that need to be filled by further research before a scientifically based decision can be made on a particular issue. Analysis might also lead to recommendations that specify the gaps and define the research needed to fill them. For example, a number of submissions to the Nairn Review of Australian quarantine (Nairn *et al.* 1996) argued that where there is significant uncertainty or where there are significant gaps in knowledge needed to conduct a risk assessment, quarantine

authorities should take a conservative or precautionary approach. Some submissions went further and advocated adoption of the 'precautionary principle' (or a variant of it) in cases they deemed involved significant uncertainty, probable delayed identification or reporting of incursions, or inadequate or no means of containing, controlling or eradicating incursions.

The 'precautionary principle' has been defined in various ways but may be simply seen as the principle of adopting a conservative approach when the relevant information needed to make an informed decision is limited — the greater the uncertainty, the more conservative should be the decision. Although the SPS Agreement does not use the term 'precautionary principle', Article 5.7 states that "in cases where relevant scientific information is insufficient" Members may provisionally adopt "sanitary or phytosanitary measures on the basis of available pertinent information". However, the SPS Agreement also states that in such cases, Members "shall seek to obtain the additional information necessary for a more assessment of risk and review the objective sanitary phytosanitary measure accordingly within a reasonable period of time"4. Thus Member countries' international obligations preclude the ongoing or indefinite use of the a precautionary approach as grounds for not taking a decision on any quarantine import access request. This would seem to be a valid and feasible application of the 'precautionary principle', but the use of this term and its precise definition and application in other international agreements may in future have an effect on how Article 5.7 is interpreted and applied.

## The 'appropriate level of protection'

Different stakeholders can have widely divergent perceptions of the risk associated with a decision. This divergence is often the result of disagreement about the level of risk associated with a particular

<sup>&</sup>lt;sup>4</sup> The SPS Agreement is unclear on both which country (i.e. the proposed importer or exporter) has the responsibility to obtain the 'additional information necessary' and on what constitutes a 'reasonable period of time' to review a measure put in place by adopting a precautionary approach consistent with Article 5.7. Guidance on these points may be obtained through precedence from judgements made by the WTO Disputes Settlement Body.

option, in which case consensus can be approached through improving the underlying risk assessment. However, the disagreement is often more fundamental and rests on different perceptions of what level of risk a decision maker, stakeholder or society as a whole is prepared to accept - that is, the appropriate level of protection (or 'acceptable risk'). Improved risk assessment can improve the accuracy of the estimate of the risk associated with a decision, but does not help in deciding what constitutes the appropriate level of protection.

Improved risk communication and agreed guidelines or standards can help in reaching consensus, but ultimately what constitutes an appropriate level of protection is based not on science but on judgement - whether of an individual person, stakeholder group, community or country. How to determine and describe an appropriate level of protection has been the subject of considerable discussion related to WTO disputes (e.g. Walker 1998 on the growth hormones dispute) and the focus of increased attention by quarantine authorities in recent years (e.g. Wilson and Gascoine 2001). This concept is the subject of Part II of this volume.

## The need for a multidisciplinary approach

Risk assessment (particularly using more quantitative approaches) is an extremely demanding, complex and resource-intensive process. It involves consideration of scientific and economic factors, often requiring the use of multidisciplinary teams. One of the challenges for quarantine import risk assessment is to improve the match between the outputs of scientific assessment and the inputs needed for economic assessment.

There have been few formal published economic risk assessments of specific quarantine import access requests. Those that have been completed tend to be for long-standing and high profile requests to import products. Examples in Australia include apples (Hinchy and Low 1990), salmon meat (McKelvie 1991; McKelvie *et al.* 1994) and poultry meat (Hafi *et al.* 1994). Such assessments tend to focus on those economic factors that the SPS Agreement specifies shall be considered rather than on broader economic aspects that might be

addressed in approaches such as cost-benefit analysis that economists might ordinarily apply to such questions (e.g. James and Anderson 1998). The extent to which broader economic aspects might be considered in quarantine import risk assessment will undoubtedly be a major theme of discussion at this workshop.

In complex risk analyses in areas such as quarantine or genetically modified organisms, risk assessment teams may need to include specialists with skills in disciplines such as communications, mathematics, statistics, computer modelling, ecology and environmental science in addition to those in risk analysis, animal or plant health, and economics. There is also a need to include specialists in law, especially in international and trade law, to ensure both that the risk analysis process meets statutory obligations domestically and that it takes account of all relevant international obligations.

It can be expected that future consideration of issues related to risk and trade will require detailed risk analysis. Some of these issues will require detailed scientific risk assessments, which will tend to use more quantitative approaches where possible, if only to provide a basic sensitivity analysis and comparison of the effect of different risk management options. Many will also require detailed economic assessment of the potential effects. For example, in quarantine import access requests, economic assessment may be required of both the specific cost of the potential establishment of an exotic disease (for inclusion in the import risk analysis itself) and of more general economic effects of the trade on prices and markets (for consideration in possible industry adjustment measures or other Some will options). issues also require detailed environmental risk assessment, and there is a particular need for economists to work with scientists to develop better standards and methods such assessment. Similar requirements multidisciplinary input also occur in other areas of risk analysis related to trade (e.g. trade in genetically modified organisms).

#### Conclusion

The standards, guidelines and recommendations provided for sanitary and phytosanitary measures (by WTO, the SPS Agreement and TBT Agreement, and the use of OIE, IPPC and Codex) provide a sound framework for the application of risk analysis to international trade in animals, plants and their products. This framework, although still evolving and imperfect, offers a practical and tested approach to the complexities of evaluating risks related to international trade. It is certainly worth careful consideration in the development of similar standards, guidelines and recommendations in other areas of risk analysis related to trade. There is thus an opportunity for greater interdisciplinary collaboration to develop better both improved methods for risk assessment and better standards, guidelines and recommendations for risk analysis across all areas of potential risk related to international trade. It is to be hoped that this workshop will help to encourage greater interdisciplinary understanding and, ultimately, collaboration in improving the international framework for risk analysis as applied to international trade in animals, plants and their products.

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# The WTO dispute settlement framework and operation

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The member countries of the World Trade Organization (WTO) have designed a set of rules governing international trade. The rules are legally binding on members and were designed to regulate and expand trade. The dispute resolution system is central to encouraging, facilitating and ensuring compliance with these rules. The rule-oriented system favours mutually agreed solutions and is designed to secure voluntary compliance with removal of inconsistent trade actions. The procedures are detailed and of a quasi-judicial nature. They include timetables, an appeal process, and follow-up to ensure implementation. The system permits little scope for economic considerations.

The first section of this chapter briefly describes the WTO dispute settlement process. The second section outlines how it has been used in three specific disputes concerning the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement), and the outcome of those disputes. The final section contains some reflections on the extent economic factors are or are not taken into consideration in the dispute settlement process.

<sup>\*</sup> The views expressed are those of the author only and do not necessarily reflect the views of the World Trade Organization.

## The dispute settlement process

The primary emphasis in the WTO dispute settlement system is to find a mutually satisfactory solution. The first step in the formal dispute settlement procedure is that the complaining Member Country formally requests consultations with the disputed Member through the WTO Dispute Settlement Body. This step is mandatory even though the parties to the trade dispute may have already gone through extensive bilateral attempts to solve the problem.

If these formal consultations fail, the complaining country may request the establishment of a dispute resolution panel. This panel is normally composed of a chairperson and two members. The panel members should be unbiased and are approved by both countries. If the parties to the dispute cannot reach agreement on the composition of the panel, the WTO Director-General may be asked to appoint individuals to serve on the panel.

The panel receives written arguments and evidence from both parties, and holds two meetings at which the parties present oral arguments and questions to each other. In addition, the panel provides an opportunity for interested third parties to submit their written or oral arguments. For disputes alleging violation of the SPS Agreement, panels should seek advice from relevant technical and scientific experts. These experts are to be selected in consultation with the parties to the dispute, and their advice may be sought either on an individual basis or through the establishment of an expert review group. The panel process is strictly confidential.

The panel prepares a report containing a factual description of the situation, a summary of the claims and main arguments of the parties (including any third parties), the scientific advice provided, and the panel's findings and conclusions. The panel normally provides its report within six months to one year. The panel report is made public.

A panel report is adopted by the Dispute Settlement Body within 60 days after issuance, unless there is a consensus against adoption or if one of the parties to the dispute appeals the decision. The Appellate Body is a permanent body established by the WTO and composed of

seven persons acting as judges. Three Appellate Body judges are appointed to consider an appeal. The Appellate Body may uphold, modify or reverse any or all of a panel's legal findings and conclusions, but its review is limited to issues of law. The Appellate Body issues its report within 60, or exceptionally 90, days. The adoption of the Appellate Body report is subject to adoption by the Dispute Settlement Body on the same "negative consensus" basis as the panel reports. Once adopted, the rulings are legally binding on the country involved.

If the panel and/or Appellate Body conclude that the defending party's actions were inconsistent with one or more WTO agreements they will recommend that the country bring its actions into conformity with the agreements. Occasionally, ways to do this are recommended.

The defending country has 30 days to inform the DSB how it will implement any recommendations. If immediate compliance is not possible, the DSB approves a reasonable period of time for implementation. If no agreement on "a reasonable time" can be reached, an arbitrator may be asked to rule. If the implementation is not undertaken within the reasonable period of time, the parties to the dispute may negotiate a temporary compensation, usually in the form of reduced tariffs or easier access for products from the complaining country into the market of the other.

If no agreement on compensation is reached, the party which brought the complaint may request the authorisation of the Dispute Settlement Body to retaliate by suspending concessions on trade from the offending party. If the parties do not agree on an appropriate level of retaliation, the determination may be referred to the original panel. This arbitration on the appropriate level of retaliation is the only step in the settlement of SPS-related disputes in which economic considerations are of primary importance.

If the defending party modifies its actions and claims to have complied with the judgement against it, but the challenging country does not agree, the matter may be referred back to the original panel for re-examination.

# Disputes on sanitary and phytosanitary measures

Many disputes involving quarantine and other sanitary measures are resolved without recourse to the formal dispute settlement system. Bilateral consultations, formal or informal, are often sufficient to clarify any misunderstandings. The SPS Committee also acts as a forum for specific trade concerns and through informal discussions helps prevent disputes between trading partners. Raising an issue in the SPS Committee meetings also permits other countries to express their interest and concerns, and may lead not only to resolution of the problem at hand but also to the avoidance of future problems.

As of October 2000, over 200 disputes had been formally raised under the WTO's dispute settlement system. Of these, 18 alleged violation of the SPS Agreement. In five of these 18 cases, panels have been established: two regarding the EC ban on meat treated with growth-promoting hormones; two regarding Australia's restrictions on imports of fresh, chilled or frozen salmon; and one regarding Japan's requirement that each variety of certain fruits be tested for the efficacy of fumigation treatment. In several cases, the parties found mutually agreed bilateral solutions; other cases are still pending.

#### Case 1: The EC hormones ban

The complaint by the United States and Canada against the European Community's ban on imports of meat treated with growth-promoting hormones was the first SPS Agreement dispute referred to a panel. This dispute goes back to the 1970s, when European consumers became concerned over the use of growth-promoting hormones in livestock. European consumer organisations called for a boycott of veal suspecting that hormonal irregularities in teenagers had been caused by veal treated with illegal hormones (DES).

In 1980, the EC Council of Ministers banned the use of oestrogen. In 1988, the European Community banned the use of other hormones for growth promotion, including three natural hormones (oestradiol 17β, progesterone and testosterone) and three synthetic hormones

(trenbolone acetate, zeranol and melengestrol acetate (MGA)). The European Community also banned imports of meat and meat products unless the exporter could prove the meat had not been treated with the banned hormones. The European Community argued the ban was necessary to protect human health from potential risks caused by the consumption of meat containing the residues of veterinary drugs. The use of the three natural hormones for therapeutic and for herd-management purposes remained authorised.

In 1996, the United States and Canada separately requested a WTO panel to examine the case. The main arguments of the United States and Canada were: (i) no scientific evidence showed risks to human health from the proper use of these hormones for growth-promoting purposes; (ii) the EC measure was not based on international (Codex) standards; (iii) the EC measure was not based on a risk assessment; (iv) the level of risks accepted by the European Community with respect to hormones was inconsistent with the level of risk the European Community accepted in other comparable situations; and (v) there were less trade restrictive measures the European Community could impose to ensure health protection.

Two separate panels were established, in May 1996 (United States complaint) and in October 1996 (Canadian complaint). The panel sought expert advice concerning the human effects of veterinary hormones and drugs used in animals for human consumption; on the role of hormones in human cancer; and on the Codex process of developing international standards for food safety. Both panel reports were issued in August 1997. All parties appealed some findings. The Appellate Body report was issued in January 1998, and adopted by the Dispute Settlement Body the following month (WTO 1998a).

# Legal issues and findings

According to Article 3.1 of the SPS Agreement, Members shall base their requirements on international standards. The Panel decided this meant a measure needed to reflect the same level of protection as the international standard. The Codex Alimentarius Commission

had established standards for five of the six hormones in question. According to Codex, intake levels of the three natural hormones did not have to be limited. For two of the three synthetic hormones, Codex had identified levels of residues below which there was no evidence of any human health risk. The Panel concluded that the ban on imports of hormone-treated meat was not based on the Codex standards (the recognised international standard), since it achieved a significantly higher level of protection. The Appellate Body decided that "based on" meant that a measure could adopt some, but not necessarily all elements of an international standard.

Article 3.3 of the SPS Agreement allows a country to have requirements that achieve a higher level of health protection than the international standard. However, these higher requirements must be scientifically justified, or be the consequence of the Member's appropriate level of health protection. These requirements thus must be based on a scientific assessment of the health risks involved as required by Article 5 of the SPS Agreement. Although the Panel considered Article 3.3 to be an exception to Article 3.1, while the Appellate Body considered it an "autonomous right", both agreed that the European Community had violated Article 3.3 because it had not based its ban on a risk assessment.

According to Article 5.1 of the SPS Agreement, Members should base their SPS measures on an appropriate risk assessment. The definition of a risk assessment, in the case of food-borne risks, is an evaluation of the potential for adverse effects on human health. The European Community had invoked several scientific reports on five of the hormones, and the panel accepted that some of them could be considered to be risk assessments. However, none of the studies supported a ban on hormone-treated meat and the panel concluded that the EC measure was not based on the scientific evidence submitted. The Appellate Body confirmed that the EC ban was not based on a risk assessment and clarified that a rational relationship between the measure and the risk assessment was necessary. With respect to MGA, and to the potential health risks invoked by the European Community, the Appellate Body reached the conclusion that no risk assessment had been undertaken.

Although governments have a sovereign right to decide what level of health risk they accept, the SPS Agreement (Article 5.5) prohibits governments from requiring different levels of health protection in different situations, if these differences are arbitrary or unjustifiable and result in discrimination or a disguised restriction on trade. The panel compared the EC ban on imports of meat treated with natural or synthetic hormones with the EC tolerance of naturally occurring hormones in untreated meat and other food, such as broccoli or eggs. The panel found these situations comparable, since they involved the same hormones and therefore the same potential adverse health effects. The levels of protection were different; in one case the ban existed, in the other case there was no limit on endogenously occurring hormones. The panel found this difference in levels of protection arbitrary or unjustifiable because the hormones had the same potential carcinogenic effect in both cases. The total residue level of hormones in meat from treated animals fell well within the range of levels found in meat from untreated animals. The level of endogenous natural hormones in products such as eggs and soy oil was much higher than the level in treated meat. The Appellate Body reversed this finding, however, arguing that there was a fundamental difference between added hormones and naturally occurring hormones in meat and other foods.

The panel also compared the use of hormones for growth promotion to the European Community's allowed veterinary uses of hormones for therapy or herd management. Entire herds were often treated with hormones, for extended periods of time. The hormones were the same and the potential adverse health effects of consuming the meat would seem to be the same. Having already found the above violation, the panel decided there was no need to make a finding on this comparison. The Appellate Body concluded that the therapeutic use (of hormones) involved closer supervision of correct use and concluded that the difference was not arbitrary or unjustifiable.

The panel also compared the ban on imports of hormone-treated meat with the use of growth promoters (such as the anti-microbials carbadox and olanquindox) in swine production. Here the panel found an unjustifiable difference in the levels of protection. Carbadox and olaquindox are known to be carcinogenic yet the

European Community allowed their use without setting maximum residue levels. The panel reasoned that this unexplained difference in protection showed that imports faced discrimination or a disguised restriction on trade. The panel found three additional factors to support this finding. When the ban on imports was initially introduced, the European Community was trying to reduce its beef surpluses by increasing domestic consumption. Secondly, before the ban on hormone treatment, the percentage of hormone treated animals in Europe was significantly lower than in Canada and the United States. In addition, the hormones had been used in a sector where the European Community was trying to limit surpluses. In contrast, carbadox and olaquindox were used in the surplus-free swine sector. Regarding other growth-promoters, the Appellate Body agreed that the distinction in the levels of protection was arbitrary or unjustifiable, but it did not agree that this resulted in discrimination or a disguised restriction of international trade.

The European Community invoked the "precautionary principle" to defend its ban. It argued that the precautionary principle was a customary rule of international law or, at least, a general principle of law. Article 5.7 of the SPS Agreement permits Members to take provisional actions in cases where relevant scientific evidence is insufficient. However, the European Community did not invoke Article 5.7, explictly stating that the import ban was not a provisional measure. The Appellate Body did not take a position on the status of the precautionary principle in international law. However, the Appellate Body agreed with the panel that the precautionary principle (to the extent it is not explicitly incorporated in Article 5.7) does not override the provisions of the SPS Agreement.

# *Implementation*

The panel report, modified by the Appellate Body, was adopted on 13 February 1998. Because the parties could not agree on a "reasonable period of time" for the European Community to implement the findings, an arbitrator determined that this period was 15 months. Shortly before this deadline expired the European Community stated it would not be in a position to comply as it had

commissioned 17 scientific studies which would take longer than 15 months to conclude. The parties were unable to agree on compensation by the European Community for the lack of implementation, so the United States and Canada requested the right to suspend trade benefits they had previously given to the European Community. The parties could not agree on the amount of benefits to be suspended, and the original panel was asked to arbitrate. On the recommendation of the arbitrators, the Dispute Settlement Body authorised the United States to raise tariffs by 100 percent on EC products worth US\$116 million per year, while Canada was authorised to suspend concessions with a value of CAN\$11.3 million per year. As of October 2000, both countries were continuing to apply these tariffs, as the European Community has not yet brought its measure into conformity with the SPS Agreement.

## Case 2: Australian restrictions on salmon imports

The complaint by Canada against Australia's import restrictions on fresh chilled and frozen salmon was the first dispute regarding measures taken to protect animal health from the potential introduction of diseases. In 1975, Australia prohibited imports of fresh chilled and frozen salmon, allegedly to avoid the introduction of exotic fish diseases into Australia. The importation of heat-treated salmon, including canned salmon, was permitted under conditions established by Australia. Following formal consultations with Canada under the GATT (WTO precursor) dispute settlement provisions in 1994, Australia agreed to undertake an analysis of the disease risks of importing uncooked salmon and to examine, in the first instance, adult, wild, ocean-caught Pacific salmon from Canada and the United States.

A draft risk assessment of imports published in May 1995 concluded that if specific certification conditions were met, imports of adult, wild, ocean-caught Pacific salmon posed a negligible risk to Australia. A final risk assessment, published in December 1996, concluded that possibly 20 exotic fish diseases could be introduced by imports of salmon, and that although the probability was small, the economic consequences could be great. On the basis of this final

report, the Australian government maintained its ban on the importation of fresh chilled and frozen salmon.

Canada requested a panel under the WTO dispute settlement procedures, claiming that salmon imported for human consumption was very unlikely to lead to the introduction of fish diseases. Canada's main arguments were: (i) Australia's requirements were neither based on international standards nor on a proper risk assessment; (ii) the level of risk accepted by Australia with respect to salmon was inconsistent with the level of risk Australia accepted from other fish; and (iii) there were less trade restrictive measures which Australia could impose in order to ensure its chosen level of health protection.

A panel was established in April 1997. The panel consulted scientific experts chosen, in consultation with the parties, from lists of experts provided by the International Office of Epizootics (OIE). Expert advice was sought on fish diseases, risk assessment and the OIE.

# Legal issues and findings

The panel observed that Australia had conducted a risk assessment on adult, wild, ocean-caught Pacific salmon, and assumed that this risk assessment met the requirements of a risk assessment contained in Articles 5.1 and 5.2 of the SPS Agreement. However, the panel found that the actions Australia had taken were not based on the risk assessment, i.e. there was no rational relationship between this risk assessment and the import ban on Pacific salmon. For all other types of salmon, the panel found that Australia had not done a risk assessment and was thus in violation. The panel considered that Australia's action prohibiting imports of fresh chilled or frozen salmon could also be described as a requirement that the salmon be heat-treated.

The Appellate Body rejected the panel premise that the heattreatment requirement was the SPS measure at issue. The Appellate Body examined Australia's risk assessment on the basis of the definition of a risk assessment found in Annex A of the SPS Agreement. The Appellate Body concluded that the risk assessment (of Pacific salmon) met the first criteria of the definition, in that it (i) identified the diseases in question, as well as the associated biological and economic consequences. However, the Appellate Body found that the risk assessment did not (ii) evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated biological and economic consequences; and did not (iii) evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied. It concluded that Australia had acted inconsistently with Article 5.1. It further concluded that no risk assessment had been done for the remaining types of salmon.

With respect to Article 5.5 of the SPS Agreement, the panel compared Australia's ban on salmon imports with the allowed importation of whole frozen herring for bait and the allowed importation of live ornamental finfish (aquarium fish). The panel looked at (i) differences in the levels of protection adopted in different, but comparable situations; (ii) if these differences were arbitrary or unjustifiable (iii) and whether they resulted in discrimination or a disguised restriction on trade. Although in all situations there was at least one disease in common, the panel found that the levels of protection were quite different. Salmon importation was prohibited, herring were allowed in without controls, and ornamental fish were allowed with few controls. The panel found the differences in protection to be arbitrary or unjustifiable, since bait was directly introduced into the aquatic environment, and ornamental fish often became released into the wild. Based on these arbitrary or unjustifiable differences, the violation of Article 5.1, the sudden change in conclusions between the 1995 and 1996 versions of the risk assessment, and the lack of restrictions on the internal movement of fish, the panel concluded that the ban on salmon imports was discriminatory or resulted in a disguised restriction on trade. The Appellate Body upheld this finding.

The panel next examined whether Australia violated Article 5.6 of the SPS Agreement, which requires that a measure be no more trade-restrictive than needed to achieve the appropriate level of protection. It examined if other measures: (i) were reasonably available, taking into account technical and economic feasibility; (ii) achieved

Australia's appropriate level of protection; and (iii) were significantly less restrictive to trade.

The panel noted that Australia's risk assessment identified seven technically and economically feasible options and indicated that it was "extremely difficult to distinguish between the levels of risk" that each option presented. Some of the options were clearly less trade-restrictive than the import ban/heat treatment requirement imposed by Australia. The Panel concluded that less trade-restrictive measures existed which could have been used by Australia (WTO 1998b).

The Appellate Body reversed the finding on grounds that the panel had based its considerations on the heat-treatment requirement, not on the import prohibition. Because of insufficient factual findings, the Appellate Body found itself unable to conclude whether Australia had violated Article 5.6 (WTO 1998c).

## *Implementation*

The parties were unable to agree on a 'reasonable period of time' for Australia to implement the findings. An arbitrator set the reasonable period of time for compliance as 8 months after adoption of the reports. Australia claimed it had fully implemented the panel and Appellate Body recommendations in July 1999, two weeks after this deadline expired. Australia had carried out a new import risk assessment for fresh chilled and frozen salmon for human consumption and other non-viable marine finfish, and a separate risk analysis for live ornamental fish. Based on the 1999 risk assessment, Australia's new actions allowed the importation of all kinds of Canadian salmon, under certain conditions.

Canada challenged Australia's claim of implementation and requested authorisation to take retaliatory trade action on Australian exports worth CDN\$45 million. Australia asked for arbitration over this amount of "retaliation". The Dispute Settlement Body asked the original panel to consider Australia's compliance (Article 21.5 of the DSU) and to decide the appropriate level of "retaliation" (Article 22.6 of the DSU). Both countries agreed to wait for the panel decision on compliance before proceeding with arbitration over possible trade actions.

The same panel Member s had also been charged with examining a complaint by the United States against Australia on the same issue. However, the United States also decided to wait for the judgement on compliance before pursuing its complaint.

## Determination of compliance

Based on its new risk assessment for all fresh chilled and frozen salmon, Australia set new conditions on imports. In addition to requiring that fish be eviscerated, head and gills removed, washed internally and externally and certified, Australia specified that the product had to be processed to a "consumer-ready" state to be released from quarantine. The definition of what constituted consumer-ready product included a requirement that skin be removed from all products larger than 450 grams. Salmon that was not in consumer-ready form would have to be processed to consumer-ready form in approved premises to reduce risks from improper disposal of large quantities of skin, bone, etc.

The panel noted the compliance deadline had not been strictly met and that some of the new measures on fish other than salmon (to comply with the consistency requirement) were to be phased in at later dates.

Next, the Panel considered whether Australia's measures affecting salmon imports were based on a risk assessment. It found that the new risk assessment met the requirements of the SPS Agreement, i.e. it *identified* the diseases and *evaluated the likelihood* of entry, establishment or spread of these diseases, as well as the associated biological and economic consequences *according to the SPS measures which might be applied*. However, the Panel found that the requirement for salmon products to be in a specified consumerready form was not *based on* a risk assessment and thus was contrary to Article 5.1 of the SPS Agreement.

The Panel also found the definition of the consumer-ready product to be more trade restrictive than required to achieve the desired level of health protection, in violation of Article 5.6. Australia argued the consumer-ready requirement was to limit any risk from untreated waste from salmon processing plants. The Panel thought that less trade-restrictive requirements, such as consumer packaging, would also avoid unsafe processing and achieve the desired health protection.

The report of the panel on compliance was adopted without appeal on 20 March 2000. Australia and Canada started consulting, and reported on 18 May 2000 that a mutually agreed solution had been reached.

## Case 3: Japan's variety-by-variety testing requirement

The third panel process relating to the SPS Agreement was a complaint by the United States against Japan. To help assure that imported fruit did not harbour codling moth, Japan permitted entry only of those fruit varieties which had been subjected to extensive testing as to the efficacy of fumigation treatment. Japan claimed this measure was a provisional measure necessary to protect plant health. The United States claimed that there was no scientific justification for requiring each variety of a particular fruit (ie., each distinct variety of apple) to be separately tested. The main US arguments were that the Japanese requirement was not based on scientific principles and was maintained against scientific evidence that showed it was not necessary.

The panel was established in November 1997. It consulted entomology and fumigation experts chosen in consultation with the parties, from lists provided by the IPPC.

# Legal Issues and Findings

Both parties agreed the codling moth presented a risk to Japan. The panel focussed on whether there was sufficient scientific evidence (required by Article 2.2) supporting the need for the variety testing requirement. It concluded that there was no rational relationship between the scientific evidence submitted by Japan and the action that had been taken (WTO 1998d). The Appellate Body upheld this finding (WTO 1999).

Japan invoked Article 5.7, claiming that its measure was provisional. According to this article, in cases where relevant scientific evidence

is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information. They must then seek the additional information necessary for a more objective assessment of risk, and review the measure within a reasonable period of time. The panel found no evidence that Japan had actively sought to obtain additional information to review its measure within a reasonable period. The Appellate Body agreed with the panel.

The panel also considered whether Japan had adopted the least trade-restrictive measure which would provide its desired level of health protection. The United States proposed product-by-product testing. The panel concluded it did not have sufficient evidence to determine if this option would achieve Japan's appropriate level of protection. The experts advising the panel suggested a second option. If there were differences in the way fruit varieties responded to the treatment, these would be related to different levels of sorption of the fumigant by the fruit variety in question. Testing for differences in sorption levels was relatively easy. The panel considered that the determination of sorption levels could be a less trade-restrictive alternative to the varietal testing requirement.

The Appellate Body upheld the panel's finding on the product-byproduct testing method proposed by the US. Regarding the determination of sorption levels, the Appellate Body found that the panel had made an error of law by considering an alternative that had not been proposed by the United States, who bore the burden of proof that an alternative measure existed.

According to Annex B, Members must publish all SPS regulations. Japan had not published the variety testing requirement. Japan argued the testing requirement was not actually an SPS regulation because it was not mandatory, the exporting countries were allowed to demonstrate quarantine efficiency by other means. The panel and Appellate Body found that measures had to be published regardless of whether they were mandatory, and that Japan had therefore acted inconsistently with this obligation.

## *Implementation*

The United States and Japan agreed that it would be reasonable to give Japan until the end of 1999 to implement the rulings. Throughout 2000, both parties continued to report that they were close to finding a mutually acceptable solution.

# Economic considerations in dispute settlement

The WTO agreements, including the SPS Agreement, are legal texts. The dispute settlement system is a quasi-judicial procedure. Little consideration was given to economic arguments or considerations during the actual examination of the three disputes outlined above, other than in the calculation of allowable retaliation. The text of the SPS Agreement makes reference to economic factors in only three provisions: Article 5.3, Article 5.6 and the definition of a risk assessment in Annex A.

Nonetheless, economic factors are important in a country's implementation of the SPS Agreement. One concern is the potentially high cost of undertaking an appropriate risk assessment (required by Article 5.1 of the SPS Agreement). It should be remembered that the legal requirement is that a measure be based on a risk assessment, not that the importing country undertake this risk assessment itself. In judging whether a risk assessment is indeed "appropriate to the circumstances", it is conceivable that a future dispute panel might give consideration to arguments of the affordability of a particular risk assessment, in particular if a developing country is defending its actions.

The definition of a risk assessment, in the case of risks to animal or plant health, as contained in Annex A is:

"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 sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences ...".

According to Article 5.3 of the SPS Agreement, in assessing the risk to animal or plant health and in determining the measure it will apply, a Member is to 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."

Some of these economic factors were considered in the risk assessments put forward by Australia in the salmon dispute. The panel implicitly accepted the factors considered by Australia and the manner in which they were included in the risk assessment. However, if in some future dispute the economic factors considered in a risk assessment were challenged, they could be subjected to intensive scrutiny by a panel.

The third provision of the SPS Agreement which contains a particular reference to economic considerations, Article 5.6, requires that a government put in place the least trade restrictive measure which is capable of achieving its appropriate level of health protection, taking into account economic and technical feasibility. One difficulty panels face in examining compliance with this provision is the vagueness of the way governments describe their 'appropriate level of protection'. It is difficult to determine if a measure achieves the appropriate level. Panels therefore examine other forms of possible action that seem to address the principal risks, and seek expert advice as to the technical and economic feasibility.

In the salmon dispute, the panel considered that any action taken to appropriately reduce risk which had been identified as a possible response in Australia's own risk assessment could be considered to be technically and economically feasible. In the variety testing dispute, experts advising the panel identified an alternative testing procedure that was much simpler and less costly than the procedure prescribed by Japan, hence the panel considered that this alternative was economically feasible. It should be noted that in both of these

disputes, the Appellate Body overturned the panel's ruling, although not because of the question of economic feasiblity.

## Implementation - suspension of concessions

In contrast to the examination of compliance with the legal obligations of a WTO agreement, economic considerations are a critical element during the implementation phase. When a country fails to bring its measures into line with its WTO obligations within the prescribed "reasonable period of time", the preferred option is that it provide compensation for the resulting loss of trade opportunities. When there is no agreement on compensation, the complainant in the dispute can request authorisation to suspend trade benefits previously given to the non-complying country. The complainant party identifies the value of trade benefits it wishes to suspend, and provides a list of products (tariff lines) that may be affected. In the few cases to date in which retaliation has been sought, the party affected by the suspension has challenged the proposed level of retaliation, and the matter was referred to the original dispute settlement panel for arbitration on the appropriate level.

The task of the arbitrators is to determine the normal annual level of imports from the complainant that would have existed if the challenged party had fully implemented the panel and Appellate Body findings at the end of a 'reasonable period of time'. In the beef hormones case, the United States requested the right to suspend concessions on imports from the European Comunity valued at US\$202 million, and Canada sought authorisation for suspension on CDN\$75 million. The arbitrators had to determine what the annual value of EC imports of hormone-treated beef from the United States and from Canada would have been if the European Community had lifted its import restrictions on 13 May 1999.¹ The WTO procedures do not provide for retroactive compensation, for lost trade opportunities during years when the measure was in place, in this case since 1988.

<sup>&</sup>lt;sup>1</sup> The decision of the arbitrators is contained in WTO documents WT/DS26/ARB (US case) and WT/DS48/ARB (Canadian case).

The arbitrators considered both the potential trade in high-quality beef and in edible beef offal. EC imports of high-quality beef from the United States and Canada are limited by a tariff-rate quota of 11,500 tons. This quantitative constraint exists irrespective of the hormones ruling. The quota represents a negligible portion of total EC beef production, and tariff rate quotas allocated to other suppliers of high quality beef are usually filled. Given the high production and export capabilities of both the US and Canadian beef industries, the arbitrators assumed that without the hormone ban, the European Community would import at least 11,500 tons of high quality beef from the United States and Canada.

The arbitrators estimated the share of this quota that would normally be filled by each country. The estimate was based on the respective historic shares with adjustments to reflect the general trend of Canada's increasing share of high-quality beef markets.

The parties to the dispute each provided per unit prices and estimates of the expected value of high quality beef. The arbitrators considered the current value of high quality US and Canadian beef (not hormone treated) in the EC market, and what effect changes in cuts and quantities might have on prices if hormone-treated beef were permitted. The arbitrators eventually decided that the US suggested price, very close to the EC suggested price, was reasonable.

From the quantity and unit value calculations, the arbitrators estimated the total value of high quality beef from the United States and Canada which could be expected to enter the European Community annually had the ban on hormone-treated beef been removed in May 1999. However, the arbitrators made further adjustments to this calculation. They deducted the value of US and Canadian high quality beef (not hormone treated) that was actually entering the EC market despite the ban. They also took into account the effects on current US export levels of an EC "hold and test" procedure for all shipments of US high quality beef that the European Community had imposed on the grounds that some of the US meat contained prohibited hormones.

The calculation of lost trade opportunities for edible beef offal from the United States and Canada was more complicated because there was no quota setting potential maximum import levels. The arbitrators took as a base the average annual US (or Canadian) exports of offal to the European Community in the years before the ban. A number of adjustments were made to account for the decline in EC consumption – recognising that a portion of this decline could be due to the hormone ban itself. The arbitrators calculated the difference between the trend in import volumes for the years immediately following the imposition of the ban (extrapolated from actual import volumes preceding the ban) and the actual import volumes for these years. The annual average difference was then added to actual imports in each of the years 1995-97 and used to calculate the expected EC consumption in the absence of the ban.

The arbitrators then considered the probable per unit value of edible beef offal. The United States and European Community suggested very similar prices, a lower level was suggested by Canada. The arbitrators noted the US price was lower than the current actual price but was considered reasonable because prices could be expected to fall if the ban were lifted, as a result of the impact increased imports would have upon the European price.

In making their calculations, the arbitrators deducted the value of US and Canadian edible beef offal coming from non-treated animals that currently entered the EC market. A complication arose because a portion of EC imports of edible beef offal is destined for pet food, not for human consumption. Offal for pet food is not subject to the hormone ban, but is included in data under the same tariff line as that destined for human consumption. The parties did not agree as to what proportion of potential US and Canadian offal exports would go into pet food. The European Community was unable to substantiate its claim that over 31per cent was destined for pet food so the arbitrators used the US and Canadian estimates (5 and 10 per cent, respectively) to reduce their calculation of the total value of US and Canadian exports of edible beef offal that would be entering the European Community except for the hormones ban.

The arbitrators finally judged that if the European Community had complied with the findings of the WTO dispute settlement panel and Appellate Body by the set deadline, the United States could have expected to export an additional US\$116.8 million per year of high quality beef and edible beef offal to the European Community. The value of the lost trade to Canada was estimated as a maximum of CDN\$11.3 million per year. The Dispute Settlement Body thus authorised the United States and Canada to suspend trade benefits on an equivalent value of trade from the European Community.

#### Conclusion

To date, economic factors have been of little importance in the consideration of disputes over sanitary and phytosanitary measures, despite the economic implications of the SPS Agreement for countries. These include the benefits of imports, the potential losses associated with pest or disease introduction, the costs of undertaking a risk assessment, and of implementing appropriate measures.

Another potential economic concern to governments is the cost of involvement in a formal dispute under the WTO procedures. Although the WTO does not collect a fee or charge governments using the dispute resolution system, governments face important financial and resource costs when they are bringing a challenge, or defending their requirements. Nonetheless, one should not exaggerate these costs, as in many cases the actual costs are reduced because most of the participants are already in place and thus can be considered as a fixed cost to their governments. The variable costs include additional travel, special studies and overtime for employees, as well as opportunity costs of time and resources.

Given these costs, it might be expected that a complaint would only be brought concerning export products of major economic importance, ie. those which have an important political constituancy in the exporting country. There is no doubt that the potential economic gains in the hormones and variety testing disputes are substantial; they seem to be considerably less in the salmon case. However, the WTO dispute settlement process does not screen complaints nor refuse those where potential trade gains would be minimal.

Each dispute considered at the WTO is judged on its own merits. Economic factors are of most direct relevance only when the legal decisions have not been implemented, and the value of compensation or retaliation for lost trade opportunities must be determined. Although the economic evaluation of lost trade opportunities will be unique to each dispute, the hormones case provides a useful example of the methodologies that might be used, the factors which may be examined and the manner in which adjustments may be made to reflect the relevant economic considerations.

Countries trade for economic benefits. Economics, by nature, is the basis of any trade discussion. The need to protect human, animal and plant health leads governments to impose restraints on trade. The SPS Agreement and the WTO dispute resolution system provide a legal and institutional framework for regulating these restraints on the economic process. The focus of the SPS Agreement and the WTO process on health and legal, rather than economic considerations, should thus come as no surprise.

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# Implications of recent SPS dispute settlement cases

GAVIN GOH AND ANDREAS ZIEGLER\*

The Agreement on the Application of Sanitary and Phytosanitary Measures (hereafter, the SPS Agreement) imposes science-based disciplines on quarantine risk management. Article 2.2 of the SPS Agreement provides a basic obligation that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health, be based on scientific principles and are not maintained without sufficient scientific evidence. This is given specific application by Article 5.1 which requires that measures be based on a scientific risk assessment. Given its "science-based" focus, to what extent can economic considerations be incorporated into quarantine decision-making under the SPS Agreement?

In this chapter we show that the SPS Agreement, as interpreted by WTO panels and the Appellate Body in the disputes *EC – Hormones*, *Japan – Varietals* and *Australia – Salmon*, permits and indeed *requires* economic analysis in quarantine decision-making. Any risk assessment must evaluate the likelihood of entry, establishment or spread of the pest or disease, as well as the associated potential biological and economic consequences. Moreover, a Member's appropriate level of protection reflects its optimal balance between

<sup>\*</sup> The authors wish to thank Joan Hird and Vanessa Findlay for their constructive comments on the paper. The views expressed and the responsibility for any errors are the authors' own.

the economic benefits of trade and the potential biological and economic impact of pest or disease establishment.

Economic considerations are also relevant to the capacity of Members to adopt WTO-consistent measures. Under Article 5.6, Members are only required to take less trade-restrictive alternative measures where these are demonstrated to be technically and economically feasible. However, a number of potential problems relate to the legal test of Article 5.5 which gives rise to a presumption of WTO-inconsistency where a Member adopts different measures on different products; the obligations of Members in relation to pre-1995 measures; and the reasonable period of time for implementing WTO findings.

# The 'appropriate level of protection'

The SPS Agreement recognises the sovereignty of WTO Members to determine their own appropriate level of protection. Paragraph 6 of the preamble to the SPS Agreement declares as an objective the harmonisation of SPS measures on the basis of international standards and guidelines "without requiring Members to change their appropriate level of protection of human, animal or plant life or health". Accordingly, the appropriate level of protection is defined as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory" (Annex A, paragraph 5). A Member may adopt SPS measures which result in a higher level of protection than would be achieved by international standards or guidelines, if these do not meet the Member's appropriate level of protection (Article 3.3).

# A balance of economic considerations

A Member's appropriate level of protection reflects its individually acceptable level of risk. It is a political determination which seeks to balance the economic benefits of trade to the particular Member against the potential biological, economic and environmental consequences of pest and disease establishment. In the case of

Australia, the Australian Quarantine Inspection Service (AQIS)<sup>1</sup> recently stated:

"Australia has the sovereign right to determine its ALOP [appropriate level of protection] which reflects government policy and community expectations. This element of quarantine policy precedes and is separate from the establishment of quarantine measures by AQIS."

"A guide to the ALOP may be found in community and industry acceptance of quarantine policy and practice over the years. It reflects value judgements of the Australian community that take into account the benefits of trade and community access to imported goods and the consequences of pest or disease introductions on industry, the environment and society in general." (AQIS 1999a).

The SPS Agreement does not require that an appropriate level of protection be expressed in quantitative terms, for example a minimum magnitude of economic consequences. However, the Appellate Body in *Australia – Salmon* considered that "this does not mean, however, that an importing 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, such as Article 5.6, becomes impossible".<sup>2</sup>

Australia's appropriate level of protection has been consistently and explicitly stated by the Commonwealth government to be a high or very conservative level aimed at reducing risk to very low levels, while not based on a zero-risk approach. This reflects Australia's status as a significant agricultural producer and exporter, the biodiversity of Australia's environment including the variety of plants and animals produced, and Australia's relative freedom from exotic pests and diseases as an island continent. It therefore strongly, but not exclusively, reflects *economic considerations* such as

<sup>&</sup>lt;sup>1</sup> The responsibility for quarantine risk analysis (import and export) has now been taken out of AQIS and now resides with Biosecurity Australia, a group within the Department of Agriculture, Fisheries and Forestry - Australia

<sup>&</sup>lt;sup>2</sup> WT/DS18/AB/R, para. 206.

the potential economic impact of pest or disease establishment and the benefits of trade.

It is also noted that the economic asset value of a product is not limited to its commercial value as can be determined in the market-place. There is, for example, a socio-economic value in the protection of wild fish for recreational fishing. Similarly, the environmental impact of pests and diseases can have associated economic costs.

## Distinctions in the 'appropriate level of protection'

Given finite resources for risk management, a Member is unlikely in practice to have in place measures which meet its appropriate level of protection in respect of *all* products. Measures will be adopted on a product-by-product basis, on the biological or economic significance of the product. It is therefore within a Member's prerogative to adopt minimal risk management measures where the biological and economic consequences will be minimal, and even to utilise pests or diseases as biological control agents for species with negative economic value (for example, rabbit calicivirus). An AQIS policy memorandum describes Australia as adopting a "managed risk" approach to quarantine:

"The current Government has endorsed the 'managed risk' approach to quarantine. This is the only appropriate approach in view of increasing international trade and tourism and the finite resources available to AQIS to prevent entry of unwanted disease agents at the border. There is also a constant threat of introduction of unwanted diseases via natural routes, such as wind-borne spread of pests and vectors of disease and the discharge of ballast water by international shipping." (AQIS 1999b)

While Members are free to adopt different measures for different products, they must act in a manner consistent with Article 5. This requires that Members "avoid arbitrary or unjustifiable distinctions in the levels [of protection] it considers appropriate in different situations, if such distinctions result in discrimination or a disguised

restriction on international trade". The Appellate Body in *EC - Hormones* emphasised that the goal of consistency "does not establish a *legal obligation* of consistency of appropriate levels of protection ... the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided."

## The legal test under Article 5.5

The Appellate Body has identified three elements that must be satisfied for a Member to be acting inconsistently with Article 5.5 of the SPS Agreement:

- 1. the Member adopted different appropriate levels of protection in several "different situations";
- 2. the levels of protection exhibit differences which are "arbitrary or unjustifiable"; and
- 3. the measure embodying those differences results in "discrimination or a disguised restriction on international trade".4

Under the first element, situations exhibiting different levels of protection cannot be compared "unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable". The Appellate Body in *Australia – Salmon* considered situations to be comparable where they involve: (1) a risk of entry, establishment or spread of the same or a similar disease, e.g. where different species are host to the same or similar disease agent; *or* (2) the same or similar associated potential biological and economic consequences.

<sup>&</sup>lt;sup>3</sup> WT/DS26/AB/R, para. 213.

<sup>&</sup>lt;sup>4</sup> WT/DS18/AB/R, para. 140.

<sup>&</sup>lt;sup>5</sup> EC - Hormones, WT/DS26/AB/R, para. 217.

<sup>&</sup>lt;sup>6</sup> WT/DS18/AB/R, para. 146.

The legal test established under Article 5.5 - in particular the first element - does not reflect scientific principles and effectively reverses the burden of proof against Members maintaining SPS measures. Under the first element, situations are comparable where they involve "a risk of entry, establishment or spread of the same or a similar disease, or a risk of the same or similar associated potential biological and economic consequences".7 As a starting point, the definition of risk assessment in Annex A refers to an evaluation of the likelihood of entry, establishment or spread of a pest or disease according to the measures which might be applied, and the associated potential biological and economic consequences. The replacement of the word "and" with "or" in the Annex does not reflect the disease-by-disease basis of quarantine risk management, nor that quarantine risk is comprised of the risk of entry, establishment or spread of a disease and the associated consequences. It therefore exposes a Member to undefined claims of differential treatment between products on broad economic grounds.

In the Article 21.5 *Salmon* implementation panel,<sup>8</sup> Canada sought to make broad distinctions between Australia's treatment of imported salmon on one hand, and the measures Australia applied on domestic fish (including wild native fish) which may or may not share diseases in common with salmon. This was rejected by one of the scientific experts to the panel. Dr McVicar advised that what was relevant was the measures for the specified diseases in the same fish species or the same diseases in other products, for example other salmonids, non-salmonids and ornamentals. The fact that a country adopted more relaxed controls for other non-specified diseases, for example for wild fish products or indigenous diseases with limited distribution, was not relevant to the discussion on salmonids. Each product and each disease warranted independent evaluation.<sup>9</sup>

<sup>&</sup>lt;sup>7</sup> WT/DS18/RW, para. 7.90; also WT/DS18/AB/R, para. 146.

<sup>&</sup>lt;sup>8</sup> This examined, pursuant to Article 21.5 of the Dispute Settlement Understanding, the measures taken by Australia to comply with the panel/Appellate Body findings on *Australia – Salmon*.

<sup>&</sup>lt;sup>9</sup> WT/DS18/RW, Annex 1 para. 31.

It is also scientifically invalid to assume that diseases in common between different species involve the *same risk* of entry, establishment or spread. Different strains of the same disease agent may show marked differences in pathogenicity, infectiveness and therefore risk. For example, some atypical strains of the disease *A. salmonicida* do not cause significant disease in salmonids when they come from non-salmonids.<sup>10</sup> Dr McVicar also warned against the unrestricted use of published host-disease lists: "The dangers associated with the use of such data as a basis for risk assessment is illustrated by the ease by which it is possible to break down natural barriers of host susceptibility under experimental conditions". This was recognised in international regulations where experimental studies cannot be used as evidence of host susceptibility.<sup>11</sup>

Canada sought to argue the different measures applied by Australia for the disease VHSV on pilchards on the one hand, and salmon on the other. The Article 21.5 *Salmon* panel concluded that while VHSV was a disease in common between salmon and pilchards, the differential treatment and any difference in the appropriate level of protection was not arbitrary or unjustifiable under the second element of Article 5.5. However it was Australia, the responding Member, that had demonstrated this. The following diagram (Figure 5.1) is useful for illustrative purposes.

Two issues need to be discussed here. Firstly, in determining the measures to be applied on salmonids and non-salmonids, the potential biological and economic consequences of each VHSV strain on all susceptible species were taken into account. It was assessed that the marine strain of VHSV has limited consequences for species of fish occurring in Australia, including salmonids. By contrast, the biological and economic consequences of the freshwater strain of VHSV was assessed to be far more significant. Secondly, while VHSV is a recognised disease of salmon, the occurrence of VHSV in pilchards was assessed to be an exceptional event. There has been only one recorded instance of VHSV in pilchards in the cooler waters of North America. Australia sources

<sup>&</sup>lt;sup>10</sup> WT/DS18/RW, para. 6.82.

<sup>&</sup>lt;sup>11</sup> WT/DS18/RW, Annex 1, para. 28 and 35.

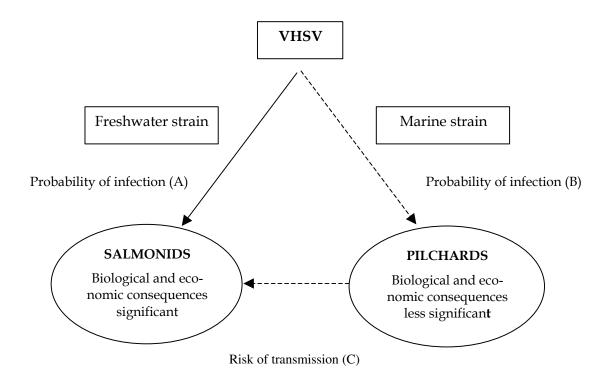


Figure 5.1: Disease and fish interactions

its pilchards from warmer waters where VHSV has not been reported.

It could therefore be concluded that given different strains of VHSV exhibit differences in pathogenicity among different species, the likelihood of entry, establishment and spread of VHSV for pilchards (B) was considerably lower than for salmonids (A). Furthermore, the risk of entry, establishment and spread of VHSV from pilchards to salmonids (C) was not considered to be significant. The different measures applied by Australia on pilchards and salmonids did not constitute arbitrary or unjustifiable distinctions in levels of protection.

Canada also sought to compare the different measures applied by Australia on diseases of imported salmon on the one hand, and on domestic fish such as redfin perch for the disease EHNV.<sup>12</sup> It was again Australia that successfully demonstrated that: EHNV had

<sup>&</sup>lt;sup>12</sup> Epizootic haematopoietic necrosis virus (EHNV).

minimal impact and would not be expected to have particularly significant consequences if spread; the primary host of EHNV was redfin perch, a wild recreational fish found in most regions where salmonids were located, including Tasmania; and that EHNV was not a disease reported in salmon. The different situations did not therefore involve a risk of entry, establishment or spread of the same or a similar disease, or the same or similar associated potential biological and economic consequences.

It is apparent that the legal test under Article 5.5 effectively reverses the burden of proof in a WTO dispute. It gives rise to a natural presumption of WTO-inconsistency where different measures are applied on different species for unspecified pests and diseases. It is then incumbent for the Member maintaining the SPS measures to submit scientific evidence, under the second and third elements, to rebut this.

A more appropriate test would be to require the complaining Member to demonstrate that different situations involve the risk of entry, establishment or spread of the same or similar disease, *and* the same or similar associated potential biological and economic consequences, for them to be comparable under the first element of Article 5. This would reflect scientific and economic realities and the product-by-product approach of quarantine risk management.

# Import risk analysis (IRA)

Article 2.2 imposes a basic obligation on Members that SPS measures be based on scientific principles and not maintained without scientific evidence. This is given specific application by Article 5.1 which requires that SPS measures be based on a risk assessment:

"Members shall ensure that their sanitary or phytosanitary 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."

Annex A paragraph 4 provides a definition of "risk assessment":

"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 sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences;"

The Appellate Body in *Australia – Salmon* considered that a risk assessment within the meaning of Article 5.1 must:

- i. *identify* the pests or diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these pests or diseases;
- ii. *evaluate the likelihood* of entry, establishment or spread of these pests or diseases, as well as the associated potential biological and economic consequences; and
- iii. evaluate the likelihood of entry, establishment or spread of these pests or diseases according to the SPS measures which might be applied.<sup>13</sup>

Article 5.1 also requires that the measures be *based on* the risk assessment. A measure is based on a risk assessment if there is "a rational relationship between the measure and the risk assessment". These requirements are broadly reflected in the three stages of risk analysis – (1) hazard identification, (2) risk assessment and (3) risk management - for example in the OIE *International Animal Health Code* (1999) guidelines on the conduct of animal and animal product risk analysis. The extent to which economic considerations can be incorporated into quarantine decision-making shall be examined for each stage.

# Hazard identification

The OIE International Animal Health Code defines hazard identification as "identifying the pathogenic agents which could

<sup>&</sup>lt;sup>13</sup> WT/DS18/AB/R, para. 121.

<sup>&</sup>lt;sup>14</sup> EC - Hormones, WT/DS26/AB/R, para. 193.

potentially produce adverse consequences associated with the importation of a *commodity*". (OIE 1999, chapter 1.4.2.2). In essence, hazard identification is "a categorisation step, identifying biological agents dichotomously as potential hazards or not". Whether a pest or disease is a potential hazard will clearly flow from the biological and economic consequences associated with its entry, establishment or spread.

As a "categorisation step", hazard identification does not require a minimum magnitude of economic consequences for a pest or disease. It is sufficient that it identifies the potential biological and economic consequences *associated with* the entry, establishment or spread of the diseases. The risk of entry, establishment and spread, and whether the associated biological and economic consequences meets the appropriate level of protection, is examined under the risk assessment stage.

For example the 1999 IRA on salmonids identifies disease agents of concern as those which are infectious, and either exotic to Australia or present in Australia but subject to official control, and if the disease agent is OIE-listed or would be expected to cause significant harm in Australia. Significant harm is defined as including *significant economic harm* e.g. increased mortality, reduced growth rates, decreased product quality, loss of market access, increased management costs (AQIS 1999a, p. 10).

#### Risk Assessment

A risk assessment must evaluate the likelihood of entry, establishment or spread of the pest or disease, as well as the associated potential biological and *economic consequences*. Article 5.3 SPS Agreement expressly requires Members to take into account economic considerations in risk assessment and risk management:

In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate

<sup>&</sup>lt;sup>15</sup> WT/DS18/AB/R, para. 121.

level of sanitary or phytosanitary 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.

The OIE *International Animal Health Code* identifies four steps in risk assessment: release assessment, exposure assessment, consequence assessment and risk estimation. The consequence assessment describes the potential consequences of a given exposure to a pest or disease agent. There must be a causal process "by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences". Examples of economic consequences include surveillance and control costs, compensation costs and potential trade losses (OIE 1999, chapter 1.4.2.4).

The 1999 IRA on salmonids largely reflected the OIE guidelines. Quarantine risk was defined as comprising two related factors – the probability of the entry and establishment of a disease agent in Australia, and the expected impact or significance (consequences) of such establishment (AQIS 1999a, p. xiv). The consequences of the establishment can have biological effects, economic effects on industry and environmental effects (AQIS 1999a, pp.11-12). Biological effects include morbidity and mortality, as well as economic considerations such as the costs of controlling or eradicating a disease, the destruction of in-contact healthy fish and the effect on productivity in subsequent generations. The 1999 IRA states that economic effect is normally evaluated in terms of the costs arising from the biological effects and the commercial implications for domestic and international marketing of affected animals and their products.

While Biosecurity Australia does not take into account the economic effects of trade competition when considering the risks associated with importation, this may be relevant under the third test of Article 5.5. The Article 21.5 *Salmon* panel accepted Australia's evidence that salmon from New Zealand was generally considered to be amongst the most competitive in the Australian market (ABARE 1999), but that given its low disease imports from New Zealand were subject to less restrictions than imports from other sources. This indicated that the measures applying on salmon did not result in discrimination or a disguised restriction on international trade inspired to avoid import competition, but were rather quarantine measures to protect Australia against diseases.<sup>16</sup>

The 1999 IRA classified the impact or significance of the establishment of disease into five categories: catastrophic, high, moderate, low or negligible (AQIS 1999a, pp. 12-13: box 1.5, 1.6). These categories are stated to "lie within a continuous range of consequences" and are indicative of expected outcomes in terms of biological and economic consequences. The economic consequences included economic effects at an enterprise/industry/ national level such as product marketing.

The then AQIS then employed a risk evaluation matrix to evaluate quarantine risk before and after the implementation of risk management measures. For each disease, the matrix determined whether the risk of establishment and its consequences would meet Australia's appropriate level of protection in the absence of specific risk management measures (AQIS 1999a, pp. 12-14: figure 1). For example, the risk of a disease with a negligible probability of establishment and catastrophic consequences was acceptable and no specific risk management necessary. The risk of a disease with moderate probability of establishment and low consequences, however, was not acceptable and importation could not be permitted without further risk management.

<sup>&</sup>lt;sup>16</sup> WT/DS18/RW, para. 7.106.

## Risk management

A risk assessment must evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.<sup>17</sup> The measures must also be "based on" the risk assessment. Article 5.3 requires that in determining the measure to be applied for achieving the appropriate level of protection, Members take into account relevant economic factors. Economic considerations will be relevant to risk management in:

- i. determining and implementing measures which meet the appropriate level of protection;
- ii. assessing the economic feasibility and cost-effectiveness of measures; and
- iii. ensuring measures are not more restrictive than necessary in their economic impact on trade.

Firstly, the OIE *International Animal Health Code* defines risk management as "the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised" (OIE 1999, chapter 1.4.2.5). Given the appropriate level of protection is a Member's expression of its tolerance of biological and economic consequences of pest and disease establishment, balanced against the economic benefits of trade, determining measures which meet the appropriate level of protection implies economic considerations. It is also an evaluation of the degree to which risk management options reduce the likelihood and/or magnitude of adverse biological and economic consequences (OIE 1999, chapter 1.4.2.6).

Secondly, given the finite resources for quarantine management, measures must be assessed on their practicality and cost-effectiveness. Article 5.3 lists as a relevant economic factor the relative cost-effectiveness of alternative approaches to limiting risks.

<sup>&</sup>lt;sup>17</sup> WT/DS18/AB/R, para. 121.

Similarly, the OIE guidelines provide for an evaluation of feasibility – focusing on technical, operational and economic factors – in implementing risk management options. The 1999 IRA on salmonids states: "In developing measures, Australia must consider matters such as practicability and ease of implementation, cost of compliance, cost-effectiveness of the measures and impact on trade, subject to the over-riding requirement that measures reliably achieve the ALOP." (AQIS 1999a, p.140).

Thirdly, Article 5.6 requires that Members ensure that measures "are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility". Footnote 3 provides that a measure is more trade-restrictive than required whenever "there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary and phytosanitary protection and is significantly less restrictive to trade".

The 1999 IRA on salmonids concluded that the risk associated with the commercial processing of imported salmonids would not meet Australia's appropriate level of protection. Accordingly, commercial processing would only be permitted in approved premises with conditions on location, waste disposal and related matters (AQIS 1999a, pp.146-148). To prevent the diversion of imported product to commercial processing in *non-approved* premises, the then AQIS would only permit the release from quarantine of "consumer-ready" product e.g. skin-on fillets of less than 450 grams in weight. This was defined as product the uncontrolled processing of which would not give rise to significant amounts of waste. The consumer-ready requirement was based on economic practicality – it was not economically feasible for the then AQIS to monitor all possible processing sites to ensure that unapproved commercial processing did not take place.

In the Article 21.5 *Salmon* case, Canada's claim that alternative measures were reasonably available was based on an assertion that: "Individually, each of the measures required by Australia can be presumed to be reasonably available, taking into account technical

and economic feasibility".<sup>18</sup> Australia argued that the feasibility of one measure may be dependent on the existence of another. It could not therefore be presumed that individual measures or sets of measures were technically and economically feasible in practice.<sup>19</sup> The Article 21.5 panel agreed with Canada that since the current Australian requirements were reasonably available taking into account technical and economic feasibility, a regime without the consumer-ready requirements would be so.<sup>20</sup> The panel also considered individual and commercial packaging before release from quarantine would also be reasonably available given that similar requirements were imposed by New Zealand.<sup>21</sup>

It is not clear from the language of Article 5.6 the extent to which "technical and economic feasibility" incorporates a subjective standard. However, a panel is likely to accord the importing Member due deference on technical and economic feasibility where the Member was a developing country. This will reflect the preamble to the SPS Agreement which recognises the special difficulties of developing country Members in formulating and applying SPS measures in their own territories. There may also be scope under Article 5.1 to take into account the technical and economic capacity of developing country Members, i.e. a risk assessment *as appropriate to the circumstances*.

# The 'precautionary principle'

Finally, some comment can be made on the 'precautionary principle' and its relationship to the SPS Agreement. The precautionary principle is an emerging principle of (international) environmental law which provides that mere lack of scientific certainty on potential adverse effects should not prevent a country from taking action to

<sup>&</sup>lt;sup>18</sup> WT/DS18/RW, para. 4.274.

<sup>&</sup>lt;sup>19</sup> WT/DS18/RW, para. 4.276.

<sup>&</sup>lt;sup>20</sup> WT/DS18/RW, para. 7.146.

<sup>&</sup>lt;sup>21</sup> WT/DS18/RW, para. 7.147.

protect the environment.<sup>22</sup> In the context of quarantine, the question arises whether a Member can invoke the precautionary principle in situations of lack of scientific certainty on the potential biological or economic consequences of pest and disease establishment. The issue goes towards the balance, implicit in the SPS Agreement, between science-based decision-making and the potential consequences of pest and disease establishment.

The Appellate Body in the *EC - Hormones* case considered that the precautionary principle was "reflected" in the right of Members to take provisional measures under Article 5.7, and in the right to determine their own appropriate level of protection under Article 3.3 and the sixth paragraph of the preamble to the SPS Agreement. A panel examining whether sufficient scientific evidence warranted the measure should also "bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible". The precautionary principle does not, however, justify measures otherwise inconsistent with specific provisions of the SPS Agreement.<sup>23</sup> Uncertainty of the potential economic consequences of pest and disease establishment does not therefore permit a Member to override the science-based obligations of the SPS Agreement.

#### Economic considerations and pre-1995 measures

In common with almost all WTO Members, Australia maintains a positive list system of quarantine. Under the *Quarantine Act 1908* and the *Quarantine Proclamation 1998*, if the import of a product is not expressly permitted, it is prohibited. This prohibition may or may not be based on a proper risk assessment or an international standard.

Given the limited technical capacity of Members to conduct risk assessments, and the fact that Members are receiving new import

<sup>&</sup>lt;sup>22</sup> See for example Principle 15 of the Rio Declaration on Environment and Development which provides for a precautionary approach to environmental protection.

<sup>&</sup>lt;sup>23</sup> WT/DS26/AB/R, para. 124.

requests on a constant basis, to what extent does the SPS Agreement require that all pre-1995 measures be based on a proper risk assessment? In particular, does the SPS Agreement provide a derogation for pre-1995 measures from the general risk assessment obligations and if not, to what extent does Article 5.7 provide a plausible defence or justification?

## The general obligations of the SPS Agreement apply to pre-1995 measures

The Appellate Body in *EC – Hormones* rejected the argument that the application of Articles 5.1 to 5.5 of the SPS Agreement was limited to measures enacted after the entry into force of the SPS Agreement. The SPS Agreement did not contain any express provision which limited its application or any provision to post- 1 January 1995 measures. In the absence of such a provision, it cannot be assumed that the negotiators intended that central provisions of the SPS Agreement, such as Articles 5.1 and 5.5, do not apply to measures enacted before 1995 but which continue to be in force thereafter.<sup>24</sup> The WTO Agreement, unlike the GATT of 1947, did not contain "existing legislation" exceptions or "grandfather rights".

Importantly, the Appellate Body recognised that the requirement that an SPS measure be based on a risk assessment imposed practical and economic burdens on Members in relation to the many pre-1995 measures in existence. The Appellate Body noted that "Article 5.1 stipulates that SPS measures must be based on a risk assessment, as appropriate to the circumstances, and this makes clear that the Members have a certain degree of flexibility in meeting the requirements of Article 5.1."<sup>25</sup> The Appellate Body did not define the term "as appropriate to the circumstances."

#### Article 5.7: provisional measures

Article 5.7 of the SPS Agreement permits Members to adopt provisional measures. Where relevant scientific evidence is

<sup>&</sup>lt;sup>24</sup> WT/DS26/AB/R, para. 128.

<sup>&</sup>lt;sup>25</sup> WT/DS26/AB/R, para. 129.

insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

While the burden of proof in a WTO dispute lies with the complainant, the responding Member bears the burden in invoking Article 5.7 to rebut claims of inconsistency with Articles 5.1 and 2.2. The Appellate Body in *Japan – Varietals* considered that Article 5.7 "operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures within sufficient scientific evidence". Article 5.7 sets out four requirements, relating to initial application of the measure and continuing compliance:

- i. the measure is adopted where relevant scientific information is insufficient;
- ii. the measure is adopted on the basis of available pertinent information;
- iii. the Member seeks to obtain the additional information necessary for a more objective assessment of risk"; and
- iv. the Member reviews the measure accordingly within a reasonable period of time.

Given that WTO obligations do not have retrospective application, the fact that a pre-1995 measure did not satisfy the first two requirements of Article 5.7 at the time it was introduced does not preclude justification under Article 5.7. It is however uncertain when or even *if* the first two requirements must be satisfied in relation to pre-1995 measures. Neither the Panel nor the Appellate Body in *Japan – Varietals* examined the first two elements of Article 5.7.

One interpretation is that a Member is required to demonstrate, as on 1 January 1995, that all pre-1995 measures were continuing to be

<sup>&</sup>lt;sup>26</sup> WT/DS76/AB/R, para. 80.

maintained in a situation where relevant scientific information was insufficient and that the measure was maintained on the basis of available pertinent information. This ignores the practical impossibility of such compliance. An alternate interpretation is that a Member must demonstrate at the time of a WTO dispute panel, that the measure was being maintained according to the first two requirements.

Where a panel does proceed to examine the first two requirements of Article 5.7, it is uncertain what must be demonstrated in terms of the scientific evidence. The term "sufficient" under Article 2.2 has been interpreted to be a relational concept, which "requires the existence of a sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific evidence".<sup>27</sup> Extrapolating the reverse interpretation in relation to "insufficiency" is however unhelpful.

It is nevertheless clear from the Article 5.1 jurisprudence in *Salmon* and *Hormones* that the scientific evidence does not have to be conclusive. Experts advising a panel would probably be asked about the sufficiency of scientific data that might be available in order to arrive at a scientific judgment. A complainant could also be expected to document available data and to compare the "sufficiency" of such data drawn upon in risk assessments on other products by the importing Member and other Members. A panel could well be influenced by evidence that other WTO Members had undertaken risk assessments based on the same data.

The Appellate Body noted that the SPS Agreement did not set out explicit prerequisites on the additional information to be collected, a specific collection procedure, or what actual results must be achieved. However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct "a more objective assessment of risk". The information sought must therefore be germane to conducting a risk assessment, i.e. the evaluation of the likelihood of entry, establishment or spread of a pest or disease,

<sup>&</sup>lt;sup>27</sup> WT/DS76/AB/R, para. 73.

according to the measures which might be applied.<sup>28</sup> In *Japan – Varietals*, the information collected by Japan was found not to examine the appropriateness of the SPS measure at issue and did not address the core issue as to whether varietal characteristics cause a divergence in quarantine efficacy.<sup>29</sup>

On the fourth requirement, it is noted that "review the measure" within the reasonable period of time does not equate to "complete a risk assessment". "Review the measure" only requires that Members *commence* a risk assessment - if there was sufficient scientific evidence for a more objective assessment of risk - within a reasonable period of time.

The Appellate Body in *Japan - Varietals* considered that what constitutes a "easonable period of time" has to be established on a case-by-case basis and depends 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.<sup>30</sup> In that case, the scientific experts had advised that studies to determine whether varietal differences mattered for quarantine efficacy could be carried out relatively easily, i.e. it was relatively easy to collect the necessary additional information. While the obligation "to review" the varietal testing requirement has only been in existence since 1 January 1995, Japan had not reviewed the measure "within a reasonable period of time".<sup>31</sup>

#### Practical implications for WTO members

The Appellate Body in *Hormones* recognised the practical difficulties associated with pre-1995 measures and appeared to leave open some flexibility for Members in interpreting "as appropriate to the circumstances" under Article 5.1. This does not, however, displace the Article 5.1 requirement that there must be some sort of risk assessment on which the measures are based on. "As appropriate to

<sup>&</sup>lt;sup>28</sup> WT/DS76/AB/R, para. 92.

<sup>&</sup>lt;sup>29</sup> WT/DS76/AB/R, para. 92; WT/DS76/R, para. 8.56.

<sup>&</sup>lt;sup>30</sup> WT/DS76/AB/R, para. 93.

<sup>&</sup>lt;sup>31</sup> WT/DS76/AB/R, para. 93; WT/DS76/R, para. 8.56.

the circumstances" therefore qualifies the *standard* of the risk assessment and not whether there should be a risk assessment *per se*. Article 5.7 is therefore the relevant provision in respect of pre-1995 measures.

There is insufficient jurisprudence to determine the extent to which Article 5.7 provides a plausible defence or justification for pre-1995 measures. A strictly literal interpretation of Article 5.7 - read in the context of the Appellate Body's statements that SPS provisions do not confer "grandfather rights" – would preclude Article 5.7 as such a defence. Balanced against this is the impossibility of Members' compliance – given practical and economic realities – under this interpretation.

It will ultimately be a question of "reasonableness" to be determined on a case-by-case basis, balancing the rights and obligations of the importing Member and the Member seeking quarantine access. Relevant factors might include: the *bona fides* of the parties, i.e. whether the measure was being maintained as a disguised restriction to trade; the technical and economic capacity of the importing Member to conduct only a limited number of risk assessments at any one time; the number of import requests received; when the import request was first brought to the attention of the importing Member; and the ease of collecting additional information and reviewing the measure.

In practice, WTO panel and appeal processes could take up to 14 months from the date of the request for consultations to the date of adoption of the panel/Appellate Body reports by the DSB. A Member will then have a reasonable period of time to implement the DSB findings. Given that full WTO processes could take anywhere between 18 to 28 months, Members would be reluctant to initiate complaints which could well be overtaken by events, i.e. the completion of a proper risk assessment.

In cases where a risk assessment is scheduled or in progress, WTO panels are likely to accord a Member time to complete it. Article 5.7 only requires Members to "review ... the measure accordingly within a reasonable period of time", it does not provide that Members must

conduct risk assessments within this period. Where no risk assessment was scheduled or in progress, the question will turn on what constitutes the reasonable period of time for reviewing the measure. On a balance of rights and obligations, there is little economic detriment to an exporting Member in respect of a pre-1995 measure maintained by a Member, but for which no import requests have been made. It is also a question of reasonableness, given the practical and economic constraints on Members, whether a Member is required to review all pre-1995 measures regardless of whether or not there is any economic interest in importing a particular product.

A number of practical conclusions can be made. Firstly, the refusal to conduct simultaneous risk assessments may not, by itself, preclude the application of Article 5.7. A panel interpreting the 'reasonable period of time' may take into account the practical constraints on Members conducting risk assessments on all requested products of all Members at the one time. Where resources are limited, it may be reasonable for a Member to refuse simultaneous risk assessments to maintain equity between importing Members. However, this will only be one factor to be considered in the "reasonableness" matrix.

Secondly, while Members are likely to be accorded time to complete a risk assessment, it is uncertain what this period of time is. 'reasonable period of time' in Article 5.7 only relates to the requirement to "review" the measure. It does not provide guidance on the time to conduct a proper risk assessment. Panels are likely to consider the practice of other WTO Members, the complexity of the subject matter and the resource constraints on the importing Member. Panels may also take into account domestic legal processes such as delays from Australian Administrative Decisions Judicial Review challenges.

Finally, in terms of an importing Member's work program, priority for conducting risk assessments should be given to products for which import requests have been received, according to their economic significance, and with priority to the earlier requests. This reflects the likelihood of WTO challenge by exporting Members. There is little risk of a WTO challenge with respect to historical

measures covering products for which there was little or no interest in trade.

#### Implementation of WTO dispute settlement findings

Article 21.3 of the Disputes Settlement Understanding (DSU) provides that in the event of a finding of WTO-inconsistency - for example that an SPS measure was not based on a proper risk assessment - the Member has a 'reasonable period of time' to bring its measures into conformity.

Where parties fail to agree on a period, this is determined by binding arbitration. The guideline for arbitration is that the reasonable period of time should not exceed 15 months from the date of adoption of a panel or Appellate Body report. This period may be shorter or longer, depending upon the particular circumstances (Article 21.3 (c) DSU).

Arbitrators have to date interpreted 15 months to be the outer limit for the reasonable period of time. In both *Korea – Alcoholic Beverages* and *Australia – Salmon*, the arbitrators noted that the 15 month period was a guideline and not an obligation.<sup>32</sup> According to the arbitrators, the reasonable period of time is the minimum period at which a Member can implement within its legal system. Where implementation could be effective by purely administrative and non-legislative means, the reasonable period of time could be considerably shorter. Conversely, arbitrators have provided parties longer time frames where implementation necessitated legislative amendment.

This distinction between legislative and administrative implementation arbitrarily discriminates between different Members on their systems of government. It is also incorrect to assume that administrative implementation is necessarily faster than legislative implementation. Most non-legislative systems embrace strong natural justice and administrative law requirements, for example Australia's *Administrative Decisions* (Judicial Review) Act

<sup>&</sup>lt;sup>32</sup> WT/DS75/16, para. 36; WT/DS18/9, para. 38.

1977. These impose minimum time-frames and consultation requirements for administrative decision-making and acceleration of processes could give rise to risks of judicial challenge.

Importantly, the reasonable period of time *does not* take into account economic factors such as the resources and time necessary to conduct a proper risk assessment.<sup>33</sup> Implementation may be bywithdrawal of the measure. This is consistent with Article 21.1 of the DSU which declares the prompt compliance with recommendations and rulings of the DSB as essential for the effective resolution of disputes.

In *Australia – Salmon*, the arbitrators repeated that the reasonable period of time should be the shortest period possible within the legal system of the Member to implement the WTO findings. Conducting risk assessments was not pertinent to the determination of the reasonable period of time. Given that implementation could be effected by administrative means, the reasonable period of time was determined to be eight months i.e. 6 July 1999. The then AQIS conducted accelerated import risk analysis processes for salmonids, other marine finfish and live ornamental fish, and new measures were announced on 19 July 1999.

#### Conclusion

It has been shown that economic considerations are very much a part of, and are not inconsistent with, science-based quarantine decision-making under the SPS Agreement. Firstly, a Member's appropriate level of protection reflects economic considerations such as the economic benefits of trade and the potential economic impact of pest or disease establishment.

Secondly, in conducting a risk assessment a Member must evaluate the likelihood of entry, establishment or spread of the pest or disease, as well as the associated potential biological and *economic* consequences. Article 5.3 of the SPS Agreement expressly requires Members to take into account economic considerations in risk

<sup>&</sup>lt;sup>33</sup> WT/DS26/15, para. 41.

assessment and risk management such as: the potential damage in terms of loss of production or sales from 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 cost-effectiveness of alternative approaches to limiting risks.

The SPS Agreement is however less accommodating of economic considerations on the technical and economic capacity of Members to implement WTO-consistent measures. Firstly, the legal test of Article 5.5 gives rise to a presumption of inconsistency where a Member adopts different measures on different products and does not reflect scientific or economic practice. Secondly, pre-1995 measures remain a potentially serious issue for importing Members. However, panels and Members are likely to adopt a flexible approach to pre-1995 measures to take into account the practical and economic constraints on full compliance. Finally, the reasonable period of time for implementing WTO findings does not include the time or resources necessary to conduct a proper risk assessment. This reflects the fundamental object of the DSU which is the prompt settlement of disputes.

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### **PART II**

The 'appropriate level of protection'

# The 'appropriate level of protection': a European perspective

SPENCER HENSON

As traditional barriers to agricultural trade have diminished, there has been increased attention focused on the impact of sanitary and phytosanitary (SPS) measures on trade. The implementation of the SPS Agreement has defined a series of rights and principles for the regulation of SPS measures that have the potential to impede trade. Furthermore, the enhanced transparency of SPS measures provided for under the Agreement, and the desire to avoid the great economic costs associated with the WTO's dispute settlement procedures, are engendering greater discipline in the application of SPS measures amongst Members. Simultaneously, however, the increased application of SPS measures and growing use of new technologies, for example biotechnology, are likely to generate increased tensions and disputes between trading partners regarding the legitimacy of these measures.

The SPS Agreement confirms the right of Members to implement SPS measures provided they satisfy the requirements of the Treaty, in particular a commitment to apply measures that are least trade distortive. Furthermore, the Agreement permits Members to define their own 'appropriate level of protection' (ALOP), that level of protection deemed to be acceptable and which the SPS measures applied aim to achieve. This chapter explores the concept of ALOP as applied in the European Union (EU). It describes the concept of ALOP as defined by the SPS Agreement, explores how this concept is applied by the EU and evaluates the extent to which this accords

with the Agreement. Two key issues associated with the EU's ALOP are explored, namely the 'precautionary principle' and the role of 'other legitimate factors' in establishing SPS measures.

#### Food safety concerns in the European Union

Before proceeding to explore the concept of ALOP as applied in the EU, it is important to recognise the social and political environment within which SPS measures, and more specifically food safety controls, are developed and applied in the European context. Food safety is a highly sensitive issue in the EU, probably more so than in other developed countries. Food safety issues typically receive extensive coverage in the media and as a result there is a public debate about the safety, or otherwise, of food products and technologies. A case in point is agricultural biotechnology, which has received greater and increasingly negative media attention in the UK, for example, than the United States (Figure 6.1). Furthermore, the EU has been plagued by a series of high-profile food safety problems, the most notable of which are BSE and contamination of animal feed with dioxins. These have served to heighten consumer concerns about food safety and raised questions about the efficacy of existing controls.

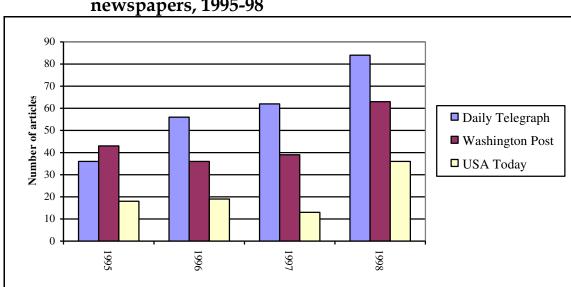
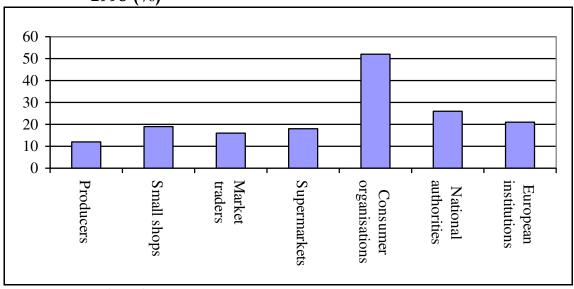


Figure 6.1: Coverage of agro-biotechnology issues in UK and US newspapers, 1995-98

Source: Kalaitzandonakes and Marks (1999).

There is evidence that consumers in the EU lack confidence in institutions charged with regulating food safety, both at the Community and Member State levels, both in terms of the information they provide and their ability to ensure food is 'safe' to eat. For example, Figure 6.2 presents the results of a pan-European study on consumer attitudes towards food safety undertaken for the European Commission in 1998. These results suggest a distinct lack of trust in producers, food retailers, national governments and pan-European institutions with respect to information on food safety. Furthermore, there are perceptions that existing food safety controls lack transparency and are too closely oriented to the needs and demands of agricultural producers and the food industry, rather than the protection of public health and other consumer interests. Thus, food safety has become a major political issue both within the Member States and the Commission, with a perceived need to demonstrate that consumer interests are paramount and that a high level of precaution is applied to ensure food is as safe as possible.

Figure 6.2: Proportion of respondents considering that persons or organisations always tell the truth about food safety, 1998 (%)



Source: INRA (1998).

Responding to consumer concerns and the consequent political pressure to enhance the level of protection afforded consumers, a program of reforms has been implemented within the Commission as well as individual Member States (CEC 1997, 2000a; James,

Kemper and Pascal 1999). On the one hand, proposal have been put forward for the revision of EU food safety legislation, with the objective of enhancing the coverage and efficacy of existing controls. On the other, institutional structures have been, and continue to be, reformed in an attempt to engender consumer confidence. For example, in 1997, responsibility for food safety policy within the Commission was moved from the Directorate General (DG) responsible for agriculture to that responsible for consumer protection. At the same time, the system of expert committees through which scientific advice is provided to the Commission was reformed to enhance transparency and ensure consumer interests are to the fore. More recently, proposals have been published for a European Food Authority, separate and independent of the Commission. These changes serve to further illustrate the political sensitivity of food safety within the EU.

## The SPS Agreement and the 'appropriate level of protection' concept

The SPS Agreement asserts the right of Members to take SPS measures for the protection of human, animal or plant life or health, provided they are consistent with the provisions of the Agreement (Pauwelyn 1999). For the purposes of the SPS Agreement, SPS measures are defined as any measures applied to:

- protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- protect human life or health from risk arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; and

<sup>&</sup>lt;sup>1</sup> For a more detailed discussion of the provisions of the SPS Agreement see Chapters 2 and 4 in this volume, by Roberts and Stanton.

• prevent or limit other damage from the entry, establishment or spread of pests.

The basic tenants of the Agreement are that measures should only be applied under the following circumstances:

- to the extent necessary to protect human, animal or plant life or health;
- if based on scientific principles; and
- not maintained, with one exception (see later), without sufficient scientific evidence.

It can be inferred, therefore, that Members do not have a right to take such measures unless these conditions are satisfied (McGovern 1995).

The SPS Agreement places great emphasis on the need for SPS measures not to be "maintained without sufficient scientific evidence". Providing the measures applied by Members satisfy this requirement, however, they are free to define their own ALOP. The Agreement does not explicitly define ALOP, but notes that many Members refer to it as the level of risk. This suggests that ALOP is the level of risk that Members deem 'acceptable' in establishing an SPS measure. Implicit in the Agreement is an obligation to determine the ALOP. This does not need to be specified in quantitative terms, but Members are not at liberty to determine the level of protection with such ambiguity that the provisions of the Agreement cannot be applied effectively.

Although zero risk is not a meaningful scientific objective of SPS measures, it can be the level chosen by a Member as its ALOP (WTO 1998c). In this case, the Member would presumably aim to achieve the lowest level of risk that could be scientifically determined. If a Member fails to define their level of protection with sufficient precision, it may be established by dispute panels on the basis of the measure applied (WTO 1998c).

The requirement to base SPS measures on "sufficient scientific evidence" is presumed to be satisfied by measures that "conform" to the standards, guidelines and recommendations defined by the international standards organisations.<sup>2</sup> The Appellate Body has also identified a category of measures that, whilst not conforming to international standards, are based on them, as is specified in the language of the SPS Agreement (WTO 1998a). The SPS Agreement, thus, aims to encourage the harmonisation of SPS measures amongst WTO Members and implicitly their ALOP.

Whilst Members are free to implement SPS measures that result in a level of protection that differs from those based on the standards specified by the international standards organisations, in such circumstances specific scientific justification is required. Members are required to demonstrate that such measures are based on a risk assessment, as appropriate under the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the international standards organisations. The SPS Agreement provides two definitions of 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; and
- the evaluation of the potential for the adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages of feedstuffs.

The expression "as appropriate in the circumstances" gives Members a degree of flexibility in satisfying the requirements of the Agreement (Pauwelyn 1999). This reflects the difficulties that Members face in adjusting SPS measures in force prior to the Agreement (WTO 1998a). The existence of unknown or uncertain

<sup>&</sup>lt;sup>2</sup> Most notably Codex Alimentarius, the International Office of Epizooties (OIE) and the International Plant Protection Convention (IPPC).

elements does not negate the requirement to undertake a risk assessment (WTO 1998c).

The first of these definitions of risk assessment is associated with the first, third and fourth categories of SPS measure detailed above, as defined by the SPS Agreement, namely those broadly associated with the risks associated with pests and diseases. Such an assessment consists of three key stages (WTO 1998c):

- identify the relevant pest or disease(s) and the associated biological consequences.
- evaluate the likelihood of the entry, establishment or spread, and of the consequences (for each pest or disease if several have been identified). 'Some' evaluation is not sufficient. Likelihood means probability, assessed either quantitatively (for example, a probability of 0.32) or qualitatively (for example, high probability).
- carry out these evaluations according to the measures that might be applied.

The second definition of risk assessment has a narrower focus and is associated with the second category of SPS measure detailed above, namely, the risks to human and animal health associated with foods, beverages and feedstuffs. In this case, the specific form of the assessment has not been clearly defined, although it would clearly need to examine the alternative measures that might be applied in order to identify that which is best suited to the risk involved.

The Appellate Body has determined that the obligation to base SPS measures on a risk assessment does not imply a requirement to establish a quantified minimum level of risk. However, the risk must be more than a theoretical uncertainty arising because science is unable to provide absolute evidence that a substance is safe. Furthermore, there must be an objective relationship between an SPS measure and a risk assessment, rather than simply taking the assessment into account when promulgating the measure. Merely obtaining the data required to undertake a risk assessment is not sufficient to justify that a measure is justified scientifically (WTO)

1999d). This does not mean, however, that a Member may not rely on a divergent opinion coming from a qualified source, for example, especially where there is a clear and imminent threat to life (WTO 1998a).

As described above, the SPS Agreement obliges Members not to maintain measures without sufficient scientific evidence. When a Member has reason to believe that an SPS measure implemented by another Member restricts (or has the potential to restrict) its exports and is not based on the relevant international standards, guidelines or recommendations, an explanation of the rationale for the measure must be provided on request. Furthermore, the Appellate Body has ruled that failure to provide evidence of this when requested to do so would be a strong indication that it did not exist (WTO 1999). Thus, it has encouraged dispute settlement panels to draw adverse inferences where a Member fails to provide information in its possession.

In cases where "relevant scientific evidence is insufficient", a Member may provisionally adopt measures "on the basis of available pertinent information". However, Members must seek to obtain the additional information necessary for a more objective risk assessment and must review the measure within a "reasonable period of time". What is considered "reasonable" will depend on the particular circumstances involved (WTO 1999). In the case of the report of the panel on measures affecting imports of salmon, for example, 20 years was not regarded as "provisional" (WTO 1998b).

The SPS Agreement, aims to engender consistency in the application of the concept of ALOP against risks to human, animal or plant life or health. Thus, Members are required to avoid arbitrary and unjustifiable distinctions in the levels of protection considered to be appropriate in different situations, if such distinctions act to impede trade. However, this does not imply that the ALOP adopted by a Member is expected to be absolutely consistent (WTO 1998a), only that any differences should be non-arbitrary and justifiable. Furthermore, consistency is seen as a long-term objective and implicitly aimed at preventing discrimination between Members where identical or similar conditions prevail (WTO 1998a).

In judging consistency, situations can only be compared if they possess some "common elements" (WTO 1998a; Pauwelyn 1999). These elements are indicated by the definition of risk assessment applicable to the measure (see above). In the case of the first definition, situations may be compared where they involve the same or a similar disease or a risk associated with the same or similar biological or economic consequences, irrespective of whether the products involved are the same. It is sufficient, for example, that situations have in common the risk of entry, establishment or spread of a particular disease (WTO 1998c). The SPS Committee is currently developing guidelines to provide practical guidelines on the interpretation of consistency. These are likely to include, for example, differences in consumer perceptions of risks to human health.

In summary, the SPS Agreement permits Members considerable flexibility in determining the level of protection they deem appropriate given their own particular circumstances, and to apply measures in order to achieve this level of protection. In so doing, however, Members are required to demonstrate scientifically that the measures applied to achieve the desired ALOP are justified and that the ALOP is applied consistently. The specific rules laid down by the SPS Agreement are, however, subject to interpretation and their specific meaning is only being established through case law (Selheimer 1998; Pauwelyn 1999; Thomas 1999). Indeed, issues such as the scientific justification of measures and consistency of the ALOP have been key elements of the three disputes on which the Dispute and Appellate Panels have ruled to date.

#### The European Union's ALOP

Whilst there is general agreement between the signatories to the SPS Agreement on the need for SPS measures to be based fundamentally on scientific evaluation, risk assessment is not an accurate process of measurement, but of approximation often based on scientifically plausible hypotheses rather than established facts (Somogyi 1999). As a result it is virtually unavoidable to introduce elements of value judgement when undertaking risk assessment. Consequently, whilst attempts have been made to develop international guidelines on, for

example, principles and procedures for test methods and means of evaluation, it is extremely difficult to reach an international consensus regarding an appropriate value for the ALOP (Somogyi, Gori and Appel 1999). This is apparent, for example, in discussions and negotiations in the international standards organisations, in particular *Codex Alimentarius*.

Explicit reference to the EU's ALOP is made in the Treaty establishing the Community. The European Commission is required to adopt a "high level of protection" under Article 95 (3) of the Treaty:

"The Commission, in its proposals envisaged ...... concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

#### Likewise, Article 152 states that:

"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."

Whilst what is considered a "high" level of protection will be interpreted and determined in the context of specific areas of environmental and consumer protection, the Treaty appears to commit the institutions of EU to pursuing a relatively cautious approach given the state of current scientific knowledge.

The European Commission takes a rather wide perspective when determining the ALOP applied in the application of SPS measures. Reference is made to the need to balance the rights and freedoms of individuals, industry and organisations with the need to reduce the risk of adverse effects to human, animal or plant life or health or the environment (CEC 2000a). This perspective appears to differ somewhat from the policy of certain other countries, for example the US, which purport to focus specifically on the scientific basis for any

measures applied. This is evident, for example, from the dispute between the EU and US over restrictions on the use of growth hormones in beef production. The EU, in justifying these restrictions, cited consumer anxiety over the safety of beef and implicitly equated these perceptions with the requirement to protect public health (Carter 1997). The US, however, asserted that these restrictions lacked any scientific basis and were motivated by protectionism.

As well as differences in the range of factors deemed salient when establishing the ALOP, methodological approaches to risk assessment can also differ between countries. Such differences exist, for example between the US and EU, particularly in the case of carcinogenic substances (Somogyi 1999). In the US, specific methods of quantitative risk assessment are applied, whereby data from animal experiments are extrapolated to derive a 'virtually safe dose' (VSD) with the theoretically possible incidence in humans of the particular form of toxicity associated with the substance. In the EU, however, a case-by-case evaluation based on the 'weight of evidence' approach is applied (Scientific Committee for Food 1996). Whereas this approach also takes as a starting point data from animal experiments, determination of the likely potency of the substance is derived by consideration of a wide range of other toxicological data.

Whilst it is evident that the EU strives to achieve a high ALOP in the context of SPS measures, there are clearly inconsistencies in the level of protection applied by individual Member States and to different products. Thus, for example, whilst there are concerns about the safety of genetically-modified crops for which no risk to human health has been demonstrated to date, products such as unpasteurised cheese, which are acknowledged to be 'high risk', are widely consumed in certain Member States (see Box 6.1). These differences reflect consumer perceptions of the risk associated with food and, in turn, social demands for different levels of protection. In the case of unpasteurised cheese, whilst there have been debates about the need for stricter regulation, consumer demand for such products limits the scope of regulators.

## Box 6.1: Cheese manufactured from unpasteurised milk cheese in the EU

Although there is significant evidence of considerable consumer concerns about food safety within the EU, there is widespread consumption of some foods which scientists judge to be 'high risk'. One example is cheese manufactured from unpasterised milk, which is consumed widely in Member States such as France, Belgium and Italy. In these countries, where a wide range of cheese from small-scale producers is available, the fact that cheese is made from unpasteurised milk is frequently judged to be a positive quality characteristic. The European Commission has introduced harmonised requirements to permit these products to move freely within the EU and they are now widely available in many Member States (Maze, Letablier and Valceschini 1996). Indeed, new cheeses produced from unpasteurised milk have been introduced in other Member States, for example UK and Ireland.

The European Commission has argued, most notably within *Codex Alimentarius*, that good hygiene practice in the production of cheese from unpasteurised milk can ensure an appropriate level of food safety. However, many countries do not permit such products to be manufactured, or require extended periods of maturation before they can be marketed. Examples include the US and Canada.

#### The 'precautionary principle'

An aspect of the EU's ALOP that has caused controversy internationally is the 'precautionary principle'. Whilst the need for a precautionary approach to risk analysis is generally accepted amongst high income countries (OECD 2000), there are clearly differences of opinion, in particular regarding whether precaution is purely an element of risk assessment, or also extends to risk management. The European Commission has recently published a consultation document on the 'precautionary principle' which outlines its views on the role of precaution and how it might be applied in the promulgation of SPS measures (CEC 2000a). At the current time, the 'precautionary principle' is defined within the Treaty, although only with respect to protection of the environment (Article 174):<sup>3</sup>

"Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles

<sup>&</sup>lt;sup>3</sup> The notion of the precautionary principle, at least in broad terms, is also incorporated into the law of certain EU Member States, for example Germany.

that preventive action should be taken, that environmental damage should as a principle be rectified at source and that the polluter should pay."

However, the Commission has determined that the principle is applicable more generally to situations where (CEC 2000a):

".... scientific evidence is insufficient, inconclusive or uncertain and there are indications through objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."

Furthermore in April 1999, the Council of Ministers adopted a resolution urging the Commission (Council of Ministers 1999):

"To be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and its other consumer-related activities and develop as clear and effective guidelines for the application of this principle."

This suggests that the Commission might actually be obliged by EU law to adopt the 'precautionary principle' when faced with scientific uncertainty, although the definition of the principle is yet to be fully established.

The Commission's views on the legitimacy of the 'precautionary principle', at least within the context of the EU, is supported by recent EU case law. For example, in its ruling on measures restricting exports of beef from the UK to control the spread of BSE (Cases C-157/96 and C-180/96), the Court of Justice stated that:

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."

This conclusion has subsequently been confirmed by further rulings of the Court of Justice and the Court of First Instance.

Furthermore, the Commission's view is that the use of the 'precautionary principle' is sanctioned by the SPS Agreement, although the term itself is not explicitly used. Broadly, this views seems to be supported by the Appellate Body which has stated that, although the 'precautionary principle' cannot be invoked as a general principle of international law to limit the obligations of the SPS Agreement, it is reflected in the text of the Agreement (WTO 1998a). Furthermore, in determining whether there is sufficient scientific evidence, at least where there is risk of damage to health, prudence is a valid approach.<sup>4</sup>

Within the context of the EU, the application of the 'precautionary principle' is seen to involve a three-stage iterative process (Carr 2000):

- A risk assessment is undertaken to identify potential risks to human, animal or plant life or health. If the scientific evidence is insufficient, inconclusive or uncertain and there are reasonable grounds for concern, the precautionary principle may be invoked.
- In the light of the risk assessment and the remaining uncertainties a decision is taken whether to invoke the 'precautionary principle'. This needs to balance the freedom and rights of suppliers with the actions required to achieve the desired ALOP, the acceptability of the risk and, in certain circumstances, public opinion.
- If the 'precautionary principle' is adopted, the measure to be applied needs to be selected from those available. Possible measures range from regulatory actions to the initiation of a research project or forms of risk communication. The Commission specifies that such precautionary measures should be: (i) proportional to the ALOP; (ii) non-discriminatory in their application; (iii) non-discriminatory in their application; (iv) consistent with similar measures already taken; (v) based on an examination of the potential costs and benefits of action or lack of

<sup>&</sup>lt;sup>4</sup> It is evident, however, that under the SPS Agreement, the adoption of precautionary measures is a right rather than an obligation.

action; and (vi) subject to review in the light of new scientific evidence.

The Commission, therefore, clearly sees the 'precautionary principle' as not negating the need for science-based risk assessment, but an additional stage once an assessment has been undertaken. Furthermore, it is risk assessment that indicates the potential need for the 'precautionary principle' to be applied, by indicating potential harmful effects on human, animal or plant life or health combined with uncertainties in the available science. Similarly, the choice of precaution-based SPS measures is based on science-based principles and obligations under the SPS Agreement, as detailed in point (iii) above.

In contrast, decisions regarding the application, or not, of the 'precautionary principle' itself are seen as political, taking into account the desired ALOP and other salient factors, including public opinion. The Commission's communication, however, says little about how such political and other considerations can be integrated in a structured way with science-based risk assessment. This is the issue that is of most concern to many of the EU's trading partners and in their eyes, therefore, it tends too raise almost as many questions as it answers.<sup>5</sup>

A key message that comes from the Commission's communication is the central role of scientific evidence and risk assessment in the application of the 'precautionary principle'. Furthermore, it promotes the view that scientific uncertainty is generally temporary and can be overcome in time through further research (Carr 2000; Wynne 2000). This suggests that the precautionary principle is regarded as a temporary measure, and thus in accordance with the SPS Agreement.

A key question regarding the 'precautionary principle', as defined by the European Commission, is the extent to which it differs from the precautionary approach that many high-income countries

<sup>&</sup>lt;sup>5</sup> The USA, for example, has responded to the Commission's Communication with a list of questions regarding such elements of the document in discussions within the OECD and *Codex Alimentarius*.

purport to apply (see, for example, OECD 2000). Precaution or prudence is generally accepted to be a routine element of risk assessment, whereby conservative assumptions are applied where there is uncertainty in scientific evidence.<sup>6</sup> The 'precautionary principle', however, is regarded as an element of risk management and additional to any elements of precaution inherent to the process of risk assessment, which is invoked when a full assessment of the risk is not possible and the chosen ALOP may be in jeopardy.

It has been suggested that adoption of the 'precautionary principle' represents a shift in the burden of proof, by requiring the safety of an activity to be proven before it is permitted (Mathee and Vermersch 2000). Traditionally, policy-makers have applied the preventive principle, which is based on scientific proof that a violation of preventive measures will result in the occurrence or increase of damage to human, animal or plant life or health. Thus, the preventive principle requires scientific identification of the risks involved, perhaps after having incorporated a specific safety factor to allow for scientific uncertainty regarding the level of risk. The 'precautionary principle' on the other hand allows, and might even oblige, governments to adopt measures, in the absence of scientific certainty, if a reasonable risk of serious and/or irreversible damage exists. It implies that a certain activity is assumed to be dangerous until proven safe. It has been suggested that this may conflict with obligations under the SPS Agreement, which require Members that adopt a measure to demonstrate the scientific rationale on which they are based (Matthee and Vermersch 2000).

The European Commission's policy on the application of the 'precautionary principle' has not been without its critics within the EU. There are concerns, for example, that the 'precautionary principle' is open to 'misuse' by organisations with a vested interest in exaggerating the hazards and dangers of new technologies (Gremmen and van den Belt 2000a; 2000b). It is thus feared that the

<sup>&</sup>lt;sup>6</sup> Examples include: (i) use of safety factors when extrapolating the results of animal-based studies to humans; and (ii) use of safety factors and/or algorithms to extrapolate from Lowest Observed Effect Levels to No Observed Effect Levels.

principle will become devalued if there are insufficient safeguards to prevent this occurring. Furthermore, the European Parliament Committee on the Environment, Public Health and Consumer Policy has emphasised the need for the Commission to clearly define the 'precautionary principle' if the concept is to be successfully applied (European Parliament 2000).

It is evident that there are very different views on the meaning of the 'precautionary principle' and the legitimacy of applying it to risk management decisions between the EU and its major trading partners (OECD 2000). For example, the United States has voiced concerns about the potential for the 'precautionary principle' to be used as a disguised form of trade protection. Furthermore, it has emphasised the need for transparency in any application of precaution where decisions regarding SPS measures are not fully supported by current scientific evidence (Agra Europe 2000). There have been efforts, however, within the Codex Committee on General Principles to derive a generally acceptable definition, at least in the context of food safety. Most notably, the US, EU, and certain other Members have proposed the following (Codex Alimentarius 2000):

"When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food<sup>7</sup>, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect health of consumers without awaiting additional scientific data and a full risk assessment......"

However, an alternative definition has been proposed by other Members, most notably Malaysia:

"Where relevant scientific evidence is insufficient, precaution can be exercised as an interim measures to protect the health of consumers. However, additional information for a more

<sup>&</sup>lt;sup>7</sup> It is recognised that hazard identification is a crucial step in this process.

<sup>&</sup>lt;sup>8</sup> Some Members refer to this as the 'precautionary principle'.

objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe."

Both definitions have been inserted into the draft Codex Working Principles as alternatives, which have been returned from step five to step three of the standards-setting process. It should be emphasised, however, that a number of Members continue to contest that the concept of a 'precautionary principle' is not generally recognised or defined in relation to food safety and that precaution is anyway inherent to the risk analysis processes as recognised in the current Working Principles. It is evident, therefore, that the 'precautionary principle' will remain a dominant issue in relations between the EU and its major trading partners.

A good example of the application of the 'precautionary principle' in the EU is the regulation of genetically-modified (GM) crops (see Box 6.2). In the face of considerable political and social pressure, the Commission has been forced to adopt a highly cautious approach to the approval of GM crops, despite the fact that this has created tensions with some of its major trading partners, in particular the US. The implication is that the approval of GM varieties of, for example, maize in the EU lags behind that in other developed countries (Table 6.1). Furthermore, it reflects a fundamental shift in the focus of the debate over the regulation of these products from a burden of proof that they do not pose a risk to human health towards positive scientific evidence that they are safe.

#### 'Other legitimate factors'

A second concern that has been raised by the EU's major trading partners is the role of factors other than science in decisions regarding the implementation of SPS measures, specifically as part of risk management. Whilst the Commission emphasises the prominent role of science-based risk analysis, it also acknowledges that (CEC 2000b):

".... other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade can also be taken into account."

Table 6.1: Approval of genetic-modification processes for maize in various countries as of October 2000

Process	Country			
	USA	Japan	EU	Canada
Mon810	~	<b>~</b>	~	<b>~</b>
T25	~	~	~	<b>~</b>
Mon810/T25	~	<b>~</b>	х	<b>~</b>
GA21	~	~	х	<b>~</b>
DBT418	~	<b>~</b>	х	<b>~</b>
DLL25	~	~	х	<b>~</b>
T14	~	<b>~</b>	х	<b>~</b>
CBH351	~	х	х	~
E176	~	~	~	~
Bt11	~	~	~	<b>~</b>
Mon810/GA21	~	<b>~</b>	х	<b>~</b>
Mon809	~	х	~	<b>~</b>
Mon202	~	х	х	<b>~</b>

The Commission gives examples of such 'other legitimate factors', including environmental considerations, animal welfare, sustainable agriculture, consumer expectations regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods.

#### Box 6.2: Regulation of GM crops in the EU

The EU has adopted a cautious approach to the regulation of genetically-modified (GM) crops, arguably more cautious than other major trading nations such as the US, Canada, Australia and New Zealand. Within the EU, regulation of GM crops is supposed to proceed in a step-by-step manner, with precaution being progressively relaxed as more experience is gained and initial uncertainties reduced through research (Carr, 2000). In reality, however, as GM crops have become available for commercial exploitation, precaution has actually been tightened, reflecting growing objections to these products in a number of Member States, most notably Denmark and Austria. Furthermore, when GM crops have actually been introduced to the market, for example soya beans in 1996-97, objections have intensified across most Member States. This is reflected in the level of media attention given to GM crops.

In response to these concerns, control measures have been implemented by commercial companies and/or Member State governments. Examples include labelling requirements and monitoring of environmental impacts. Subsequently, many of these initiatives have been adopted by the European Commission and become Community-wide requirements. For example, shipments of grains must be labelled unless conventional and GM crops are segregated, or the grain used only for animal feed. Furthermore, there have been considerable delays in the approval of new GM crop varieties. Indeed, no new products have been approved since June 1998 (Table 6.1).

The regulation of GM crops in the EU has concerned many of its major trading partners, most notably the US and Canada, who have questioned the scientific basis on which these controls are based. They argue that there is no scientific evidence that GM crops harm to human health or the environment. Some critics have gone further and accuse the EU of taking protectionist measures to enable the European biotechnology sector to 'catch-up' with its North American competitors (Carr 2000). The Commission, however, has defended its actions by reference to the 'precautionary principle' which (it is claimed) is established in international law, at least with respect to protection of the environment.

The Commission and a number of Member States have undertaken risk assessments of GM crops, although with a more broad focus than, for example, in North America. However, there is an on-going debate within the EU over the range of potentially harmful effects of GM crops that should be included within the scope of a risk assessment. The potential indirect effects of GM crops were initially excluded from these assessments, even though some Member States (for example Denmark) considered them to be relevant considerations. More recently, however, a growing number of Member States (for example UK and France) have pressed for the risk assessment of GM crops to have a broader focus, in line with consumer concerns. For example, the Commission has argued that the potential spread of herbicide-tolerant weeds as a result of the introduction of GM crops is not a harmful effect, but merely a normal economic problem for farmers. Some Member States, however, regard agriculture as part of the natural environment and that such effects are a relevant component of a risk assessment (Carr 2000).

Furthermore, the EU and certain other Members have promoted discussion within the Codex Committee on General Principles on the role of factors other than science in risk management. The current draft Working Principles includes a reference reflecting this, although it is acknowledged that there will need to be considerable redrafting before agreement can be reached on this point within Codex (Codex Alimentarius 2000):

"Risk management should follow a structured approach, be grounded on science-based risk assessment and take into account other legitimate factors as appropriate. ....."

The Commission is aware that the incorporation of such factors into the process of risk analysis may fall foul of its commitments under the SPS and TBT Agreements and has attempted to focus on the relationship between these 'other' factors and environmental and consumer protection. A case in point is animal welfare (CEC 2000a), which the Commission has attempted to align with the activities of the proposed European Food Authority whose remit is food safety, and which it has said "need to be integrated more fully into food policy" (CEC 2000b). This reflects recognition within the Commission that the rationale for taking such factors into consideration in the development of SPS measures must be, at least in part, science-based if tensions within the WTO are to be avoided.

A good example of the role of 'other legitimate factors' within the EU is the regulation of Recombinant Bovine Somatropin (rBST) (see Box 6.3). In this case, first concerns about the impact on the market for dairy products, and in particular farm incomes, and subsequently the implications for animal health and welfare have motivated the measures applied – a moratorium followed by a ban on use of rBST. Furthermore, the Commission has pursued this line of reasoning in negotiations over Maximum Residue Levels (MRLs) for rBST in Codex Alimentarius, which have been rejected by most other Members.

## Box 6.3: Regulation of Recombinant Bovine Somatropin (rBST) in the EU

Recombinant Bovine Somatropin (rBST) is the manufactured form of BST, which naturally occurs in cow's milk. The manufactured form is a genetically-engineered synthetic analogue of the natural hormone which can be employed to boost milk yields and, therefore, is subject to EU requirements for the approval of veterinary medicines. The use of rBST has been subject to a moratorium in the EU since 1993, although foods produced using rBST can be imported from Third Countries. On 16 December 2000, a permanent ban on the use of rBST in the EU was introduced.

A total of 20 countries permit the use of rBST, including the US, Mexico and South Africa (Bureau and Doussin 1999). The use of this hormone has, however, been controversial even in countries where its use is widespread (Jarvis 2000; McGuirk and Kaiser 1991; Kronfeld 1993). Concerns encompass three main issues: 1) safety of milk produced using rBST; 2) impact on the health and welfare of dairy cattle; 3) impact on the milk markets, in particular incomes of small producers. These concerns have been voiced even more strongly in countries that do not currently permit the use of rBST, including the EU and Canada.

Although concerns have been raised in the EU about the safety of milk produced using rBST, to date no firm evidence has been presented of any detrimental affect on human health. Indeed, the Committee for Veterinary Medicinal Products concluded in 1993 that rBST is safe for use (CEC 1993). Furthermore, in July 1999 the European Medicine Evaluation Agency Committee determined that "there are no public health grounds for establishing a Maximum Residue Level for BST", reaffirming that Third Countries that use the hormone could continue importing dairy products. The Commission is, nevertheless, funding further studies into the impact of rBST on human health in an attempt to bridge 'gaps' in current scientific knowledge (Agra Europe 1999).

The original rationale of the moratorium on the use of rBST in the EU was concern that it would exacerbate existing milk surpluses. Subsequently, however, the continuation of the moratorium and introduction of a permanent ban on its use has been based on animal health and welfare considerations. In particular, there are concerns that use of rBST increases the risk of mastitis, foot and leg disorders and reproductive problems, as well as potentially severe reactions to the injection of the hormone itself.

Codex Alimentarius has attempted to agree MRLs for rBST, but these were blocked in 1995, 1997 and 1999, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has confirmed it is safe. The vote to defer a decision has on each occasion been based predominantly on the concerns of certain Members regarding either the impact on animal health/welfare and/or the fact that the safety of milk produced using rBST has not been proven. Furthermore, the Commission has pressed for "other legitimate factors than scientific analysis" to be taken into consideration, although this has not been endorsed by most other delegations (Bureau and Doussin 1999).

#### Conclusion

This chapter has provided an overview of the concept of ALOP as applied in the EU and the social and political environment within which it is determined in the EU context. Whilst all developed countries undoubtedly strive to achieve a high level of protection, it is evident that the perspective of the EU differs to that of its major trading partners, most notably the US. In particular, whilst science-based risk assessment is central to the regulatory process, other factors play a more prominent role, both in terms of the level and manner in which precaution is applied and the range of socioeconomic factors regarded as salient in determining the ALOP. In turn, this is reflected in the SPS measures that are applied, particularly in the case of food safety, as the selective cases illustrate.

The EU's approach to determining the ALOP has raised tensions in bilateral relations with a number of Third Countries, with claims that it uses SPS measures in a manner that is protectionist and which may be incompatible with the SPS Agreement. In response, the Commission has attempted to both justify and clarify its position through, for example its Communication on the 'precautionary principle' (CEC 2000a). Furthermore, the Commission has made efforts to engender recognition of the 'precautionary principle' and 'other legitimate factors' in determining the ALOP within Codex Alimentarius. It is evident, however, that, whilst these efforts have served to fuel debate on these issues, considerable differences in opinion remain between the EU and its major trading partners, and that these are likely to be the source of friction into the future.

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# The 'appropriate level of protection': an Australian perspective

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The appropriate level of sanitary or phytosanitary protection, otherwise referred to as the acceptable level of risk, is defined in the WTO Agreement on the *Application of Sanitary and Phytosanitary Measures* as the "level of protection deemed appropriate by the [WTO] Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." It is well established that the determination of its appropriate level of protection is a matter in which the national sovereignty of a Member prevails, consistent with Article 2.1 of the Agreement which says that "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health." However the SPS Agreement requires that "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects" (Article 5.4).

Members are also obliged, under Article 5.5 of the Agreement, to "avoid arbitrary or unjustifiable distinctions in the levels [considered] to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction as

<sup>\*</sup> The views expressed are the author's and are not necessarily those of the Department of Agriculture, Fisheries and Forestry – Australia or of Biosecurity Australia (the unit within the Department which is responsible for import risk analysis).

international trade." No guidance is provided by the Agreement on what might constitute an arbitrary or justifiable distinction or as to what kind of justification might be offered. However the statement in the same paragraph that in developing guidelines to further the practical implementation of this provision, the SPS Committee "shall take into account all relevant factors including the exceptional character of human health risks to which people voluntarily expose themselves" strongly implies that these risks might justifiably be managed in a different way from other sanitary risks.

"Risk" is not defined, but from the definition of risk assessment in Annex A of the SPS Agreement it is clear that risk is to be regarded as a function of both the potential for entry, establishment and spread of a pest or disease in an importing country and the magnitude of the consequences. There is no suggestion that risk in this context is to be considered in a relative rather than an absolute sense.

## Elaborating the concepts in the SPS Agreement

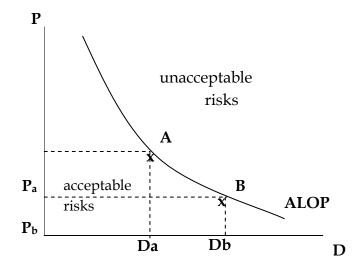
Drawing these elements together, and expressing their implications in a practical way, a WTO Member may understand its obligations in relation to ALOP to be as follows:

- all SPS measures applied by a Member which are intended to protect animal or plant life or health should reflect a consistent approach to risk management, consistent at least to the extent necessary to avoid discrimination or a disguised restriction on international trade;
- a similar consistency of approach must be followed with respect to human health risks, save for exceptional risks which are voluntarily accepted;
- the Members must decide, therefore, what ALOP will be the goal across the board for all measures intended to protect animal and plant health, and similarly for human health, and apply the relevant ALOP uniformity; and

 ALOP for a Member should restrict trade as little as possible so long as the necessary health protection can be achieved by the measures applied.

In simple graphical terms, a Member's ALOP can be thought of as the boundary between points in a two-dimensional (probability/consequences) space which reflect either acceptable or unacceptable levels of SPS risk associated with particular trade flows, as shown in Figure 7.1.

Figure 7.1: Relationship between the probability of disease importation and its consequence



Consistency in risk management requires that the line representing ALOP be some kind of iso-quant such that where SPS measures are necessary to limit risk associated with trade in commodities A and B, the result is that a similar degree of risk is accepted i.e. Pa x Da equals Pb x Db where P is the probability of damage occurring and D is the amount of damage measured in some appropriate unit. Points below the ALOP line would generally represent risk associated with trade in commodities for which no SPS measures need be applied. Exceptionally points below the line might also reflect risk in situations where SPS measures do have to be applied but the only measures available which are technically and economically feasible cause risk reduction to overshoot acceptable

risk. At the origin are clustered all those potential trades which cannot occur because the only measure or set of measures which is capable of reducing risk to an acceptably low level is one which is so strict as to effectively prevent trade from occurring. All other points illustrating actual risk associated with trade where SPS measures are applied must be on the line; otherwise the measures being applied would not be the least trade-restrictive consistent with maintaining ALOP. Points lying above the ALOP line represent all potential commodity trades for which measures would need to be applied to reduce risk to an acceptably low level.

Rationally a WTO Member would wish to position its ALOP frontier so as to maximise the ratio of net benefits from trade (taking into account differentials in consumer and producer surpluses attributable to trade) to the associated risks of damage from introduction of exotic pests and diseases. The choice of discount rate might have some bearing on the optimal position if there is reason to believe, for example, that the stream of net benefits from trade is likely to occur sooner than the stream of costs from pest or disease incursions (at least for those pests and diseases which take some time to establish and spread to the point of becoming economically important). Superficially, it is not impossible that a more optimal position may be obtainable by a Member choosing to either raise or reduce its ALOP.

As noted above, according to Article 5.4 of the SPS Agreement, a Member must take into account the objective of minimising negative trade effects when determining its ALOP. The theoretical optimisation strategy described here does take into account the maximisation of net benefits of trade and therefore, presumably would conform with Article 5.4.

It is conceivable that a Member may from time to time wish to reposition its ALOP. A new government may be elected with a different attitude to risk acceptance than its predecessor; or a significant change in national pest or disease status (such as the successful eradication of a disease which has been a major impediment to export sales) may have occurred. In this event, the objective of consistency would seem to require that appropriate

adjustments to the stringency of measures in place be made across the board; the revised ALOP cannot be reflected only in new SPS measures.

## An alternative interpretation

The outline given here is not the only interpretation that has been put on the relevant Articles and definitions in the SPS Agreement. Some have argued that it would be in conformity with the provisions of the Agreement for a Member to select an appropriate level of protection in relation to each decision it makes on the application of sanitary or phytosanitary measures. One advantage suggested for this approach is that it would allow the application of cost/benefit analysis on a case-by-case basis to optimise trade benefits over risks to animal/plant/human health.

Whether such an approach is acceptable in terms of Article 5.5 would depend upon the defence which would be offered against criticism that each such decision would be arbitrary or unjustified and, if discrimination or a disguised restriction on international trade resulted from the decision, would be in violation of the Article. In fact any such decision would also have to be tested against Article 2.3, which incorporates into the SPS Agreement the fundamental GATT tenets of national treatment and nondiscrimination. ("Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably Members where identical or discriminate between conditions prevail, including between their own territory and that of other Members.")

In reality, following this approach would result in a Member maintaining an SPS regime in which the degree of restriction by SPS measures on trade in a particular commodity from a particular country would reflect in part the relative economic competitiveness of domestically produced and imported supplies of the commodity. For example, quarantine controls on imports of a commodity from either of two countries which had the same disease status would have to be stricter on that supplier country which had the less efficient export industry because its product would contribute

relatively less to the creation of consumer surplus (net of any reduction in producer surplus) in the importing country. Similarly, SPS restrictions applied by the importing country would be modulated so as to be relatively less strict on commodities where the international competitiveness of the domestic industry was lowest.

It follows that commodity-by-commodity (or trade-by-trade) cost benefit analysis as a basis for establishing SPS measures cannot be consistent with the goal of a non-discriminatory GATT-type trade regime.

## **ALOP** in practice

In practice, no WTO Member has articulated its ALOP with any degree of precision, although there are one or two examples where responsible national authorities have given partial expression to acceptable risk in quantitative terms (e.g. the acceptable number of exotic pest incursions as a consequence of trade in a particular commodity over a specified period). In part this may be a reflection of the political sensitivity inherent in acknowledging that any level of risk is acceptable: stakeholders are likely to be more comfortable with a policy statement that risk of illness or death from, say, pesticide residues in food is to be minimised than with a statement that a certain number of illnesses or deaths per million of exposed population per year is regarded by government as acceptable. A much more important explanation, however, is that it is practically impossible for governments to provide any degree of precision in describing ALOP, either qualitatively or quantitatively. The reasons include the complexities of analysing risks involved with biological systems and the lack of relevant technical and economic data. Australian Governments have used various qualitative descriptors for the appropriate level of protection in relation to risks to animal or plant life or health. The terms used are typified by a statement such as "Australia takes a very conservative approach to the management of quarantine risk, with the intention of reducing risk to negligibly low levels." Recent work within the Department of Agriculture, Fisheries and Forestry - Australia has sought to find

ways of expressing Australia's ALOP more precisely, but this work has yet to bear fruit.

However, each WTO Member maintains SPS measures, and each of these measures is a reflection of a risk management decision. On this basis a Member's historical ALOP can theoretically be ascertained by scrutinising the measures it has put in place in the past and is still maintaining, in so far this set of measures reflects a reasonably consistent ALOP approach.

As to how WTO Member governments know that the ALOP being applied is optimal, it seems likely that this judgment is made not on the basis of detailed and comprehensive analysis of quarantine risks accepted and trade advantages foregone, but on the basis of the progressive accumulation of evidence on the performance of measures in place. Performance will be indicated by the number and significance of incursions of pests and diseases that are apparently attributable to failure of SPS controls, and by the apparent effect of SPS controls on volumes of trade (which, given appropriate analysis, are indicative of benefits to purchasers of imported goods). Normally such information will be in anecdotal form, and will be evaluated in an impressionistic way. Re-evaluation of ALOP is likely to be provoked by some shock, such as incursion of a pest or disease which may cause very significant damage.

Other considerations for government in judging whether the established ALOP is indeed appropriate may include whether the ALOP bears a rational relationship to other sources of sanitary or phytosanitary risk that are not capable of being addressed by the imposition of measures. Thus, for example, a WTO Member that is highly vulnerable to SPS risk by virtue of natural movements of pests or diseases across borders may see limited value in applying very strict border measures if their contribution to reduction of aggregate risk is small.

For those making the risk management decisions, policy guidance from the political level often may consist of the absence of any indication from government that the new measure being promulgated, or the existing measures in place, are unacceptable or inappropriate from a risk management perspective – in other words, "keep doing what you're doing unless we tell you to stop". Risk managers therefore make a judgement as to whether a proposed measure conforms with the national ALOP by making comparisons with other measures which are already in place and which have not attracted negative comment or been rejected by government. This approach at least has the advantage that it fosters consistency ("avoidance of arbitrary or unjustifiable distinctions," etc.) over time and across different sources of risk. The procedure is facilitated (as is conformity with the SPS Agreement) if risk management decision-makers make pair-wise comparisons between situations that are as alike as possible.

As a practical matter, risk management decisions almost invariably rely on expert judgement – that is, the judgement by experienced analysts of sanitary and phytosanitary risks. Greater quantification of risks is a goal for many government agencies which have responsibility for designing and applying SPS measures, but the lack of essential empirical data greatly constrains use of the good methodology available for this purpose.

#### Conclusion

The concept of appropriate level of protection is central to the SPS Agreement. It is readily apparent that if effective disciplines of the kind set out in the Agreement were not applied to risk management via the provisions relating to ALOP, the Agreement's ability to prevent egregiously trade-distorting actions would be crippled. Economic analysis has a useful role to play in further teasing out the meaning and implications of the ALOP concept, and in particular its relationship to the theory of comparative advantage, the proper treatment of externalities (SPS measures have the effect of both limiting and internalising the cost of externalities such as pest/disease risks), and so forth. While there is arguably no scope for economic analysis to contribute to decision-making on individual measures via cost/benefit analysis, it remains possible that analysis along these lines could make a significant contribution to the examination of ALOP *per se*, especially if it were possible to

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conduct an array of studies on the benefits and costs of measures applied to a representative basket of SPS-restricted imports.

# The 'appropriate level of protection': a New Zealand perspective

HUGH R. BIGSBY

One of the outcomes of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) was the provision for reductions in a range of agricultural trade barriers. In particular, certain types of barriers, such as tariffs, export subsidies, embargoes, import bans, quotas, supply management regimes, domestic price supports, licensing and exchange controls, were able to be dealt with by converting them into 'tariff-equivalent' levels of protection through a system of 'tariffication'. The key success of this approach was that different 'quantifiable' trade barriers could then be compared, reduced or negotiated in a common framework of tariffs. What remained to be resolved after the Uruguay Round were a range of trade barriers that were largely non-quantifiable in terms of tariff-equivalent levels of protection. These barriers, termed 'Technical Barriers to Trade' (TBT), included rules and standards directed at health, safety or the environment.

A key feature of TBT's, which differentiates them from quantifiable trade barriers, is that they are not specifically targeted at trade or production issues. Under GATT rules, countries are "generally allowed" to adopt health, safety or environmental policies which take precedence over other rules. The caveat to this, however, is that these policies are only allowed as long as the purpose of the policy or standard is to meet a legitimate domestic objective, and as long as domestic and foreign producers are treated in the same manner.

Among the most prevalent types of TBT's are those that deal with concerns about human, animal and or plant health (Hillman 1978, 1991). With the reduction in quantifiable barriers to trade, concern has been raised that countries will turn to TBT's as a way of blocking imports rather than just meeting legitimate sanitary and phytosanitary concerns (Ndayisenga and Kinsey 1994). This concern has led to major efforts internationally to ensure that sanitary and phytosanitary measures do not evolve as major trade barriers.

Under the World Trade Organization (WTO), TBT's related to animal and plant health issues are dealt with under the Sanitary and Phytosanitary (SPS) Agreement. Under the umbrella of the SPS Agreement, the International Plant Protection Convention (IPPC) has produced standards for determining the 'appropriate level of protection' (ALOP), or justified quarantine measures, for plants (FAO 1996). The major problem faced by the IPPC is the lack of a system that can convert diverse technical or scientific barriers related to plant health into a common framework which would allow comparison of quarantine measures within a trade, or economic, forum. A common theme of the activity of the IPPC is a need to develop systems that will provide a measure of the ALOP. This in turn will show whether health or phytosanitary standards are being imposed in a way that is consistent with both internal and external standards.

Another important change with the Uruguay Round's SPS Agreement has been a move to focus on risk assessment and management with an overall objective of minimising negative trade impacts (Papasolomontos 1993). This is a considerable departure from past practice in the quarantine area. Historically SPS has been the domain of scientists, and the key criteria for applying trade barriers has been an assessment of probability of occurrence (Smith 1993; Patterson 1990). This is an objective, but one-sided, application of standards in a trading environment. Under the Uruguay Round, risk consideration assessment now requires of consequences as well as probability of occurrence. In addition, risk management now requires the consideration of trade-offs in probability of establishment and economic consequences, and in the context of choosing the least trade-distorting path.

This chapter presents a risk analysis system, an iso-risk framework, which addresses the problems created by TBTs in the post-Uruguay Round environment. The iso-risk framework does this by combining the key elements of risk analysis, probability of occurrence and economic impact, into a single analytical system, providing a quantifiable measure of the level of protection associated with a quarantine measure.

#### An iso-risk framework

The major problem presented by TBTs is the lack of a system which can convert diverse technical barriers related to plant or animal health into a common framework which allows for comparison in a trade forum. What kind of a measure will adequately combine the key features of risk analysis, risk of introduction and economic consequences, in a way that facilitates comparison and negotiation? The greatest need is to convert barriers to values that are common in a trade environment, typically currency measures. A way to elicit the value of a TBT is by measuring implicit or explicit economic effects that are created by the barrier. This could be done in the context of measuring the value of events related to a TBT. Examples of this could include measuring the additional costs associated with compliance with a regulation, new labelling or packaging, or reducing residues. This could also be done in the context of measuring the value of an outcome without a technical barrier in place. In this case the consequences of an economic impact such as a pest infestation could be measured.

An important component of assessing risk or levels of protection is a methodology that uses both economic effects and probability of introduction to manage risk (FAO 1996). Although the FAO's draft standards do not specify how to combine economic effects and probability of introduction, the implication is that they should be considered together to measure 'pest risk'.

A common way for these two factors to be combined is to calculate pest risk as,

Pest Risk = Economic Effect x Probability of Introduction

Use of both the probability and consequences of a particular event to express risk appears in many areas of risk analysis (Kaplan and Garrick 1981, Cohrssen and Covello 1989, Miller *et al.*. 1993, Ministry of Health 1996). The framework discussed here follows this approach and comes from discussions during the development of the draft Pest Risk Analysis Standards by the IPPC working group (Orr 1995) and has been further developed in New Zealand (Bigsby 1996; Bigsby and Crequer 1998; Bigsby and Whyte 1998, 2000).

Calculated this way, pest risk represents the expected value of the economic effect of pest introduction during the time period for which the probability of introduction has been assessed. If a quarantine authority used this definition for pest risk, risk management options would be considered in the context of some benchmark or acceptable level of pest risk (equivalent to ALOP) and the need to alter the probability of introduction or the economic consequences of establishment. A critical component is the establishment of a benchmark level of acceptable pest risk, so that subsequent management strategies can be systematically evaluated against the benchmark.

## Pest versus commodity risk assessment

Many quarantine risk assessments focus on the risk associated with a particular pest. However, trade restrictions and most pre-entry quarantine measures are directed at entire commodities rather than particular pests. In this chapter, 'commodity' refers to a specific product and country/pathway combination. The important distinction here is that commodities with more types of pests will represent a greater risk, per unit, than commodities with fewer types of pests. A purely pest-based analytical approach, while useful for some types of analyses, such as categorising pests into quarantine and non-quarantine, may not give a measure of the overall risk associated with a commodity.

Commodity-based risk assessments, such as those produced by the USDA (USDA 1996), rely on assessments of each pest associated with a commodity. Similarly, ALOP can be defined for a commodity by considering the appropriate levels of protection for each

individual pest of the commodity. Given the distinction between the two different approaches, risk assessment for individual pests and commodities will be discussed separately.

#### Pest evaluation

The iso-risk framework for individual pests is illustrated in Figure 8.1. Pest 1, with an economic impact of EI1 and a probability of establishment of r1, has a pest risk¹ of PR1, where

$$PR1 = EI1 \times r1$$

Pest 2 has an economic impact of EI2 and a probability of introduction of r2. As can be seen in Figure 8.1, different pests, having different potential economic consequences and probabilities of introduction, may still share the same value of pest risk. Both PR1 and PR2 lie on the same line where all combinations of (EIi x ri) have the same value (hence, the 'iso-risk' line). Note that the iso-risk line is straight only when both the x and y axes are plotted with logarithmic scales.

A key requirement for carrying out risk assessment, or determining entry conditions, is a pre-determined benchmark level of pest risk, or ALOP, from which to base decisions. In Figure 8.1 there will be an infinite number of iso-risk lines representing different levels of pest risk, with higher iso-risk lines indicating higher pest risk. Iso-

Pest risk is depicted in Figure 8.1 as a point estimate or single value. This is done for purposes of illustration in developing the general methodology in this chapter. In practice, there would be a problem in providing only a point estimate because it gives no quantitative picture of the uncertainty surrounding either the probability of establishment or economic impact values used in the pest risk estimate. This means that there is no information on whether a particular estimate represents the most likely value, or one of a host of equally likely values over a wide range (for example, Cohrssen and Covello 1989). Since pest risk is actually based on a probability distribution for both risk of introduction and economic impact, rather than being a point estimate, a plot of pest risk would be an area. Given a distribution of outcomes, a decision maker would be in a position to make a better-informed assessment of the appropriate management actions for a particular pest than with only a point estimate.

risk lines allow pests to be compared to each other, and compared to a particular acceptable level of pest risk. This ability to compare in turn provides the basis for determining appropriate actions. In particular, the result of pest risk management should be a pest risk that does not exceed the ALOP, with a reasonable level of confidence. In the context of Figure 8.1, since all points on an iso-risk line have the same expected value, the ALOP represents the highest iso-risk line that will be accepted by a quarantine authority.

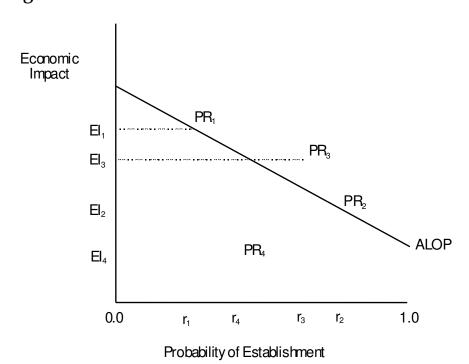


Figure 8.1: Iso-risk framework

Given this definition, individual pests can be evaluated against an ALOP. If the pest risk of a particular pest is greater than the ALOP, actions should be taken to reduce pest risk to the ALOP. For example, if the iso-risk line in Figure 8.1 has been determined to be the ALOP, a pest with a pest risk of PR3 would be subject to actions to reduce the risk to acceptable levels. The pest corresponding to PR4 falls within acceptable limits, and requires no additional quarantine actions.

## Commodity-based risk assessment

The pest risk of a commodity (PRC) can be considered as the cumulative expected value of all the associated pests for that commodity. If PRC is the expected value of pest risk for a commodity, then,

$$PRC = \sum_{i=1}^{n} (Ri \times Ei)$$

where Ri is the probability of establishment of pest i, Ei is the economic impact of pest i, and n is the number of pests associated with the commodity. Since PRC is the sum of a number of individual pest risks, it can take any value from 0 to  $\infty$ , as is shown in Figure 8.2.

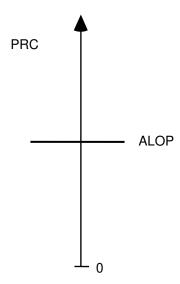
With this approach, a quarantine authority could consider commodities having similar values of PRC, regardless of the number or type of pests involved, with the same level of concern. A benchmark ALOP can also be defined for commodities as follows: the ALOP is the highest value of commodity pest risk that will be accepted by a quarantine authority.

In Figure 8.2, the ALOP would represent a cut-off point on the axis. Appropriate entry conditions would ensure that the commodity risk does not exceed the ALOP with a reasonable level of confidence.

## Application of the iso-risk framework

The discussion thus far has been based on what is effectively a quantitative assessment of risk, or one that consists of a continuous set of numeric values from which to estimate ALOP (the iso-risk line). Some quarantine agencies have developed qualitative rather than quantitative guidelines for pest risk assessment. For example, APHIS-PPQ in the US has produced a set of guidelines that identify pest risk in terms of high, medium or low (USDA 1996). The difference between the two approaches is that a measure of pest risk based qualitative values results in discrete, categorical values.

Figure 8.2: Commodity pest risk (PRC)



As long as pest risk is expressed in terms of probability of introduction and economic impact though, either approach can be expressed in terms of the iso-risk model. Applications of both the quantitative and qualitative approaches to risk assessment using the iso-risk framework are provided in the following sections.

## Quantitative risk assessment

Whyte (1998) provides an application of the iso-risk framework to Mediterranean fruit fly, *Ceratitis capitata*. Risk assessments for the Mediterranean fruit fly were used to examine risk assessment and management for pests entering New Zealand by both commercial and non-commercial pathways. The risk assessments showed that with no quarantine measures the annual probability of introduction was effectively 1.0. The economic consequences to producers of Mediterranean fruit fly establishment on an annual basis, after population stabilisation, were predicted to be \$100 - \$130 million (Whyte 1998). Using a midpoint for economic impact of \$121 million, the initial pest risk is \$121 million. This is shown as Point 1 in Figure 8.3, lying on an iso-risk line for \$121 million.

For commercial pathways, the introduction of a probit 9 treatment or area freedom reduces the annual probability of introduction to about 0.0017 and the pest risk becomes \$206,000. This is shown as the horizontal shift of pest risk from the initial position to the new probability of introduction at Point 2 in Figure 8.3 lying on an isorisk line for \$206,000. For non-commercial pathways, the introduction of x-ray machines to international airports has reduced the annual probability of introduction to about 0.02 and the Pest risk becomes \$2.42 million. This is shown as the horizontal shift of pest risk from the initial position to the new probability of introduction at Point 3 in Figure 8.3 lying on an iso-risk line for \$2.42 million.

Figure 8.3: Quantitative risk assessment

Note: Both axes are plotted in log scales

While it might be tempting to imply from this limited example that New Zealand's ALOP lies between \$0.206 and \$2.42 million, additional measures to limit the risk of Mediterranean fruit fly establishment are also employed. In addition to the probit 9 treatment for commercial pathways and the use of x-ray machines for non-commercial pathways, a detection and response system for Mediterranean fruit fly is also provided. A surveillance system

consisting of trimedlure trapping has been put in place that allows for rapid detection and response to an establishment.

Using the cost of the 1996-97 Mediterranean fruit fly response of approximately \$5.3 million and assuming a five percent chance that an eradication attempt would fail even with the early warning system (Bigsby and Whyte 1998, Whyte 1998), the effect of this additional risk management system can be estimated. The early warning and eradication program further reduces the probability for either pathway that there would be an establishment that had an economic impact. In terms of the iso-risk model, this system means that the expected annual economic impacts would be reduced to approximately \$11.35 million for the either pathway. Given that the commercial pathway still has a probability of 0.0017 for an establishment, the new pest risk is \$19,300, shown as Point 4 in Figure 8.3. For the non-commercial pathway the probability of establishment is still 0.02 so the new pest risk is \$227,000, shown as Point 5 in Figure 8.3. This would reduce the implied ALOP based on this example to somewhere between \$19,300 and \$227,000.

# Qualitative measures of pest risk

As was mentioned previously, some agencies, such as APHIS-PPQ in the US, have developed qualitative guidelines for pest risk assessment. This results in discrete, categorical values to express pest risk. However, as long as pest risk is expressed in terms of probability of introduction and economic impact, qualitative values can be adapted to fit the iso-risk model.

An example of how this adaptation can work is the US pest risk assessment system (USDA 1996). Similar to the iso-risk framework, the US guidelines provide the basis for ranking pest risk based on potential consequence of introduction and likelihood of introduction. Rather than a dollar value though, potential consequence of introduction is comprised of five "risk elements". The risk elements, climate-host interaction, host range, dispersal potential, economic impact and environmental impact, are each given a score of high, medium or, with a score of high given 3 points, medium 2 points and low 1 point. A cumulative score for the

five risk elements is then calculated. A similar process is carried out for likelihood of introduction, but with only two risk elements, quantity of commodity imported and pest opportunity (survival and access to suitable habitat and hosts). In each case, the cumulative risk element score results in a new risk rating of high, medium or low, again with the same corresponding risk scores for each as before. In the last step of the process, likelihood of introduction and consequences of introduction are combined by calculating a cumulative value based on the risk score for each component. The cumulative value provides a pest risk potential, rated high, medium or low depending on the score.

If the raw risk scores for likelihood of introduction and consequences of introduction are used rather than the high, medium and low ranking, this system of scoring can be adapted to the isorisk framework. As is shown in Figure 8.4 the APHIS-PPQ system allows for a maximum score for consequence of introduction of 15 and for likelihood of introduction of 18. Based on how the APHIS-PPQ guidelines translate combinations of cumulative risk element scores for likelihood of introduction and consequences of introduction into risk management options, Figure 8.4 can also be separated into risk management zones (Bigsby and Whyte 1998).

If Figure 8.4 is put in the context of Figure 8.1, the similarities in terms of iso-risk and management options can be seen. With the cruder measures of economic impacts and probability of establishment, the iso-risk line becomes less distinct, but nonetheless can be defined in terms of combinations that represent acceptable levels of risk. The major difference from Figure 1 is that there is now a zone of risk that creates a wide bound in which the actual, but undefined, iso-risk line lies. This wide bound arises due to the wide range of values from the cumulative risk element scores for either the consequence of introduction or the likelihood of introduction which are collapsed in the US system. In Figure 8.4, the iso-risk line/zone is defined by the shaded cells. Pests with risk values in the shaded cells represent unacceptable levels of risk for which quarantine measures might be undertaken.

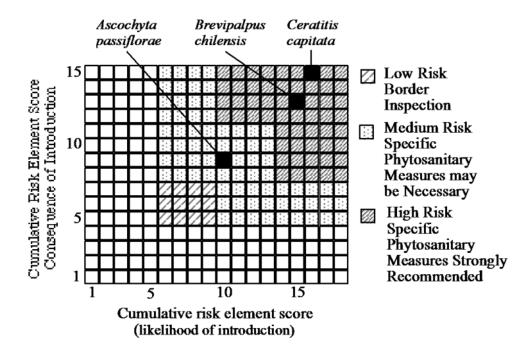


Figure 8.4: Qualitative risk assessment

An example of how a qualitative risk assessment could be adapted is a pest risk assessment for the import of Purple Passionfruit (*Passiflora edulis*) from Chile to the US (Firko and Podleckis 1996). Three potential pests associated with Purple Passionfruit were identified *Ascochyta passiflorae*, *Brevipalpus chilensis*, and *Ceratitis capitata*. Based on information provided by Firko and Podleckis (1996), the cumulative risk element scores for consequence of introduction and likelihood of introduction respectively are 9 and 10 for *Ascochyta passiflorae*, 13 and 15 for *Brevipalpus chilensis*, and 15 and 16 for *Ceratitis capitata*. These values are plotted in Figure 8.4.

Since Firko and Podleckis (1996) provide a qualitative risk assessment only, they made no attempt to suggest risk management options or to fit them within the risk assessment framework. The expectation would be that risk management would modify the likelihood of introduction. This would move the combined cumulative risk for each of the potential pests horizontally to the left far enough to provide an acceptable level of risk.

One complicating factor with the use of qualitative inputs is that the categorical values are derived from a range of factors (risk elements) that have no common denominator. This means that "expected value" from combining an economic impact and a probability is not applicable here. Risk scores for consequence of introduction and likelihood of introduction can still be multiplied, but the resulting is something different than an expected value. The combined risk rating can still be used to rank a pest and to form an iso-risk line, but only relative to this risk rating system.

## Methodological issues

The use of economic effects and probability of occurrence or introduction to calculate an expected value, while relatively straightforward, can only be done after considering what constitutes an appropriate measure of economic effects and probability of introduction. The iso-risk model described so far has been based on a broadly defined measure of economic impacts. There are however, a number of potential economic impacts that could be included in an assessment, ranging from potential pest-related damage to the benefits of lower world prices for commodities. This in turn raises the question about what the objective of the assessment should be, and in particular, whether it is designed to provide a safety standard or welfare maximisation. In a similar way, a broadly specified risk of introduction masks the fact that probability of introduction is related to the volume of trade. This raises a question of whether the risk assessment process is attempting to provide an envelope to risk or whether it will let risk fluctuate with trade levels.

# Safety standard versus welfare maximisation

One of the issues to be considered is what should be included under economic effects in the model. Generally speaking, there are two broad perspectives on what should be included, each related to the underlying objective of the analysis. One is that the objective of the analysis should be safety and that the development of a safety standard is a key outcome. The other is that the objective of the analysis should be welfare maximisation. Which of these

perspectives is chosen is important because it will influence which economic effects are measured and how they will be interpreted.

Before comparing these two perspectives, it is useful to look generally at how economic effects might be measured. In the context of pest risk assessment, at a basic level economic effects might be considered as either direct or indirect pest effects. Direct pest effects would be direct impacts of a pest on a host plant, and would cover host-specific impacts like yield loss or mortality. Indirect pest effects would be non-host specific impacts. These would be general effects that are created by the presence of a pest, but not specific to the pest-host dynamic, including public health issues, restrictions on traffic flow, key ecosystem function compromised, research requirements, market access problems, and tourism. At a broader level, economic effects could extend to the market for the products covered by the analysis, expanding the analysis to include consumers.

The types of economic analysis that are relevant are linked to the scope or level of economic activity that is being measured. Following the FAO (1996) guidelines, economic analysis can be grouped into partial budget, partial equilibrium, equilibrium and non-commercial/environmental analyses. Partial budget analysis is the narrowest in scope and deals mainly with changes to the profits of individual producers. Examples of this approach in quarantine risk assessment include Cowley et al... (1993), DPIE (1997), Whyte et al. (1995), Whyte and Cowley (1996), and Whyte et al. (1998). Partial equilibrium analysis is wider in scope than partial budget, dealing with a production sector as whole rather than individual producers. Examples of this approach in quarantine risk assessment include James and Anderson (1998), Roberts et al.. (1999) and USDA (1991). General equilibrium analysis extends the analysis to encompass an entire economy, and allowing the effects on wages, exchange rates and national welfare to be measured (as in chapter 16 in this volume). These approaches form a progression of analytical opportunities that are available as the scope of an impact increases, moving from the narrowest to the widest in scope.

With a safety perspective and safety standard objective, the key motivation is minimising the potential for negative outcomes. The focus on negative outcomes in turn means that the economic analysis would be limited to the measurement of the negative impacts of a potential pest on an economy. This limits what is considered in an economic analysis rather than the level of the analysis. Since economic effects are linked to how a pest or disease manifests itself, the extent of physical effects a pest has on a host, the number of potential hosts, the effect of existing control measures, and the effect of existing management practices becomes important. In terms of the iso-risk framework, the safety standard objective means reducing potential negative effects towards an identified ALOP. An important outcome of this approach is that the benchmark for decisions (safety standard or ALOP) is constant across all decisions.

With a welfare maximisation perspective, the objective becomes one of welfare maximisation rather than attempting to meet a particular standard. Benefits to consumers, as well as negative impacts on producers would be considered in the analysis. A possible outcome of this approach is that quarantine measures would be rejected because consumer benefits outweighed producer costs. The problem with this perspective as tool for setting quarantine policy is that the decision on how any particular commodity would be treated would depend on the nature of the market for the commodity.

The Mediterranean fruit fly example discussed earlier provides an example of the issues raised in adopting a welfare-maximising approach rather than a safety approach to determining quarantine standards. The two pathways in this example could instead be two different commodities that carried the same pest but presented different risks. Using the safety approach, both commodities would be subject to sufficient and possibly different quarantine measures to reduce their pest risk to a common acceptable level. Under the welfare-maximising approach, if the commodity which had a high probability of introducing the pest also provided a higher net welfare gain to consumers if it was unregulated rather than regulated, the commodity would be unregulated. This would compromise the effect of the quarantine measure imposed on the other commodity and raise questions about the justification of the measure.

## Global or individual appropriate level of protection

One factor that must be considered is the 'level' of risk that will be considered. The choices of level of risk for a regulator are (1) whether there is a desire to fix total risk associated with all trade within a given period, or (2) whether there is a desire to fix the risk associated with a particular commodity or pest. A key factor in this decision is the correlation between the likelihood of introduction of a pest and the volume of trade that is carried out.

In the case of fixing total risk associated with all trade, the regulator determines a maximum expected value that will be accepted, aggregated over all commodities imported during a particular period. In the case of fixing risk for particular commodities or pests, this means determining an acceptable level of PR or PRC. Combining all of these options creates a matrix of choices for a regulatory authority (Figure 8.5).

There are two different management options available for fixing total risk. A commodity-based management regime to fix total risk is shown by Box A in Figure 8.5. In this strategy, the regulator fixes the total acceptable risk over all trade, and then manages that risk by varying the acceptable risk for each commodity traded. In terms of the iso-risk framework, this is equivalent to determining a maximum sum for PRC over all n commodities traded.

Total Risk = 
$$\sum_{i=1}^{n} PRC_i$$

Management of total risk is then done by managing PRC for each commodity. This is typically done by altering the likelihood of introduction. In order to stay within total risk, as trade volume increases or new commodities are introduced, more stringent phytosanitary measures would be required for some or all commodities. This could be done through changing any of the many factors influencing introduction potential, including trade volumes.

Figure 8.5: ALOP matrix

	Commodity Risk Management	Pest Risk Management
Fixed Total Risk	A	В
Fixed Individual Risk	C	D

A pest-based management regime to fix total risk is shown by Box B in Figure 8.5. In this strategy, the regulator fixes the total acceptable risk over all trade, and then manages that risk by varying the acceptable risk for each potential pest. In terms of the iso-risk framework, this is equivalent to determining a maximum sum for PR over all n potential pests.

Total Risk = 
$$\sum_{i=1}^{n} PR_i$$

Management of total risk is then done by managing PR for each potential pest. This again is typically done by altering the likelihood of introduction.

In contrast to the fixed total risk, fixed individual risk means that the risk presented by any particular potential pest or commodity will be fixed, and the total risk will be variable, fluctuating with the level of trade. A commodity-based management regime to fix individual risk is shown by Box C in Figure 8.5. In this strategy, the regulator fixes the individual acceptable risk for a commodity, and then manages the risk directly for each commodity traded. In terms of the iso-risk framework, this is equivalent to determining PRC for each commodity traded, following the process discussed earlier. A pest-based management regime to fix individual risk is shown by

Box D in Figure 8.5. In this strategy, the regulator fixes the individual acceptable risk for a commodity, and then manages the risk directly for each pest. In terms of the iso-risk framework, this is equivalent to determining PR for each potential pest, following the process discussed earlier. In either case, total risk increases with the volume of trade.

In essence, fixing total risk means that individual risk is variable. This complicates management since management efforts must change with changes to trade volumes. This can be done either by modifying the risk accepted for the marginal product traded, leaving the risk accepted for earlier volumes at a higher level, or by modifying the risk of all products imported. In a practical sense, fixing total risk (either A or B) is likely to be an inappropriate basis for developing phytosanitary standards.

#### Conclusion

This chapter has presented a methodology, an iso-risk framework, for quantifying technical trade barriers that contain elements of risk of occurrence and economic impacts. The method provides a means for creating benchmarks and comparing quarantine treatments. This is an improvement on previous practice in that both economic and scientific criteria can be included in an analysis. This ensures that barriers can be treated on the basis of expected outcome rather than the technical characteristics of the barrier. As such, it is possible to move beyond simple considerations of whether the barrier involves an insect or a bacteria, and instead focus on whether a potential event behind the barrier is above, below or within an expected dollar value.

The iso-risk framework provides a solution to some of the problems created by SPS in a trade environment. In particular it allows for the even treatment of technical barriers and satisfies the need for transparent and measurable criteria for justifying decisions to trading partners. Using iso-risk, equivalent treatment requires that technical barriers or SPS have similar outcomes. This means that two exporters can be subjected to different quarantine requirements, but not violate WTO rules on equal treatment since the outcomes of

the measures are similar. Justification of quarantine measures also becomes easier since decisions can be shown to be consistent within an overall domestic policy context.

Development of standards for objectively comparing quarantine measures is going to require some consensus on the appropriate economic impact to measure, the appropriate calculation of risk of establishment, and the appropriate ALOP. Initially, a country would only be able to determine whether from an internal perspective it is treating its trading partners consistently using domestic definitions of economic impact and probability of establishment. This internal consistency of quarantine policy would be relative to a domestic ALOP. At a later stage, when a number of countries were basing decisions on iso-risk, it is possible that an international norm for ALOP would emerge. A country could then establish, or perhaps be challenged, as to whether its treatment of trading partners was consistent with international norms.

The problem of arriving at an ALOP 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 ALOP, a sufficient sample of pests would first need to be evaluated for probability of entry and potential economic impacts after post-quarantine treatment. ALOP should emerge from the pattern of plotted results, being represented by a line above which there would be no plots. An ALOP for commodities could be determined by a similar process. A value for ALOP implicit in existing quarantine regulations should emerge from the analysis. The process is not likely to be easy in practice since such an analysis may show inconsistencies in existing quarantine policies based on the resulting values of commodity and pest risk.

While providing a clearer picture of ALOP, experience in New Zealand has shown that there is a significant increase in information and analysis required by a quarantine authority when it has to include economic impact assessment and a specific probability of introduction. In many cases, little will be known about the economics of particular crops, much less the expected economic

impact on a particular plant or probabilities of introduction. In addition to the problem of basic data, there is a problem with producing a rapid analysis for quarantine decisions if the level of detail implied by iso-risk is required for each commodity that is traded. Models to facilitate rapid analysis have been developed for New Zealand Ministry of Agriculture and Forestry that calculate probability of introduction (Greer and Bigsby 1995; Greer *et al.* 1995) and economic impacts (Bigsby and Crequer 1995; Bigsby 1995) based a standardised set of factors.

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## Beyond iso-risk to include benefits under the SPS Agreement

GIL RODRIGUEZ, NICO KLIJN, ANNA HEANEY AND STEPHEN BEARE

Countries restrict imports through quarantine controls to reduce the risks and expected costs of pest and disease incursions. Countries have also used trade barriers such as import tariffs and quotas to protect domestic industries against competition from imports. The higher benefits that could be obtained under freer trade regimes have prompted international agreements to liberalise trade under the General Agreement on Tariff and Trade (GATT) and, its successor, the World Trade Organization (WTO).

Under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, a Member has the sovereign right to determine the level of sanitary and phytosanitary protection it deems appropriate and to institute plant and animal health and food safety measures to protect against bona fide risks. Sanitary and phytosanitary measures, such as disease-free certification requirements, are instruments that importing countries use to lower the risk of pest and disease incursion. To prevent the use of SPS measures as disguised trade barriers, WTO Members can institute SPS measures provided they are:

- based on a sound scientific assessment process;
- not more trade-restrictive than necessary to achieve the desired level of protection against pests and diseases; and

• nondiscriminatory - sanitary and phytosanitary measures must not discriminate between Members where identical or similar conditions prevail, including between their own territory and that of Members.

Implementing SPS measures that meet these guidelines in a consistent manner within and between countries is proving to be difficult and several Member countries, including Australia, have been drawn into the lengthy and expensive WTO dispute settlement process. This inability to establish consistent SPS protocols may lead to a greater number of disputes in the future and reduce the effectiveness of the SPS Agreement to facilitate trade.

While a Member Country is free to set an appropriate level of protection (ALOP), it is unclear how such a level of protection can be defined in terms of specific SPS measures. Under the Agreement, the criterion used by a Member to establish an ALOP could be, for example, a maximum probability of a disease incursion per time period or a maximum expected cost of incursion over the future in present value terms. However, none of these criteria are related to whether SPS measures are economically viable. That is, whether the expected benefits from reducing the risk of pest or disease incursions exceed the forgone gains from trade.

The potential value of considering the expected benefits from accepting an import risk when establishing an SPS framework such as ALOP is considered in this chapter. It is shown that accepting high risks can be justified when there are net benefits from trade.

### Determining a criterion for setting the 'appropriate level of protection'

There have been attempts to define a criterion for determining an appropriate level of protection within the guidelines of the WTO's SPS Agreement. Bigsby and Whyte (1999), for example, define ALOP as equivalent to the highest expected pest and disease cost associated with the import of any single commodity that is acceptable to society. The expected cost is the weighted sum of all costs of pest or disease incursion. These depend on the probability

of incursion per time period, and all costs of an incursion per time period. The probability of incursion is the chance of a pest or disease occurring in that period. The economic factors that determine this cost are lost income from production forgone following the establishment and spread of a pest or disease, the costs of eradication and the cost effectiveness of alternative approaches to limiting risks (Article 5.3 of the SPS Agreement). Sanitary and phytosanitary protocols could be applied when the expected disease costs associated with unrestricted imports of a good exceed the maximum acceptable expected cost to a Member Country.

Bigsby and Crequer (1996) proposed an iso-risk approach. The cost of a pest or disease incursion refers to income from production forgone and the cost of eradication. The iso-risk line is a locus of points with combinations of risk and actual disease cost that result in the same expected cost (Bigsby and Whyte 1999):

#### (1) probability of incursion\*disease cost = constant

In this context, if the criterion used for setting the ALOP is the highest acceptable expected pest and disease cost, then the iso-risk line defines the boundary between commodities with acceptable risks and those with unacceptable risks. An iso-risk line close to the origin denotes a low expected cost and if this expected cost was used to set the ALOP, a high level of sanitary and phytosanitary protection would be provided. The iso-risk line is further from the origin if higher expected pest and disease costs are acceptable to society.

### Limitations of using the iso-risk criterion for setting an ALOP

While the use of the iso-risk criterion for setting an ALOP appears to be objective and straight forward, it has several limitations. First, the specification of a locus of iso-risk points is specific to the characteristics of a pest or disease incursion and it may not be possible to rank or compare different quarantine risks. The approach proposed by Bigsby and Crequer is valid, for example, when eradication occurs with certainty within the period of

incursion such that each new period starts with a disease-free state and another probability of incursion applies in this period. The problem becomes more complex when time is introduced into the analysis and it may not be possible to uniquely define an ALOP within the iso-risk framework.

Consider the case of a disease with a constant probability per year of incursion through imports (*p*) and an annual cost of infection (*c*) where eradication is not cost-effective and not attempted. Over a long period of time the probability of incursion in that period approaches unity while the costs of an incursion late in the period are discounted and approach zero. Here we must consider the probability that an incursion will or will not occur over an increasing interval of time in order to determine the expected cost of an incursion. The expected cost of an incursion, from a disease free state is given by

(1) 
$$E(\cos t) = c \sum_{t=0}^{\infty} \frac{p(1-p)^t}{(1+r)^t}$$

where r is the discount rate. Taking the limit of summation yields

(2) 
$$E(\cos t) = \frac{cp(1+r)}{r+p}$$

which when set to a constant yields another iso-risk locus. The locus is still hyperbolic but different in shape from that of Bigsby and Crequer. A comparison of the iso-risk formulas is given in Figure 9.1 (with a constant value of 100 and a discount rate of 7 per cent). The two classes of incursion cannot be compared directly using an iso-risk approach. Pests and diseases for which cost-effective eradication takes place over an extended time period or where eradication is only partially effective may also constitute different classes of incursions, and cannot be compared directly under the iso-risk approach.

Further, the state of science for SPS risk analyses is highly uncertain and in many instances there is insufficient evidence to undertake a

quantitative assessment of risks to human, animal or plant health (Powell 1997). Under conditions of uncertainty, probabilities for scientific or economic risk are often unknown or ambiguous because of the scarcity of observations of events and of information on underlying causes. Within the Bigbsy and Crequer iso-risk framework, the expected cost is proportional to, and thus sensitive to, the probability of disease incursion in a time period (Heaney, Rodriguez and Abdalla 1999). This uncertainty can skew the distribution of costs and benefits. An ALOP based on a criterion of expected probabilities of disease incursion not higher than an expected maximum dollar amount may not adequately represent the risks of relaxing a quarantine restriction.

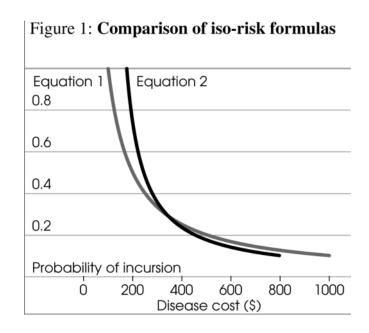


Figure 9.1: Comparison of iso-risk formulas

The limitations discussed above suggest that there is not a simple methodology that can be applied consistently for determining the expected cost of a pest or disease incursion. Data and analytical requirements are likely to be considerable and may vary significantly between different pests and diseases, and in different environments. As a result, most estimates of expected cost will be highly uncertain.

More importantly, establishing an ALOP on the basis of a maximum expected cost does not take into account the benefits from imports of individual commodities — benefits arise from importing goods that were previously not available or that were produced domestically at higher cost. Bureau, Marette and Schiavina (1998) argue that the settlement of international disputes on SPS issues should be based on cost/benefit analysis, rather than relying on scientific considerations. This is because a more systematic economic analysis would reflect also the interests of users, including final consumers, in the WTO dispute process.

One implication of failing to consider the benefits of trade is the likelihood of distorting the setting of an ALOP to favour large rather than small industries. The potential reductions in income resulting from disease incursion are likely to be greater the larger the industries. If the ALOP was set in consideration of industries with a large gross value of output (GVO), then those with a small GVO would not be provided any protection from pest and disease incursions, even when the probability of incursion was sufficiently high to generate a net cost to Australia. Industries with a small GVO in Australia include horticulture and aquaculture.

#### The cost/benefit issues

The WTO Agreement aims to achieve open and nondiscriminatory trade and requires Member countries to adopt trade policies consistent with this aim. Cost/benefit analyses of alternative quarantine protocols could be used to systematically assess all components of welfare. Cost/benefit analysis could provide estimates of the forgone trade benefits and the probability distribution of potential costs of pest and disease incursions, allowing the ranking of potential protocols according to net benefits. Consequently, this information would enable a Member to identify the protocol that yields the highest net benefit.

Benefits from unrestricted imports may outweigh the increase in the risks and costs of the incursions of pests and diseases. However, if imports of a commodity increase the risk of disease, there may be considerable costs to exporters. The introduction of disease leads to higher costs of production due, for example, to increased use of inputs. Further, potential damage to the disease-free status of exporters could result in loss of access to some export markets and in other export markets the loss of export price premiums.

However, the SPS Agreement does not explicitly endorse the consideration of benefits associated with different risk mitigation measures, and the relevant economic factors outlined in Article 5 make no mention of welfare impacts on consumers (Roberts 1998). In the context of the Agreement, the assessment of SPS protocols tends to be limited to consideration of measures that will achieve the risk target, and of the costs of administering the protocol. The Agreement does not, however, specifically exclude the use of economic techniques (such as cost/benefit analysis) in assessing different protocols.

If using cost/benefit analysis, however, Members must conform to the SPS consistency provision (Article 5). This provision ensures that Members apply measures consistently to different commodities that pose similar risk of introducing the same disease. Where different commodities pose similar risks, allowing imports of one commodity (based on higher net benefit from imports) while banning the other would contravene the SPS consistency provision (Article 5).

There are a number of examples of cost/benefit analysis applied to Australian quarantine protocols. James and Anderson (1998) demonstrated that removing Australia's ban on banana imports would increase net social welfare in Australia by \$100 million a year even if the domestic banana industry shut down as a result of imports. A US ban on Mexican avocados is another example of trade-restrictive phytosanitary measures that have consumer welfare losses that exceed the domestic benefits from preventing pest infestations (Orden and Romano 1996).

These import protocols, implemented to lower phytosanitary risk to domestic producers, demonstrate how SPS decisions based on risk assessment only can lead to a decrease in social welfare. Such policies pay little regard to the benefits from trade forgone as a result of restrictive trade policy. Further, these studies demonstrate

that estimating benefits from trade through the relaxation of quarantine restrictions is not fundamentally more difficult or less objective than estimating the expected cost of an incursion.

The inclusion of benefits in the decision making process through benefit-cost analysis is likely to lead to the implementation of SPS protocols that are less trade-restrictive than those based on risk assessment only (James and Anderson 1998). Moreover, cost/benefit analysis can account for changes in risk and benefits associated with imports over time. For example, the decision to import feed grains into Australia in a severe drought year and restrict imports of feed grains in other years may be optimal from a cost/benefit perspective. However, managing such a situation under the iso-risk approach to determining the ALOP would be very difficult. Recognition within the SPS Agreement that higher benefits justify taking greater quarantine risks will make it easier for countries to implement consistent quarantine policies across commodities and over time.

#### Conclusion

There is a trade-off between the benefits of importing commodities with a quarantine risk and the expected cost of potential pest or disease incursions. Benefits from unrestricted imports largely accrue to users of imports and import-competing goods. However, producers are likely to face considerable costs if imports of a commodity increase their risk of a pest or disease incursion.

A criterion for setting a Member's ALOP that is based on risk of incursion, or on maximum expected cost does not take into account all the potential benefits and costs from imports. This is likely to result in the implementation of SPS protocols that are more traderestrictive than if the ALOP were determined using a full cost/benefit analysis. Furthermore, failure to account for trade benefits is likely to lead to the adoption of SPS measures that favor high-valued industries and may disadvantage small and emerging industries.

The failure of the SPS Agreement to allow for both risk and trade benefits to be considered in determining an ALOP may make it difficult for Members to maintain consistent SPS measures across commodities or over time. It may also push countries to adopt overly conservative levels of quarantine protection and limit the potential gains from the SPS Agreement.

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## 10

## Integrating import risk and trade benefit analysis

RICHARD H. SNAPE AND DAVID ORDEN\*

Economists have long emphasised the gains from international trade, but have acknowledged that there can be external diseconomies, including pest and disease risks, associated with importing plant and animal products. The General Agreement on Tariffs and Trade (GATT), both in the original 1947 version and in the 1994 World Trade Organization (WTO) extension of it, follows this lead, with the general rules constraining trade barriers and facilitating their reduction, but with allowance for exceptions, such as for quarantine purposes.

Quarantine scientists and administrators, environmentalists, and farmers facing threats, competitive and pestiferous, from imports, tend to emphasise the risks to production and the environment from trading, rather than the gains to consumers from imported products. This attitude is reflected in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The emphasis of the SPS Agreement is on the determination of risks from plant and animal imports, the appropriate level of protection against these risks, and securing consistent application of these criteria across similar products and from similar sources. There is little if any scope for distinguishing between products with similar risk according to the level of consumer benefit which would accrue if the products

<sup>\*</sup> Nothing in this paper should be taken as expressing the views of the Productivity Commission or the Australian Government.

were to be imported. Nevertheless the SPS Agreement is written as an "exception" to the general rules of GATT 1994.

Some economists have called for more recognition of the gains from trade – in particular the gains to consumers from imported products – in the application of quarantine laws. A few recent studies have provided estimates of these gains and have shown that the benefits of trade exceed expected costs due to pest risks in certain cases (e.g. James and Anderson 1998, and Chapter 11 in this volume by Orden, Narrod and Glauber). Several chapters in this volume and elsewhere (e.g. Chapter 2 by Roberts and Roberts 2000) also examine conceptual and pragmatic dimensions of the relationship between risk evaluation and cost/benefit analysis in quarantine decisions.

In this chapter we present a simple diagram to illustrate the risk-focused versus cost/benefit approaches to policy decisions about trade of products that may pose SPS risks. In Figure 10.1, the horizontal axis measures the risk (weighted by probabilities) of trading particular products. Several authors have developed 'isorisk' diagrams, with the economic impact of the imports of pests or diseases (if they were to become established domestically) on one axis and the probability of such establishment and spread on the other (e.g. Chapters 8 and 12 in this volume by Bigsby and Binder respectively). The horizontal axis of our Figure 10.1 is simply the dollar value of their iso-risk curves.

The vertical axis of Figure 10.1 shows the other net benefits from importing products that may carry pests or diseases. These are the traditional gains from trade. For any products which are tested or otherwise treated for quarantine purposes, the costs of treatment or testing should be taken into account in determining this other net benefit. Such testing or treatment would of course also reduce the risk (on the horizontal axis) of that product, as shown for example in movement from D' to D in Figure 10.1.

Figure 10.1: Risks and benefits from trade

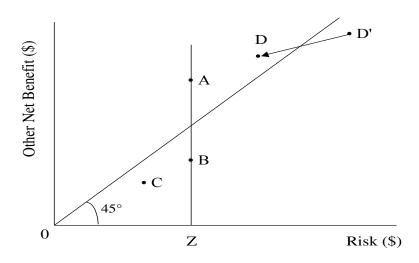


Figure 1

With both the risk and the other net benefits shown in dollar terms (and with consistent time discounting for both) a 45-degree line from the origin indicates the equating of these expected effects of trade. For a neutral policy attitude to risk, this line shows the boundary of positive trade-off of the benefits and risks of imports of particular products. Risk-averse policy would be shown by a steeper curve; risk-loving policy by a flatter one. Based on economic cost/benefit criteria, under a neutral policy attitude toward risk all products with coordinates that are located above the 45-degree line (when the cost-appropriate testing and treatment is accounted for) should be imported. Those products that cannot be raised above the line under any quarantine conditions and treatments should not be imported.

The general rules of the GATT can be viewed as focusing on the vertical axis of Figure 10.1. For products for which there is zero risk, the coordinates lie on this axis and so are above the 45-degree line (at the origin). The general GATT objective for these products is to facilitate the reduction of trade barriers. Reduction of these trade barriers is in the national economic interest of the importing country (leaving aside large-country optimal tariff and similar arguments). But for various political economy reasons, countries often fail to remove trade barriers unilaterally, which is detrimental also to exporters among their trading partners through lost market opportunities. The GATT general rules are an institutional response designed to facilitate mutually beneficial trade barrier reductions. The underlying aim is to achieve the gains from trade by facilitating the international movement among Members of the WTO of products that lie on the vertical axis of Figure 10.1 (involving no risk).

The SPS Agreement as an exception to the GATT general rules can be viewed as predominantly concerned with the horizontal (not the vertical) axis of Figure 10.1. The first aim is to bind countries' policies away from the origin: if there is no credible scientific basis for risk, then quarantine policies are not to be established to limit trade. The second aim of the SPS Agreement is to require countries to select a point on the horizontal axis, such as point Z, that is a standard for their acceptable level of risk or appropriate level of protection (ALOP), and to apply it consistently for all products and for all country sources (including domestic sources). Essentially the aim is to evaluate products relative to a vertical line through point Z - to prevent arbitrary and unjustified quarantine distinctions between products, distinctions that could be used for protection against economic competition. Under the SPS Agreement, products to the left of the vertical line through Z should be permitted; those to the right of *Z* may be prohibited.

Having determined Z, the application of the SPS Agreement would not distinguish between products A and B, even though, on a full cost/benefit analysis, product A should be imported, while product B should not (assuming it is in this location after the best possible quarantine treatment). Even worse from an optimum cost/benefit policy perspective, under the ALOP principle and the specification of point Z, imports of product C would be allowed while those of D would not. By forcing this distinction, the SPS Agreement could preclude a country from implementing a desirable policy from a national cost/benefit perspective.

It may be argued that a product at a point such as D poses no problem as far as the SPS Agreement is concerned because an importing country could decide to relax its quarantine rules to allow the imports of a product with a level of risk above Z, and exporting countries are not likely to complain in such cases. Moreover, if an importing country finds that a large number of products for which it has precluded trade have coordinates like D, it might conclude unilaterally that its ALOP is set too conservatively. A shift of the ALOP to the right would allow more gains from trade to be realised with a consequent increase in risk.1 Yet there remains concern that countries have Z too conservatively, set indistinguishably from the vertical axis itself. The result may be too many products with coordinates like D that are excluded from trade by quarantine decisions, causing net economic losses.

For the initially chosen Z, a different problem that arises with allowing trade of product D comes through precedent. A WTO Dispute Settlement Panel might later conclude that excluding product C but allowing product D was not consistent with the SPS requirement that an ALOP be applied consistently where similar sources of risk exist.

Quite apart from the precedent set by allowing imports of D products, a problem with respect to trading partners and the potential importing country arises from products with coordinates such as C. Here a decision to exclude is trade restricting, and the decision to exclude cannot be justified under the SPS Agreement in terms of the ALOP set at Z (nor are quarantine procedures justifiable

<sup>&</sup>lt;sup>1</sup> Digby Gascoine and Ken Forsythe have pointed out that if past quarantine decisions are resulting in products being excluded that lie above the 45-degree line, priority for re-examination should be given to those products whose coordinates are expected to be close to the country's ALOP and furthest above the 45-degree line.

under the Agreement that might reduce risk and move the coordinates of C above the 45-degree line). The problem in this case is that just as countries are not expected to suffer net losses from other trade liberalisation measures under the GATT, no country should be required to bear a burden of risk costs that exceeds the other net benefits from trade (measured for the country as a whole). Yet, that is what application of the principles of the SPS Agreement to product C would require.

Whether excluding products with coordinates such as D or admitting products with coordinates such as C proves more problematic under the SPS Agreement depends on how conservatively the acceptable level of risk is set. The SPS Agreement as interpreted allows for different levels of risk for plant, animal and human health. It may also turn out that the level of risk adopted as acceptable by a country is allowed by WTO Dispute Settlement Panels to be based on scale factors: for example, the dollar value of risk measured relative to the size (e.g. volume of sales) of the industry. These considerations could cause the location of Z to vary among products (or at least among classes of products), but the basic dichotomy would remain between a decision-rule based on setting a level of risk versus a decision rule based on comparing the other net benefits to risks.

Should the SPS Agreement be amended to allow (or even require) Members of the WTO to make quarantine decisions based on cost/benefit assessments instead of ALOP? This would involve not just permitting an adjustment of risk by a scale factor, but also permitting distinctions between products according to the benefits (particularly to consumers) accruing from importing products. This might allow (or even require) countries to adopt best economic policy practices for the benefit of their citizens as a whole, and escape from the emphasis on producer benefits from import restrictions which so often dominate in trade (including quarantine) policy.

But it can also be argued that the purpose of the SPS Agreement is simply to prevent countries from 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.<sup>2</sup> This could undermine what was intended to be achieved under the WTO Agreement on Agriculture. In such event, the alternative decision rule could facilitate what many observers have 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.

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<sup>&</sup>lt;sup>2</sup> Pacé textiles and clothing protection in developed countries, and Article 26 of the Biosafety Protocol for Trade in Genetically Modified Organisms (Phillips and Kerr 2000, pp. 72-3)

### **PART III**

Adding more economics to risk analysis

## 11

## Least trade-restrictive SPS policies: an analytic framework is there but questions remain

DAVID ORDEN, CLARE NARROD AND JOSEPH W. GLAUBER

This chapter examines the choice among sanitary and phytosanitary policies of those that are least trade-distorting. In addressing this choice, we highlight the potential for complementarity between science-based risk assessment and economic-based cost/benefit analysis in regulatory decision processes. We make the argument for fuller integration of these approaches than is often the case. Integrating risk assessment and cost/benefit simultaneously into the regulatory process provides decision makers with a rich two-dimensional nexus of information. It is too optimistic to expect that for all regulatory decisions a fully optimal policy choice can be achieved when only a single dimension of information is considered. The two-dimensional risk assessmenteconomic analysis nexus gives decision makers an opportunity to evaluate the trade-offs that are faced when they choose among regulatory measures. The criterion "least tradealternative restrictive" (or more generally, "least trade-distorting") is one that policy makers can apply to these decisions. It is not a complete decision-making rule, nor is it the only criterion on which policy options might be ranked, but least trade-restrictive is a criterion mandated by the WTO for consideration in SPS policy determination.

The chapter is organised as follows. The next section provides a brief discussion of the concept of a policy being least tradedistorting. We follow by summarising results from two case studies that were re-analysed using somewhat different approaches than those utilised in regulatory decisions. The possibility for either convergence or divergence between the inferences drawn from risk assessment versus cost/benefit analysis is demonstrated for the case of regulation of avocados entering the United States from Mexico. The value of integrating cost/benefit analysis and risk assessment simultaneously into evaluation of risk management options is demonstrated for the case of setting internal US Karnal bunt guarantine rules. We draw on these two case studies in a final section to offer some conclusions about the criterion "least tradedistorting" and about integrating risk assessment and cost/benefit regulatory decision-making. The into framework for identifying a policy that is economically efficient as being least trade-distorting is well defined. The hard part is providing the risk and economic assessments on which such decisions rest in specific cases. In addition, decision makers may not want to consider the full range of options that risk assessment and cost/benefit analysis lay before them.

#### What does least trade-distorting mean?

What does it mean to say that a policy is least trade-distorting, and why is this phrase so appealing to trade negotiators, but less so to trade economists? The answers to these questions come from recognising that being least trade-distorting is only one attribute of a policy being most efficient at achieving a stated objective. That there is an objective other than trade liberalisation which the policy is intended to achieve is implicit in the notion that a given policy is least trade-distorting. But achieving that policy objective may itself not be optimal on economic grounds, such as those often used to argue for benefits of liberalised trade.

The general theory of economically efficient policy intervention suggests that policies be directed specifically at the given objective, because such policies attain their ends without imposing other distortions on the economy. A subsidy to producers is a more efficient policy for increasing output than a tariff, for example, since the production subsidy does not raise prices paid by consumers, and

thus avoids distorting their optimal consumption decisions along with production levels. Likewise, if the policy objective is to subsidise use of labour, a wage subsidy is more efficient than a general production subsidy, which is more efficient than a tariff. In short, intervention policies should be targeted toward the intended objective, and the more precisely they can be targeted, the better. The more efficient the policy intervention, the less trade-distorting that policy will be for any given level of the objective achieved by the intervention.

The theory of efficient policy intervention applies equally well to interventions aimed at correcting market failures. For example, if domestic production causes a negative local externality, a tax on production is the efficient policy, as opposed, for example, to an import subsidy that lowers the product price to producers and consumers. If the use of a particular input causes a negative externality, then the optimal policy instrument would be a tax on use of that input, not a tax on production *per se*.

There is another consideration when policies are directed at externalities. When there is no externality, there is no optimal objective of the policy intervention inherent in standard economic welfare analysis; instead the level of the intervention has to be presumed to be set exogenously, or to emerge from an implicit political economy model. When there is an externality, not only is there a corresponding optimal policy instrument, but there is an inherently optimal level of intervention that maximises economic welfare. Policy can err by applying the wrong instrument, but also by applying the optimal instrument at too low or too high a level.

Sanitary and phytosanitary regulations on trade can be optimal policy instruments when trade of a commodity is associated with the risk of incurring a negative externality of a deleterious effect on domestic plant, animal or human health. The SPS Agreement makes it perfectly clear that SPS regulations are not acceptable policies for achieving other objectives. They would not be least trade-distorting policies for these other objectives, and their use would raise additional problems.

Suppose one approaches the issue of SPS regulations along only the risk assessment dimension. If the mandate of regulatory authorities to protect the domestic economy from negative SPS externalities is stated in strong terms, as it often is, then product import bans and other severe quarantine measures emerge quite naturally as policy outcomes. A product ban is a high level of intervention to address an SPS externality, but a ban does eliminate the externality risk to the extent that trade is its proximate cause. Within the risk assessment dimension, there is room for dispute over whether an externality threat exists in a given situation. And a ban may or may not be least trade-distorting - perhaps there is another way to eliminate the externality risk, one that allows the product to be traded under some specified conditions. Either way, when the policy decision is perceived only in the risk assessment dimension, there is no impetus to ask whether the cost of the policy is warranted by the expected benefits; that is, whether the level of intervention needed to achieve the risk-reduction objective is also desirable on economic criteria, such as maximising the expected contribution of the affected markets to national welfare.

There are dramatic alternatives to SPS-risk-induced policies such as product bans. If strong property rights could be assured to those who might suffer the damages from an externality, and if insurance markets were sufficiently developed, then one could do away with many SPS regulations, and let market outcomes evolve unfettered, with the externality internalised by the assignment of property rights. Neither WTO laws, nor other international laws, nor domestic liability laws, nor risk-sharing markets are strong enough for this option to emerge in the short term.

Instead, the challenges to existing SPS regulations are coming primarily as requests for easing of the most severe trade-restricting policies. The key to these alternatives is often a systems approach to risk management, whereby a set of procedures are specified that in principle reduce the externality risk associated with trade of a commodity. Requests for adoption of systems approaches rest on a firm foundation in the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (WTO 1994). Specifically, Article 5.6 states that:

"Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."

#### The footnote 3 in the Agreement states that:

"For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."

Three basic questions about policy decisions arise when a systems approach is considered. A set of procedures to be applied to a commodity in order for it to qualify for importation are specified with the objective to reduce risk, perhaps to (essentially) zero, equivalent to a product ban. First, a risk assessment question arises: does the specified set of procedures achieve the risk objective? Second, a least trade-distorting question arises: does the specified set of procedures distort trade the least among possible options? Finally, a larger economic efficiency question arises: is the targeted level of risk reduction itself justified by the economic welfare effects that are associated with it? The latter two questions bring the cost/benefit dimension into policy considerations, along with the risk assessment dimension.

# Convergence and divergence between risk assessment and cost/benefit analysis: the case of importation of Mexican avocados by the US

Our first case study illustrates the potential for convergence or divergence between policy decision criteria based on risk assessment versus cost/benefit analysis. In many cases, sound science and sound economics will correspond—as when pest risks have expected economic costs that outweigh the benefits of trade. These cases provide an implicit economic rationale for the scientific focus of international SPS agreements. However, some SPS regulations may have economic net costs even if they have solid scientific justification. In these latter cases, a regulation is not good economic policy in terms such as maximising expected national welfare, even if the regulation does not violate the SPS Agreement of the WTO.

One of the most contentious SPS disputes between Mexico and the United States concerns US restrictions on importation of Hass avocados.¹ Mexico argues that its principal avocado producing region has low incidence of pests of quarantine significance, that the Hass avocado is not a preferred host for some pests of concern, and that a systems approach to handling fruit for export has proven effective in eliminating risks of pest infestations being carried abroad. The US avocado industry, which is concentrated in southern California, bitterly contests opening its domestic market to exports from Mexico. The industry acknowledges that it receives prices well above those of Mexican exports, but argues that its fear is not competition in the marketplace but risks of pest infestations associated with trade. Domestic US producers challenge Mexican assessments of pest risks and the effectiveness of the systems approach to risk management.

The US Department of Agriculture is caught in the middle of this controversy. Its Animal and Plant Health Inspection Service (APHIS) and Agricultural Research Service (ARS) have engaged in intense bi-national technical negotiations with Mexican authorities about pest risk evidence and export protocols that might sustain easing of the import ban. Following four years of negotiations, in September 1994, APHIS accepted a Mexican work plan proposing a systems approach to pest risk mitigation. With some further safeguards, a proposed rule was published by USDA in July 1995 to allow imports into the northeastern United States of Mexican

<sup>&</sup>lt;sup>1</sup> Roberts and Orden (1996) provide a detailed analytic chronology of the avocado dispute.

avocados grown and processed under specified conditions. Imports were to be limited to the winter months when the risk of establishment of pests is further mitigated by adverse weather.

The geographic and seasonal restrictions of USDA's proposed rule implied that the partial easing of the avocado import ban opened less than five per cent of the annual US market to Mexican products. The domestic avocado industry fought against even this limited trade rule, but in February 1997 USDA announced it would ease the avocado ban. Since that time, limited avocado trade has been allowed. By 2000, Mexico requested additional access to the US market, and subsequent regulatory assessments are pending.

To evaluate the economic impacts of US-Mexico avocado trade, Orden and Romano (1996) examined the effects of full or partial easing of the import ban.<sup>2</sup> Estimates are derived of a linear supply function that is inelastic in the short run (0.28, when lagged quantity is held constant) and elastic in the long run (1.18, when quantity is in a steady state). A linear estimate of demand is inelastic (-0.45) but estimation of a nonlinear demand specification yields a price flexibility of -0.65, corresponding to an elasticity of -1.53. Thus, the estimated supply and demand functions provide point estimates that span a range from inelastic to elastic behavioral responses. Orden and Romano apply the elastic values as a long-run model and the inelastic values as a short-run model in which producers and consumers are less price responsive. For both models, the assumption is made that Mexican supply is perfectly elastic at the wholesale price for delivery of avocados from Mexico to New York

<sup>&</sup>lt;sup>2</sup> Orden and Romano draw on specifications of avocado supply and demand derived from Evangelou et. al. (1993), in which supply is a linear function of lagged farm-level prices and production and demand is a linear function of wholesale prices, and Carman and Cook (1996), who utilised a nonlinear Box-Cox transformation on demand. Previous economic analyses of the effects of importation of Mexican avocados either had not considered impacts on consumers (Garoyan 1995; Carman and Cook 1996), had evaluated the effects of a pest infestation while restricting supply to domestic sources (Evangelou et. al. 1993), or had assumed there was essentially zero pest risk (USDA 1995). Each of these analyses was incomplete in an important dimension.

of \$878/ton, as calculated by Garoyan (1995). The assumption of a perfectly elastic supply is most plausible for a partial easing of the import ban. It is arguably an oversimplification for evaluation of the effects of the quarantine being removed completely, since the expanded traded might put upward pressure on the Mexican price.

In Orden and Romano's models of partial easing of the avocado import ban, the domestic US market is divided into two submarkets—the northeastern regional winter market and the national aggregate for all other regions and seasons. The quantity of California avocados shipped to the northeastern region during the four winter months at prevailing domestic prices was reported by Garoyan to have averaged 3,819 tons during 1986-95. In modelling limited trade, the domestic price in the northeastern winter regional market is assumed to fall to the free-trade level for imports from Mexico, inducing greater consumption than at higher past domestic prices. An aggregate price for the rest of the US market is determined by an equilibrium of domestic supply and demand with the northeastern winter demand excluded.<sup>3</sup>

Estimates of the probabilities of pest infestations are pivotal to regulatory decisions about avocado imports. Firko (1995) made the estimates utilised by APHIS. Among four potential pests (fruit flies, seed weevil, stem weevil, and seed moth), he estimated that the maximum probability of an infestation occurring in the US for partial easing of the import ban under a systems approach to risk mitigation was  $\pi_{AM} = 0.00345$ , the probability of a pest infestation associated with the introduction of stem weevil. Firko estimated that the probability of infestation of stem weevil had a minimum value  $\pi_{Am} = 1.35 \times 10^{-6}$ . These risk estimates were considered too low by the domestic industry. Nyrop (1995) calculated that the time expected to pass before an infestation of stem weevils occurred under the 1995 proposed rule ranged from less than one year to 20 years. The

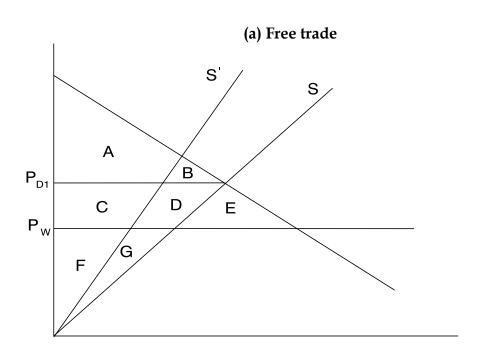
<sup>&</sup>lt;sup>3</sup> Forming a single national aggregate excluding the northeastern winter market is an oversimplification that ignores seasonal supply constraints and demand fluctuations. The added seasonal complexity would imply greater adjustments outside of the northeastern region during the winter season, but less effects during other seasons.

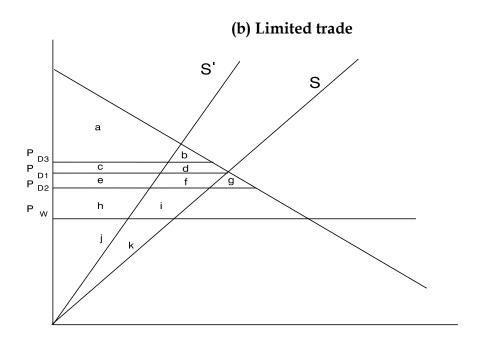
corresponding probabilities of pest infestation were treated by Orden and Romano as  $\pi_{NM}$  = 1.0 and  $\pi_{Nm}$  = 0.05. The four alternative probability estimates from Firko and Nyrop (AM, Am, NM, Nm) were used to characterise the range of risks of pest infestation (from essentially zero to certainty) that might be associated with either partial easing or complete removal of the ban.

The final parameters affecting the economic analysis are estimates of the costs from increased production expenses and lost productivity associated with a pest infestation, which are modelled as a proportional shift in the domestic supply function. Evangelou *et al.* (1993) had estimated that weevil infestation would cause a 41 per cent increase in marginal cost due to increased application of pesticides and a 20 per cent reduction in yield, but argued these estimates were somewhat overstated. Thus, Orden and Romano considered several possible impacts on production. The largest impacts were assumed to involve a 60 per cent increase in marginal costs and a 20 per cent reduction in yield (denoted 60-20). The smallest impacts were assumed to be a 20 per cent increase in marginal costs with no reduction in yield (20-0).

The effects of free trade when a pest infestation might adversely affect domestic production are illustrated in Figure 11.1(a). The domestic price  $P_{D1}$  falls to the world price  $P_{W}$  and consumer surplus increases (by C+D+E) whether or not an infestation occurs. Producer surplus falls by C+D (the trade effect) and additionally by G (the infestation effect) if pests raises production costs and lower yields with certainty, shifting domestic supply from S to S'. Consumers are always better off, producers are always worse off, and the net effect on welfare (E-G) can be positive or negative. On a probabilistic basis, the expected domestic supply function will lie between S and S', with its location depending on the assumed level of pest infestation risk.

Figure 11.1: Effects of trade when pest infestations raise domestic production costs





The analysis is more complicated when only limited quantities of imports are allowed, as shown in Figure 11.1(b). Ignoring regional sub-market considerations, which are not depicted in Figure 11.1(b) for simplicity, the limited imports would lower the domestic price from  $P_{D1}$  to  $P_{D2}$  if there were no pest infestation, rather than to the world price level. Pest infestation reduces domestic supply and affects the domestic price in the opposite direction from imports. With limited trade, the equilibrium domestic price can rise or fall. When the domestic price rises, as shown from  $P_{D1}$  to  $P_{D3}$  in Figure 11.1(b), consumers are worse off (by c+d). Producers surplus rises (by c) with the higher price but falls due to higher production costs (by f+i+k). Producers may be better or worse off than at the initial equilibrium (better if c>f+i+k). Producers may also be better or worse off than with trade but without a pest infestation (better if c+e>i+k). Whatever the outcome for producers, social welfare falls (by d+f+i+k) compared to its level at the initial equilibrium, or compared to its level at price PD2 with trade but without pest infestation (by d+f+i+k+g).4

#### Model results

The expected economic effects of trade are shown for the avocado case in Table 11.1 for a long-run model with estimated elastic supply and (nonlinear) demand. The initial equilibrium with avocado imports prohibited occurs in this estimated model at a domestic price of \$1385 and output of 132,430 tons. Consumer surplus is \$134.4 million and producer surplus is \$91.6 million. If trade were completely liberalised and no pest infestation occurs, the domestic price falls to \$878, consumption increases to 222,722 tons, and domestic production declines to 83,904 tons. Consumer surplus rises by \$87.5 million, producer surplus falls by \$55.2 million, and the net

<sup>&</sup>lt;sup>4</sup> If the net effect of trade and a pest infestation is for the equilibrium domestic price to fall (not shown), consumers are made better off and producers worse off than without trade or pest infestation, consumers gain less and producers may lose more or less than with trade but without pest infestation, and net welfare may rise or fall (compared to the initial equilibrium) depending on whether the net consumer gain from lower prices exceeds the infestation losses of producers.

welfare gain is \$32.4 million (14 per cent of initial consumer plus producer surplus).

A pest infestation exacerbates the adverse effects of free trade on domestic producers through a lower price, and reduces the net welfare gain. In the worst case scenario of certain infestation ( $\pi_{NM}$  = 1.0) and highest costs (60-20), producer surplus falls by an additional \$18.4 million in the long-run model. There remains a net welfare gain even in this case, although it is reduced to \$13.9 million. Thus, even when free trade is bad phytosanitary policy, it is good economic policy, in the sense of raising net national welfare. For probabilities of pest infestation at Nyrop's minimum (Nm) or lower, the effect of an infestation on expected producer surplus is less than \$2 million, and the expected net welfare gain remains above \$30 million.

The partial easing of the avocado import ban under USDA's rule has smaller economic effects than free trade when no pest infestation occurs, as shown in the lower half of Table 11.1. The net national welfare gains is \$2.5 million (about 2 per cent of initial total consumer plus producer surplus). In the northeastern region, winter consumption increases and consumer surplus rises by \$2.5 million (not shown separately in the Table) as the price falls to that of exports from Mexico. The domestic price for the aggregate US market with the northeastern winter demand excluded falls by 1.3 per cent (from \$1385 to \$1368), as domestic consumption displaced from the northeastern winter market is absorbed by a combination of expanded consumption elsewhere and reduced domestic supply. Consumer surplus increases by \$2.2 million outside of the northeast, but producer surplus falls by a similar amount (the net welfare gain is only \$33,337 outside of the northeastern winter market). Thus, the limited opening of trade under the proposed partial easing of the import ban has positive effects on northeastern winter consumer surplus, and limited positive effects on other consumers and negative effects on domestic producers.

When imports are restricted under partial easing of the import ban, increased marginal costs and lowered yields reduce producer surplus by \$45.8 million for the worst-case scenario of a pest

infestation. The reduced supply pushes the equilibrium domestic price up (excluding the northeastern winter market) from \$1385 to \$1795. The price increase offsets \$31.1 million of the loss of producer surplus, leaving a net loss of \$14.7 million, still almost seven times as large as the effect from limited trade alone. A larger economic effect of the pest infestation is felt by consumers outside of the northeastern winter market. With the increased domestic price in the worst-case scenario, their consumer surplus falls by \$43.5 million. Thus, negative economic impacts of pest risk are borne by consumers outside the northeastern winter market as well as producers when trade is opened only to a limited extent.

The potential losses to consumers and producers under certainty of a pest infestation are large enough that the net welfare loss is still \$13.6 million under the lowest assumed costs to production (20-0) from the infestation. Thus, for high probabilities of pest risk, the limited easing of the avocado import ban is both bad phytosanitary policy and bad economic policy. Under the assumption of highest pest-infestation costs, expected consumer surplus rises at risk probabilities as high as the Nyrop minimum risk level (Nm), but the expected gains of consumer surplus is less than the expected loss of producer surplus with limited trade for this level of pest infestation risk. Only at lower risk levels, or lower infestation costs, is a partial easing of the import ban a regulatory decision that raises expected net economic welfare.

Sensitivity of the economic results to the elasticity assumptions is illustrated by comparing the above results to the outcomes from a short-run model with inelastic estimates of supply and demand, shown in Table 11.2. For the estimated short-run model, the initial equilibrium with avocado imports prohibited occurs at a domestic price of \$1950 and output of 140,496 tons. Consumer surplus is \$189.1 million and producer surplus is \$230.9 million. Under the assumption of free trade without pest infestation, consumer surplus

Table 11.1a: Expected economic impacts of avocado imports from Mexico with free trade or limited trade (long-run model)

	Lui Expecteu	Domestic		Domestic	Import		umer Surpl		Producer Surplus			Net
		Price (\$/Short ton)	Output (Short tons)	Consump- tion (Short tons)	Value (\$)	Total	Gain	Loss	Total	Transfers to Consumers	Infestation Loss	Welfare Gain (\$)
A	Autarchy	1385	132,340	132,430		134,382,870			91,636,967			
		T	ı	1	Effec	ts under Free	Trade		1			
		878	83,904	222,722	121,882,204	221,930,370	87,547,500	0	36,833,761	55,189,763	0	32,357,73
	NM (π=1)	u	41,952	u	158,716,060	u	u	u	18,416,881	u	18,416,881	13,940,85
Free	Nm ( <sup><math>\pi</math></sup> =.05)	и	79,905	u	125,393,326	u	u	u	35,079,772	u	1,753,990	30,603,74
Trade (and risk)	AM ( <sup>π</sup> =.00345)	и	83,615	и	122,135,946	u	u	u	36,707,122	u	126,640	32,231,09
(60-20)	Am (π=1.35E-06)	и	83,904	u	121,882,204	u	u	u	36,833,711	u	51	32,357,68
	NM ( <sup>π</sup> =1)	u	69,920	u	134,160,156	u	u	и	30,694,801	и	6,138,961	26,218,79
Free	NM ( <sup>π</sup> =.05)	и	83,073	u	122,611,822	u	u	u	36,469,070	и	364,692	31,993,04
Trade (and risk)	AM ( <sup>π</sup> =.00345)	u	83,846	u	121,933,128	u	u	u	36,808,363	и	25,399	32,332,33
(20-0)	Am (π=1.35E-06)	u	83,904	u	121,882,204	u	u	u	36,833,751	u	11	32,357,72

Table 11.1b: Expected economic impacts of avocado imports from Mexico with free trade or limited trade (long-run model)

					Effects	under Limite	ed Trade					
	Domestic Price		Price Output Consump-			ump- Value (\$)				Producer Surplus (\$)		
		(Outside Northeast) (\$/Short ton)	(Short	tion (Short tons)	(\$)	Total	Gain	Loss	Total	Gain	Loss	Gain (- implies loss) (\$)
No	o pest risk	1368	130,725		5,642,906	139,101,665	4,718,845	-	89,412,656	-	2,224,256	2,494,589
Limited	NM ( <sup>π</sup> =1)	1795	85,753	92,180	u	93,354,884	2,526,401	43,554,336	76,951,094	31,132,088	45,817,906	-55,718,753
Trade	Nm (#=.05)	1396	127,071	133,498	u	135,458,148	2,526,401	1,451,073	88,708,792	1,434,495	4,362,615	-1,852,792
(and risk)	AM (π=.00345)	1370	130,464	136,891	u	138,840,525	4,457,705	-	89,363,780	1	2,273,132	2,184,573
(60-20)	Am (**=1.35E-06)	1368	130,725	137,152	u	139,101,665	4,718,845	-	89,412,535	-	2,224,377	2,494,468
Limited	NM ( <sup>π</sup> =1)	1475	117,464	123,891	u	125,821,613	2,526,401	11,087,608	86,631,104	10,266,095	15,271,902	-13,567,014
Trade (and	Nm (π=05)	1374	129,973	136,400	и	138,354,269	3,971,449	-	89,271,005	-	2,365,907	1,605,542
risk)	AM (π=.00345)	1368	130,673	137,100	u	139,052,265	4,669,445	_	89,402,802	-	2,234,110	2,435,335
(20-0)	Am (π=1.35E-06)	1368	130,725	137,152	u.	139,101,665	4,718,845	_	89,412,632	-	2,224,280	2,494,565

Table 11.2a: Expected economic impacts of avocado imports from Mexico with free trade or limited trade (short-run model)

- TIO	a. Expected e	comonne	impacts	or avocat	io impe	Tto Home	TEXICO WI	tii iicc t	luuc of 1.	iiiiitea tiat	ic (blidle la	111 1110 010
		Domestic Domestic		Domestic	Import	Consumer Surplus			Producer Surplus			Net
		Price	Output	Consumpt- ion	Value	Total	Gain	Loss	Total	Transfers to Consumers	Infestation Loss	Welfare Gain
		(\$/Short ton)	(Short tons)	(Short tons)	(\$)							(\$)
A	utarchy	1950	140,496	140,496		189,071,119			230,894,67			
	Effects under Free Trade											
No	No pest risk		116,223	196,445	70,435,46	369,643,632	180,572,513	0	93,314,846	137,579,827	0	42,992,68
	NM ( <sup>π</sup> =1)	u,	87,013	u	96,081,43	u	u	u	72,033,251	u	21,281,596	21,711,09
T T 1	Nm (π=.05)	u,	113,441	u	72,877,93	u	u	u .	91,288,028	u	2,026,819	40,965,86
Free Trade (and risk)	ΑΜ (π=.00345)	u	116,022	и	70,611,80	u	u	u	93,168,508	u	146,338	42,846,34
(60-20)	Am ( <sup>π</sup> =1.35E-	u	116,223	u	70,435,53	u	u u	u	93,314,789	u	57	42,992,62
Free	NM ( <sup>π</sup> =1)	u .	112,909	u	73,345,04	u	u	u	91,860,054	u	1,454,792	41,537,89
Trade (and	NM ( <sup>π</sup> =.05)	u	116,026	u	70,608,30	u	u	"	93,228,423	u	86,423	42,906,26
risk)	AM ( <sup>π</sup> =.00345)	<i>u</i>	116,209	и	70,447,49	и	u	"	93,308,828	u	6,019	42,986,66
(20-0)	Am ( <sup>π</sup> =1.35E-	u	116,223	u	70,435,46	u	u	u	93,314,844	u	2	42,992,68

Table 11.2b: Expected economic impacts of avocado imports from Mexico with free trade or limited trade (short-run model)

	Effects under Limited Trade											
	Domestic Price Domestic		Domestic Import Consump- Value		Consumer Surplus (\$)		Producer Surplus (\$)			Net Welfare		
		(Outside Northeast) (\$/Short		tion (Short tons)	(\$)	Total	Gain	Loss	Total	Gain	Loss	Gain (- implies loss) (\$)
No	pest risk	ton) 1899	tons)	145,009	4,977,302	201,309,856	12,238,737	-	223,755,40		7,139,269	5,099,468
Limited Trade	NM ( $\pi$ =.1) Nm ( $\pi$ =.05)	2540 1951	136,593	111,508 142,262	u	122,523,752 194,062,485	5,210,869 5,210,869		232,350,83		59,093,506 5,627,953	-65,091,202 -416,802
(and risk)	AM (π=.00345)	1902	139,144	144,813	u u	200,788,946	11,717,827	-	223,885,01	-	7,009,663	4,708,164
(00-20)	Am ( $\pi$ =1.35E-NM ( $\pi$ =.1)	1899 2000	139,340 134,076	145,009 139,745	u u	201,309,652 187,548,223	12,238,533 5,210,869	6,733,765	223,755,45	6,655,440	7,139,218 7,174,549	5,099,315
Limited Trade	Nm ( <sup>π</sup> =.05)	1904	139,042	144,711	u .	200,514,470	11,446,351	-	224,144,12	-	6,750,549	4,695,802
(and risk) (20-0)	Am (π=.00345) Am (π=1.35E-	1899 1899	139,319	144,988 145,009	u u	201,254,773 201,309,835	12,183,654 12,238,716	-	223,782,45	-	7,112,219 7,139,259	5,071,435 5,099,457

increases by \$180.5 million, producer surplus falls by \$137.6 million, and the net welfare gain is \$43.0 million (10 per cent of the initial sum of consumer and producer surplus). Pest infestations compound losses of producer surplus under free trade in the short-run model, but again there is a net welfare gain even when pest infestation occurs with certainty and has high cost.

As before, the effects on producers and consumers with limited trade and no pest infestation are much smaller than under free trade. The domestic price (outside the northeastern winter market) falls to \$1899 in the short-run model, total consumer surplus increases by \$12.2 million, producers surplus falls by \$7.1 million, and the net welfare gain is \$5.1 million. For the worst-case scenario of certain pest infestation and high costs, the domestic price is pushed up to \$2540 in the short-run model with limited imports. Consumer surplus falls by \$66.6 million (gain of \$5.2 million in the northeastern winter market, but loss of \$71.8 million elsewhere). Partial easing of the import ban is only good economic policy when low risk probabilities and costs are assumed, as in the long-run model.

With the domestic price pushed up to \$2540 in the short-run worst-case scenario, producers are better off when limited imports are associated with a pest infestation than when limited trade occurs without an infestation (producer surplus is greater by \$8.5 million). Generally, when trade is only partially opened, producers are expected to be better off in the short-run model the higher the probability of pest infestation (this was not the case in the long-run model). Producers are even slightly better off with limited trade and pest infestation than they are at the initial equilibrium under the assumption of highest costs of an infestation.

To summarise, the economic analysis for US policy on imports of Mexican avocados suggests that free trade would raise consumer surplus, lower producer surplus, and increase national welfare even if pest infestations were certain to occur. With the partial easing of the ban and limited imports that have been adopted, expected consumer and net welfare gains from trade are relatively small and can be exceeded by the expected costs of pest infestation when risks

of infestation are high. With limited trade and high probabilities of pest risk, consumers bear more of the economic costs from the risk of pest infestation than do producers. At lower pest-risk levels, expected consumer surplus increases, and the expected gains offset expected producer surplus losses, so expected net welfare rises. In the long-run model (with elastic supply and demand) pest infestations add to the losses of producers that result from allowing limited trade. But in the short-run model (with inelastic supply and demand) the increased producer surplus from higher domestic prices more than offsets the loss of producer surplus from higher costs and lower yields, so pest infestation risks have the net effect of lessening the decrease in expected producer surplus compared to limited trade without pest infestation.

# Integrating risk assessment and cost/benefit analysis in quarantine design: the case of the US Karnal bunt regulations

The preceding analysis illustrates the possibilities for convergence or divergence between risk-reduction objectives versus cost/benefit objectives, but it does not explicitly bring cost/benefit analysis to bear on the design of quarantine procedures. Doing so requires an evaluation of how various aspects of the systems approach affect risk reduction, and the expected levels of benefits and costs realised. For avocados, limiting imports on a geographic and seasonal basis were one component of the systems approach to risk mitigation. An approximation to the upper bound on the efficacy of this dimension of risk management can be derived under the assumption that an infestation is certain to occur with full trade liberalisation, whereas with limited trade the risk is reduced to the minimum level determined by Firko (1995). Under this crude assumption, the trade limitations are effective as part of the systems approach to risk reduction, but achieving that risk reduction reduces expected welfare gains.

Glauber and Narrod (2000) present a more systematic analysis of the marginal risk reduction effects and expected benefits and costs associated with various protocols of an SPS regulation. They rework the original USDA risk analysis used to design a quarantine to prevent the spread of Karnal bunt within the United States in 1996. This case study illustrates how cost/benefit analysis can be integrated with risk assessment to assess the marginal efficacy of specific components of a quarantine policy.

Karnal bunt is a fungal disease affecting wheat, rye and triticale. While posing no risk to human health, Karnal bunt can cause production losses to wheat in the form of reduced yields due to the infestation of kernels and reduction in the quality of wheat flour. Karnal bunt was first detected in the United States (in Arizona, New Mexico and Texas) in March 1996. As a result, USDA quickly established testing for Karnal bunt teliospores, and regulations that quarantined all of Arizona and portions of New Mexico and Texas to avoid spread of the disease to other wheat growing regions of the country. Glauber and Narrod provide a detailed account of the regulation associated with the quarantine. They also review the risk assessments by Podleckis and Firko (1996a, b, c, d; 1997) that were used in design of the quarantine, and the cost/benefit analysis that was conducted.

In their analysis, Glauber and Narrod recreate the original Karnal bunt risk model, which focused on measuring risk of individual potential pathways for disease spread. With movement of positivetested grain and seed outside of the quarantine area prohibited, these pathway for spread of the disease from negative-tested wheat still included: (1) millfeed (by-products of wheat milling that is fed to cattle); (2) transporting grain from the quarantined area to domestic grain storage facilities, mills and export elevators; (3) use outside the quarantine area of combines and other harvesting machinery; (4) infection through railcars that had transported infected wheat; and (5) planting of wheat seed originating in the quarantined area. These pathways led to regulations being considered on the following articles: (1) farm machinery and equipment used to produce wheat; (2) conveyances from field to handler, such as farm trucks and wagons; (3) grain elevators, equipment and structures at facilities that store and handle grain; (4) conveyances from handler to other marketing channels, such as railroad cars; (5) plant and plant parts, such as grain for milling,

grain for seed, and straw; (6) flour and milling byproducts; (7) manure from animals fed wheat/wheat byproducts from the quarantine area; (8) used sacks; (9) seed-conditioning equipment; (10) byproducts of seed cleaning; (11) soil-moving equipment; (12) root crops with soil; and (13) soil.

Glauber and Narrod modified the initial risk assessment analysis to examine the overall level of risk of a Karnal bunt outbreak from any source originating in the quarantined area. They estimated the probability of at least one outbreak of Karnal bunt occurring outside the quarantined area,  $p^*$ , as:

$$p^* = 1 - (1 - p_1)(1 - p_2)(1 - p_3)(1 - p_4)(1-p_5)$$

where:

 $p_1$  = probability of an outbreak of Karnal bunt outside the quarantined area from millfeed;

 $p_2$  = probability of an outbreak of Karnal bunt in host fields outside the quarantined area from grain in transit to mills or export elevators;

 $p_3$  = probability of an outbreak of Karnal bunt outside the quarantined area from combines or other harvesting machinery;

 $p_4$  = probability of an outbreak of Karnal bunt outside the quarantined area from railcars after grain is unloaded at mills or export elevators;

 $p_5$  = probability of an outbreak of Karnal bunt outside the quarantined area from seed.

Glauber and Narrod found that the probability of outbreak via a given pathway was positively correlated with the number of railcars or other conveyances transporting grain or seed outside of the quarantined areas. Thus, a higher infestation of Karnal bunt within the quarantined area would mean less negative-tested wheat available for export or domestic milling purposes, lowering the probability of outbreak outside of the quarantined area. This interaction was incorporated into the risk assessment.

Glauber and Narrod's analysis addresses the sensitivity of the overall level of risk of a Karnal bunt outbreak outside of the quarantine area, and finds it to be mostly influenced by the riskier pathways. Changes in the probability of outbreak in a given pathway with relatively low probability may be large in absolute terms, but have little effect on the overall level of risk. By focusing on individual pathways, the risk reducing potential of a specific protocol of the quarantine may be overestimated. For example, in the initial analysis a controversial requirement to heat-treat millfeed to eliminate risk of spread of Karnal bunt through manure of animals consuming this by-product was justified by USDA on the basis of the relatively sharp reduction in the risk of outbreak from contaminated millfeed from the heat-treatment procedure. When this factor is isolated, the results indicate that the millfeed treatment requirement reduced the mean risk of Karnal bunt outbreak from contaminated millfeed from 1 in 15,674 to 1 in 68 million. Yet the effect of the heat-treatment protocol was negligible in reducing the overall level of risk. Likewise, restrictions on the movement of negative-tested seed outside the quarantine area had a relatively small effect on the overall risk of outbreak.

#### Model results

In their reassessment of the original risk analysis for the Karnal bunt quarantine, Glauber and Narrod consider eight quarantine options by which risk of spread of the disease could be reduced. These options are based on four basic protocols. The first protocol restricted the movement of positive-tested grain and seed outside the quarantine area, but allowed all negative-tested grain and seed to move without significant additional restrictions. The second protocol required that all railcars be cleaned after delivery of wheat from the quarantined area. The third protocol restricted the movement of negative-tested seed outside of the quarantine area. The fourth protocol required the heat treatment of millfeed from quarantine-area wheat. These protocols were chosen as the focus of the analysis because they imposed the largest costs on the wheat industry in the Southwest when the quarantine was imposed and, as a result, were controversial.

Stochastic assessments of the effects of the eight options on reducing the risk of an outbreak of Karnal bunt outside the quarantine area are shown in Table 11.3. The options are based on the four protocols, singly and in combination. The baseline (option 1) reflects the least restrictive policy, with the quarantine protocol limited to restrictions on the movement of positive-tested grain and seed. Grain and seed that twice tested negative for Karnal bunt teliospores would be free

Table 11.3: Probability of an outbreak of Karnal bunt under eight

quarantine options

Quarantine Option	Probability of outbreak <sup>1</sup>					
	Mode	Median	Mean	95th percentile		
Option 1 – Baseline <sup>2</sup>	6.03E-03	2.37E-02	5.49E-02	2.09E-01		
	<b>()</b> <sup>3</sup>	()	()	()		
Option 2—Railcar cleaning	3.67E-04	1.91E-03	3.33E-03	1.04E-02		
	(0.06)	(0.08)	(0.06)	(0.05)		
Option 3–Restrictions on seed	4.94E-03	2.21E-02	5.36E-02	2.12E-01		
Movement	(0.82)	(0.93)	(0.98)	(1.01)		
Option 4-Millfeed treatment	6.53E-03	2.35E-02	5.47E-02	2.12E-01		
	(1.08)	(0.99)	(1.00)	(1.01)		
Option 5-Railcar cleaning;	8.77E-05	8.12E-04	1.91E-03	6.70E-03		
restrictions on seed movement	(0.01)	(0.03)	(0.03)	(0.03)		
Option 6-Railcar cleaning;	4.46E-04	1.85E-03	3.27E-03	1.05E-02		
millfeed treatment	(0.07)	(0.08)	(0.06)	(0.05)		
Option 7–Restrictions on seed	2.16E-03	2.18E-02	5.36E-02	2.12E-01		
movement; millfeed treatment	(0.36)	(0.92)	(0.98)	(1.01)		
Option 8-Railcar cleaning;	1.95E-04	7.58E-04	1.88E-03	6.71E-03		
restrictions on seed movement; millfeed treatment	(0.03)	(0.03)	(0.03)	(0.03)		

<sup>&</sup>lt;sup>1</sup> Expressed in scientific notation; e.g.,  $6.03E-03 = 6.03 \times 10^{-03} = .00603$ .

Source: Glauber and Narrod (2000)

<sup>&</sup>lt;sup>2</sup> Benchmark procedure includes prohibition of movement of positive testing grain and seed from quarantined area; all negative-testeed grain and seed moved in sealed hopper cars; all combines disinfected before leaving quarantined area. Options 2-8 include benchmark procedures plus additional protocols as indicated.

<sup>&</sup>lt;sup>3</sup> ( ) denotes percentage of risk relative to baseline.

to move to domestic and export locations with no additional restrictions. Railcars would not be required to be cleaned. Options 2, 3 and 4 consider the other protocols individually in combination with the baseline restrictions. Of the individual protocols considered, railcar cleaning (option 2) had the largest effect on the overall level of risk of outbreak because of the relatively high risk of contamination through railcars. Restrictions on the movement of negative-tested seed (option 3) and millfeed treatment requirements (option 4) had minimal effects on the overall level of risk. Options 5 through 8 include combinations of the proposed protocols. Among these, option 8 reflects the system put in place by APHIS following the discovery of Karnal bunt in Arizona. Taken together, the protocols in option 8 reduced the mean level of risk by 97 per cent compared to the baseline (option 1).

The original USDA regulatory impact analysis assumed that failure to implement the quarantine would jeopardise US exports to those countries that maintained restrictions against wheat from Karnal bunt infected countries at the time the disease was discovered in Arizona. The United States was exporting about 1.2 billion bushels of wheat annually in 1995-96, with an estimated value of \$3 to \$4 billion. About one-half of US wheat exports were shipped to countries that had Karnal bunt restrictions. Thus, effects on the wheat market from spread of the disease beyond the quarantine area were considered that ranged from a 10 per cent net loss of export markets to a 50 per cent loss. For example, a decrease of 10 per cent in exports was estimated to cause a \$0.22 per bushel drop in the wheat price and reduce wheat sector income by over \$500 million per year. A decrease of exports of 50 per cent was estimated to cause the price of US wheat to fall by 30 per cent and lower net sectoral income by \$2.7 billion annually. These estimates took into account a dampening effect on domestic wheat prices as wheat for export was routed into the domestic consumption market, animal feed outlets, and inventory. In the impact analysis accompanying the final Karnal bunt regulations on compensation, USDA (1997) concluded that:

"...our quarantine measures were appropriate and justifiable when compared with the magnitude of the benefits achieved.

Even a 10per cent reduction in wheat exports would have a significant effect on wheat sector income. It is estimated that a 10 per cent decline in wheat exports would cause a decline in wheat sector of over \$500 million."

USDA emphasised the 10 per cent loss of export markets in its assessment because substitution and arbitrage opportunities made it unlikely that a Karnal bunt outbreak would lead to more than this amount of trade being diverted from countries imposing restrictions because of the disease.

In reviewing the USDA argument, Glauber and Narrod note that the original impact analysis failed to consider changes in consumer welfare resulting from lower domestic prices if wheat were diverted from export markets. Using observed price and domestic demand levels, and applying the domestic demand elasticity assumed by USDA, they estimate consumer surplus effects for each level of wheat export diversion. The resulting estimated annual effects on net welfare measured by consumer plus producer surplus ranged from \$261 million for a 10 per cent loss in exports to \$976 million assuming a 50 per cent reduction in exports.

Glauber and Narrod also conclude that the effects due to an outbreak of Karnal bunt outside the quarantined area should be evaluated on the basis of net present value of annual losses over the full period in which an outbreak is expected to have an adverse effect. Using an 8 per cent discount rate and assuming losses sustained for ten years, they estimate that the discounted welfare effects ranged from just over \$2 billion (\$2.016 billion) for a 10 per cent loss of exports to nearly \$7.5 billion for a 50 per cent loss.

In the original regulatory analysis, USDA estimated that the costs of the Karnal bunt regulations in 1996 incurred by producers, handlers, and other affected parties would be \$44 million. These costs arose from six requirements: 1) plowdown of fields planted with infected seed (\$1.2 million); 2) diversion of infected grain to animal feed (\$4.2 million); 3) cleaning and disinfecting of railcars (\$0.6 million); 4) loss of seed value (\$6.0 million); 5) loss of value of negative-tested grain

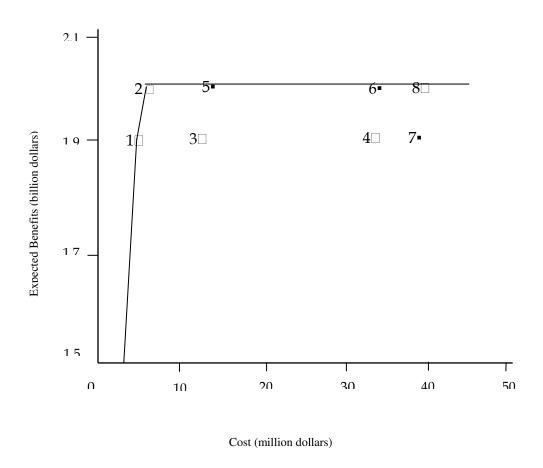
from millfeed treatment costs (\$28.0 million); and 6) other assorted costs (\$4.1 million).

Cost/benefit analysis for the eight quarantine options can be completed under the assumptions given above. For the baseline (option 1), the costs of destroying crops planted with contaminated seed and diverting positive-tested wheat to feed markets and is \$5.4 million. The probability of an outbreak outside the quarantine area was reduced from certainty with no protocol to 0.0549. For a 10 per cent diversion of exports with present value of costs of \$2.016 billion, the expected loss due to an outbreak of Karnal bunt outside of the quarantined area is \$110.7 million, and the welfare gain from utilising the baseline option is \$1.905 billion dollars. Each of the other quarantine options also shows a large expected cost/benefit ratio.

A large expected cost/benefit ratio does not imply, however, that each option is an economically efficient quarantine policy. Three options: 3 restrictions on seed movements; 4 millfeed treatment; and 7 restrictions on seed movements and millfeed treatment) achieve little risk reduction compared to the baseline (option 1). Four other options: 2 railcar cleaning; 5 railcar cleaning and restriction on seed movement; 6 railcar cleaning and millfeed treatment; and 8 railcar cleaning, restrictions on seed movement, and millfeed treatment) are more efficient policies in providing expected benefits for a given level of outlays. These options, along with the baseline (option 1), lie on or near an expected cost/benefit frontier, as shown in Figure 11.2. Options 3, 4 and 7 are economically inefficient. Greater levels of risk reduction and expected benefits can be achieved with lower cost by other choices.

The results in Figure 11.2 also show that most of the expected benefits of any quarantine procedure are achieved by the baseline (option 1). Using additional protocols adds to quarantine costs, but adds little to expected benefits. Consider the efficient baseline (option 1) and options 2, 5 and 8—in which the three protocols of railcar cleaning, restrictions on seed movement, and millfeed

Figure 11.2: Expected benefits and costs of Karnal bunt quarantine options



Source: Glauber and Narrod (2000).

treatment are added sequentially. The expected benefits of each option, the marginal cost of each added protocol, and the expected marginal benefits of that protocol, at the mean value of risk and the more conservative 95<sup>th</sup> percentile of risk, are shown in Table 11.4. The results demonstrate that the use of railcar cleaning (option 2) provides \$104 million in additional benefits for additional costs of only \$0.6 million. The addition of a protocol restricting the movement of negative-tested seed (option 5) imposes an additional cost of \$6 million, while the welfare gain is only \$2.9 million when

evaluated at the mean probability estimate. The added seed protocol is shown to be marginally cost effective when evaluated using the more conservative 95<sup>th</sup> percentile value for the risk of outbreak. Finally, the protocol of millfeed treatment (option 8) adds \$28 million to quarantine costs at the margin, but has a marginal benefit that is less than \$0.1 million.

As shown in Table 11.3 (and Figure 11.2), options 2 and 6 achieve nearly identical reductions of risk, as do options 5 and 8. Within each pair there is an efficient choice: 2 dominates 6, and 8 is dominated by 5. If the very similar levels of risk associated with

Table 11.4: Expected benefits, marginal costs and marginal benefits of alternative

Quarantine options (million dollars)

Quarantine option	Expected Marginal		Marginal benefits:			
	benefits	cost	Probability o	f outbreak		
			evaluat	ed at:		
			Mean value of	95 <sup>th</sup>		
			risk	percentile of		
				risk		
Option 1 — Baseline	1,905.1	5.4	1,905.1	1,594.5		
Option 2Railcar cleaning	2,009.0	0.6	104.0	400.3		
Option 5-Railcar cleaning; restrictions on seed movement	2,011.9	6.0	2.9	7.4		
Option 8-Railcar cleaning; restrictions on seed movement; millfeed treatment	2,012.0	28.0	0.1	0.0		

Source: Glauber and Narrod.

these two choice-pairs are both considered acceptable by decision makers, then option 2 emerges as the most efficient among all four options, and thus is the least trade-distorting (including, in this case, trade in the internal market).

To summarise, Glauber and Narrod find that the original Karnal bunt regulatory impact analysis ignored the effects of the quarantine policies on consumers, and therefore tended to overestimate the benefits of the quarantine. The original analysis also failed to look at the expected marginal benefits and costs of various quarantine protocols. Had the expected marginal effects been considered in the quarantine decisions, it is likely that at least two of the more controversial protocols, seed restrictions and the millfeed requirement, would have received closer scrutiny and possibly been rejected.<sup>5</sup> The use of restrictions on movement of positive-tested grain and seed, together with railcar cleaning, results in significant risk reduction in an efficient manner.

#### Conclusion

This chapter highlights the potential for complementarity between science-based risk assessment and economic-based cost/benefit analysis in regulatory decision processes. In particular, we use two case studies to highlight a key point: that economic cost/benefit analysis *ought* to play an explicit role in decision-making about SPS

<sup>&</sup>lt;sup>5</sup> Indeed, in subsequent USDA assessments, implications similar to those from the marginal benefit-cost analysis worked their way into the quarantine regulations, but for somewhat different reasons. During a national survey of elevators in the fall of 1996, USDA detected Karnal bunt-like spores in a number of grain facilities in the Southeast. It was determined that the teliospores were for a fungus that affects ryegrass but not wheat. As the spores were indistinguishable from Karnal bunt teliospores, USDA did not impose a quarantine. In 1997, USDA changed the standard to define quarantine areas based on the presence of bunted kernels rather than Karnal bunt teliospores. The immediate effect of the regulatory change was the removal of the millfeed treatment requirement. In 1998, USDA relaxed the quarantine to allow commercial seed to move outside of the quarantine area. With these changes much of the original quarantine area returned to normal marketing. Karnal bunt losses in recent years have been small and confined to positive-tested grain.

regulations. The SPS Agreement of the WTO does not require countries to take into account cost/benefit analysis in making regulatory decisions—doing so might be considered a "WTO-plus good regulatory practice," as opposed to one, as Donna Roberts has previously described it, that is "merely legally defensible" (Roberts, Orden, and Josling 1999). A WTO-plus approach to regulation is unlikely to bring objections from trade partners since the results are likely to open trade opportunities otherwise precluded. The WTO agreement does require that countries employ measures that are least trade-restrictive. This requirement alone can push countries some distance toward economically sensible SPS regulatory decisions, since for any given objective in terms of achieving a specified level of risk, the least trade-distorting policies are those that achieve the risk objective most economically efficiently.

The avocado case study demonstrates the possibilities for either convergence or divergence between the policy implications from risk assessment and cost/benefit analysis. The USDA decision that a systems approach to risk management kept pest-infestation risk low enabled regulators to partially ease a longstanding ban on avocado imports from Mexico. This was a move to a less trade-distorting policy, and for this move there is convergence of decision-making criteria, at least in the sense that the limited-trade decision is only estimated to have a net positive effect on expected national welfare when pest risk is relatively low. The cost/benefit analysis also suggests an increase in welfare from a free trade policy even if pest infestation occurs with certainty. Free trade has not been considered a viable decision in recent policy determination, but additional steps toward trade opening will be evaluated. There is simultaneity between the rule, pest risk, and expected welfare. The more trade is opened, the higher may be the infestation risk, but also because of more trade, the less sensitive are the expected net welfare gains to the level of risk. One can imagine additional moves toward less trade-distorting policies that raise infestation risk (while still keeping that risk below a level deemed acceptable) simultaneously yield substantial net economic benefits. example, what is the risk associated with avocado imports into the entire eastern United States over the full year? Perhaps such a policy

captures most of the expected economic gains from free trade with relatively little additional risk exposure.

The Karnal bunt analysis by Glauber and Narrod, allows evaluation of just such relationships between quarantine options. Among eight options, they show a limited approach that restricts the movement of positive-tested grain and seed together with railcar cleaning achieves much of the potential risk reduction and expected welfare gains for the least direct cost. By highlighting the marginal cost and benefit of each protocol, they identify the most efficient options, and hence the options that would be least trade-distorting because they impose the least costs on producers within the quarantine area. Two of their option pairs achieve nearly identical reductions of risk. Within each pair, there is an efficient and an inefficient choice. Moreover, if the very similar levels of risk associated with these two choice-pairs are both considered acceptable by decision makers, then the single benchmark-railcar cleaning option emerges as being the most efficient among the four options. Cost/benefit analysis can not make risk management decisions for policy makers, as between the two similar risk levels in the Karnal bunt case. But cost/benefit analysis can help policy makers choose the efficient protocol if they are willing to consider such a trade-off, and understand the costs incurred, and for what ends, if they are not.

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# 12

## Quarantine decision-making in Australia

**MONIKA BINDER\*** 

A fundamental economic question about the Australian Government's decision-making process governing the import of animals, plants and their products is posed in this chapter. Does the process generate measures that not only reduce quarantine risk but are also consistent with the best possible use of Australia's resources? In other words, is Australia as a whole getting value for money from import decisions?

The chapter looks at import risk analysis (IRA) — the analytical tool that underpins quarantine decisions — as well as cost/benefit analysis (CBA) — an analytical tool of economists. It then examines the scope for incorporating CBA in import decision-making under the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement). The determination of the acceptable level of risk, and of risk conservatism.

#### Import risk analysis

The decision-making process that currently applies to requests to import animals, plants and their products is illustrated in Figure 12.1. It is administered by Biosecurity Australia within the Department of Agriculture, Fisheries and Forestry — Australia

<sup>\*</sup> The views expressed in this paper are those of the author and do not necessarily reflect those of the Productivity Commission.

INITIATION Initiated by AQIS 1.1 Import proposal lodged with AQIS stakeholder contact 1.2 proposal acknowledged priority considered (where required) type of risk analysis determined by AQIS program specialists proposed IRA approach approved by ED AQIS and stakeholders advised NON-ROUTINE RISK ANALYSES ROUTINE RISK ANALYSIS 2.1 risk analysis conducted 3.1 after consultation with stakeholders; issues, timing, Risk Analysis Panel determined draft IRA paper with recommendations agreed not agreed published, and comment invited on 3.2 appeal to Director of technical issues **3.3** appeal determined by director of Quarantine and stakeholders advised Panel 3.4 issues paper published and commend invited 3.5 risk analysis conducted 3.6 draft IRA paper with recommendations published and comment invited on technical issues DETERMINATION comment reviewed and risk analysis recommendations finalised 4.2 risk analysis recommendations submitted to ED AQIS **4.3** import proposal determined by ED AQIS determination and final IRA pape published and stakeholders determination agreed 4.5 appeal to Director of Quarantine on the process 4.6 appeal considered by Import Risk Analysis Appeal Panel appeal upheld & deficiency addressed appeal rejected 4.7 appellant & applicant advised IMPORT RISK ANALYSIS POLICY APPLIED

Figure 12.1: Import decision-making process

Source: AQIS (1998).

(AFFA). (Until recently, the Australian Quarantine and Inspection Service (AQIS) was the administrating agency.) It 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 sets out an appeal mechanism. It is distinct from the determination of the Government's response to any industry adjustment effects from allowing imports; that matter is handled separately (and independently) by another part of AFFA (DPIE 1997, p. 41).

A core element of the process is IRA. This was viewed by the Nairn Committee and the National Task Force as encompassing: 'risk assessment', 'risk management' and 'risk communication'. As Box 12.1 shows, their definitions of each of these terms are fairly similar, although the terminology does not accord strictly with that contained in the SPS Agreement, nor with the international guidelines of the International Office of Epizootics (OIE) and the International Plant Protection Convention (IPPC). It also differs from the approaches of other nations' quarantine regulators.

OIE and IPPC guidelines are relevant to Biosecurity Australia's IRAs (AQIS 1998 and 1999, p. 10). The current OIE 'model' of IRA was finalised in 1999. The current IPPC model was issued in 1996, with a new draft circulated for comment in 1999. The basic components of all these models are summarised in Table 12.1 using the terminology of the relevant organisation. Although the terminology frequently differs, all the models involve the identification of the risk of concern, the estimation of that risk, and an identification and evaluation of options to reduce that risk. The table also highlights where the models permit a degree of economic input.

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

### **Box 12.1: 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: 'risk assessment', 'risk management' and 'risk communication'. They defined these components as follows:

Tollows.		
IRA component	Nairn Committee	National Task Force
Risk assessment	The process of identifying and estimating the risk associated with an import and evaluating the consequences of taking those risks.	The process of identifying, estimating the statistical probabilities and evaluating the consequences potentially associated with the import of an animal, plant or product.
Risk management	The process of identifying, documenting these risks 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 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: Nairn et a	l (1996, p. 85); DPIE (1996, p. 10	08).

**Table 12.1: Basic components of three IRA models** 

OIE Guidelines (1999)	IPPC Guidelines (1996)	IPPC Draft Guidelines (1999)		
Hazard identification	Initiating the pest risk analysis process	Initiation		
	Pest risk analysis initiated by a pathway	Initiation points		
	Pest risk analysis initiated by a pest review of earlier pest risk analyses	Identification of pest risk analysis area		
	Conclusion	Information		
		Conclusion		
Risk assessment	Pest risk assessment	Pest risk assessment		
Release assessment	Geographical and regulatory criteria	Pest categorisation*		
Exposure assessment	Economic importance criteria*	Probability of introduction and spread assessment of economic consequences*		
Consequence assessment*	Introduction potential	Degree of uncertainty		
Risk estimation	Conclusion	Conclusion		
Risk management	Pest risk management	Pest risk management		
Risk evaluation	Options to reduce risk	(Acceptable) level of risk		
Option evaluation*	Efficacy and impact of options*	Technical information required*		
Implementation	Conclusion	Acceptability of risk		
Monitoring and review		Identification and selection of appropriate risk management options*		
		Phytosanitary certificates and other compliance measures		
		Conclusion		
Risk communication	Documentation	Documentation		

<sup>\*</sup>indicates that a degree of economic input is required within the particular component of the IRA model.

Sources: OIE (1999, section 1.4), IPPC (1996) and IPPC (1999).

Quarantine risks involve externalities. Importers of animals, plants or their products seldom have sufficient incentive (due to an absence of market price signals) to reduce the disease or pest risks associated with their imports. This is because, if diseases or pests were introduced, the associated costs would not be borne fully, or at all, by importers, but by local producers. Little recourse is available to local producers (say from common law negligence actions) to recover these costs from importers.

However, even though a *prima facie* economic rationale exists for governments to reduce quarantine risks, community well being overall may not be enhanced if the total cost of such intervention exceeds the total benefit. A fundamental trade-off is between the benefit to producers from reducing a particular quarantine risk and the cost to consumers from being denied cheaper products or products of different qualities or varieties.

A formal economic approach to help decide the full extent of the trade-offs involved in measures to reduce quarantine risk is CBA. <sup>1</sup>

#### **CBA** involves:

- identifying and measuring all the costs and benefits of a measure in reducing a quarantine risk to particular community groups relative to a situation of unrestricted trade;<sup>2</sup>
- determining the extent of net benefits (or net costs) to the community as a whole from implementing the measure;
- ranking the measure against alternative risk-reducing measures according to the magnitude of its net benefit (or net cost); and
- choosing the measure with the highest net benefit.

<sup>1</sup> 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.

<sup>2</sup> Here, the costs and benefits are measured by 'opportunity costs' and 'willingness to pay', respectively.

A result which found that all quarantine risk-reducing measures under consideration relative to unrestricted trade yielded net costs suggests that community well being would be enhanced by not placing restrictions on imports of the product.

#### Nature of costs and benefits

So what are the costs and benefits of measures to reduce quarantine risk relative to a situation of unrestricted trade?

The key costs 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. The extent of the cost to consumers will depend on the level of the import parity price (that would occur if trade were unrestricted) relative to domestic price that arises because of the measure in place, as well as the extent to which consumers are responsive to price changes (price elasticities of demand).<sup>3</sup>

The key benefits of measures to reduce quarantine risk are:

- a reduction in the expected cost to producers of disease or pest control;
- a reduction in the expected cost to producers of output losses associated with disease or pest entry and establishment; and
- the maintenance of Australia's disease or pest-free status (which facilitates access to export markets and benefits Australian consumers).

The magnitude of the benefits are often uncertain. In the absence of measures to reduce quarantine risk, different outcomes may occur for producers. One outcome is that diseases or pests do not enter and establish, in which case there would be no change in costs of production and output levels (and, thus, no benefits from introducing a measure to reduce quarantine risk). An alternative

<sup>3</sup> It is assumed that the domestic and imported products are identical. If they are not, then there would be costs from excluding imports which are associated with loss of variety or seasonality. This does not affect the essence of the analysis.

outcome is that diseases or pests do establish and substantially reduce output and access to export markets (which may mean there are not benefits from introducing a measure to reduce quarantine risk).

#### Acceptable level of risk

CBA does not involve specifying the acceptable level of risk explicitly. Underlying a measure with the highest net benefit is a level of risk which, if the measure is chosen, the community implicitly 'accepts' - zero being just one of a range of accepted risk levels. In this sense, from a community wide perspective, the acceptable level of risk is 'optimal'. Moreover, the optimal risk does not necessarily coincide with risk minimisation. This is very different to the meaning of acceptable level of risk given in the SPS Agreement and by quarantine regulators.

One way of visualising this is Figure 12.2. The top panel shows the community benefits and costs of reducing quarantine risk for a particular product below R°, which is the level of quarantine risk which would exist in the absence of any risk reducing measures. Associated with each level of risk below R° is a particular measure. The shape of the benefits curve assumes that there are decreasing marginal (or incremental) benefits to the community from reducing quarantine risk below R°. The cost curve assumes that the marginal costs of reducing risks below R° 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 benefit 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 quarantine risk. An issue raised later in this chapter is whether such differences might amount to discrimination under the SPS Agreement and thus bar CBA from having a role in import decision-making.

\$ Costs of risk reduction C\* Benefits of risk reduction B\* 0 Probability of disease or pest incursion \$ Net benefits of risk reduction NB<sup>2</sup> + 0  $R^{cb}$ R\* Probability of disease or pest incursion

Figure 12.2: An example of benefits and costs of quarantine risk reduction

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 quarantine risk-reducing measures: indeed, a matrix of outcomes could be envisaged. Table 12.2 provides a stylised example of what this might look like for three disease or pest events for the same product and three measures. The data used assume that the net benefit to the community declines as the degree of disease or pest incursion increases and also as the measure becomes

more restrictive (with import protocol B being more restrictive than import protocol A). In this example, nine net benefit outcomes are possible.

Whether or not probabilities could be assigned to these outcomes would depend crucially on the risk assessments undertaken in the IRAs. 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 measure. Indeed, a rule could be designed to reflect the community's attitude to risk. However, given that the SPS Agreement provides that SPS measures must be based on 'risk assessments', it is questionable whether such rules could be used. Moreover, the choice of decision rule is subjective; no one rule is objectively superior to the other.

If probability estimates could be assigned, then expected values could be estimated for each measure. For example, Table 12.2 gives indicative probabilities for the three disease or pest events. The probabilities of the adverse events (that is, events involving disease or pest incursion) decline as the measures become more restrictive. Conversely, probabilities of no disease or pest incursions increase. Thus, using the indicative probabilities in the table, the expected net benefit of allowing unrestricted imports is:  $0.7 \times 100 + 0.2 \times 70 + 0.1 \times 60 = \$90$  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. However, as will be seen later, this might not be an appropriate rule where the community is risk averse.

#### Accommodating risk aversion in cost/benefit analysis

Risk aversion implies that a measure to reduce quarantine 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 well being (or wealth), is preferred to a higher, but uncertain, level.

Table 12.2: A stylised matrix of net benefit outcomes

Measure	Net benefit if:						Expected net benefit for each measure	
	No disease entry or establish	· •	Disease/pest entry but no establishment		Disease/pest entry and establishment			
	\$m	prob.	\$m	prob.	. \$m	prob.	\$m	
Allow imports without restriction	100	0.7	70	0.2	2 60	0.1	90	
Import protocol A	80	0.8	65	0.15	50	0.05	76	
Import protocol B	30	0.9	20	0.075	5 5	0.025	29	

The results of CBA could be extended in various ways to accommodate risk aversion (as well as other risk attitudes). One approach where probability estimates are absent is to apply particular decision rules ('maximin' or 'minimax regret') which emphasise worst case outcomes. Other approaches where probability estimates are available are discounting and expected utility maximisation. Because of the questionable legitimacy of using decision rules under the SPS Agreement, only those approaches based on the availability of probability estimates, and their main limitations, are reviewed below.

Before reviewing them, it is worth noting that risk aversion could also be encompassed in the 'risk assessment' component of IRAs. This could arise, for example, where Biosecurity Australia estimates quarantine 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 accounting' of risk aversion if these risk estimates were to be used in CBA.

#### Discounting

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

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 subjective judgement.

#### Expected utility

Another approach to accommodating risk aversion where probability estimates are known is to apply a utility function which reflects the decision maker's subjective valuation of alternative risky prospects (probability distributions of wealth or gambles). A utility function would be based on specific assumptions about the decision maker's preferences. It could be applied to choosing amongst alternative risky prospects, with the aim of maximising the expected utility value.

The following stylised example shows how this approach can be applied. Suppose a utility function exists which reflects the decision maker's aversion to risk (say):  $U(w) = \log_{10}w$  where w is a net benefit (or cost) outcome from applying a particular measure. Now suppose the removal of an import ban is considered. There are two possible net benefit outcomes from unrestricted trade: \$100 million with probability 0.7 (where no diseases or pests enter or establish) and \$60 million with probability 0.3 (where diseases or pests enter and establish). The expected value of this net benefit is:  $0.7 \times $100 \text{ million} + 0.3 \times $60 \text{ million} = $88 \text{ million}$ . The expected utility of the net benefit is:  $0.7 \times $100 \text{ million} = $100 \text{ million}$ 

Now consider another measure which replaces an import ban with an import protocol. The net benefit outcomes are \$80 million with 0.8 probability (where there are no diseases or pests) and \$50 million with 0.2 probability (where diseases or pests enter and establish). The expected value of net benefit is \$74 million and the expected

utility of net benefit is:  $0.8 \times U(\$80 \text{ million}) + 0.2 \times U(\$50 \text{ million}) \Rightarrow 0.8 \times \log_{10} (\$80 \text{ million}) + 0.2 \log_{10} (\$50 \text{ million}) = 0.8 \times 7.9 + 0.2 \times 7.7 = 7.86.$ 

In choosing between the two measures — removal of the import ban and imposition of an import protocol — the aim is to maximise the expected utility value. Hence, the measure involving removal of the import ban would be preferred because the expected utility value of this measure is higher than that of the protocol.

There have been various criticisms of the theoretical underpinnings of the expected utility approach. They have generally focused on the realism of the assumptions (or axioms) concerning the decision maker's preferences over risk prospects, which invariably demand a good deal of rationality.

#### Is there a role for cost/benefit analysis?

As noted earlier, CBA has the potential to inform import decisionmaking by providing an insight into the community-wide resource effects of measures to reduce quarantine risk.

However, CBA has not played a role in IRAs undertaken in the past by Biosecurity Australia's predecessor, AQIS, or indeed, in other countries' quarantine regimes. The economic input which applied was of a limited nature. In its handbook on the import decisionmaking process, AQIS stated:

"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' 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 loss of markets due to an outbreak [of pests or disease]." (AQIS 1998, 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]." (AQIS 1998, p. 11).

And recently it said at the 2000 Outlook conference:

"In setting its [appropriate level of protection], a World Trade Organization Member strikes a balance between the risk of pest or disease incursion (and the associated potential for damage) and the benefits of trade (which include access to produces of other countries for both consumption and production improvement)." (Gascoine, Wilson and McRae 2000, p. 176).

This limited economic input is apparent in a recent IRA report by AQIS on the importation of crocodile meat from Zimbabwe. In that report, economic input comprised during:

- *risk assessment* (under the heading of 'consequence assessment') of qualitative assessments of surveillance and control costs, compensation costs (to local producers), potential trade losses and adverse effects on other industries; and
- *risk management* of qualitative assessments of the impact of options on the consequence assessment (AQIS 2000).

An issue thus arises as to whether CBA should play a greater part in import decision-making and, in particular, in determining the measure to be applied to achieve, in the parlance of the SPS Agreement, an 'appropriate level of Protection'.

Various arguments have been put forward against such a proposal (for example, see Sinner 1999). These arguments generally focus on the potential for CBA to breach the SPS Agreement.

One argument is that, in deciding amongst measures to be applied to reduce quarantine risk, Article 5.3 does not include consideration of the competition- or trade-related impacts of allowing or restricting imports on consumers or producers. 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 diseases or pests, it simply does not address the competition- or trade-related impacts of allowing or restricting imports on consumers or producers. There is nothing in the Article to suggest that only specified factors must be taken into account in choosing amongst measures to reduce quarantine risk.

A second argument against the use of CBA 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 about the use of CBA is that it 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 quarantine risks, which face different demand and supply conditions in Australia. Here, it is possible that one CBA suggests that the preferred measure is to restrict imports, while the second CBA suggests that imports be allowed.

However, this argument may really be one against defining the scope of CBAs (and even IRAs) too narrowly, not against CBA itself. For example, it is possible that divergent results would not arise for 'generic' CBAs, that is, CBAs which focus on a product from all countries, not just a particular country, or on products which are close substitutes. Even if the argument were valid, one option would be to not act in accordance with divergent results from a CBA.

A third argument against the use of CBA is that it could lead to 'distinctions' in the levels of acceptable risk in 'different situations' and thus breach Article 5.5. This Article (known as the consistency requirement) 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 WTO's Appellate Body in the Hormones and Salmon cases provided guidance on the interpretation of this Article. For the Article to be breached, the Appellate Body stated that three elements must be present:

- the Member imposing the measure complained of has adopted its own acceptable levels of risk in several different (but comparable) situations;
- those acceptable levels of risk 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 of international trade.

The SPS Committee's guidelines on this Article appear to largely codify the views of the Appellate Body (WTO 2000).

Although differing levels of acceptable risk could emerge from CBA in different situations, this does not mean that they are 'arbitrary or unjustifiable'. Indeed, it could be argued that linking acceptable risk levels to CBAs is a way of avoiding a breach of this Article as it ensures decisions are backed by objective analysis.

A final argument is that the use of CBA is limited by Article 3.1 which requires measures to be 'based on 'international guidelines (as well as standards and recommendations) where they exist, except as otherwise provided in the Agreement. Nonetheless, as the Appellate Body noted in the Hormones case, 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. Thus, there is still scope for CBA to be used even where there are international guidelines, standards and recommendations advocating a specific SPS measure.

Interestingly, OIE and IPPC guidelines do not appear to discount the use of CBA in their IRA models. Although the OIE model is non-committal on the nature of economic input in risk management, both IPPC models explicitly allow the choice of measures to be based on CBA. Indeed, the IPPC Draft Guidelines provide that in selecting measures to reduce pest risk, 'cost/benefit analysis for each of the minimum measures found to provide acceptable security may be estimated' (IPPC 1999, section 3.4).

Thus, there does not appear to be anything in the wording of the relevant provisions of the SPS Agreement, WTO Appellate Body guidance to date, or in the OIE and IPPC guidelines that expressly rules out the use of CBA in the risk management component of IRAs. Provided that the minimum requirements of the SPS Agreement in respect of 'risk assessment' and determining the 'appropriate level of protection' are satisfied, it would be in the interest of the overall Australian community that CBA (or at least cost-effectiveness analysis) be applied.

This is not to say that a CBA should be undertaken in every case. It (and, indeed, a full IRA) is resource intensive and, accordingly,

should be rationed. The following are some suggestions about how and when it could be used.

A CBA could be unnecessary if Biosecurity Australia assesses the quarantine risk in a particular case to be 'zero or negligible'. This approach is similar to ensuring that the assessed risk falls within a target or threshold level of risk before proceeding into the risk management component of IRA. (Indeed, as discussed below, a target of 'zero or negligible' risk could be perceived as an 'acceptable level of risk').

Generic or more broadly based CBAs could be undertaken. For example, instead of focusing on a particular product from a particular country, a CBA could be extended to encompass a particular product from all countries. In taking this approach, however, consideration may need to be given as to whether the scope of IRA overall could feasibly be broadened.

Qualitative CBAs, which are not so data intensive, could be undertaken. In this regard, adherence to the guidelines on Regulatory Impact Statements - effectively a template of CBA - set out by the Office of Regulation Review (1998) may prove sufficient.

#### The acceptable level of risk

The SPS Agreement gives Members a right to determine their own level of acceptable risk (or, in the words of the SPS Agreement, 'appropriate level of protection') provided they:

- take into account the objective of 'minimizing negative trade effects' (Article 5.4); and
- meet the consistency requirement (Article 5.5).

Although it is not clear from the SPS Agreement what acceptable level of risk means — it is tautologically defined — the WTO's Appellate Body provides some guidance. In the Salmon case, the Appellate Body said that:

• it is a prerogative of the Member concerned;

- it is an 'objective' and its determination is an element in decisionmaking 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.

According to comments by the Government and AQIS, Australia's acceptable level of risk is low, but not zero. The Government has said 'there will always be an element of risk' with imports (DPIE 1997, p. 10). AQIS has said that 'quarantine policies are based on the concept of the management of risk to an acceptably low level' (AQIS 1998, p. 11). AQIS said that 'a guide to the [appropriate level of Protection] is community and industry acceptance of [previous] quarantine decisions taken' (AQIS 1999, p. 15, and Senate Rural and Regional Affairs and Transport Legislation Committee 2000, p. 82).

Apart from these comments, there is no guidance as to what 'acceptably low' means or how the concept is applied in individual cases. Indeed, the Senate Rural and Regional Affairs and Transport Legislation Committee (2000, p. 97) expressed disquiet recently over the vagueness of the concept, when it said:

"The Committee is concerned about the difficulty of defining 'Appropriate Level of Protection'. .... putting in place quarantine measures determined against a concepts which is inherently vague and unsubstantiated, and which can only be inferred from analysing decisions on quarantine applications, is a recipe for inviting confusion and criticism."

In general, there are a number of approaches to determining whether a quarantine risk is acceptable. As noted earlier, CBA is one approach. Alternative approaches involve the following:

• Expressly identifying a risk target or threshold and then comparing the particular quarantine risk of concern against this target. There are various ways of expressing the risk target. For example, the IPPC Draft Guidelines (IPPC 1999, section 3.1)

suggested that 'acceptable level of risk' may be expressed in 'reference to existing phytosanitary requirements, indexed to estimated economic losses, expressed on a scale of risk tolerance or [expressed] in comparison with the level of risk accepted by other countries'.

- Examining the risks associated with decisions taken in respect of other similar products with similar risks, from the application of a particular technology or process, or from certification that a product is 'disease or pest free', and then comparing these risks with the particular quarantine risk of concern (see Box 12.2).
- Focussing on particular trade-offs (but not CBA trade-offs) such as between the particular risk of concern and the benefits of trade ('risk benefit analysis') or between the particular risk of concern and other risks ('comparative risk analysis').

A common feature of these alternative approaches is that they involve limited or no consideration of the community wide tradeoffs associated with importing a product with quarantine risk.

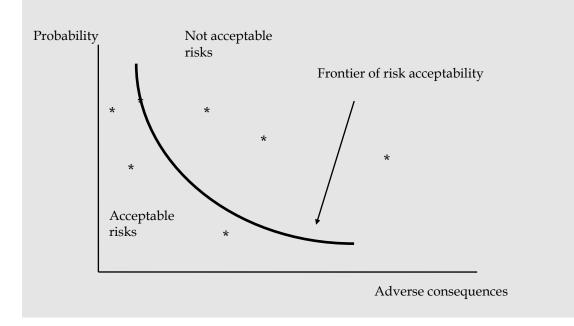
Given the significance of the concept under the SPS Agreement and the lack of clear guidance to date by either the Government or by Biosecurity Australia (or its predecessor AQIS), it appears that issuing detailed guidelines on acceptable risk would make transparent this crucial aspect of import decision-making. At the very least, more detail could be given by Biosecurity Australia in its IRA reports about what is, in a particular case, the 'acceptable' risk and how it is determined. This approach was effectively endorsed by the Senate Rural and Regional Affairs and Transport Legislation Committee (2000, p. 97) recently when it said:

"the standard against which the risk is being determined must be subject to some standards, guidelines or definition. ... [Furthermore] the determination of the [appropriate level of Protection] is a matter for Government and not one which is appropriate for individual agencies. Nor should the determination of the [appropriate level of Protection] be seen to be within the scope of one particular agency's functions."

### Box 12.2: Inferring risk acceptability

One approach to determining whether an assessed quarantine risk is acceptable or not is to compare it with the quarantine risks associated with other situations (such as previous quarantine decisions). 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 acceptable risk levels could be drawn. A slight variant of this approach is the 'risk evaluation matrix' devised by AQIS (see Senate Rural And Regional Affairs and Transport Legislation Committee 2000, p. 144).

Although this approach ensures consistency in decision making, it does not of itself explain all the factors relevant in determining whether or not a risk is acceptable.



#### Conservatism in IRA

Conservatism in IRAs can occur during the risk assessment (for example, in the choice of data, assumptions and risk estimation techniques) and in risk management components.

It could be argued that this is consistent with Australia's conservative attitude to risk. However, applying a conservative approach to both risk estimation and to risk management can unnecessarily bias decision-making away from measures which

enhance community well being. Indeed, as noted earlier, it could lead to a kind of 'double accounting' of risk attitudes.

In principle, it would be preferable if the assessment of risk involves, as far as possible, an objective appraisal of data and information. This means avoiding the incorporation of particular risk attitudes in risk assessment. Otherwise, risk estimates could be biased towards the 'high end' and risk attitudes would be better incorporated in deciding among the measures to reduce risk. For example, risk attitudes could be incorporated in the choice of risk target to be achieved or, if CBA is used, in applying a specific risk aversion factor or decision rule.

#### Conclusion

Biosecurity Australia's predecessor, AQIS, has done much in recent years to address the shortcomings of its previous approach to IRA and import decision-making (see the following chapter in this volume, by Tanner). There is now a more formalised appellable decision-making process with greater opportunity for stakeholder participation. There is also in place a program of review of IRAs on aquatic animals. As well, quarantine proclamations have been rationalised, and the informative quality of IRAs has increased markedly.

That said, there is scope for futher improvement. Provided the minimum requirements of the SPS Agreement are met, consideration by Biosecurity Australia of the well-being of the Australian community should be paramount in its import decision-making process. Implementing measures to reduce quarantine risk, although yielding benefits, is not cost-free. In the context of IRA, priority attention should be given to incorporating some form of CBA (or cost-effectiveness analysis), issuing general guidelines on the 'acceptable level of risk' (or at least expressing its meaning more clearly in particular IRA reports) and avoiding a double accounting of risk attitudes in IRAs.

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# 13

# Quarantine reform: Australia's recent experience

**CAROLYN TANNER\*** 

Three years after the Australian government announced major changes to Australia's quarantine system, quarantine-related issues continue to elicit strong interest from the media, some industries and foreign governments, and quarantine remains high on the policy agenda. It is therefore time to ask: what have been the major outcomes of reforming the Australian quarantine system and what now are the key issues from an economic perspective?

This chapter addresses these questions by first briefly reviewing the background to and major tenets of the report of the Australian Quarantine Review Committee (Nairn *et al.* 1996) which formed the basis for the government's fundamental reforms to the quarantine system announced in August 1997 (DPIE 1997). The chapter examines the broad outcomes resulting from the government's reforms before focusing on the key issues of managed risk (in particular, import risk analysis) and the continuum of quarantine (that is, expanding the scope of quarantine to include pre-border, border and post-border activities that assist in achieving the quarantine objective). Finally some comments are made about the performance of quarantine delivery and the goal of quarantine from an economic perspective.

<sup>\*</sup> The author wishes to thank Mal Nairn, Andrew Inglis, Mike Nunn and Warren Vant for helpful comments and Mark Kethro, Warren Vant and Neil McWaters for assistance with the tables.

# Australian quarantine reform

The efficacy of the Australian Quarantine and Inspection Service (AQIS) — the organisation responsible for the development of Australia's quarantine policy and programs — was called into question in the early 1990s by the entry into Australia of a succession of exotic pests and diseases that attracted wide media attention¹. Concern about the adequacy of Australia's quarantine system was exacerbated by a highly politicised and public debate concerning the entry conditions for a number of products on which AQIS and industry representatives were unable to reach common ground for deciding issues on their scientific merit. As Nairn *et al.* (1996, p.3) observed, the debate was 'resource-intensive and time-consuming' and led to 'community concern about Australia's quarantine services'.

Coincident with the controversy concerning the Australian quarantine system, major developments were occurring in world trade and other areas relating to quarantine, including:

- the conclusion of the Uruguay Round, which opened up trade opportunities and enhanced exporters' expectations with respect to market access;
- the negotiation of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement), which defined the rights and obligations of Members of the World Trade Organization (WTO) with respect to the development and implementation of quarantine controls;
- the increasing use of the 'clean, green' reputation by food exporting nations such as Australia, partly in response to increased consumer concern for food safety;

<sup>&</sup>lt;sup>1</sup> With the restructuring of Agriculture, Fisheries and Forestry – Australia (AFFA) which occurred in mid-2000, these activities have been relocated in the Market Access and Biosecurity group of AFFA, but the same staff are involved. To avoid confusion and for consistency with the *Handbook*, staff conducting IRAs will be referred to as AQIS staff throughout this chapter.

- rapid increases in the volume of world trade and international passenger movements (in the order of 10 per cent per year); and
- significant scientific advances in surveillance and identification techniques for animal and plant pests and diseases (Nairn *et al.* 1996, pp 3–4).

In response to mounting criticism of the Australian quarantine system from primary producer groups, the scientific community and the general public, the then government set up an independent review of Australia's plant and animal quarantine policies and procedures in December 1995, chaired by Professor Malcolm Nairn. Following a general election in March 1996, the review was endorsed by the Coalition Government and the Review Committee's report was presented to the new Minister for Primary Industries and Energy (the Hon. John Anderson MP) in November 1996.

The report - *Australian Quarantine: A Shared Responsibility* - proposed fundamental changes to the culture of the quarantine service and the way quarantine policies are developed and put into effect. Central to the Nairn Review's recommendations was the need to develop a 'partnership approach' that embraced industry, governments and the wider community. The basic tenets of the Nairn Review can be summarised as follows:

- development of a partnership approach to quarantine policies and programs involving the whole Australian community - the general public, industry and governments;
- establishment of a statutory authority to develop national quarantine policy and ensure national delivery of quarantine services;
- establishment of a more balanced approach to animal and plant health and quarantine by providing additional inputs for plant health and quarantine;
- development of a more formally structured process for conducting risk analyses to provide a scientifically based foundation for a policy of manageable risk;

- acknowledgment of the importance of quarantine to the natural environment;
- expansion of the scope of quarantine by recognising the importance of activities in all three elements of quarantine pre-border, border and post-border as a continuum; and
- enhancement of the focus on pre-border and post-border activities of the continuum of quarantine in the achievement of Australia's quarantine goal (Nairn *et al.* 1996, pp. 11–12).

In its response (DPIE 1997), the government accepted the basic principles and recommendations of the Nairn Review — with the exception of the recommendations to set up a statutory authority to be responsible for quarantine policy and programs, and to establish a key centre for quarantine-related risk analysis — and provided funding in the order of A\$76 million over a four-year period.<sup>2</sup>

# **Key outcomes**

In its response to the Nairn Review, the government stressed the of Australia's quarantine system for potential importance agricultural exports and the need for 'a credible quarantine policy that is consistent with international rules and standards' (DPIE 1997, p. 8). The government emphasised the need to 'accept the international rules with which we expect our trading partners to comply' and to base quarantine decisions 'on the weight of scientific evidence and judgement' (DPIE 1997, p. 8). In providing additional funds to enhance the quarantine system, the government placed particular emphasis on increasing community awareness, applying the principle of 'manageable risk' (based on science) to quarantine decisions, protection of Australia's unique environment and recognition of the continuum of quarantine (that is, quarantine needs to be seen as a continuum of pre-border, border and postborder measures). Greater emphasis was also to be given to improved consultation in import risk analysis, increased monitoring

<sup>&</sup>lt;sup>2</sup> The government's response was a joint response to the Nairn Review and to the National Task Force on Imported Fish and Fish Products (DPIE 1996).

for pests and diseases, and enhanced national preparedness and response capacity (especially for plants and aquatic animals).<sup>3</sup>

In providing significant funding for quarantine - at a time of overall budgetary stringency - the government demonstrated its commitment to maintaining a strong quarantine system (Tanner and Nunn 1998). Consistent with the government's endorsement of the underlying rationale of the Nairn Review of a 'shared responsibility', two-thirds of the funding has been provided by government, with the remainder being contributed by industry through the application of AQIS's existing full cost-recovery policy.

The Government's endorsement of the partnership approach established a framework for a change in the culture of quarantine that recognises that quarantine is not the sole responsibility of government but that all members of the community as well as industry and governments need to be involved. Overall, the reforms that have been made to the Australian quarantine system have led to greater transparency, which is consistent with Australia's international obligations and trade objectives as a major agricultural exporter and leader of the Cairns Group. At the same time, the quarantine system has been strengthened and its focus extended beyond the border. Strengthening the pre-border and post-border elements of the continuum of quarantine is particularly important in managing the quarantine threats inherent in increasing volumes of trade and numbers of tourists (Tanner and Nunn 1998).

In its response to the Nairn Review, the government indicated that it had been guided by 'seven key quarantine themes':

- managed risk (based on science);
- a continuum of quarantine;
- community responsibility;
- consultative decision-making;

<sup>&</sup>lt;sup>3</sup> For the allocation of additional funds to major functional areas, see DPIE (1997, p. 10).

- external input to quarantine policy;
- enhanced capacity in plant quarantine protection and policy; and
- delivering quarantine objectives (DPIE 1997, p. 9).

The seven quarantine themes set out above are clearly inter-related and have led to a suite of reforms. Arguably, the first two are of greater significance and will be discussed in more detail.

### Managed risk

At the time of the Nairn Review, import risk analysis (IRA) was a highly controversial issue, and addressed in many submissions. Despite the changes that have been made to the IRA process, Australia's quarantine risk analyses continue to attract criticism from Australia's major trading partners, some domestic stakeholders — particularly those whose economic interests are affected by the IRAs — and the media. In addition to the scrutiny of the WTO Panels, the IRAs carried out by the then AQIS for uncooked Pacific salmon products have been the subject of a recent Senate Committee inquiry (Senate 2000).<sup>4</sup>

Each of Australia's quadrilateral partners has expressed concerns about Australia's quarantine regime — for example, New Zealand with respect to apples, Canada with respect to salmonids and pigmeat, and the United States with respect to chicken meat, pigmeat, salmonids and table grapes — as have the ASEAN countries, notably Thailand (on durian and chicken meat) and the Philippines (on tropical fruits). The European Union (EU) has long held and expressed concerns about Australia's quarantine policies as they affect EU plant and animal exports. It is well recognised in international trade circles that such concerns about Australia's quarantine policies can have an adverse impact on market access for Australian export products, as recent events in the Philippines

<sup>&</sup>lt;sup>4</sup> It should be noted that the 1996 IRA on salmon was undertaken prior to the new IRA process being implemented and the 1999 IRA was conducted under an accelerated procedure due to time constraints arising from the WTO proceedings.

clearly demonstrated. Recently, Australia's quarantine goals have also come under scrutiny by economists (see, for example, James and Anderson (1998) and Rodriguez *et al.* (2000) - the particular issues raised by economists are addressed in the next section).

The Nairn Review endorsed the government's 'managed risk' approach to quarantine. This is the only appropriate approach in view of the increasing levels of international trade and tourism and the finite resources available to AQIS to prevent establishment of pests and diseases. There is also the constant threat of pests and diseases entering through 'the natural movement of wildlife, such as migratory birds, or [being] borne long distances on wind or sea currents' (Nairn *et al.* 1996, p. 21). The community therefore needs to accept a pragmatic approach to quarantine that is consistent with increasing trade and tourism and the threat of disease and pathogen entry through natural pathways.

The Nairn Review identified a number of fundamental principles that should apply to import risk analysis, similar to those that apply in other disciplines such as food safety (ANZFA 1996) and environmental sciences (Norton, Beer and Dovers 1996). In summary, risk analysis should be:

- conducted in a consultative framework;
- based on science and politically independent;
- transparent and open;
- consistent with other government policy and Australia's international obligations;
- harmonised to take account of international standards, guidelines and recommendations; and
- subject to appeal on process (Nairn et al. 1996, pp. 89-90).

These six principles were endorsed in the government's response and incorporated into the new IRA process that came into effect in 1997 (DPIE 1997 p. 21). The major differences between the new IRA processes and the previous practice adopted by AQIS is in the 'duration, timing and consultative requirement, and the provision for an appeal mechanism' (Tanner and Nunn, 1998 p. 450). *The AQIS Import Risk Analysis Process Handbook*, which was published in August 1998, sets out — for stakeholders and other interested parties — the process that Biosecurity Australia follows in

Table 13.1: Plant and animal quarantine decisions, 1993/1994 to 1999/2000

Number of	1993/	1994/	1995/	1996/	1997/	1998/	1999/	Totals
decisions	1994	1995	1996	1997	1998	1999	2000	
Plant	5	13	11	5	8	7	5	54
Reviews	2	5	5	5	8	1	3	29
IRAs <sup>a</sup>	3	8	6			6	2	25
Animal	15	13	16	20	14	22	20	120
Reviews	9	6	8	16	7	12	5	63
IRAs <sup>a</sup>	6	7	8	4	7	10	15	57
Total	20	26	27	25	22	29	25	174
Reviews	11	11	13	21	15	13	8	92
IRAs	9	15	14	4	7	16	17	82

a. Caution should be used in comparing activity before and after the new IRA process (which was introduced in September 1997). The new process is more extensive, thorough, consultative, transparent and significantly more resource intensive. Before the new process, all the animal quarantine decisions followed a period of stakeholder consultation while for plant issues a large percentage (50%) were based on pre-existing policy and required minimal consultation. Those included above as 'IRAs' are ones that involved new policy and more extensive analysis than those counted as reviews.

Source: Biosecurity Australia.

conducting an IRA. As shown in Table 13.1, many of the import requests received by Biosecurity Australia can be addressed relatively quickly without the need for a formal IRA process. Those requests that involve significant variations in established policy require an IRA to be carried out. For the period 1993/94 to 1999/2000, 174 plant and animal quarantine decisions were made in

response to requests to import products or material not previously permitted. Of these decisions, more than half could be dealt with using the less formal review process, whilst the remainder - some 82 decisions - involved more complex issues, requiring a full IRA. Although caution needs to be exercised in comparing data before and after the introduction of the new IRA process, Table 13.1 indicates that the proportion of requests being addressed via IRAs has increased. This is largely a function of the increased funding of risk analysis that has allowed a greater number of IRAs to be undertaken simultaneously.

An IRA may be conducted on a 'routine' or 'non-routine' basis, depending on the complexity of the issues involved, but either way there is opportunity for extensive consultation with stakeholders who may lodge appeals if not satisfied that the process — as set out in the AOIS Handbook - has been followed. Routine IRAs are handled 'in-house' by Biosecurity Australia, with scientists and other experts both within Biosecurity Australia and outside being consulted, as required. More complex proposals (non-routine risk analyses) involve the establishment of an expert panel (called a risk analysis panel or RAP) to conduct the IRA. Staff of Biosecurity Australia's Plant and Animal Quarantine Policy Branches are responsible for assigning priorities to import requests, conducting management options developing risk IRAs, and recommendations to the Director of Quarantine as to which option meets Australia's appropriate level of protection (ALOP) or level of manageable risk in the least trade-restrictive way.5 These staff are also responsible for arranging stakeholder consultations and the negotiation of the final import protocol with the exporting country's relevant agency.

The process is designed to ensure that the risks of entry, establishment and spread of pests and diseases, and their potential

<sup>&</sup>lt;sup>5</sup> With the restructuring of Agriculture, Fisheries and Forestry — Australia (AFFA) which occurred in mid-2000, these activities have been relocated in the Market Access and Biosecurity group of AFFA, but the same staff are involved. To avoid confusion and for consistency with the *Handbook*, staff conducting IRAs will be referred to as AQIS staff throughout this chapter.

impacts are fully evaluated. Imports are only permitted where such risks can be managed in a way that is consistent with Australia's very conservative approach to quarantine risk management. The ALOP is essentially Australia's quarantine goal and the import decisions and quarantine protocols are the means of achieving that goal. The concept of ALOP is discussed in detail above in Chapters 6 to 10 of this volume. Suffice to say here that Australia's ALOP is not quantified (nor is any other country's). Despite being relatively straightforward in concept, ALOP is not easy to define and is often not well understood by stakeholders. Consistency in the application of the concept is 'achieved by reference to existing Australian policies and procedures, by reference to relevant international standards, guidelines and recommendations, and through the contribution of experienced risk analysts' (Tanner and Nunn 1998, p.451).6 The additional funding for risk analysis provided by the government has allowed additional scientific staff to be hired by AQIS and outside expertise to be contracted, as appropriate.

The transparency of the overall process has increased since the publication of the *Handbook*. In addition, Biosecurity Australia maintains public files for all IRAs (accessible to all parties), a register of stakeholders is established for each IRA, and registered stakeholders receive progress reports on the IRAs.<sup>7</sup> As of mid-2000, 26 IRAs had been completed under the new procedures that were implemented in 1997. A further 46 IRAs are in process and over 150 requests for import market access — some dating from the early 1990s — await consideration.

<sup>&</sup>lt;sup>6</sup> As discussed in AQIS (1999a), while Australia's ALOP is illustrated by the body of quarantine decisions, inevitably 'outliers' will occur. This is particularly the case with older decisions or in cases where new scientific evidence has emerged or new technologies have been developed. Review of such decisions is an on-going process.

<sup>&</sup>lt;sup>7</sup> Biosecurity Australia is developing a publication on the technical guidelines used in undertaking an IRA and developing risk management procedures to complement the *Handbook* and to make the overall process more transparent. The method of analysis used by Biosecurity Australia is based on the international standards produced by the Office International des Epizooties (OIE) and the International Plant Protection Convention (IPPC) and are consistent with the requirements of the SPS Agreement.

Experience with the new IRA process suggests that the majority of IRAs — particularly those involving products that do not compete directly with Australian industry or provide new genetic material — are not controversial. Criticism of AQIS and the new IRA process has often come from industries that perceive their economic interests are threatened by entry of competing product from overseas if quarantine restrictions were lessened or removed. Of the IRAs completed under the new process, the IRAs on table grapes and durians have been particularly contentious. Since the right to appeal was introduced, there have been appeals in 12 IRAs, with the stakeholder concerns ranging from the priority accorded the IRA and the composition of the Risk Analysis Panel to criticisms of the risk analysis itself (see Table 13.2 for details of appeals and their outcome). Major criticisms by stakeholders include claims that the then AQIS:

- failed to attach sufficient weight to scientific evidence submitted by domestic industry (or judgements of their nominated experts);
- lacked sufficient scientific basis for the conclusions reached;
- failed to explain adequately how it reached its conclusions both about the assessment of risk and the efficacy of the proposed risk management procedures for reducing the risk;
- was not sufficiently conservative in interpreting the ALOP; and
- did not consult widely enough when the routine process was used.

The two Import Risk Analysis Appeal Panels that considered the appeals on durians and table grapes each concluded that the then AQIS did not fail to consider significant bodies of relevant scientific evidence but that AQIS had failed to provide sufficient transparency in respect to certain technical matters. Notwithstanding these criticisms, the process exhibits a higher degree of transparency and stakeholder involvement, compared with the earlier process used by the then AQIS and the IRAs conducted by major trading partners. Notwithstanding, there is still room for greater understanding by stakeholders of the underlying principles of the IRA process and the

international framework within which Australia operates, greater transparency in the risk analysis itself and more consultation with stakeholders in the early stages.

Overall, the changes that have been made to the IRA process, together with additional funding, have enhanced the technical capacity of Biosecurity Australia to undertake IRAs and ensured that the six fundamental principles of risk analysis are met. The process is clearly structured, transparent and consultative. It is common practice to involve outside experts in both routine and non-routine IRAs, thus ensuring a strong scientific and technical basis for risk analysis and quarantine decisions. While continuing to maintain a very conservative quarantine policy, recent decisions clearly indicate that Biosecurity Australia is implementing a managed risk approach (based on science), consistent with Australia's international obligations. In commenting on the effectiveness of Australia's quarantine protocols, Gascoine et al. (2000, p. 177) note that Australia's import protocols '... are among the most stringent in the world' and that 'no pest or disease incursions have been attributed to import decisions by the then AOIS'.8

<sup>&</sup>lt;sup>8</sup> See AQIS (1999b) for a list of pest and disease incursions since 1997 and likely source of introduction.

Table 13.2: Summary of appeals received in Australia

Subject of IRA	Basis of Appeal/s	Appeal/s Considered by	Outcome
Prawns and	RAP membership	Director of	Dismissed
prawn products	Consultation process	Animal and Plant	
-		Quarantine	
		(Director APC)	
Bulk maize from	Priority accorded to	Director APC	Dismissed: not an
the United States	the IRA		appealable matter
Psittacines	RAP membership	Director APC	Dismissed
Non-viable	Timetable	-	Encompassed into
salmonid	RAP membership		a broader
products	• Scope		accelerated IRA
Live and novel	Inconsistency in the	-	Inconsistency
veterinary	final conditions		addressed and
vaccines			appeal withdrawn
Non-viable	RAP membership	Director APC	Dismissed
bivalve molluscs	_		
Hatching eggs of	No details provided	-	Withdrawn
domestic ducks			
Edible eggs and	• Scope	Director APC	Dismissed
egg products	• Timetable		
	RAP membership		
Fresh durian	Transparency of the	Import Risk	Upheld on
fruit from	process	Analysis Appeals	transparency on
Thailand	Risk analysis failed	Panel (IRAAP)	the basis that
	to consider a		AQIS had failed to
	significant body of		fully explain four
	relevant scientific or		technical issues
	technical information		
Table grapes	• Transparency of the	IRAAP	Upheld on
from California,	process		transparency on
United States	Risk analysis failed		the basis that
	to consider a		AQIS had failed to
	significant body of		fully explain two
	relevant scientific or		technical issues
	technical information		
Uncooked	RAP membership	Director APC	Dismissed
chicken meat	• Scope		
	• Timetable		
	• Approach		
Camelids from	• ALOP	IRAAP	Not an appeal-
Chile and Peru			able matter

Source: AFFA

# Continuum of quarantine

Putting into effect the concept of a continuum of quarantine — involving pre-border measures to reduce the threat of entry, well-targeted border controls and post-border measures such as monitoring and surveillance to detect incursions at an early stage, backed up by emergency response plans to contain, control or eradicate pests and diseases when incursions occur — is one of the major outcomes of the quarantine reform. Although border activities continue to be central to the quarantine system, greater emphasis is now placed on pre-border and post-border activities than was the case in the past.

#### Pre-border measures

Pre-border measures are essentially a means of managing the quarantine risks off-shore. Measures include the identification, surveillance and monitoring of quarantine threats off-shore and managing these risks through co-operative programs of training, research and education; pre-clearance of goods off-shore; and promotion of quarantine awareness among Australian and overseas travelling and trading communities. Major initiatives include accrediting fumigation treatment providers, establishing timber certification standards for Canada and the United States, and extensive awareness promotions in the travel industry and with national Olympic committees in the period leading up to the Olympic Games in Sydney. The Northern Australia Quarantine Strategy (NAQS) has achieved considerable success in looking for and identifying threats in Papua New Guinea and Indonesia.

The government has endorsed the expansion of pre-clearance activities as part of the pre-border phase of importation. Pre-border activities, which are monitored at the border, include pre-cleared fruit and vegetables from a number of countries including New Zealand and Japan, pre-cleared military and agricultural equipment, and inspection of athletes' personal effects and equipment before their return to Australia (used for the Olympic Games in Atlanta and the Commonwealth Games in Malaysia). Since Australian troops were deployed in East Timor, Biosecurity Australia staff have

been stationed in East Timor and additional staff have been stationed in Darwin to mitigate the threat posed by the frequent movement of personnel and equipment between East Timor and Australia.

#### Border measures

The implementation of the government's response to the Nairn Review has seen the deployment of additional staff and other resources aimed at improving border integrity. The focus of the Nairn Review's recommendations was that there should be better targeting of border activities to focus on paths identified as involving high risk of pest and disease incursion. As a result there has been significant data collection and analysis in a number of areas (including air passengers, air couriers and international mail exchanges, and external container inspections) to assist in risk profiling. In addition, performance indicators have been identified and a number of border activities have been reviewed and documented to achieve national consistency and to ensure appropriate risk management. A priority area for border programs is to continue to work with industry towards co-regulatory arrangements that are designed to outsource low-risk quarantine functions to industry, thus freeing AQIS resources to concentrate on higher risk areas.

#### *Post-border measures*

Effective monitoring and surveillance for pests and diseases are essential if Australia is to fulfil its international obligations under the SPS Agreement. Article 6.3 requires countries to establish scientifically that they are free from pests and diseases, rather than simply claiming such freedom. The Nairn Review identified deficiencies in the post-border area of quarantine, particularly in relation to plants and aquatic animals. The establishment of the position of Chief Plant Protection Officer (analogous to the Chief Veterinary Officer) and of Plant Health Australia (analogous to Animal Health Australia) has enhanced Australia's plant health infrastructure and ability to respond to disease incursions. Aquatic animal health capacity has been increased through the appointment of experts to a special Fish Health Unit in AFFA (and additional

experts to Biosecurity Australia to carry out IRAs). An emergency response plan - AQUAPLAN - has been developed for aquatic animals along the lines of the AUSVETPLAN which has proved very effective for livestock diseases. The benefits of regular monitoring and early detection of pests and diseases were clearly demonstrated by the detection and subsequent eradication of black-striped mussels in Darwin harbour in 1998. This pest has the potential to impose significant costs on shipping through the fouling of hulls.

Notwithstanding the improvements made in the post-border area as a result of the additional funding following the Nairn Review, the 1999 Australian National Audit Office report - *Managing Pest and Disease Emergencies* - identified the need to further enhance emergency planning for and response to animal and plant pest and disease incursions. Under a new program, the government will allocate \$22.3 million over the next four years to enhance Australia's emergency management capacity for animal (including aquatic animals) and plant diseases and pest emergencies and secure a national approach to animal and plant health infrastructure.

#### **Economic considerations**

## Performance of quarantine delivery

A key question in any analysis of Australia's quarantine reforms is how effective and efficient have the reforms been in achieving their goal? The goal of Australia's quarantine policy (the ALOP) is clearly articulated in Recommendations 1 and 2 of Nairn *et al.* (1996):

- that the vision for quarantine be 'that Australia will maintain its relative freedom from unwanted pests and diseases while fulfilling national and international obligations in a responsible manner'; and
- that the goal of national quarantine should be to prevent the establishment and spread within Australia of exotic pests and diseases that are deemed to have a significant

deleterious effect on humans, animals, plants or the natural environment.

Australia's ALOP - which can best be described as 'very conservative' (AQIS 1999a) - is achieved through a managed risk approach to quarantine.

As previously indicated, analysis of incursion data shows that there has been no increase in the rate of pest and disease incursions since the time of the Nairn Review and - more importantly - no increase in the rate of establishment (AQIS 1999b). Of the 19 incursions reported to the National Office of Animal and Plant Health in the period 1997 to 1999, 10 have been eradicated (or are in the process of being eradicated), three were of no economic significance, one is controlled by normal management procedures, two are still being evaluated, and three have established, for which management programs are in progress. This result has been achieved at a time of increases in the number of international visitors, aircraft movements and entry of vessels, and the amount of international mail and cargo entering the country. Enhancement of pre-border and post-border quarantine, together with increased use of risk profiling to target resources in areas of highest risk in all parts of the quarantine continuum have contributed to the improved effectiveness and efficiency of the system. Greater quarantine awareness and the development of a partnership approach with industry (involving coregulatory arrangements) have contributed to the improved performance of the quarantine system.

A good example of how risk profiling and better targeting of resources can improve effectiveness and efficiency of the system is the international mail program. More than 160 million articles of mail enter Australia each year, many containing items of high-risk quarantine concern such as foodstuffs, plant material, seeds and animal products. The increased funding provided to the international mail program has been used for extra staff and detector dogs and the introduction of scanning equipment. In conjunction with the Australian Customs Service, AQIS has refined its approach to targeting mail items of quarantine concern. The number of high-risk items seized has increased as has the number of

seizures per officer and the number of seizures compared with the number of items of quarantine interest referred for closer examination (AQIS 1999c).

Consistency in the application of quarantine protocols is an important aspect of performance from a National Competition Policy perspective and one that attracted considerable comment at the time of the Nairn Review. The differences in the delivery of quarantine services reported by the Nairn Review were an inevitable outcome of the changes that have occurred in quarantine delivery nationally. Before 1994, all Commonwealth quarantine services were delivered under agency arrangements by State quarantine services, on behalf of the Commonwealth. In October 1994, a meeting of the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) resolved to transfer delivery of quarantine services to the Commonwealth. However, failure by the Ministers from Northern Territory, Western Australia and Tasmania to agree to such a transfer has resulted in a situation where AQIS officers perform Commonwealth quarantine services in most States while State officers appointed as Quarantine Officers by the Commonwealth perform the border functions in Northern Territory, Western Australia and Tasmania (Nairn et al. 1996, p. 121).

Differences in delivery of quarantine services between States have the potential to be anti-competitive and to encourage the undesirable practice of 'port shopping'. AQIS has expended considerable effort in developing a nationally consistent quarantine service through documenting various procedures, increased staff training, introduction of performance indicators and regular program reviews. Although the 'mix' of service delivery persists, differences in service delivery no longer appear to be a major issue for stakeholders.

Regular oversight of AQIS and now Biosecurity Australia's performance is undertaken by the Quarantine and Exports Advisory Council (QEAC) which was established as part of the government's response to the Nairn Review. Its terms of reference include, *inter alia*, to oversee the implementation of the Nairn Review and Fish

Task Force Reports, to provide advice on AQIS's program delivery and to help AQIS to evaluate its performance. The regular reports that have been made to QEAC during its three years of operation demonstrate improved levels of effectiveness and efficiency, supported by the use of performance indicators and regular surveys of client satisfaction. Overall, the reforms to the quarantine service have led to a better allocation of resources through the use of risk profiling and targeting resources to areas of highest quarantine risk.

## The goal of quarantine

As already indicated, Australia's goal of quarantine (ALOP) is set at a 'very conservative' level that is consistent with Australia's trade profile as a major exporter of agricultural products and the trade benefits that flow from maintaining Australia's relative freedom from pests and diseases. Under the SPS Agreement, it is up to the Member Countries of the WTO to determine their appropriate level of sanitary and phytosanitary protection. To achieve this level of protection, Member s can apply quarantine measures that protect against potential pests and diseases provided such measures are:

- based on a sound scientifically based assessment procedure;
- not more trade-restrictive than necessary to achieve the desired level of protection; and
- non-discriminatory.

The methods currently used by Biosecurity Australia for undertaking IRAs and determining quarantine protocols are consistent with the SPS Agreement.

Not surprisingly, if the ALOP is changed, the range of products that can be imported — and the associated trade flows — will change. This has been demonstrated by a recent ABARE study by Heaney, Rodriguez and Abdalla (1999), who use an iso-risk approach developed by Bigsby and Whyte (1999) to define the boundary between commodities with acceptable risks and those with unacceptable risks. Heaney *et al.* (1999) show that for the six commodities studied (apples, bananas, chicken, pilchards, salmon

and wheat), none would be imported at a very conservative ALOP (of \$700 per year) except for chicken meat from the United States. If the ALOP is raised to \$24.5 million per year, imports of pilchards and bananas, as well as chicken meat from the United States, would be permitted. At an ALOP of \$33 million per year, all of the case-study commodities would have unrestricted access.

One might expect that the debate would now be focused on quantifying the ALOP for Australia but — at least amongst economists — the debate seems to have shifted to whether the current approach used by Biosecurity Australia, which is clearly consistent with the SPS Agreement, should be replaced by a cost/benefit approach to quarantine policy (James and Anderson 1998; Rodriguez *et al.* 2000). From a purely economic perspective, a cost/benefit approach is preferable because it allows all the costs and benefits associated with the import decision to be considered. The Biosecurity Australia approach, which is focused on scientifically based risk analysis, considers only the following economic factors:

- the potential damage (in terms of loss of production or sales in the event of entry, establishment or spread of the pest or disease);
- the costs of control or eradication of an outbreak, and the costs of programs to manage such responses;
- the costs of the loss of markets either nationally or internationally; and
- the relative cost effectiveness of alternative approaches to limiting risks (Gascoine *et al.* 2000).

The Biosecurity Australia approach excludes from any analysis important trade-related benefits resulting from consumers gaining access to imported product at competitive prices and agricultural producers obtaining access to superior genetic material. The

<sup>&</sup>lt;sup>9</sup> See Rodriguez *et al.* (2000) for a discussion of the various costs and benefits associated with a quarantine decision.

omission of these benefits may lead to a sub-optimal outcome for society as a whole.

Although a cost/benefit approach to quarantine decision-making has considerable appeal to economists, some fundamental factors need to be taken into account, including:

- Is a cost/benefit approach compatible with the SPS Agreement?
- Is further change in quarantine decision-making desirable at this stage, given the relatively recent introduction of the SPS Agreement and the recent reforms to the Australian quarantine system?
- Are the data available to undertake cost/benefit analyses of quarantine decisions?
- Will the greater complexity of cost/benefit analyses lead to a higher level of disputation and more appeals to the WTO? and
- Will developing countries, in particular, have the resources to implement such an approach?

The question of compatibility with the SPS Agreement is something that will probably have to be tested legally before a definitive answer is possible. Certainly there are those such as Roberts (1998) who argue that there is scope to include welfare impacts on consumers within 'relevant economic factors' (Article 5.3 of the SPS Agreement). However, the inclusion of benefits to consumers is likely to lead to violation of the consistency requirement. Article 5.5 ensures that Members apply measures consistently to different commodities that pose a similar risk of introducing the same diseases. Where different commodities pose similar risks, allowing imports of one commodity (based on higher net benefits from imports), while banning the other, would contravene the SPS consistency provision. Violation of this provision was one of the key issues in the WTO Australia - Salmon case. Whilst renegotiation of the SPS Agreement to accommodate cost/benefit analysis is always an option, it would not seem prudent to do so at this time as some countries may wish to weaken the current provisions.

Much of the wording of the SPS Agreement is fairly general and imprecise but its meaning is being clarified through the legal dispute settlement process. The SPS Agreement is still relatively new and many countries are still coming to grips with the changes necessary to make their quarantine decision-making processes consistent with the agreement. Although minor changes to the way quarantine decisions are made in Australia are likely to occur—indeed, some changes will be required by the recent restructuring of AFFA—major changes to the framework would be undesirable while the recently introduced reforms are still settling down.

The idea of applying cost/benefit analysis to quarantine, while gaining support in recent years, is not particularly new. Hinchy and Fisher (1991) argued very persuasively for the use of cost/benefit analysis in quarantine almost a decade ago. The desirability of applying cost/benefit analysis to quarantine decision-making to justify the allocation of resources to the quarantine services was clear to the Nairn Review. However, the approach proved infeasible due to data limitations. One suspects that little has changed in the intervening period. Many developing countries are finding it difficult to undertake the necessary scientific and technical analysis to meet the current requirements of the SPS Agreement and to comply with quarantine protocols. Any change to the current SPS Agreement that increases its complexity would disadvantage developing countries in particular and is likely to lead to an increase in trade disputes.

From a trade perspective, the application of the current SPS rules is leading to greater market access and increased trade. Market access for Australian animal, plant and food products has been opened up or maintained in no less than 640 cases since 1993/94. In 1998/99, 44 new markets were opened and over 100 existing markets were protected from market disruption or closure. On the import side, the number of products for which entry is permitted is increasing. The additional resources allocated to risk analysis through the government's reforms have increased the number of IRAs being

<sup>&</sup>lt;sup>10</sup> See Pauwelyn (1999) for an excellent discussion of how the first three SPS disputes have clarified the SPS Agreement.

conducted simultaneously but a backlog of requests still exists, creating some trade tensions.

#### Conclusion

The reforms that have been made to the Australian quarantine system have improved the effectiveness and efficiency of quarantine delivery. This has been achieved through increased use of risk profiling to target resources to areas of highest risk and greater focus on pre-border and post-border activities. Fundamental to the changes to the quarantine system has been the development of a partnership approach between the general public, industry and governments. This is being developed through initiatives to increase quarantine awareness, enhanced consultation and the development of co-regulatory agreements with industry.

Despite the changes that have been made to the risk analysis process to make it more transparent, consultative, structured and independent, to ensure it is based on sound science and to make the process appealable, IRAs continue to attract controversy. While there is scope for further enhancing the transparency of the risk analysis itself and the amount of consultation involved, the greatest deficiency at present appears to be the lack of clarity of the ALOP and the level at which it is set. Economists have a role in contributing to this debate. The current very conservative level effectively takes no account of the significant trade-related benefits that result from importation of many products. Shifting to a higherbut still conservative - ALOP would be tantamount to recognition of those benefits. Cost/benefit analysis has a useful role to play in quantifying those benefits to ensure a more informed debate on the level at which Australia sets its ALOP.

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# 14

# Evaluating economic consequences of livestock diseases: a US perspective

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This chapter provides an overview of selected approaches to evaluating the economic consequences of livestock diseases. The presentation focuses on general types of analysis that may be needed, some examples of analytical tools, and discusses the linkages between some of the available tools. While the context of this discussion is primarily in the area of livestock diseases, these same concepts apply broadly and may be useful in the phytosanitary area as well.

Also discussed in the chapter is the international context for applying these analytical tools in terms of the World Trade Organization's *Agreement on Sanitary and Phytosanitary Measures* (the SPS Agreement) and the Office International des Epizooties (OIE) International Animal Health Code (OIE, 1999). In addition, the practicalities of consequence evaluation in regulatory environments are discussed as well as potential analysis trade-offs in the face of very limited resources.

Economic analysis is essential to understanding the risks of livestock diseases. As discussed in a recent workshop conducted by the US Department of Agriculture, "when decision-making is complex, economic analysis is often useful for putting probabilistic outcomes,

<sup>\*</sup> The views expressed herein are those of the author and do not necessarily represent the position of the US Department of Agriculture.

which are the results of risk assessment, in perspective. For example, economics can translate the impacts of a disease outbreak termed 'serious' by veterinarians into economic losses to the livestock sector, which might then be compared to total livestock revenues. Thus, economic analysis can provide a basis for comparing different sources or types of risks. For example, two diseases could be equally likely to occur and take hold in a livestock population, but in terms of economic impacts one could be devastating and the other relatively benign." (USDA 1998, p.4)

# The SPS Agreement

Economic evaluation of risk is recognised as necessary part of the overall risk assessment process defined by the SPS Agreement. This agreement defines risk assessment as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease...according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences...". It is clear from this definition that consequence analysis is intended as part of the risk assessment process and that it consists of at least two major elements, a biological element and an economic element.

How information about economic consequences of disease introduction is to be used in decision-making and establishing appropriate levels of protection, however, has been the subject of considerable debate. Two provisions of the SPS Agreement give some indication of the role of economic analysis in the risk assessment process. These provisions are contained in Articles 5.3 and 5.4.

Article 5.3 states 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 sanitary and phytosanitary 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 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."

Article 5.4 states that "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects." This statement recognises the fact that pest or disease risk mitigation measures can have negative economic consequences on the benefits that both the importing country and exporting country obtain when engaging in trade. It instructs Members to minimise these negative consequences. The need to determine whether such consequences are minimised by the selected measures implies a need to evaluate the consequences that these measures and alternative measures may have on the potential benefits of trade.

At a recent workshop conducted by the US Department of Agriculture it was stated that "Formulating guidelines for international trade in animals, plants, and animal, plant, and food products continues to pose special challenges. Traded animals, plants, and animal and plant products can carry with them diseases (or disease-causing additives, contaminants, toxins, or organisms) and pests that can threaten the health of native plants and animals, cultivated crops, livestock populations, or humans. It is therefore widely accepted in the international community that, despite the benefits of trade, nations must be allowed to provide protections against legitimate pest and disease threats. The Uruguay Round's Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO/SPS Agreement) reflects that consensus. It recognises the sovereign rights of nations to provide these protections while, at the same time, it delineates a set of principles designed to ensure that SPS measures do not pose 'a disguised restriction on international trade' and, when SPS measures are imposed, 'to minimise their negative effects on trade.' Thus, the SPS Agreement strives for balance between the desirable benefits and undesirable risks of international trade" (USDA 1998, p.3).

In same workshop, however, it was also discussed that the word "benefits" does not appear in the SPS Agreement. Considerable controversy surrounds the question of how consumer benefits might be used in combination with disease consequence information to decide on the appropriate level of protection and the application of SPS measures (USDA 1998, p.10).

There appears to be general agreement that the economic consequences of entry may be considered in a risk assessment. Many also argue, however, that explicit calculation of the benefits of trade and comparison of these benefits to the estimated consequences to determine the acceptable level of risk would be a violation of not only Article 5, but also of Article 2 of the SPS Agreement requiring measures to be based on scientific principles. If the expected costs of the trade (defined as the product of the likelihood of entry and establishment and the associated biological and economic consequences) were equivalent in two separate instances, but the welfare benefits were unequal, then from this perspective it would be economics, and not science, that determined the SPS measure chosen.

Roberts (1998) uses an example to illustrate the complex debate over using trade benefits in conjunction with economic consequences as part of determining what an acceptable level of risk might be. She illustrates a hypothetical case where the expected costs of an animal disease introduction are identical for two different decisions. One decision is regarding a poultry import, the other a beef import.

In the example, based on objective analysis, there is a greater benefit to the beef importation than to the poultry importation. In fact, the difference in benefit is such that the analysis shows that for the beef importation the benefits exceed the risk and consequence-based costs, but for the poultry importation they do not. From an objective economic efficiency standpoint, a sensible decision by regulators may be to allow the beef importation, but disallow the poultry importation.

Both decisions in the example involve legitimate disease hazards with substantive probabilities of disease-based production and economic losses. If the importing country is publicly and transparently presenting the basis for its decision, there is no issue regarding whether any action taken on either decision involves a disguised protectionist barrier. In each case there is a real and recognised disease threat present. The question that remains is, what is the importing country permitted to do under its SPS obligations in making its own decisions regarding how much risk it is willing to accept in each case?

One viewpoint is that the country whose import request for poultry is turned down, given that the beef import is accepted, would be justified in arguing that this decision is evidence of arbitrary and unjustifiable discrimination that is prohibited by SPS Article 2. This is despite the objective analysis and rationale presented for the decision.

An opposing viewpoint is based on the SPS Agreement's commitment to the principle of sovereignty. From this perspective, the importing country is justified in its decision that takes into account the benefits derived from the trade. It is justified provided that the benefits information was used in a scientifically sound and transparent manner and that the same approach to decision-making is applied consistently to all SPS-related decisions; including those decisions relating to domestic disease and pest control. From this viewpoint, the importing country would be in compliance with Article 2.

A third viewpoint, positioned somewhat between the other two, is that benefits information can be used to help guide the establishment of a country's overall acceptable level of protection (ALOP). From this perspective, a country sets a single ALOP for all SPS decision-making strictly in terms of the expected costs of the trade (defined again as the product of the likelihood of entry and establishment and the associated biological and economic consequences). In other words, a threshold (representing the ALOP) is set and defined as a level of expected costs that would be accepted for all SPS-related decisions. The benefits of trade could also be estimated, but only for the purpose of informing policymakers about the efficiency, or lack thereof, of the existing ALOP threshold.

Policymakers might then take this benefits information into account for the purpose of considering periodic revisions to the overall ALOP.

This latter approach avoids the discriminatory problems suggested in Roberts' example above because the individual decisions do not depend on the benefits associated with the different commodities. Instead, since each individual decision from the beef and poultry trade example is evaluated against the current overall ALOP, and since the expected costs for each were identical, if the beef trade was viewed as acceptable, then the poultry trade would be accepted as well. Or, if the expected costs of the poultry trade were viewed as being unacceptably high, then the beef trade would be refused as well. Over time, by accumulating information about benefits gained and foregone over many individual decisions, policymakers might publicly and transparently adjust the overall ALOP on a periodic basis to attempt to maximise the gains and minimise the foregone opportunities.

From an economic efficiency standpoint, this latter approach seems likely to present a second-best solution when compared to the alternative of basing each individual decision on a balancing of the benefits of trade versus the expected costs. However, policymakers may deem this efficiency loss to be an acceptable cost of complying with SPS non-discrimination requirements. Obviously, variations on all of the above themes are possible.

The question ultimately comes down to, what information can an importing country take into consideration, and in what manner, in determining its appropriate level of protection or acceptable level of risk? Clearly, it would be inappropriate to set SPS restrictions in place based on benefits information when there is no legitimate pest or disease risk (no pest or disease-based consequences). The less obvious issue is if or how benefits information can be combined with pest or disease-based consequence information in deciding on the appropriate level of protection once a legitimate risk of disease introduction has been established. None of the formal challenges handled through the SPS dispute resolution process has yet addressed this question, so the answer remains elusive.

Recognition of the need to balance the benefits of trade against risk-based disease consequences and costs is given in the International Animal Health Code published by the Office International des Epizooties (OIE 1999). OIE is the animal health standard setting body recognised in the SPS Agreement Article 3.4. In describing the accepted principles of risk management, the OIE states "the objective is to manage risk appropriately 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 it obligations under international trade agreements." While the word "benefits" is not explicitly used by OIE, the concept of balancing risk and disease-based consequences against trade benefits in decision-making is evident in the Code.

### The International Animal Health Code

The overall framework for risk analysis described in the Code consists of hazard identification, risk assessment, risk management, and risk communication. The definitions for these four components are as follows (OIE 1999):

*Hazard identification* – "identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation *of a commodity*."

*Risk assessment* - the Code describes four interrelated steps for risk assessment: release assessment, exposure assessment, consequence assessment, and risk estimation.

- (a) release assessment describes the biological pathways necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimates the probability of that complete process occurring.
- (b) exposure assessment describes the biological pathways necessary for exposure of animals and humans in the importing country to the pathogenic agents and estimates the probability of exposure.

- (c) consequence assessment describes the relationship between specified exposures to a biological agent and the consequences of those exposures. Examples of consequences include: (1) animal infection, disease, and production losses, (2) public health consequences, (3) surveillance and control costs, (4) compensation costs, (5) potential trade losses, (6) adverse consequences to the environment.
- (*d*) risk estimation integrates the results from the release, exposure, and consequence assessments to produce overall measures of risk.

Risk management – the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately 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 fulfill its obligations under international trade agreements. Risk management includes an evaluation of the degree to which a [measure] reduces the likelihood and/or magnitude of adverse biological and economic consequences.

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

The evaluation of consequences is therefore specified as a part of risk assessment in both the SPS Agreement and in the OIE Code. In both cases, this evaluation is to consist of both biological and economic components. Leaving aside the issue of how the economic consequence information is to be used in decision-making, let us turn now to the issue of how these consequences can be evaluated.

### Biological/epidemiological consequences

The evaluation of economic consequences of a pest or disease introduction cannot take place in isolation. It must be conducted in concert with a biological/epidemiological evaluation of the potential spread and impacts of the pest or disease. The tools for conducting these different types of analysis must therefore be compatible with one another so that they can be linked in some logical way.

There are a variety of different analytical tools available that can assist with the biological and epidemiological aspects of consequence modelling. A few that are commonly used include state-transition models, Markov Chains, Reed-Frost models, SEIR models (Susceptible, Exposed, Infectious, and Removed), and various spatial analysis tools (Haining 1998; Martin *et al.* 1987; Olsen and Schaffer 1990; Miller *et al.* 1994; Miller *et al.* 1997).

Ultimately, the objectives of using these tools include determining the number, type, and temporal distribution of herds, flocks, fields, groves, etc. of animals, birds, plants, trees, etc. that may be affected if the pest or disease agent were introduced into the importing region. This information, combined with information about the biological and physiological effect of the pest or disease agent on the individual susceptible host (for example the individual animal or plant), provides the linkage to the economic evaluation of consequences.

It is important to keep in mind that, in general, these tools would be used to evaluate pest or disease events that have not actually occurred. The purpose of the evaluation is usually to support decision-making about whether or not to take a certain pest or disease risk by importing a commodity under certain conditions. It may therefore be necessary to use epidemiological investigations into past events in the same or similar circumstances to generate estimates of various model values for a variety of possible scenarios.

There is, however, always a great deal of uncertainty and variability about the way that a pest or disease agent may interact with susceptible hosts and their environment. This uncertainty and variability must be addressed and then also reflected in the resulting economic values. Dealing with this uncertainty and variability is an extremely challenging aspect of estimating potential biological and epidemiological consequences before they occur.

### **Economic consequences**

Armed with information obtained about the potential biological and epidemiological consequences of a pest or disease agent, the evaluation of economic consequences may begin. The evaluation of economic consequences must take place at two broad levels. These are the microeconomic level and the macroeconomic level.

The microeconomic level of evaluation takes into account the firm-level effects or effects on individual herds, flocks, etc. This can be done using an economic tool known as partial budgeting. Partial budgeting looks at only those aspects of a firm's budget that are affected by the change being analysed. In this part of a disease consequence analysis, for example, the biological and physiological effects that a disease has on individual animals, as well as the costs of veterinary care, vaccines, etc. are translated into a monetary impact to the firm. Because there are many different types of firms that may be affected by the pest or disease agent, partial budget impacts would have to be estimated for each different type. The partial budget impacts on firms that are not necessarily directly affected by the disease but that are indirectly affected by quarantines or other control measures should also be included.

In a broader context, although not microeconomic in nature, the budget impacts to the government of control, eradication, monitoring and surveillance that result from the introduction of exotic pests and diseases must also be assessed. Although a separate process, the estimation of government budget impacts at the macroeconomic level is similar from a procedural standpoint to the estimation of partial budget impacts at the microeconomic level.

The combination of the information about the biological and epidemiological consequences of pest or disease spread and the information about partial budget impacts provide a basis to begin a macroeconomic analysis. The macroeconomic analysis evaluates the industry-level or regional-level impacts of the pest or disease introduction. The biological/epidemiological and partial budget information can be linked to the macroeconomic evaluation by using it to estimate the magnitude and temporal distribution of shifts in the industry's supply function during and in the wake of the pest or disease epidemic.

Impacts on consumers' demand functions are possible as well. In the event that the pest or disease introduction has a public health impact through the consumption of a particular commodity, consumers are likely to avoid this commodity and consume one or more unaffected substitute commodities. Even if there is no real public health impact, the simple perception of such an impact could lead to similar consumption behaviour.

The discussion below will focus primarily on the evaluation of shifts in the industry's supply function that directly result from a pest or disease incursion. These concepts, however, can also be applied to shifts in consumers' demand functions.

Once the magnitude and temporal distribution of the pest or disease induced industry supply shifts have been estimated, they can be used as input in determining the effects of the incursion on economic welfare. The economic welfare analysis specifically evaluates how: (i) market prices and quantities adjust as the pest or disease spreads through the domesticated livestock population, and (ii) consumers and producers are affected by the adjustments in market prices and quantities.

These effects on consumers and producers are measured in terms of changes in the difference between what consumers are willing to pay and what they actually pay for products (a measure of utility known as consumer surplus), and in producers' revenue beyond their variable costs (a measure of returns to fixed investment known as producer surplus) (Houck 1986; Just *et al.* 1982). These welfare effects can be modelled over time to capture the effects as the pest or disease spreads.

Economic welfare analysis is a standard tool that has been used widely for public policy analysis as well as the analysis of the impacts of various animal and plant health programs (Ebel *et al.* 1992; Forsythe and Corso 1994; Forsythe and Evangelou 1993; Haley and Dixit 1988; Lichtenberg *et al.* 1988; Miller *et al.* 1994; Ott *et al.* 1995; Roberts *et al.* 1997).

### Single market impacts

The most straightforward application of economic welfare analysis is to examine only those economic impacts in the single market that is directly affected by the disease. Even if the disease in question affects multiple species, these impacts could be measured separately and independently of one another. This approach would not, of course, account for any interaction effects between markets that are simultaneously affected by a multi-species disease such as foot-and-mouth disease. This type of modeling is known as partial price equilibrium modeling.

Partial price equilibrium means that the model results are based on maintaining commodity price equilibrium in a limited portion of an overall economy (Houck 1986). Markets not explicitly included in the model are assumed to have a negligible influence on the model results.

### Multi-market impacts within the agricultural sector

Multi-market applications of economic welfare analysis can evaluate the effects of changes in closely related markets that result from a pest or disease-induced change in any one market.

Cross-commodity effects, for example, are effects on the demand or supply of a commodity that result from price changes in commodities that are substitutes or complements (Hirshleifer 1984). These effects can occur on both the demand and supply sides of a market.

For example, beef is a potential substitute for pork both on the demand and supply sides. If the price of beef goes up, consumers may demand more pork because it has become relatively cheaper, and vice-versa. Likewise, if the price of beef goes up, some producers may shift resources away from pork production into beef production, and vice-versa. Because of the fixed nature of investment in production activity these types of shifts may only happen in response to long-term events, such as if a pest or disease becomes endemic in a new region. Hamburgers and buns are a classic example of a complementary relationship on the demand side. The strength and nature (substitute or complement) of the relationship between such markets can be represented and captured in the analysis.

Multi-market analyses can also capture vertical market effects, such as changes in the derived demand for inputs into commodity production (Haley and Dixit 1988). For example, a change in the price of beef will affect the demand for the corn that serves as an input into beef production. Clearly, a major disease event that impacts the beef market will also be felt in the corn market. The magnitude of such impacts can be captured in a multi-market model.

### Macroeconomic consequences in non-agricultural sectors

The economic consequences of major pest or disease events are not limited to the agricultural sector. The impacts in other sectors of the economy resulting from major events in the agricultural sector can be evaluated using tools such as input-output accounting and modelling.

Input-output accounting describes commodity flows from producers to intermediate and final consumers. Total industry purchases of commodities, services, labour, land, capital, management, and imports are equal to the value of the commodities produced, some of which are exported.

Purchases of goods and services by consumers (final demand) are the stimulus for the model. Industries producing goods and services for final demand create these goods and services by purchasing inputs (goods and services) from other producers. These other producers, in turn, purchase goods and services from yet another set of producers. This intermediate buying of goods and services (indirect purchases) in a regional economy continues until leakages (out-of-region purchases) stop the cycle. The larger the region, the smaller will be the leakages.

These indirect and induced (household spending) purchases can be mathematically derived and are the summation of the round-by-round purchases. The resulting totals, when normalised, yield multipliers that describe the change in output (or employment, wages and salaries, value added, etc.) for each unit change in final demand.

An economic impact analysis to the different economic sectors can then be conducted by specifying a series of expenditures and applying them to the region's multipliers. In the case of a disease impact analysis these expenditures might be derived from a single market or multi-market analysis within the agricultural sector. The multipliers can then be used to estimate effects through the remainder of the economy.

The basis of a multiplier rests upon the difference between the initial effect of a change in final demand and the total effect of that change. Total effects can be calculated either as direct (direct production function purchases) and indirect (inter-industry production function purchases) effects, or as direct, indirect and induced (plus household spending) effects. Direct effects are production changes associated with the direct purchases or final demand changes. Indirect effects are production changes in backward-linked (supplier) industries caused by the changing input needs of directly affected industries (for example, additional purchases to produce additional output). Induced effects are the changes in household spending caused by changes in household income generated from the direct and indirect effects (USDA 2000).

### Level of detail in analyses

Clearly, the evaluation of biological and economic consequences of pest and disease incursions can become extremely complex. This evaluation, however, can also vary greatly in terms of the amount of detail incorporated into any given analysis. The choice of the level of detail to incorporate is frequently dictated by available resources, time and data. This choice is particularly important in regulatory environments where there may be a great number of decisions to be made about a great many pests and diseases. The difficulty of the choice is compounded by the potential severity of the consequences of many of these pests and diseases.

Models of lesser detail, given that they are appropriately specified, may be viewed as approximations to models of greater detail. The level of detail should also be appropriate to the specific question addressed by the analysis and based on some initial judgement about the likely magnitude of the impacts that a decision based on this analysis may have.

The guidance regarding risk analysis provided in the OIE Animal Health Code is very general and recognises that "No single method of import risk analysis has proven applicable in all situations, and different methods may be appropriate in different circumstances" (Article 1.4.1.1). This guidance also applies to the assessment of biological and economic consequences. Quantitative risk assessment is defined in the Code as simply "An assessment where the outputs of the risk assessment are expressed numerically" (Article 1.4.1.3). A risk analysis or assessment may also follow a qualitative approach which "does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision-making" (Article 1.4.1.1). As such, many analyses that are referred to as qualitative are in fact purely narrative descriptions of potential risks and consequences.

Quantitative analyses, even at a "broad-brush" level, can serve as valuable supplements to qualitative or descriptive analyses. At a minimum, the simple act of assembling a model that describes the various interrelationships of the problem at hand may lend valuable insight into the impacts of potential alternative decisions. Even if the model is not solved numerically, using mathematical language to describe the problem may lend greater rigour to the problem description. The more rigour with which the problem can be described, the less likely that some critical piece of information will

be inadvertently overlooked, or that subjective opinions will influence the outcome or resulting policy decisions.

In effect, there is a continuum of analysis "levels" that can be applied to any problem. The more complex the analysis the more it will likely cost in terms of time and resources and in diversion of these resources from other problems that may be pressing (opportunity cost). "Rational decision-makers recognise that it is costly to obtain information and make complex calculations. Although additional information and techniques that improve one's decision-making capabilities are valuable, often this potential benefit is less than its expected cost. Therefore, the sensible consumer [of analyses] will conserve on these limited resources, just as he [or she] conserves on other scarce resources" (Gwartney *et al.* 1982, p.9).

It does not necessarily follow, therefore, that the most complex or sophisticated application of an available analytical tool is the best choice in every situation. In some cases, however, a more sophisticated application may result in resource savings in addition to greater quality in the resulting decision. It is therefore useful to have a variety of analytical techniques available, of varying degrees of complexity and sophistication, so that the most efficient use of available analytical resources can be made for the problem at hand.

In general, the simpler the model or the approach may be, the more restrictive it is likely to be. Even a highly restrictive model can provide useful insights into decision-making, as long as the decision maker is aware of the restrictions and their implications. By definition, a model is a simplified representation of reality that will always be subject to restrictions. The choice of how far to move along the analysis level continuum is a matter of balancing the benefits derived from adding additional complexity that relieves restrictive assumptions, versus the cost in terms of depleting scarce resources and obtaining additional information.

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## **PART IV**

Specific health and environmental risks from trade

# 15

# Measuring the effect of food safety standards on African exports to Europe

TSUNEHIRO OTSUKI, JOHN S. WILSON AND MIRVAT SEWADEH\*

Many of the most important food safety issues in international trade today impact on developing countries. These countries, especially those in Sub-Saharan Africa, seek to expand access to international agricultural markets and integrate more fully into the global trade system. Questions of how to balance risk, expanding trade in agricultural products, and health concerns are at the forefront of trade debate. This chapter provides a case study of trade between Africa and Europe in agricultural products, from African exporters perspective. It presents results from empirical data and analysis on the trade effect of harmonisation of food safety standards within the European Union which we offer as a contribution to trade policy discourse on SPS standards and the multilateral trading system.

Concern about the health risks of food and appropriate sanitary standards has been increasing in industrialised countries over the past decade (Pinstrup-Andersen 2000). Debate over food safety has been especially prominent in Europe (Nielsen and Anderson 2000). The use of import bans and regulatory intervention by the European

<sup>\*</sup> This chapter and the empirical results presented draw on Otsuki, Wilson and Sewadeh (2001). The authors would like to thank Keith E. Maskus and Kyd Brenner and participants in a World Bank seminar on 11 October 2000 for helpful comments. Financial support for this work from the UK Department for International Development is gratefully acknowledged.

Commission is increasingly justified, in part, under the 'precautionary principle' which seeks to mitigate against risk even under conditions in which science has not established direct cause and effect relationships. The European Commission's approach has been challenged in trade policy talks, therefore, on the basis that import restrictions have been employed without sufficient support from internationally recognised science.

The cost of regulatory intervention by any nation with the intent to protect human health can be significant. This is especially true for developing countries attempting to penetrate developed country markets. In low- and middle- income countries, the share of food exports in total trade remained high at approximately 13 per cent in the 1990s (World Bank calculations, based on the GTAP database). If increasingly restrictive sanitary and phytosanitary measures limit market access, these countries may incur significant export losses. Many questions remain, however, including how to approach the trade-off between appropriate levels of risk to human health and costs of differing levels of protection as determined by technical barriers to international trade. In addition, we know little about the specific impact of harmonised standards shared across national boundaries, in contrast to divergent national standards.

Measuring the trade effect of sanitary and phytosanitary standards is particularly complex (Orden and Roberts 1997). Notwithstanding these complexities, it is clear the costs of regulatory intervention can be high relative to non-intervention. Food exports subject to regulatory standards may involve rejection of imports following border inspection. Between June 1996 and June 1997, the US rejection level of food additives imports from developing countries averaged 3 per cent of total food imports (Henson *et al.* 2000). The loss arising from rejection is not limited to the value of the product. It also includes transportation and other export costs, all of which are incurred by the exporter. Compliance requirements on exporters impose non-trivial costs on developing countries, such as the cost of upgrading production systems, processing and storage equipment, and quality control stations.

How regulatory costs for exporters compare with possible gains in higher sanitary and phytosanitary levels in importing countries is a key part of trade policy debate. Information on how standards affect trade flows when an international standard is in place and shared bilaterally, as opposed to conditions in which differing national standards are imposed on exporters, is increasingly valuable. As recently reviewed in Maskus and Wilson (2001a) the empirical evidence and information on the trade impact of standards is extremely limited. The importance of providing estimates of how standards impact trade flows is clear.

In this chapter we examine a European Commission proposal to harmonise aflatoxin standards, as announced in 1998 and scheduled for enforcement in 2000. This proposal raised a number of disputes between the European Union (EU) and trade partners in the World Trade Organization (WTO). The case serves as a good example of the trade-off between acceptable levels of risk, how harmonised standards affect trade, and contrasting perspectives of developed and developing countries in international trade disputes. This chapter provides empirical evidence to inform discussions of these issues through a case study of aflatoxins standards and trade in food between Africa and Europe.

Based on the Food and Agriculture Organization's cross-country survey on food safety standards, we develop an econometric method to statistically measure the trade flow effect of standards imposed through EU domestic regulation. The results are then used to calculate potential export revenue gains and losses from different standards. We examine trade in cereals, fruits, nuts and vegetables between 15 member states of the European Union and 9 African countries in the ten years prior to 1998. Instead of identifying cost elements to comply with the standards, we examine changes in trade flows, as they are a direct consequence of differing approaches to regulation which intersect debate on how best to address these issues within the WTO rules-based trading system.

### How are aflatoxins regulated in international markets?

Aflatoxins are a group of toxic compounds which contaminate certain foods and can result in acute liver carcinogens in the human body. They were discovered in 1960 following the deaths of 100,000 turkeys in the United Kingdom and high incidences of liver disease in ducklings in Kenya and hatchery trout in the United States (US Food and Drug Administration 2000). The major aflatoxins of concern are designated B1, B2, G1, and G2, and these toxins are usually found together in foods (UNDP-FAO, 2000). Aflatoxin B1 is usually predominant and the most toxic of the four categories and has been identified in corn and corn products, groundnuts and groundnuts products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts (FAO-WHO, 1997).

Aflatoxins have acute and chronic toxicity in animals. Their toxicity in humans, however, has been encountered only rarely. In developed countries, aflatoxin contamination rarely occurs at levels that cause acute carcinogens in humans, therefore studies on human toxicity from ingestion of aflatoxins have focused on their carcinogenic potential. A number of studies have revealed an association between liver cancer incidence and the aflatoxin content of the diet. These studies have not established a cause and effect relationship, but do suggest an association. A 1997 report by the joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that "aflatoxins should be treated as carcinogenic food contaminants, the intake of which should be reduced to levels as low as reasonably achievable" (FAO-WHO 1997). JECFA analysed the potential human health impact of aflatoxin for two hypothetical levels (10 parts per billion (ppb) and 20 ppb). It estimated that reducing the standard from 20 ppb to 10 ppb in countries where the percentage of carriers of hepatitis B1 is around one per cent (e.g. members of the EU) would result in a drop in the population risk of approximately 2 cancer deaths a year per billion people.

In 1997 the European Commission proposed a uniform standard for total aflatoxins setting the acceptable level of the contaminant in certain foodstuffs. For example, it set a standard at 10 ppb in groundnuts subjected to further processing and at 4 ppb in groundnuts intended for direct human consumption (this category includes cereals, edible nuts, dried and preserved fruits). It also established a level for aflatoxin M1 which is usually present in milk at 0.05 ppb.

The Commission's proposal on aflatoxins raised serious concerns among exporters of food products subject to the proposed directive (Henson et. al 2000). Bolivia, Brazil, Peru, India, Argentina, Canada, Mexico, Uruguay, Australia and Pakistan, among others, requested that Europe provide the risk assessments on which it had based its proposed standard. In comments submitted to the WTO, a representative of Gambia maintained that the proposed standard would "effectively restrict entry of Gambia's groundnuts and essentially the groundnuts from producer countries in the developing world to the European Union" (WTO, February 1998). A number of developing countries argued that the measure constituted an unjustifiable trade barrier and a violation of the Agreement on Sanitary and Phytosanitary Standards (WTO, G/SPS/R/12, 1998b; WTO, G/SPS/R/14, March 1999).

EU trading partners raised objectives to the new directive and the Commission relaxed the proposed aflatoxin levels in cereals, dried fruits and nuts (see Table 15.1). A July 1998 Commission directive, established the total aflatoxin standard in groundnuts subject to further processing at 15 ppb (8 ppb for B1), and in other nuts and dried fruit subject to further processing at 10 ppb (5 ppb for B1). It established a more stringent standards on cereals and dried fruits, and nuts intended for direct human consumption at 4 ppb (2 ppb for B1). According to the directive, EU members are to implement the necessary laws to comply with the new standards before 1 January 2001. For 8 EU members (Belgium, Greece, Ireland, Italy, Luxembourg, The Netherlands, Spain, Sweden) the new directives meant that they must reduce the acceptable aflatoxin levels in their imports of groundnuts by more than 50 per cent.

While the European Commission established a 4 ppb levels for total aflatoxins in cereals, dried fruits, and nuts intended for direct human consumption, it set the standard for aflatoxin B1 at 2 ppb for

food products intended for direct human consumption (See Table 15.1).

These levels are significantly more stringent than those set by CODEX, which does establish a standard of B1 but assumes that 50-70 per cent - or around 7.5-10.5 ppb of the total aflatoxin level of 15 ppb - is usually accounted for by aflatoxin B1 contamination. Therefore, the international standard suggests that products which contain levels of aflatoxin B1 as high as 10 ppb would be acceptable for all types of food products. This is true if the total level of aflatoxins does not exceed 15 ppb. Similarly, U.S regulations, which set a 20 ppb standard for all types of groundnuts, would effectively allow B1 contamination levels that are as high as 14 ppb. Moreover, the FAO has recommended that testing a single 20 kg sample for aflatoxin content would yield results that are reliable enough to eliminate the risk for the consumer and that stricter requirements would not bring more significant safety measures (Saquib 2000).

## Dependence of African food exports on the EU market and compliance costs of aflatoxin standards

Western Europe and other high-income countries are the major export destinations for developing countries. According to our calculation based on GTAP 1995 data, Western Europe is the major destination for exports from the Middle East and Africa, with a share of 57 per cent compared to only 16 per cent of trade between countries in these regions. Africa and the Middle-East are likely, therefore, to be strongly affected by regulatory reforms in European import markets due to their high dependency on these markets.

Developing countries are vulnerable to regulatory changes in developed countries also due to a relative scarcity of public resources to finance compliance with new and more restrictive sanitary and phytosanitary standards. While middle-income developing countries have shifted their exports to processed food,

Table 15.1: The European Commission's proposal of maximum allowable aflatoxins levels

-	allowable allatoxilis leve		Aflatoxins:	
		maximum admissible levels(1)		
		(ug/kg)		. ,
	Products	B1	B1 + B2 + G1 + G2	M1
2.1.1	Groundnuts, nuts and dried fruit			
2.1.1.1	Groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs	2(4)	4(4)	-
2.1.1.2	Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8(4)	15(4)	-
2.1.1.3	Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5(4)(5)	10(4)(5)	-
2.1.2	Cereals (including buckwheat, Fagopyrum sp.)			
2.1.2.1	Cereals (including buckwheat, Fagopyrum sp.) and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs	2	4	-
2.1.2.2	Cereals (including buckwheat, Fagopyrum sp. To be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	-	-	-
2.1.3	Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products	-	-	0.05

Source: European Commission Regulation No. 1525/98, Brussels

countries in the lowest-income regions such as Africa still largely depend on raw food exports (Ng and Yeats 1999). Furthermore, as Finger and Schuler (1999) note, the cost of compliance with WTO obligations related to the WTO Agreement on Sanitary and Phytosanitary Standards in the least-developed countries can exceed total government budgets for all expenditures and Sub-Saharan Africa is the least-developed region in the world. Thirty-eight out of 50 SSA countries fell into the lowest income group of the World Bank's classification in 1999. Fast technological changes have enhanced inspection capacities in developed countries and allowed them to adopt progressively more restrictive sanitary and phytosanitary standards. Securing sales into these major markets is expected to become more challenging and costly over time for poor countries.

### **Empirical analysis**

There is a limited number of empirical studies that have estimated the trade effect of technical standards. Quantifying the effect of standards entails complexity since standards affect market demand and supply in various ways. Unlike an analysis of the trade effect of tariff barriers, an analysis of standards requires quantifying the stringency of standards. Because of this difficulty, the majority of non-tariff-barrier (NTB) studies have attempted to measure tariff equivalent of these barriers (Calvin and Krissoff 1998; Paarlberg and Lee 1998). Since the tariff equivalent in these studies is a derived measure of stringency of NTBs, a hypothesis on whether NTBs will affect trade flow or a country's welfare cannot be tested. An independent measure of stringency of NTBs is necessary for an econometric examination of this kind of hypotheses.

Econometric approaches have been used to estimate the effect of standards on trade flows (Swann *et al.* 1996; Moenious 1999). These two studies employ counts of binding standards in a given industry as a measure of stringency of standards. While a direct impact of standards on trade flow can be estimated, the application of results to policy making is limited. In an econometric analysis of the impact of standards, Otsuki, Wilson and Sewadeh (2001) employ a direct measure of the severity of food safety standards expressed in

maximum allowable contamination. The severity of standards was thereby comparable across countries and results had clear implications for policy.

We use an econometric approach to determine the effect of European aflatoxin standards on African exports. The framework in our empirical study follows the gravity-equation model that was developed in Otsuki, Wilson and Sewadeh (2001). A gravity-equation model is a widely used method to explain trade patterns between countries using each country's measures of 'mass' and geographical distance between countries. In most countries, aflatoxins standards on foods, for example, are specified for both aflatoxin B1 alone, and total level of aflatoxins B1, B2, G1 and G2 (FAO, 1995). In practice, for the passing the B1 standard is more difficult than passing the standard for the total level of aflatoxins. This is the standard that is more likely to affect trade flows.

Our specification of the gravity equation is as follows:

(1) 
$$ln(M_{ij}^{k}) = b_0 + b_0^{k} + b_1^{k} ln(PCGNP_i) + b_2^{k} ln(PCGNP_j) + b_3^{k} ln(DIST_{ij}) + b_4^{k} YEAR + b_5^{k} COL_{ij} + b_6^{k} ln(ST_i^{k}) + \varepsilon_{ij}^{k}$$

where  $M_{ij}^{k}$  denotes value of trade from African country j to EU Member Country i. It is obtained from trade data of the United Nations Statistical Office, which include bilateral trade value across time. We use data for the time period between 1989 and 1998. Parameter b's are coefficient. PCGNP is real per capita GNP in 1995 US dollars. DIST is geographical distance between country i and j, and YEAR is a year. COL is colonial tie dummy. It equals one if a colonial tie exists between country i and j, and is zero otherwise.  $ST_i^k$ is maximum aflatoxin level imposed on import of food product, k, by EU importing country i. It is obtained from FAO survey of mycotoxin standards on food and feed stuffs in 1995 (FAO, 1995). While not explicated, dummies for exporting countries are included in order to control for unobserved factors such as production environment and product quality that may vary across these countries. The term  $\varepsilon_{ij}^{\ \ k}$  is the error term and is assumed to be normally distributed with mean zero.

We selected product categories for examination where data are available. We first conduct the analysis at an aggregate level that is defined by the two-digit STIC Revision 2 classification. The value of trade of 'cereals and cereal preparations' and 'fruits, nuts and vegetables' are regressed on the variables presented above.

United Nations trade data for 15 European countries and 9 African countries are used for value of trade flow. The European countries include Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, and United Kingdom. The African countries include Chad, Egypt, Gambia, Mali, Nigeria, Senegal, South Africa, Sudan, and Zimbabwe. We use a fixed-effect model for importing countries as cross-sectional groups, since the error term is considered to reflect common characteristics within a group of observations associated with each country.

We show in Table 15.2 that standards for aflatoxin B1 have significant negative effects on trade flows of both cereals and fruits, nuts and vegetables. It suggests that there are some sub-product-categories in both groups that were sensitive to the standards. In particular, most cereals were subject to the aflatoxins standards, according to an FAO survey. Since a double-log specification is used, the coefficient of a variable can be interpreted as an elasticity. The coefficient estimate for cereals implies that a 10 per cent tightening of the aflatoxins standards (a 10 per cent smaller maximum level of contamination) will reduce trade flow by 14.3 per cent for cereals and 3.0 per cent for fruits, nuts and vegetables.

Table 15.2 also suggests that colonial ties have significant positive implication for trade. The effect is greater for fruits and vegetable perhaps because they were specifically produced for exports (such as tropical fruits and nuts) under colonial rule. Colonial ties tend to develop dependency of former colonies in terms of language and cultural assimilation, undocumented trade rules appear, and appear as non-market barriers. Separating their effect from standards is therefore necessary.

Table 15.2: Regression results on the value of exports from Africa to Europe at the SITC 2-digit level (double-log specification)

	(double-10)	g specification	,11,	
Products	Cereals and cereal preparations		Fruits, nuts, and vegetable	
	Coefficient	t-value	Coefficient	t-value
Constant	63.4272	0.706	38.3051	0.817
GNP per capita in Europe	1.4254**	2.665	3.0476**	11.618
GNP per capita in Africa	-0.9890	-1.028	0.9378*	1.769
Geographical distance	-4.8551**	-4.201	-3.6408**	-7.323
Aflatoxin B1 Standards	1.0517**	4.144	0.4327**	4.008
Year	-0.0132	-0.285	-0.0184	-0.779
Dummy for colonisation ties	2.1195**	4.866	3.2571**	14.316
Number of observations	346		865	
Adjusted R-squared	0.2566		0.6636	

<sup>1.</sup> Fixed-effect models for importing countries are estimated.

The 'fruits, nuts and vegetables' category includes fresh, dried and preserved fruits and vegetables. Dried and preserved fruits, nuts and vegetables have been a particular focus of aflatoxin regulations since drying and preserving processes tend to grow fungus that contain aflatoxins. Consequently, we repeated the analysis under a greater disaggregation of these product categories. We focus on dried and preserved fruits, groundnuts and other nuts.

Table 15.3 shows the elasticity of aflatoxin B1 standards on trade flows in different product sub-categories. The table suggests that the standards' effect is significant both on groundnuts and the other nuts, while the magnitude of the effect is greater on groundnuts. It

<sup>2. \*</sup> and \*\* imply significance at the 10 and 5 per cent levels under a two-tail test, respectively.

also indicates that the standard's effect on 'dried or preserved fruits' is significant. Thus, products under the category of 'fruits, nuts and vegetable' that the focus of the Commission's new regulation are expected to be affected as and when this regulation comes into force in 2001.

Table 15.3: Elasticity of aflatoxin B1 standards on the value of exports from Africa

_	Elasticity of Standards	
Cereals and cereal preparations	1.0517**	
Fruits, nuts and vegetables		
Coconuts, Brazil and cashew nuts	0.7419*	
Groundnuts and other edible nuts	1.2950**	
Dried or preserved fruits	0.7705**	

Note: \* and \*\* imply significance at the 10 and 5 per cent levels under a two-tail test, respectively.

### **Simulations**

This section provides results on how trade flows between Africa and Europe would vary with respect to the maximum allowable aflatoxin B1 level imposed by the 15 European countries. This simulation analysis is performed for two commodity groups, cereals and cereal preparations, and dried fruits and edible nuts. The simulation is based on the coefficient estimates reported in the Table 15.3. In the analysis, an upper and a lower bound for the change in trade flow are imposed in order for the result to reflect the fact that negative exports are not possible and the capacity constraints on exports. Thus trade flows will not increase or decrease by more than 100 per cent.

There is a significant difference between the two scenarios. As shown in Table 15.4, the predicted loss of cereals trade flow under the Commission's new standard is US\$177 million, or 59 per cent lower than the value of EU-Africa cereal trade in 1998. The predicted value of trade flow of dried and preserved fruits and edible nuts under the Commission's new standard is US\$220 million, or 47 per cent lower than the trade of these products in 1998. The total loss of cereals, dried fruits and nuts trade

consequently is estimated to be approximately US\$400 million per year.

We also compare trade flows under two regulatory scenarios: an international standard indicated by guidelines set by CODEX, and the Commission's new standard at 2 ppb. CODEX provides a baseline for the maximum allowable total aflatoxin levels at 15 ppb. The CODEX baseline for maximum allowable level of aflatoxin B1 is imputed at 9 ppb by referring to average aflatoxin B1 composition in total aflatoxins. The predicted total trade flow under the Commission's new standard is US\$380 millions or 76 per cent lower than that under the CODEX standard in the case of cereals. It is US\$290 millions or 53 per cent lower than that under the CODEX standard in the case of dried fruits and nuts.

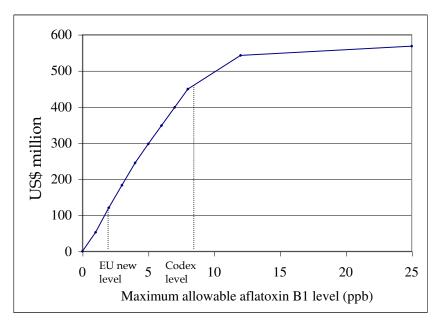
Table 15.4. Comparison of predicted European imports from Africa under alternative scenarios: cereals, dried fruits and nuts (US\$ million)

	Predicted value of		Predicted value of		Difference
	import		import		between the
					two scenarios
	EU	CODEX	EU	CODEX	
	standard	standard	standard	standard	
		(assumed		(assumed	
		level)		level)	
Cereals	-177 (-59%)	+202 (+68%)	120	500	380 (76%)
Dried fruits and nuts	-220 (-47%)	+66 (+14%)	252	539	287 (53%)

The simulation with respect to varying maximum allowable aflatoxin B1 levels is presented in the graphs in Figure 15.1 and 15.2. The graph in Figure 15.1 shows value of flow of cereals trade from the 9 African countries to the 15 European countries associated

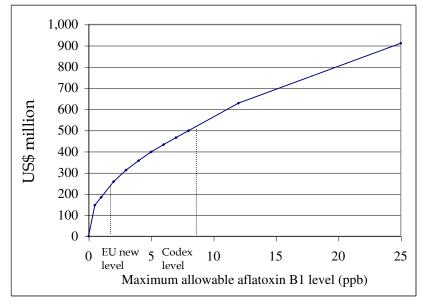
<sup>&</sup>lt;sup>1</sup> It is assumed that the EU countries harmonise the standard at each maximum allowable aflatoxin B1 level

Figure 15.1: Predicted trade flow under varying maximum allowable aflatoxin B1 level: cereals and cereal preparations



Note: The Codex level of maximum allowable aflatoxin B1 standard is assumed to be 9 ppb.

Figure 15.2: predicted trade flow under varying maximum allowable aflatoxin B1 level: dried fruits and nuts



Note: The Codex level of maximum allowable aflatoxin B1 standard is assumed to be 9 ppb.

with the aflatoxin standard levels between 0 and 25 ppb. The graph in Figure 15.2 shows the case for dried fruits and edible nuts trade. The upward slope of these graphs result from the relationship that a tighter standard (a lower number than the maximum allowable level) leads to a smaller trade flow. These figures also indicate the values of trade flow corresponding to the levels of maximum allowable aflatoxin B1 associated with the imputed CODEX maximum allowable aflatoxin B1 standard and the Commission's new standard.

#### Conclusion

This chapter provides an economic analysis of risk assessment from a development perspective and presents empirical evidence on the trade effect of a tougher food safety standard. We estimate the elasticity of aflatoxin standards on the value of trade flows from 9 African countries to 15 European countries. Our results suggest that cereals, dried fruits and edible nuts trade were negatively affected by aflatoxins standards in Europe before the new European Commission's harmonisation of aflatoxins standards. A 10 per cent lower maximum allowable level of contamination reduces trade flows by 11 per cent for cereals and 4.3 per cent for fruits, nuts and vegetables. Among fruits, nuts and vegetables, groundnuts are found to be especially sensitive to the aflatoxin standards.

There are several areas for further consideration in a public policy context based on these results. One implication of the new standard on aflatoxins in Europe is the potential application of the risk reduction level to other contaminants in food. The EU directive was developed based on the JECFA risk assessment used by CODEX to establish a less stringent international standard. The fact that the EU decided to regulate aflatoxin B1 directly to achieve deaths risk reduction is not without cost. The JECFA risk assessment suggests that 0.2 deaths per billion risk reduction will be achieved by reducing the aflatoxin B1 maximum allowable level by 1 ppb²,

<sup>&</sup>lt;sup>2</sup> JECFA estimated that implementing a 10 ppb total aflatoxin standard, population potency is 39 cancer deaths per year per billion people, with uncertainty range between 7 and 164 people. In comparison, a 20 ppb standard

which implies for the case of cereals, dried and preserved fruits and edible nuts that 1.4 deaths per billion risk reduction will be achieved under the Commission's new standard (2 ppb) as opposed to the level that follows the CODEX guideline (9 ppb). According to our simulation analysis, achieving this will cause an export loss of US\$670 million per year from the African countries.

The standard is also relevant to obligations under the WTO's SPS Agreement. The Agreement recognises the rights of Member countries to determine the "appropriate levels of protection" of human health. The level set by Europe and our findings on the magnitude of the trade effect, however, raise important questions for consideration. These include the costs of a proliferation of national standards set in absence of CODEX setting an internationally agreed level for B1 directly, as well as how the WTO addresses the economic trade-off of individual interpretations of the "appropriate level of protection" and "least trade-distorting" in SPS cases.

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will yield potency rates equal to 41 cancers per year per billion people with uncertainty range between 8 and 173 cancer deaths. This implies that the 20 ppb standard will lead to 2 additional cancer deaths per billion people compared to the 10 ppb standard. The estimates assumed a population with 1 per cent carriers of hepatitis (i.e. European population) and used potency values equal to 0.3 cancers per year per 100,000 people among carriers of Hepatitis B and .01 cancers per year per 100,000 population among non-carriers.

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## 16

### GMOs, the SPS Agreement and the WTO

KYM ANDERSON AND CHANTAL POHL NIELSEN

This chapter addresses the question: how might a new quarantine issue, namely genetically modified organisms (GMOs), impact on the World Trade Organization's rules and their interpretation by its Dispute Settlement Body. It suggests that the GMO issue is almost certain to affect the way the WTO's Sanitary and Phytosanitary (SPS) Agreement is interpreted and, should it come under sufficient pressure, re-negotiated. Since national quarantine policy officials are involved in both dispute settlement and rules-negotiating at the WTO, this chapter provides a glimpse of what might be in store for them in those capacities as well as in their work as quarantine decision-makers in the future. The chapter also includes empirical analysis of the trade and welfare effects that could be involved in GMO cases. This has two purposes. First, it provides some idea of the potential trade and welfare effects of SPS policy reactions to the GMO issue. Second, it illustrates a methodological approach that, to the authors' knowledge, is more comprehensive than any used by previous analysts for estimating the market effects of quarantine policies. The methodology would be inappropriate for cases involving just one small product in a small country. However, for across-the-board reviews of quarantine measures, and for cases involving major products and major traders -(as with GMOs) the economy-wide, general equilibrium approach used here is very relevant. And it will become even more so as and when economic assessment becomes more of a mainstream activity in quarantine analysis in the future (if not by quarantine officers, then certainly by agricultural policy advisors and trade negotiators concerned with

the domestic and trade effects of SPS measures both at home and abroad).

While the use of modern biotechnology to create GMOs through agricultural research has generated exuberance by those looking forward to a new 'green revolution', GMOs have also attracted strong criticism. The opposition is coming from groups concerned, among other things, about the safety of consuming genetically modified foods, the environmental impact of growing genetically engineered crops, and the ethics related to using that technology per se. Scepticism toward genetic engineering has been particularly rife in Western Europe, which has stunted that region's contribution to the development and use of genetically engineered crop seeds and foods. In contrast, farmers in North American and several large developing countries (notably Argentina and China) have actively developed and adopted GM crops, and citizens there generally (perhaps unwittingly) have accepted that development and consume the foods generated by it. Meanwhile many other countries, including Australia and New Zealand, are in the process of introducing strict labelling requirements on GM foods and feed.

Environmental, food safety and ethical concerns with the production and use of GM crops have been voiced so effectively as to lead to the recent negotiation of a Biosafety Protocol (UNEP 2000) with its endorsement of the use of the precautionary principle. However, if that Protocol were to encourage discriminatory trade barriers or import bans, or even just long delays in approving the use of imported GM seeds, it may be at odds with countries' obligations under the World Trade Organization. The next section of this chapter provides a brief overview of the trade policy issues at stake here. It suggests that these issues have the potential to lead to complex and wasteful trade disputes. The extent to which that potential is realised depends in large part on the economic stakes involved. They can only be determined by quantitative economic modelling, using - pending more reliable knowledge -- assumptions about the sizes of any shifts in the farm product supply (or demand) curves. The following section of the chapter illustrates one approach to such modeling. A well-received empirical model of the global economy (GTAP) is used to quantify the effects on production,

prices, trade patterns and national economic welfare of certain countries' farmers adopting GM maize and soybean crops without and then with trade policy or consumer responses in Western Europe (where opposition to GMOs is most vocal). The results suggest such policy or consumer responses can alter significantly the potential size of the global GMO dividend and its distribution. The chapter concludes by drawing lessons from the analysis for the future of quarantine policy making, for the SPS Agreement, and for the WTO's attempts more broadly to reduce excessively protectionist technical barriers to trade and provide an effective mechanism for resolving trade disputes.

# GMOs, agricultural trade policies, and the WTO

### National policy reactions to GMOs

Genetic modification or engineering is a new biotechnology that enables direct manipulation of genetic material (inserting, removing or altering genes) and thereby accelerates the development process, shaving years off R&D programs. Protagonists argue that genetic engineering entails a more-controlled transfer of genes because the transfer is limited to a single, or just a few selected genes, whereas traditional breeding risks transferring unwanted genes together with the desired ones. Antagonists, however, argue that the side effects in terms of potentially adverse impacts on the environment and human health are unknown – and probably unknowable without decades of further research and use.

GM techniques and their applications have developed very rapidly since the introduction of the first genetically modified plants in the 1980s. Transgenic crops currently occupy about 4 per cent of the world's total agricultural area (compared with less than 0.5 per cent as recently as 1996). Cultivation so far has been most widespread in the production of GM soybeans and maize, accounting for 54 per cent and 28 per cent of total transgenic crop production in 1999, respectively, with the United States accounting for almost three-quarters of the total GM crop area. Other major GM crop producers are Argentina, Canada, China, Mexico and South Africa, but India and several Eastern European countries also have a number of

transgenic crops in the pipeline for commercialisation (James 1999; European Commission 2000).

The resistance to GMO production and use also has developed rapidly in numerous countries, especially by well-organised activists in Western Europe. That triggered the imposition in October 1998 of a *de facto* moratorium on the authorisation of new releases of GMOs in the European Union (EU), and even stricter standards are mooted in the EU's revised Directive 90/220 of August 2000. These moves could be a prelude to a future EU ban on both the production and importation of food containing GMOs (following the EU ban on imports of beef produced with the help of growth hormones). Before the imposition of the moratorium, releases of GMOs were reviewed on a case-by-case basis and had to be approved at every step from laboratory testing through field testing to final marketing. By contrast, the permit procedure in the United States is far simpler and faster.

also marked differences in are national labelling requirements. The US Food and Drug Administration does not require labelling of GM foods per se, but only if the transgenic food is substantially different from its conventional counterpart. The EU, by contrast, requires labelling of all foodstuffs, additives and flavours containing 1 per cent or more genetically modified material (Regulations 1139/98 and 49/2000). Individual countries within the EU have added further requirements (OECD 2000). Numerous non-European countries, including some developing countries, also have enacted GMO consumer legislation. Australia and New Zealand are to introduce mandatory labelling for all foods containing GMOs (ie, a zero threshold), following a poll showing more than 90 per cent approved such a move. Some developing countries also are reacting: Brazil has introduced restrictive conditions on imports of GM products, and Sri Lanka has taken the extreme step of banning the imports of GMOs, pending further clarification as to their environmental and food safety impacts.

Identity preservation systems to enable reliable labelling of food can be costly, however, and more so the more stages of processing or intermediate input use a crop product goes through before final consumption. A recent European survey suggests full traceability could add 6-17 per cent to the farmgate cost of different crops (European Commission 2000). Who bears those costs, and are the benefits sufficient to warrant them? Products containing GMOs that are not verifiably different from their GM-free counterparts are not going to attract a price premium, so their producers would not volunteer to label them as containing GMOs, given (a) the cost of identity preservation throughout the food chain and (b) the negative publicity about GMOs which is likely to lower the price of goods so labelled. Coercion would therefore be required -- but for benefits that are difficult to perceive, since the label has virtually no information content (in contrast to, for example, the positive health warning on cigarette packets) because there are no known risks of consuming GMOs.

A non-regulatory alternative to positive labelling regulations is to encourage the voluntary use of negative labels such as 'this product contains no GMOs' (Runge and Jackson 2000). With perhaps the majority of processed foods now containing some GMOs, this market alternative would require labels on a much smaller and presumably declining proportion of products. And that subset, like organic food, could attract a price premium, perhaps sufficient to cover the cost of identity preservation and labelling. That still requires the separation of GM-free products from GM-inclusive ones, however. Furthermore, it begs the question as to what is the threshold below which 'this product contains no GMOs' should apply. For the label to be meaningful abroad for exported GM-free products, multilateral agreement on that threshold would be needed.

## The Cartagena Protocol on Biosafety

Given the different attitudes and national approaches to regulation of genetically modified products, future trade disputes are a distinct possibility. The Cartagena Protocol on Biosafety (finalised in Montreal on 29 January 2000) may have added to that likelihood. The Biosafety Protocol has the objective of ensuring safe transboundary movement of living modified organisms resulting from modern biotechnology, If ratified by the parliaments of 50

signatories, the Protocol will not only reconfirm the rights of ratifying countries to set their own domestic regulations but also allow each country to decide whether and under what conditions it will accept imports of GM products for release into the environment (for example, as planted seeds). This condoning of import restrictions appears also to apply to GMOs intended as food, feed or for processing.1 Importantly, the Protocol stipulates that lack of scientific evidence regarding potential adverse effects of GMOs on biodiversity, taking into account also the risks to human health, need not prevent a ratifying country from taking action to restrict the import of such organisms in order to reduce perceived risks (UNEP 2000). In essence, this reflects an acceptance of the guiding influence of the precautionary principle, that is, "better safe than sorry".2 The Protocol requires that GMOs intended for intentional introduction into the environment or for contained use must be clearly identified as living modified organisms; but modified organisms intended for direct use as food or feed, or for further processing, just require a label stating that the product "may contain" such organisms. No labelling requirements for processed foods such as cooking oil or meal were established by the Protocol.

## WTO agreements and GMOs

An important aspect of the Biosafety Protocol that is unclear and hence open to various interpretations concerns its relationship with the WTO agreements. The text states that the "Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements", but at the same time the Protocol claims that this statement is "not intended to

<sup>&</sup>lt;sup>1</sup> Details concerning the latter products are still to be decided, however, pending the findings of the FAO/WHO Codex Alimentarius Commission's Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. There is uncertainty because while the Protocol relates to biosafety rather than human safety, the phrase "... taking into account effects on human health ..." survived the drafting process. The Codex Task Force is due to report within four years of its creation in June 1999.

<sup>&</sup>lt;sup>2</sup> The precautionary principle implies that considerations of human health and the environment rank higher than possible economic benefits in circumstances where there is uncertainty about the outcome.

subordinate [the] Protocol to other international agreements" (UNEP 2000 p.1). Certainly the Protocol's objective of protecting and ensuring sustainable use of biological diversity whilst also taking into account risks to human health is not inconsistent with WTO agreements. The WTO acknowledges the need for Member states to apply and enforce trade-restricting measures in order to protect human, animal or plant health and life as well as public morals. That right for a country to set its own environmental and food safety regulations at the national level is provided for in Article XX of the GATT. But the key goal of the WTO is to achieve effective use of the world's resources by reducing barriers to international trade. For that reason WTO Members also have agreed to not use unduly trade-restrictive measures to achieve environmental or food safety goals. More than that, such measures must be consistent with the key principles of the WTO: non-discrimination among member states, 'national treatment' of imports once having entered the domestic market, and transparent customs procedures. Whether the current WTO agreements prove to be in conflict with the rights to restrict trade in living modified organisms apparently provided for in the Biosafety Protocol only time - and possibly legal proceedings via the WTO's Dispute Settlement Body -- can tell.

Members of the WTO also have trade obligations under other WTO agreements that restrict the extent to which trade measures can be used against GMOs. More specifically related to food safety and animal and plant health are the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). These agreements allow Member states to impose certain restrictions on trade if the purpose of the measure is to protect human, animal or plant life and health. The TBT Agreement also covers technical measures aimed at protecting the environment and other objectives. At the same time the Agreements aim at ensuring that applied measures and technical regulations are no more trade-restrictive than necessary to fulfil the stated objectives.

Both the SPS and TBT Agreements encourage the use of international standards, guidelines and recommendations where they exist, such as in the realms of the Codex Alimentarius (the

FAO's international food standards body). Currently there are no international standards for genetically modified products,<sup>3</sup> although the Biosafety Protocol explicitly notes that signatories "shall consider the need for and modalities of developing standards with regard to the identification, handling, packaging and transport practices, in consultation with other relevant international bodies." (UNEP 2000 p. 10, Article 18.3.) International harmonisation of regulatory approval procedures for genetically modified products is currently under discussion in several forums including the FAO and OECD. The establishment of international standards for the production, regulation and labelling of these products may be helpful as a way of reducing future trade disputes among developed countries – but could impose onerous compliance costs on poorer GM-exporting countries.

Under the SPS Agreement a country may apply higher than international standards only if these can be justified by appropriate scientific risk assessments. In other words, while the SPS Agreement explicitly allows Member states to set their own standards for food safety and animal and plant health, it requires that measures be based on scientific risk assessments in a consistent way across commodities. The TBT Agreement is more flexible because Member states can decide that international standards are inappropriate for a number of other reasons, such as national security interests (GATT Article XXI). Hence determining which WTO agreement a given trade measure is covered by is of key importance. The SPS Agreement covers food safety measures and animal and plant health standards regardless of whether or not these are technical requirements. The TBT agreement, on the other hand, covers all regulations, voluntary standards and compliance procedures, except when these are sanitary and phytosanitary measures as defined in the SPS Agreement (WTO 1998a).

The SPS Agreement's scientific requirement is important because it is more objective than the TBT Agreement's criteria for determining what is a justifiable trade restriction and what is hidden

<sup>&</sup>lt;sup>3</sup> However, the Codex Committee on Food Labelling is currently considering the adoption of an international standard on GMO labelling.

protectionism. On the other hand, the SPS Agreement may be inadequate for legally justifying restrictions introduced on the basis of some vocal groups' opposition to GM foods. Official disputes about trade in genetically modified products have not yet materialised<sup>4</sup>, but experience from earlier WTO dispute settlement cases that are comparable to the GMO debate give an indication as to how the existing rules may be applied. The SPS Agreement was used in the beef hormone dispute between the US and the EU, for example (WTO 1998c). In short, the EU import ban on meat and meat products from hormone-fed livestock was found to be in conflict with the EU's WTO obligations, the main argument being that the EU could not present documented scientific risk assessment of the alleged health risk to justify the ban.

Scientific evidence is not always sufficient for governments to make policy decisions, or it may simply be unavailable. In such cases, Article 5.7 of the SPS Agreement allows WTO Member states to take precautionary measures based on available pertinent information. At the same time, members are obliged to seek additional information so that a more objective evaluation of the risks related to the relevant product or process can be made within a reasonable period of time. The precautionary principle is an understandable approach to uncertainties about genetically modified products, but there is a risk that when used in connection with internationally traded products, it can be captured by import-competing groups seeking protection against any new technology-driven competition from abroad. It may thus be extremely difficult to assess whether a measure is there for precautionary reasons or simply as a form of hidden protectionism. For this reason, attention will focus acutely on how the provisions of the Biosafety Protocol - the most explicit acceptance of the use of the precautionary principle in an international trade agreement relating to food products to date - are interpreted given current WTO commitments.

<sup>&</sup>lt;sup>4</sup> Thailand did formally object to Egypt's ban on GM imports in the latter half of 2000, but the matter was settled without going to the trouble of setting up a Dispute Settlement panel at the WTO. It objected not to Egypt's right to impose a ban, but rather to the fact that Thai exports were singled out for exclusion.

The existing trade agreements deal with regulations and standards concerning not just products but also production processes and methods if but only if they affect the characteristics or safety of the product itself: standards for production processes that do not affect the final product are not covered by the existing agreements. In relation to genetically engineered products, if the process itself were to alter the final product in such a way that there are adverse environmental or health effects associated with consumption, use or disposal of the product, restricting trade in this product need not violate existing WTO rules, ceteris paribus. However, if genetic engineering only concerns the production process and not the final characteristics of a transgenic product, domestic regulations that restrict the use of this method of production cannot be used to restrict imports of products produced by this method simply because the importing country finds it unacceptable by its own environmental, ethical or other norms.5

This discussion leads back to the role of scientific evidence. Some would argue that genetically modified products are different from conventional products *regardless* of whether or not this can be verified scientifically in the final product. One of the priorities of the European Commission in the next WTO round of multilateral trade negotiations is to obtain a clarification of the role of non-product-related processes and production methods within the WTO (European Commission 1999). If trade restrictions based on production methods are allowed, this could lead to the inclusion of a long list of non-tariff barriers, and not only in relation to biotechnology products.

Labelling of foods in relation to international trade is normally covered by the TBT Agreement unless the label relates directly to food safety, in which case it is covered by the SPS Agreement. Only labelling programs that concern production processes affecting the final product would be covered by the existing TBT Agreement.

<sup>&</sup>lt;sup>5</sup> This product/process distinction became (and has remained) prominent at the WTO as a result of the famous tuna-dolphin case in the early 1990s. The general issue continues to be hotly debated. See, for example, the recent paper by Howse and Regan (2000).

Determining whether or not a genetic modification affects the final product will probably have to be done on a case-by-case basis. Where labelling programs are not encompassed by the TBT agreement, which potentially may be the case for many transgenic products, the other agreements of the WTO will be applicable without exceptions (Tietje 1997). GATT Article III concerning nondiscrimination, for example, stipulates that Member states may not discriminate between otherwise like goods on the basis of their country of origin. A key issue using this Article will be the interpretation of the concept of 'like goods' and whether the presence of genetically modified material is 'sufficient' differentiate products. Article III seeks to avoid measures that are based on a false differentiation of products.

In short, the emergence of GMOs in agricultural and food production introduces several new and contentious issues to be dealt with by the WTO membership and ultimately its Dispute Settlement Body (DSB). The DSB has not yet been able to resolve the dispute over the EU's ban on imports of beef produced with growth hormones (WTO 1998c), so it is difficult to see how it will be able to do any better with the far more complex issue of GM products should the EU choose to ban their importation too – particularly now that there is a Biosafety Protocol on the table condoning the use of the precautionary principle and suggesting scientific evidence need not prevent importing countries from restricting GM trade.

To get a sense of the risk of trade disputes erupting over GMOs, it is necessary to assess the economic stakes involved. That is, how large are the potential gains from GMO crop technologies, to what extent will various countries benefit (or lose) from their adoption, and how would trade policy responses or adverse consumer reactions affect those projected outcomes? It is to these questions that we now turn. In doing so, a methodology is introduced for the empirical economic analysis of quarantine policy measures generally that, to the authors' knowledge, is more comprehensive than has hitherto been used.

# An empirical illustration

Theory alone is incapable of determining even the likely direction, let alone the magnitude, of some of the effects of subsets of farmers adopting GM-inclusive seeds, without or with trade policy and consumer reactions in other countries. Hence an empirical modelling approach is needed. To illustrate the usefulness of that approach in informing GMO debates, this section summarises one recent quantitative effort by the authors. It makes use of a well-received empirical model of the global economy (the GTAP model) to examine what the effects of some (non-European) countries adopting the new GMO technology might be (Nielsen and Anderson 2001b). For such purposes the single-market partial-equilibrium approach has to give way to an economy-wide, computable general equilibrium (GCE) approach.<sup>6</sup>

The Global Trade Analysis Project (GTAP) based at Purdue University offers such a general equilibrium model.<sup>7</sup> It captures the vertical and horizontal linkages between all product markets both within the model's individual countries and regions as well as between countries and regions via their bilateral trade flows. The database used for these applications reflects the global economic structures and trade flows of 1995. It has been aggregated to a small number of regions to highlight the main participants in the GMO debate, and it focuses on the primary agricultural sectors affected by the GMO debate.

Specifically, the effects of an assumed degree of GM-induced productivity growth in selected countries are explored for maize and soybean.<sup>8</sup> Those results are compared with what they would be

<sup>&</sup>lt;sup>6</sup> Such an approach has been called for by James and Anderson (1998) and Roberts (2000).

<sup>&</sup>lt;sup>7</sup> The GTAP model is a multi-regional, static, applied general equilibrium model based on neo-classical microeconomic theory with international trade described by an Armington (1969) specification, which means that traded products are differentiated by country of origin. See Hertel (1997) for comprehensive model documentation and McDougall *et al.* (1998) for the latest GTAP database.

<sup>&</sup>lt;sup>8</sup> These two crops are perhaps the most controversial because they are grown extensively in rich countries and are consumed by people there both directly and via animal products. Much less controversial are cotton (because it

if (a) Western Europe chose to ban consumption and hence imports of those products from countries adopting GM technology or (b) some Western European consumers responded by boycotting imported GM foods. The following scenarios are based on a simplifying assumption that the effect of adopting GM crops can be captured by a Hicks-neutral technology shift, i.e. a uniform reduction in all primary factors and intermediate inputs to obtain the same level of production. 9 For present purposes the GMadopting sectors are assumed to experience a one-off increase in total factor productivity of 5 per cent, thus lowering the supply price of the GM crop to that extent.10 Assuming sufficiently elastic demand conditions, the cost-reducing technology will lead to increased production and higher returns to the factors of production employed in the GM-adopting sector. Labour, capital and land consequently will be drawn into the affected sector. As suppliers of inputs and buyers of agricultural products, other sectors will also be affected by the use of genetic engineering in GM-potential sectors through vertical linkages. Input suppliers will initially experience lower demand because the production process in the GM sector has

is not a food) and rice (because it is mostly consumed in developing countries). For a parallel quantitative assessment of the latter two products, see Nielsen and Anderson (2000).

<sup>9</sup> Available empirical evidence (see the surveys in USDA (1999) and James (1997, 1998, 1999)) suggests that cultivating GM crops has non-trivial cost-reducing effects. Nelson *et al.* (1999) suggest that glyphosate-resistant soybeans may generate a total production cost reduction of 5per cent, and their scenarios have *Bt* corn increasing yields by between 1.8 per cent and 8.1 per cent.

<sup>10</sup> Due to the absence of sufficiently detailed empirical data on the agronomic and hence economic impact of cultivating GM crops, the 5 per cent productivity shock applied here represents an average shock (over all specified commodities and regions). Changing this shock (e.g. doubling it to 10 per cent) generates near-linear changes (i.e. roughly a doubling) in the effects on prices and quantities. This lowering of the supply price of GM crops is net of the technology fee paid to the seed supplier (which is assumed to be a payment for past sunk costs of research) and of any mandatory 'may contain GMOs' labelling and identity preservation costs. The latter are ignored in the CGE analysis to follow, but further research might explicitly include them and, to fine-tune the welfare calculations, even keep track of which country is the home of the (typically multinational) firm receiving the technology fee.

become more efficient. To the extent that the production of GM crops increases, however, the demand for inputs by producers of those crops may actually rise despite the input-reducing technology. Demanders of primary agricultural products such as grains and soybean meal for livestock feed will benefit from lower input prices, which in turn will affect the market competitiveness of livestock products.

The widespread adoption of GM varieties in certain regions will affect international trade flows depending on how traded the crop in question is and whether or not this trade is restricted specifically because of the GMOs involved. To the extent that trade is not further restricted and not currently subject to binding quantitative restrictions, world market prices for these products will have a tendency to decline and thus benefit regions that are net importers of these products. For exporters, the lower price may or may not boost their trade volume, depending on price elasticities in foreign markets. Welfare in the exporting countries would go down for non-adopters but could also go down for some adopters if the adverse terms of trade change were to be sufficiently strong. Hence the need for empirical analysis.

Two maize/soybean scenarios are considered below. The first of them (scenario 1) is a base case with no policy or consumer reactions to GMOs. GM-driven productivity growth of 5 per cent is applied to North America, Mexico, the Southern Cone region of Latin America, India, China, Rest of East Asia (excluding Japan and the East Asian NICs), and South Africa. The countries of Western Europe, Japan, Other Sub-Saharan Africa and elsewhere are assumed to refrain from using or be unable at this stage to adopt GM crops in their production systems. The other scenario imposes on this base case a policy response by Western Europe: Western Europe not only refrains from using GM crops in its own domestic production systems, but the region is also assumed to reject imports of maize and soybean products from GM-adopting regions.

### Scenario 1: Selected regions adopt GM maize and soybean

Table 16.1 reports the results for scenario 1. A 5 per cent reduction in overall production costs in the maize and soybean sectors leads to increases in coarse grain production of between 0.4 per cent and 2.1 per cent, and increases in oilseed production of between 1.1 per cent and 4.6 per cent, in the GM-adopting regions. The production responses are generally larger for oilseeds as compared with coarse grain. This is because a larger share of oilseed production as compared with coarse grain production is destined for export markets in all the reported regions, and hence oilseed production is not limited to the same extent by domestic demand, which is less price-elastic. Increased oilseed production leads to lower market prices and hence cheaper costs of production in the vegetable oils and fats sectors, expanding output there. This expansion is particularly marked in the Southern Cone region of South America where no less than one-fourth of this production is sold on foreign markets. In North America maize and soybean meal are used as livestock feed, and hence the lower feed prices lead to an expansion of the livestock and meat processing sectors there.

Due to the very large world market shares of oilseeds from North and South America and coarse grain from North America, the increased supply from these regions causes world prices for coarse grain and oilseeds to decline by 4.0 per cent and 4.5 per cent, respectively. As a consequence of the more intense competition from abroad, production of coarse grain and oilseeds declines in the nonadopting regions. This is particularly so in Western Europe, a major net importer of oilseeds, of which about half comes from North America. Coarse grain imports into Western Europe increase only slightly (0.1 per cent), but the increased competition and lower price are enough to entail a 4.5 per cent decline in Western European production. In the developing countries too, production of coarse grain and oilseeds is reduced slightly. The changes in India, however, are relatively small compared with e.g. China and the Southern Cone region. This is explained by the domestic market orientation of these sales. That means India's relatively small production increase causes rather substantial declines in domestic prices for these products, which in turn benefits the other

agricultural sectors. For example, 67 per cent of intermediate demand for coarse grain and 37 per cent of intermediate demand for oilseeds in India stems from the livestock sector, according to the GTAP database.

Global economic welfare (as traditionally measured in terms of equivalent variations of income, ignoring any positive or negative externalities) is boosted in this first scenario by US\$9.9 billion per year, two-thirds of which is enjoyed by the adopting regions (Table 16.1b). It is noteworthy that all regions (both adopting and nonadopting) gain in terms of economic welfare, except Sub-Saharan Africa which loses slightly because a small change in the terms of trade. Most of this gain stems directly from the technology boost. The net-exporting GM-adopters experience worsened terms of trade due to increased competition on world markets, but this adverse welfare effect is outweighed by the positive effect of the technological boost. Western Europe gains from the productivity increase in the other regions only in part because of cheaper imports; mostly it gains because increased competition from abroad shifts domestic resources out of relatively highly assisted segments of EU agriculture. The group of high-income East Asian countries, as relatively large net importers of the GM-potential crops, benefits equally from lower import prices and a more efficient use of resources in domestic farm production. Australia and New Zealand, by contrast, lose because the terms of trade go against their exportoriented livestock producers.

# Scenario 2: Selected regions adopt GM maize and soybean plus Western Europe bans imports of those products from GM-adopting regions

In this second scenario, Western Europe not only refrains from using GM crops in its own domestic production systems, but the region is also assumed to reject imports of oilseeds and coarse grain for SPS reasons from GM-adopting regions. This assumes that the labelling enables Western European importers to identify such shipments and that all oilseed and coarse grain exports from GM-adopting regions will be labelled "may contain GMOs". Under those conditions the distinction between GM-inclusive and GM-free

products is simplified to one that relates directly to the country of origin, and labelling costs are ignored. This import ban scenario reflects the most extreme application of the precautionary principle within the framework of the Biosafety Protocol.

A Western European ban on the imports of genetically modified coarse grain and oilseeds changes the situation in scenario 1 rather dramatically, especially for the oilseed sector in North America which has been highly dependent on the EU market. The result of the European ban is not only a decline in total North American oilseed exports by almost 30 per cent, but also a production decline of 10 per cent, pulling resources such as land out of this sector (Table 16.2). For coarse grain, by contrast, only 18 per cent of North American production is exported and just 8 per cent of those exports are destined for Western Europe. Therefore the ban does not affect North American production and exports of maize to the same extent for soybean, although the downward pressure on international price of maize nonetheless dampens significantly the production-enhancing effect of the technological boost. Similar effects are evident in the other GM adopting regions, except again for India. For Sub-Saharan Africa, which by assumption is unable to adopt the new GM technology, access to the Western European markets when other competitors are excluded expands. Oilseed exports from this region rise dramatically, by enough to increase domestic production by 4 per cent. Western Europe increases its own production of oilseeds, however, so the aggregate increase in oilseed imports amounts to less than 1 per cent. Its production of coarse grain also increases, but not by as much because of an initial high degree of self-sufficiency. Europe's shift from imported oilseeds and coarse grain to domestically produced products has implications further downstream. Given an imperfect degree of substitution in production between domestic and intermediate inputs, the higher prices of domestically produced maize and soybean mean that livestock feed is slightly

Table 16.1: Scenario 1 - effects of selected regions<sup>a</sup> adopting GM maize and soybean

(a) Effects on production, domestic prices and trade (percentage changes)

						Sub-	Australia
	North So	outhern			Western	Saharan	and New
	America	Cone	China	India	Europe	Africa	Zealand
Production							
Coarse grain	2.1	1.6	1.0	0.4	-4.5	-2.3	-5.0
Oilseeds	3.6	4.6	1.8	1.1	-11.2	-1.3	-3.4
Livestock	0.8	-0.0	0.1	0.4	-0.2	-0.1	-0.8
Meat & dairy	0.5	0.0	0.1	1.3	-0.1	-0.1	-0.6
Veg. oils, fats	1.1	4.5	1.4	0.0	-0.9	-1.2	-2.1
Other foods	0.2	0.1	0.4	1.5	-0.1	0.0	-0.3
Market prices							
Coarse grain	-5.5	<i>-</i> 5.5	-5.6	-6.7	-0.5	-0.4	-0.8
Oilseeds	-5.5	-5.3	-5.6	-6.5	-1.2	-0.3	-0.7
Livestock	-1.8	-0.3	-0.4	-1.4	-0.3	-0.3	-0.4
Meat & dairy	-1.0	-0.2	-0.3	<b>-</b> 1.0	-0.2	-0.2	-0.2
Veg. oils, fats	-2.4	-3.1	-2.6	-1.0	-0.5	-0.2	-0.3
Other foods	-0.3	-0.2	-0.5	<b>-</b> 1.0	-0.1	-0.2	-0.1
Exports <sup>b</sup>							
Coarse grain	8.5	13.3	16.8	37.3	<i>-</i> 11.5	-20	-26.8
Oilseeds	8.5	10.5	8.2	21.5	-20.5	-26.5	-28.4
Livestock	8.9	-2.0	-3.3	9.4	<b>-</b> 1.1	<i>-</i> 1.5	<i>-</i> 1.5
Meat & dairy	4.8	-0.9	-0.9	5.8	-0.5	-0.2	-1.3
Veg. oils, fats	5.8	14.3	5.6	-3.8	-4.9	-5.3	-10.9
Other foods	0.2	0.1	1.6	7.6	-0.6	0.1	-1.3
Imports <sup>b</sup>							
Coarse grain	-1.6	-4.6	-4.2	-20.5	0.1	11.3	11.3
Oilseeds	-2.6	-9.2	-1.6	-8.6	2.5	16.5	13.7
Livestock	-2.1	1.3	0.9	-5.2	0.2	0.5	0.5
Meat & dairy	-1.9	0.2	0.8	-1.7	-0.0	0.1	0.0
Veg. oils, fats	-3.7	-3.6	-1.7	3.1	1.3	3.4	3.7
Other foods	0	-0.1	-0.6	-3.1	0.1	-0.1	0.4

Table 16.1: Scenario 1 - effects of selected regions<sup>a</sup> adopting GM maize and soybean *continued* 

(b) Effects on regional economic welfare

(b) Effects of regional economic werrare							
	Equivalent Variation (EV)	•	sition of welfare tion of (US\$ m				
	US\$ million pa	<b>T</b> (C :	Terms of Trade effects	Technical Change			
North America	2,624	-137	-1,008	3,746			
Southern Cone	826	120	-223	923			
China	839	113	66	672			
India	1,265	182	-9	1,094			
Western Europe	2,010	1,755	<b>25</b> 3	0			
Sub-Saharan Africa	-9	-2	-9	0			
Aust/New Zealand	-70	3	<b>-7</b> 1	0			
Japan & Asian NIEs	1,256	551	712	0			
Other developing and transition econs.	1,120	171	289	673			
WORLD	9,859	2,756	0	7,108			

a North America, Mexico, Southern Cone, China, Rest of East Asia, India, and South Africa. For space reasons, results for numerous regions are omitted from this table.

b Includes intra-regional trade.

Source: Nielsen and Anderson's (2001b) GTAP model results.

more expensive. (Half of intermediate demand for coarse grain in Western Europe stems from the livestock sector.) Inputs to other food processing industries, particularly the vegetable oils and fats sector, also are more expensive. As a consequence, production in these downstream sectors declines and competing imports increase. For equal and opposite reasons, Australia and New Zealand are not quite as badly off in this scenario as in scenario 1.

Aggregate economic welfare implications of this scenario are substantially different from those of scenario 1 (again, leaving aside any externalities). Western Europe now experiences a decline in aggregate economic welfare of US\$4.3 billion per year instead of a

boost of \$2 billion (compare Tables 16.2b and 16.1b). Taking a closer look at the decomposition of the welfare changes reveals that adverse allocative efficiency effects explain the decline. Most significantly, EU resources are forced into producing oilseeds, of which a substantial amount was previously imported. Consumer welfare in Western Europe is reduced in this scenario because, given that those consumers are assumed to be indifferent between GM-inclusive and GM-free products, the import ban restricts them from benefiting from lower international prices. Bear in mind, though, that in this as in the previous scenarios it is assumed citizens are indifferent to GMOs. To the extent that some Western Europeans in fact value a ban on GM products in their domestic markets, that would more or less than offset the above loss in economic welfare.

The key exporters of the GM products, North America, Southern Cone and China, all show a smaller gain in welfare in this as compared with the scenario in which there is no European policy response. Net importers of maize and soybean (e.g. 'Other high-income' which is mostly East Asia), by contrast, are slightly better off in this than in scenario 1. Meanwhile, the countries in Sub-Saharan Africa are affected in a slight positive instead of slight negative way, gaining from better terms of trade. In particular, a higher price is obtained for their oilseed exports to European markets in this as compared with scenario 1.

Two-thirds of the global gain from the new GM technology as measured in scenario 1 would be eroded by an import ban imposed by Western Europe: it falls from \$9.9 billion per year to just \$3.4 billion, with almost the entire erosion in economic welfare borne in Western Europe (assuming as before that consumers are indifferent between GM-free and GM-inclusive foods). The rest is borne by the net-exporting adopters (mainly North America and the Southern Cone region). Since the non-adopting regions generally purchase most of their imported coarse grain and oilseeds from the North American region, they benefit even more than in scenario 1 from lower import prices: their welfare is estimated to be greater by

Table 16.2: Scenario 2 - effects of selected regions<sup>a</sup> adopting GM maize and soybean plus Western Europe bans imports of those products from GM-adopting regions
(a) Effects on production, domestic prices and trade (percentage changes)

							Australia
		.4				Sub-	and
	North So			_ 4.		Saharan	New
	America	Cone	China	India	Europe	Africa	Zealand
Production							
Cereal grain	0.9	0.0	0.8	0.4	5.3	-2.2	<i>-</i> 5.2
Oilseeds	-10.2	-3.6	-0.8	0.8	66.4	4.4	-1.3
Livestock	1.2	0.3	0.2	0.4	-0.8	0.0	-0.4
Meat & dairy	0.8	0.3	0.2	1.4	-0.5	-0.0	-0.5
Veg.oils,fats	2.4	8.1	1.6	0.1	-3.4	0.0	-2.1
Other foods	0.3	0.4	0.5	1.6	-0.5	-0.1	-0.4
Market prices							
Cereal grain	-6.2	-6.0	-5.6	-6.7	0.8	-0.0	-0.7
Oilseeds	-7.4	-6.8	-6.0	-6.5	5.8	0.4	-0.4
Livestock	-2.2	-0.7	-0.4	-1.4	0.5	0.1	-0.3
Meat & dairy	-1.3	-0.4	-0.3	<b>-</b> 1.0	0.3	0.1	-0.2
Veg.oils,fats	-3.3	-4.0	-2.7	<b>-</b> 1.0	2.0	0.0	-0.2
Other foods	-0.4	-0.3	-0.5	-1.0	0.1	0.0	-0.1
Exports <sup>b</sup>							
Cereal grain	0.3	-2.9	5.0	23.4	15.9	-13.1	-27.1
Oilseeds	-28.8	-69.2	-18.4	-8.7	167.2	105.0	3.8
Livestock	13.7	4.0	-1.4	12.6	-3.8	-1.8	-0.4
Meat & dairy	7.5	2.1	0.1	7.1	-1.4	0.3	-1.2
Veg.oils,fats	14.4	26.2	7.0	1.3	-15.0	5.8	-12.1
Other foods	1.5	1.9	2.0	8.0	-1.4	-0.6	-1.4
Imports <sup>b</sup>							
Cereal grain	-1.9	-5.3	-2.8	-20	3.3	13.4	13.4
Oilseeds	-5.6	-21.9	3.0	-3.7	0.6	22.5	18.6
Livestock	-3.2	0.1	0.1	-5.9	0.9	0.5	0.7
Meat & dairy	-2.8	-0.5	0.8	-1.8	-0.2	-0.0	-0.2
Veg.oils,fats	-7.7	-5.5	-1.7	4.0	5.5	2.4	2.6
Other foods	-0.6	-0.6	-0.8	-2.8	0.1	0.2	0.3

Table 16.2: Scenario 2 - effects of selected regions<sup>a</sup> adopting GM maize and soybean plus Western Europe bans imports of those products from GM-adopting regions continued

(b) Effects on regional economic welfare

	Equivalent Decomposition of welfare results Variation (EV) (US\$ million pa):					
	US\$ million pa	Allocative	Terms of Trade effects	Technical Change		
North America	2,299	27	-1,372	3,641		
Southern Cone	663	71	-303	893		
China	804	74	70	669		
India	1,277	190	-3	1,092		
Western Europe	-4,334	-4,601	257	0		
Sub-Saharan Africa	42	5	38	0		
Aust/New Zealand	-52	-1	-49	0		
Japan & Asian NIEs	1,423	593	831	0		
Other developing and transition econs.	1,296	101	531	672		
WORLD	3,419	-3,541	0	6,966		

a North America, Mexico, Southern Cone, China, Rest of East Asia, India, and South Africa. For space reasons, results for numerous regions in Table 1 are omitted from this table.

b Includes intra-regional trade.

Source: Nielsen and Anderson's (2001b) GTAP model results.

almost one-fifth in the case of a Western European import ban as compared with no European reaction. In the case of Australia and New Zealand they too are slightly better off in the sense that they lose less in this than in scenario 1.

### Conclusion

The results demonstrate that the potential economic welfare gains from adopting GMO technology in even just a subset of producing countries for these crops is non-trivial. In the case considered in the first scenario it amounts to around \$10 billion per year for coarse

grain and oilseeds (gross of the cost of the R&D that generated GM technology). Moreover, developing countries would receive a sizeable share of those gains, and more so the more of them that are capable of introducing the new GM technology. The second scenario shows that the most extreme use of trade provisions, such as an import ban on GM crops by Western Europe, would be very costly in terms of economic welfare for the region itself (assuming opposition to GMOs is not very deep) - a cost which advisors to governments in the region should weigh against the perceived benefits to voters of adopting the precautionary principle in that way. More than that, exporters of GM products would not be able to reap as much benefit from the new technology in the presence of such a trade restriction. These gains foregone are sufficiently large that if policy makers ignore them when considering policy responses to appease opponents of GMOs, they risk getting into trade disputes.

The above facts may well not prevent some countries from imposing import restrictions on GM products however, for at least four reasons. First, the Biosafety Protocol might be interpreted by them as absolving them of their WTO obligations not to raise import barriers. Second, if domestic production of GM crops is banned, farmers there would join with GMO protesters in calling for a raising of import barriers so as to keep out lower-cost 'unfair' competition. Third, the on-going lowering of import barriers, following the Uruguay Round Agreement on Agriculture and the information revolution's impact in reducing costs of trading internationally, pressure import-competing farmers to look for other ways of cutting imports.<sup>11</sup> And fourth, the per capita cost of banning GMO imports in Western Europe amounts to barely US\$15 per capita per year – hardly a major impediment to imposing an import ban.

<sup>&</sup>lt;sup>11</sup> The emergence of the concept of agriculture's so-called 'multifunctionality', and the call for trade policy and the WTO to deal with environmental and labour standards issues, can be viewed in a similar light (Anderson 1998, 2000).

Given these political economy forces, is there a way for WTO to accommodate them without having to alter WTO rules? Bagwell and Staiger (1999) address this question in a more-general setting and offer a suggestion. It is that when a country is confronted from greater import competition because of the adoption of a new domestic standard that is tougher than applies abroad, it should be allowed to raise its bound tariff by as much as is necessary to curtail that import surge. One can immediately think of problems with this suggestion, such as how to determine what imports would have been without that new standard. Rather than increase tariffs, however, direct payments that have a minimal distorting effect on trade may be a preferable alternative, especially if they are consistent with WTO support commitments. Options of this sort may have to be contemplated if the alternative is to add to the EU beef hormone case a series of GMO dispute settlement cases at the WTO that are even more difficult to resolve.

Finally, the empirical results presented above show the importance of using a general equilibrium model when assessing the economic implications of quarantine measures by large countries and/or affecting large product groups. While the indirect economic effects on related groups may not be of direct concern to quarantine officers, they certainly should concern policy makers and advisors responsible for sound management of the economy, in addition to agricultural trade negotiators.

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# 17

# Food safety policy in the WTO era

**SALLIE JAMES** 

The sovereign right of a country to protect its citizens from foodborne health risks is recognised in the preamble and in Article 2.1 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) of the World Trade Organization (WTO) <sup>1</sup>. Provided that measures to protect human health meet the obligations under the SPS Agreement, Member governments of the WTO are free to employ their own choice of policy instruments for food saftey purpose.

Since the conclusion of the Uruguay Round of multilateral trade talks in 1993, there have been significant agricultural policy reform and international trade liberalisation. The general trend towards market liberalisation has, however, been matched by increases in the level and scope of regulations relating to food products (Henson 1998; Henson and Caswell 1999). This is at least partly in response to an increase in demand for food safety (Kinsey 1993). Indeed, in a recent review, Roberts and DeRemer (1997) estimated that food safety standards accounted for 20 per cent of the restrictions on US agricultural exports in 1996.<sup>2</sup> Analysts have pointed out that the increase in concern about food safety risks, particularly in wealthy

<sup>&</sup>lt;sup>1</sup> GATT (1994). For an extended discussion on the SPS Agreement and its relation to other WTO Agreements, see Roberts (1998b), Hooker (1999) and James (2000, Appendix).

<sup>&</sup>lt;sup>2</sup> The impact of food safety standards on trade is difficult to measure because of the presence of firm specific costs, according to Henson (1998), who points out that most estimates to date are limited and/or anecdotal.

democracies, is in some cases not supported by scientific evidence (Henson, 1998; Henson and Caswell, 1999).<sup>3</sup> To the extent that food safety policies reflect these concerns, risk mitigation measures may be difficult to defend under the science-based tests of the SPS Agreement.

This chapter begins by exploring key issues relating to food safety policy. Attention is then turned to a discussion of proposed solutions to the problem of how to promote and secure libral trade while honouring both legitimate consumer demands for safe food and SPS commitments.

# Issues raised in the food safety economics and trade literature

Key considerations relevant to food safety policy makers are market failure, consumer perceptions of risk, information asymmetry, and externalities. Each is explored in this section before a discussion of how they might be addressed, given the disciplines of the SPS Agreement.<sup>4</sup>

# Market failure associated with food safety

Henson and Traill (1993) and Swinbank (1993) afford a detailed examination of how the 'market' for safe food can fail. Broadly, the reasons include the divergence between perceptions and objective measures of risk; information asymmetry between buyers and sellers of food; the presence of externalities (such that the private and socially optimal levels of food safety do not concur); and distributional issues relating to willingness and ability to pay for food safety. In the context of the recent review of Australia's *Imported Food Control Act*, Tanner *et al.* (1998) outline the factors they

<sup>&</sup>lt;sup>3</sup> Nor have policy makers always fully considered trade impacts when reforming food safety policy (Hooker 1999), although the National Competition Policy Review of Australia's *Imported Food Control Act* 1992 explicitly considered Australia's international obligations (Tanner 1999).

<sup>&</sup>lt;sup>4</sup> For comprehensive overviews of the food safety literature more generally see Henson and Caswell (1999) and Swinbank (1993).

consider to be pertinent to market failure in the food industry. Kinsey (1993) suggests that agreement about the extent of regulation required to correct food safety market failures will be difficult to reach since there are wide differences in opinion about the seriousness of each source of market failure.

### Consumer perceptions of risk

There is a broad and comprehensive literature covering influences shaping consumer behaviour, especially relating to behaviour under conditions of uncertainty and to consumers' perceptions of risk (Henson and Traill 1993; Swinbank 1993; Pollack 1995; Henson, 1998; Mahe and Ortalo-Magne 1998; Roberts 1998a; Deane 1999).

Henson (1998) and Mahe and Ortalo-Magne (1998) outline the misperceptions of risk that can occur and the factors affecting consumers' evaluation of risk. For example, risks with the same probability of occurrence will frequently be estimated differently according to the nature of the risk involved. In particular, highly publicised and/or highly visible risks (like food safety scares such as BSE in Britain) tend to be overestimated such that the perceived probability of an event occurring tends to be relatively independent of its actual frequency. Mahe and Ortalo-Magne (1998) and Kerr (1999) point out that the media (at least in the short run) can exacerbate the problem by emphasising and dramatising real or ill-founded hazards, especially when scientific knowledge is uncertain. Even when scientific opinions are fairly clear and unanimous, consumers seem reluctant to adopt them if they conflict with established beliefs.

Mahe and Ortalo-Magne (1998) point out that consumer perceptions are to a large extent shaped by culture and Henson (1998) points to attitudes towards genetically modified (GM) and irradiated foods as examples of how perceptions of risk and their acceptability differ across countries). Insofar as these perceptions and demands are a primary influence on policy makers, so long as different cultures (and abilities to influence policy-makers) exist, they will challenge the WTO's objective to harmonise national health and safety standards. It will be especially difficult to achieve international

cooperation in cases when scientific evidence is limited and when environmental, health and ethical issues are all at stake (Mahe and Ortalo-Magne 1998). The debate surrounding the use of genetically modified organisms and the recent beef hormones dispute between the EC and the US is a clear example of such a case.

In the context of the *Hormones* dispute, Roberts (1998b) suggests that "...many European consumers may prefer to consume hormone-free beef no matter what scientific evaluations conclude, and consent criteria and minority rights imply that public policy should permit individuals to avoid the consumption of foods that are questionable in their view" (p 403). Whether or not a ban on hormone-treated beef production and imports is the most *efficient* way to enable consumers to avoid hormone-treated beef is quite a different matter and is explored in James (2000).

Kerr (1999) reports that consumer preferences are now being touted as a reason for restricting trade, and as an issue that is so important as to warrant special inclusion in the SPS Agreement when it is next reviewed: "...the EU would like to renegotiate the [SPS Agreement] to permit trade restrictions for reasons of consumer preference" (p. 245). Such a proposal is risky since we cannot be sure that the 'consumer groups' that lobby governments truly represent the preferences of society at large.

It is clear from the amount of literature and the diversity of issues discussed therein that any policy maker concerned with human, animal and plant health issues must acknowledge the role of consumer perceptions and the explanations behind them. As Henson (1998) points out, to ignore factors such as consumer risk perceptions may be tempting given the complexities they introduce, but to do so is unlikely to reduce the number of disputes, or to make them easier to resolve (see also Bureau and Marette 2000). In any case, ignoring consumer sentiment is unlikely to make any dispute resolutions palatable to consumers.

### Information asymmetry

There is a disparity in the amount of information available to consumers and producers about the safety of foods. Credence attributes (those product attributes which are not recognisable or verifiable by the senses) such as nutritional value and chronic (i.e. delayed reaction) safety risks are the most obvious example of issues about which the consumer must trust the claims and integrity of the food manufacturer. Various solutions have been proposed to limit the potential for food producers to neglect (costly) food safety considerations in the pursuit of higher profits. Some of these are outlined below.

#### **Externalities**

Food hazards have potential effects that reach beyond the person afflicted with the food-borne illness. For example, production losses through work absences, public health expenses and the risk of the spread of infectious disease (i.e. through an infected person handling food) are all considerations somewhat beyond the concern of the person directly involved. An individual will often consider only costs to himself (should he fall ill) when deciding on their willingness to pay for food safety. Likewise, food manufacturers are unlikely to consider the wider health implications of any risks borne by their food and will consider only private (i.e. firm) marginal costs in their food safety supply decision unless institutional structures force them to take public health issues into account. How to induce this rather imperfect market to arrive at a position of the socially optimal level of food safety is a subject of much research.

# Approaches to managing food safety risks

The following policy approaches are by no means exhaustive, nor are they necessarily mutually exclusive. On the contrary, it is likely that any credible food safety system would contain elements of all of them. At the laissez-faire end of the policy intervention spectrum, it has been suggested that the threat of loss of reputation, brandpower and/or resources (e.g. through litigation) is enough incentive for firms to provide the level of food safety required by consumers

(Swinbank 1993 and Henson 1998). Clearly in practise this is thought to provide insufficient protection, since most western democracies have some level of food safety regulations.

### Private standards

In addition to government-proscribed standards, many industries have adopted private standards (such as those of the International Standards Organization (ISO) and standards incorporating HACCP<sup>5</sup> principles) and minimum quality assurance schemes in a kind of "self regulation". Performance standards - those that specify the attributes of the final product - are generally thought to be more efficient than process standards (which dictate the method by which firms must produce their goods in order to conform to a chosen safety level) because they enable more flexibility (and therefore probably more efficiency) at the firm level (Unnevehr and Jensen 1996; Henson 1998). The mandatory adoption of preventative systems such as HACCP in some industries may be seen as a compromise between rigid, market constraining "command and control" standards and more flexible, market based solutions (such as taxes). Costs of enforcement also tend to be lower (Henson and Caswell 1999).

The Imported Food Control Act Review Committee recommended a partnership approach (or co-regulation) between the food industry and government to encourage industry (including the importers) to accept responsibility to ensure food complies with food safety requirements (e.g. through the adoption of quality assurance arrangements). The government's role would be to implement auditing and regulatory frameworks to ensure consumers that the requirements were being met (Tanner 1999). Such an approach appears to be consistent with the belief that performance standards are the best way of meeting safety standards while allowing firm flexibility.

<sup>&</sup>lt;sup>5</sup> HACCP stands for hazard analysis and critical control points.

Industry-controlled initiatives and public food safety mechanisms can be co-operative.<sup>6</sup> Private standards may themselves be a response to public requirements and in this sense may become *de facto* public standards, especially if they are widely adopted (Henson 1998). Indeed, in those markets where private standards are well established and important, they may take precedence over public standards in determining production and import conditions.

In such an environment, the ability of public regulatory reform to overcome barriers to agri-food trade is limited (Henson 1998). The effectiveness of the SPS Agreement, insofar as it has jurisdiction over the public policy domain only, may be reduced over time as private guidelines and standards become more important. It at least raises the question of how to bring private standards under SPS Agreement disciplines (Henson 1998).

The present author concedes it may be a difficult task considering the voluntary nature of many private standards. Perhaps the best way governments can prevent private standards from becoming non-tariff barriers to trade is by providing clear guidelines to industry bodies about the government's obligations to the WTO and by ensuring that incentive structures encourage private standards to abide by the spirit (if not the letter) of these obligations. Indeed, Article 13 of the SPS Agreement imposes certain obligations on WTO Members for measures developed by non-government bodies (i.e. that " Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories...comply with the relevant provisions of this Agreement" and that "Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such...non-governmental entities...to act in a manner inconsistent with the provisions of this Agreement"). A transparent, consultative

<sup>&</sup>lt;sup>6</sup> Public interventions alone may in any case be insufficient to protect humans from food borne health risks. As Unnevehr (1996) points out, foodborne pathogens have the potential to enter at any point in the food preparation chain and therefore responsibility for food safety needs to be shared between consumers and producers, with some intervention by government.

approach will deter transgressions and check the use of SPS measures as disguised barriers to trade.<sup>7</sup>

# Harmonisation (or rapprochement)

Regulatory co-operation has been suggested as the best way of minimising trade disputes (Mahe and Ortalo-Magne 1998). For example, Kinsey (1993) suggests that, while requiring more expensive inspection procedures, recognising equivalence on the basis of attributes of the final product encourages innovation in production and processing methods and facilitates trade. There are three degrees to which countries can co-operate in their efforts to reform food safety policies and minimise restrictions on trade: called rapprochement in the trade literature (Henson and Caswell 1999; Hooker 1999). At the weakest extreme this involves consultation and co-ordination in order to narrow significant differences in national food safety regulations. Mutual recognition acknowledges other regulatory systems as equivalent in their ability to achieve food safety standards. strongest level of co-ordination The harmonisation and standardisation of policies (which may involve adopting international standards), although the three types of rapprochement are to some extent co-existing and complementary.8

The potential for harmonisation is limited to the extent that countries agree on the policy *objective*: called the 'acceptable level of risk' or the 'appropriate level of protection'. In the context of GM food, Caswell (2000) says: "...recognising equivalency will not go far in smoothing over differences in acceptance of biotechnology because governments essentially are disagreeing about the

<sup>&</sup>lt;sup>7</sup> In a sense, there is an adverse selection problem inherent in publicising SPS regulations, since the least restrictive members are the ones more likely to comply with the transparency clause. Conversely, because more transparent Members are necessarily more open to challenge, Members promulgating excessive restrictions are less likely to publicise their SPS measures, unless required to do so by law. Countries are unlikely to be transparent unless obligated, hence the necessity and benefits of the transparency provisions.

<sup>&</sup>lt;sup>8</sup> The articles in the SPS Agreement most explicitly promoting rapprochement are Articles 3 and 4, which incorporate harmonisation and equivalence principles respectively (Hooker 1999).

appropriate level of protection". Similarly, Kinsey (1993) and Hooker (1999) argue that harmonisation will be difficult to achieve beyond the bilateral or regional level (where agreement on food safety standards is easier to achieve than in multilateral fora) since there are differences in opinion as to the factors to include when deciding on the appropriate level of protection.

Even if harmonisation is achieved, it provides no guarantee against discrimination in favour of domestic producers. Henson (1998) asserts "...[a] food safety standard is discriminatory if costs of greater for importers than compliance are domestic producers...[such that]...even harmonised standards discriminatory...". Domestic firms will always have an advantage over foreign firms if there are institutional and cultural advantages for incumbent firms who are familiar with the domestic regulatory environment. They also may benefit from better access to regulatory and compliance information and from economies of scale in compliance (again, those firms with a large incumbent presence may reap gains from "specialising" in domestic regulations compared to those more international firms who have a larger range of regulations with which they must comply) (Henson 1998).9

Given that all food safety standards are at least potentially discriminatory, one may well ask on what basis they are to be judged in the event of a dispute. One possible solution is to ask to what extent they are excessively discriminatory, that is, over and above what would be considered unavoidable discrimination given the inherent advantages to domestic firms outlined above.

# Labelling

The use of labels has been suggested as one way of overcoming the problem of how to allow for consumer choice while protecting the interests of consumers for safe food (Mahe and Ortalo-Magne 1998;

<sup>&</sup>lt;sup>9</sup> The transparency and notification requirements of the SPS Agreement are likely to go some way to alleviating the excessive costs placed on those firms trying to export to environments where there are language barriers and where transparency about national regulations was previously lacking, or where regulatory change was frequent.

Runge and Jackson 2000). When there are clear health risks associated with consumption of a product, labels alone might not be the most efficient or effective solution. For example, in response to the overwhelming scientific evidence linking cigarette smoking to heart and lung conditions, public authorities have responded by using some combination of labelling, excise taxes and restrictions on sales and consumption in public places. But where the scientific evidence is mixed or insufficient, and where consumers have different degrees of risk acceptance or willingness to pay to avoid risk, labels are thought to allow a sufficient degree of consumer choice to consume or avoid products which they find acceptable or objectionable. They also provide information on credence attributes.

Beyond providing information to consumers, labels also have value to producers as a way of revealing consumer preferences. If consumers base their consumption decisions on what they read on a label, then, *ceteris paribus*, the market will tend to reward those products with the attributes most desirable to consumers, and thus lead to more production of goods wanted most (Caswell and Padberg 1992). An even wider definition of the value of food labels includes their existence value: the fact that consumers may derive benefit for knowing that the composition and content of food products is being observed and regulated. Caswell and Padberg (1992) assert that the resulting consumer confidence in the food supply is important, if difficult to observe.

Still assuming that scientific evidence as to the safety and/or nutritional content of food is conflicting or inconclusive, compulsory labelling has, especially in relation to genetically modified (GM) foods, produced mixed reactions. Critics of labelling systems purport that labels may arouse fear or suspicion in consumers unnecessarily: that if there is no scientific evidence to suggest that foods may be inherently unsafe, labels may inadvertently convince consumers that they pose a health risk (Quiggin 1999).<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> The US is opposed to labels on hormone-treated beef for this reason; indeed, if there is no SPS risk associated with a product, regulations – including labels – cease to become an SPS issue and will be subject to The WTO's Agreement on Technical Barriers to Trade disciplines (Caswell 2000)

The costs of a labelling system will determine to what extent it is preferable to other SPS measures. From a cost/benefit perspective, it is possible to imagine that, should the vast majority of consumers wish to avoid certain food technologies such as GM food, labelling (assuming it is not costless) may be welfare inferior to a ban on that technology (Bureau *et al.* 1998; Caswell 2000). Whether such a ban would be legally acceptable is another matter.

# Legal implications of the Hormones dispute

The first SPS dispute – that between the EC and the US and Canada about the use of hormonal growth promotants in beef – yielded controversial results. The purpose here is not to debate the legal intricacies of the case,<sup>11</sup> but to draw out the main implications for governments wishing to use the findings of the dispute settlement bodies as guidelines for how the directives in the Agreement should be interpreted. Many commentators see the dispute as a precursor to the brewing debate about trade in GM food, since the same sorts of issues that arose in *Hormones* – uncertainty, lack of (or disagreement concerning) objective and/or conclusive scientific evidence, and differing consumer and producer perceptions of risk – are equally relevant for GMOs.

Broadly, the ruling of the Appellate Body of the *Hormones* case was thus: Firstly, that a Member's chosen 'appropriate level of protection' is not required to be the same as the relevant international standard provided that scientific evidence is obtained and presented as justification for a higher standard. Secondly, the scientific opinion on which a measure is based does not have to be that of the majority of experts in the field. And thirdly, the EC measure was not based on an adequate risk assessment and the EC should bring its policy into accordance with the SPS Agreement.

An interesting finding from a policy-makers point of view is that a measure is considered to be in accordance with the requirements of Article 5.1 so long as an "objective relationship" can be found

<sup>&</sup>lt;sup>11</sup> See Hurst (1998), Roberts (1998b), Cottier (1999), Pauwelyn (1999) and Chapter 4 in this volume, by Stanton.

between scientific evidence and the measure when the measure is challenged (WTO 1998, para. 189), implying that there is no procedural requirement to Article 5.1. If this view prevails, however, there is potential for the spirit of the SPS Agreement to be undermined. As Hurst (1998) points out, the Appellate Body's interpretation implies that a Member has a responsibility to ensure its measure is consistent with scientific evidence only when it is challenged. Conversely, the Panel found that a risk assessment must be considered in advance of implementation (WTO 1997a, para. 8.113; WTO 1997b, para. 8.116).

The study by James (1999) of the EC ban on beef produced using hormones concludes that the SPS measure chosen by the EC ostensibly to protect consumers' health is welfare inferior to free trade, under the assumptions used. It is likely that beef trade liberalisation combined with a labelling scheme is the best way of securing consumer choice while abiding by WTO rules. Furthermore, producers outside the EU will also gain from EU beef trade liberalisation, as the technological constraint imposed by the ban is removed. These conclusions will not be news to those familiar with the economics of distortions and welfare, but in the context of SPS policy it represents a new approach and a significant departure from the view that SPS measures are beyond the scope of economic analysis.

# The use of economic analysis given the disciplines of the SPS Agreement

There is a belief among some economists that the contribution of the discipline is being relegated to a minor role in the interpretation and implementation of SPS Agreement rules (Mahe and Ortalo-Magne 1998; Hooker 1999). The role of economics is widely believed to belong in the risk management phase of risk analysis – for example, in evaluating alternative strategies – which is given secondary status in the SPS Agreement (Caswell 2000).

While the disciplines in Article 5.3 allow exclusively scientific reasons in the decision to implement a particular measure, there appear to be no limits on factors that can be considered by

authorities in risk management decisions. Indeed, it is recognised as a sovereign right of a Member to choose their acceptable level of risk. There is considerable disagreement among WTO Member countries about which factors are legitimate ones to include in the risk analysis framework (Roberts 2000; Caswell 2000). For example, some Members have suggested that 'uncertainty' is a legitimate factor to consider, and they should be able to set a "zero risk" level based on the precautionary principle (Caswell 2000). This ambiguity is augmented by the somewhat imprecise line that the SPS Agreement implicitly draws between risk management and risk assessment: "...the concept of "acceptable level of risk...[on which the SPS Agreement in based] fuses risk assessment and risk management by embedding value judgements about which risks are 'acceptable' into scientific assessments" (Roberts 2000, p 34).

A major difference between the economic paradigm and the risk assessment paradigm can be summarised thus: (scientific) risk assessment is done on a commodity-by-commodity basis, but there appears to be no scope within the Agreement for commodity-by-commodity analysis on the appropriate level of protection (risk management).<sup>13</sup> The concern that has been expressed by some officials and commentators (see, for example, Bureau *et al.* 2000; Sinner 1999; Kerr 1999; Roberts 1998b and 2000) that using economic tools such as cost benefit analysis and frameworks such as that

<sup>&</sup>lt;sup>12</sup> According to Bureau and Doussin (1999), the rulings of *Salmon* and *Hormones* reaffirm the right of Member to choose their own standards so long as they are chosen in an appropriate manner: "...what is imposed is a procedure for setting regulations rather than a particular standard." (p. 4).

<sup>&</sup>lt;sup>13</sup> The most disaggregated that appropriate levels of protection are allowed to be, at least according to the Committee on Sanitary and Phytosanitary Measures (SPS Committee) guidelines, are on a broad kingdom level: a member may choose an appropriate level of protection for human health, another for animal health and yet another for plant health (Committee on Sanitary and Phytosanitary Measures 2000).

presented in James and Anderson (1998) on a case-by-case basis may be inconsistent with various Articles of the SPS Agreement.<sup>14</sup>

More specifically, using cost/benefit analysis (or any other economic tool) to justify SPS measures could breach the SPS Agreement if it engenders different results for different import sources with similar risk status; or different levels of acceptable protection in different but comparable situations.

There are no directives in the SPS Agreement to prevent governments from *removing* SPS restrictions if doing so is found to be welfare increasing, but Sinner (1999) expresses concern that such a strategy, even if it has a positive influence on trade, could fail to satisfy the consistency criteria of Article 5.5:

"...concern could arise if ... [a] government rejected, due to insufficient benefits, an application for ... goods that presented similar risks to [other] goods approved because the benefits of its importation outweighed otherwise significant risks." (Sinner 1999, p. 7)

There is another danger in allowing economic factors to be included in risk management. If economic considerations – including consumer gains from trade – can be considered when choosing or justifying a SPS measure, the opportunity may arise to use producer losses from import competition as a reason for restricting trade (see also Roberts 1998a, b and 2000; Robertson 1998; and Sinner 1999). <sup>15</sup> When advocating economic analysis in SPS decisions, it should be kept in mind that the economic efficiency test will not always yield a trade liberalisation recommendation and anyway is not a legal basis for a SPS measure under the terms of the SPS Agreement. Using welfare economics may also limit the potential for harmonisation since cost/benefit analysis is likely to yield different results in different countries (Caswell 2000).

<sup>&</sup>lt;sup>14</sup> Objections have also been raised on philosophical grounds about using cost-benefit analysis to value human life (Henson and Traill, 1993; Swinbank, 1993; Roberts, 2000), an issue beyond the scope of this paper.

 $<sup>^{\</sup>rm 15}$  Roberts (2000) sees this possibility as limited by the directives of Article 2.2

On the other hand, WTO-legal measures may be economically inefficient. Bureau et al. (2001) point out that under the terms of the SPS Agreement, "...[s]hould a country be able to prove that there is a risk of dissemination of a pathogen, and even if the risk level is small, the economic consequence of dissemination negligible, and the economic costs of the ban considerable, the ban would be legitimate." (p. 22). From an economic standpoint, this seems to be especially considering undesirable possibility, Agreement was designed to discipline the use of unnecessarily restrictive non-tariff barriers to agricultural trade. But unnecessarily restrictive measures are the fault of domestic policy makers and lie not with the SPS Agreement itself. Indeed, Article 5.6 specifies that measures should not be more trade-restrictive than required to achieve the appropriate level of protection. As Roberts (2000) points out, "[the SPS Agreement] is an international trade treaty, not a regulatory blueprint" (p. 46). While it is not possible under the terms of the SPS Agreement for a government to justify an illegal measure on economic welfare grounds, there is nothing in the Agreement to prevent governments from choosing the most efficient policy instrument so long as it adheres to its provisions.

The recently released guidelines to WTO Members on how to implement Article 5.5 of the SPS Agreement (Committee on Sanitary no and Phytosanitary Measures 2000) make binding recommendations. A few important implications emerge. Firstly, the appropriate level of protection can be different according to whether it relates to protecting human health, animal health or plant health. Secondly, when setting the appropriate level of protection, a Member should consider appropriate levels of protection already determined. If there are differences between that appropriate level of protection and the appropriate level of protection in question, the Member should consider whether those differences are arbitrary and unjustifiable and whether the represent a disguised restriction on international trade. If so, either of the appropriate levels of protection (or both) may need revision to ensure consistency. Thirdly, the Committee suggests that members may wish to the decisions of other Members, and of relevant international organisations, when determining their appropriate

level of protection. For the moment, it seems conformity to international standards is the surest way to avoid censure from a WTO body.

From the *Hormones* dispute it has become clear that the SPS Agreement provides few guidelines for situations of uncertainty, or scientific ambiguity, except for the precautionary principal embedded in Article 5.7. Measures implemented on the basis of uncertainty (and not applicable under Article 5.7) will be difficult to defend under Article 5.1, since an "uncertainty assessment" is nonsensical. This weakness in the SPS Agreement will become increasingly obvious and cumbersome with the growth of GMOs and measures to restrict their use and trade (Hooker 1999).

The role of economics in determining the appropriate level of protection was not explicitly referred to in the guidelines, but the Committee did suggest "...[a]dvice may be sought from recognised, qualified experts, and could include commenting on ...potential discriminatory trade effects..." (p. 4). The recommendation that economists be involved in providing advice about trade discrimination effects of SPS policy is shared by James and Anderson (1998), Mahe and Ortalo-Magne (1998) and Caswell (2000).

A particularly worrying comment from these guidelines is offered in the section on practical implementation of an appropriate level of protection: "...Members are not always able to indicate precisely their appropriate level of protection. In such cases, the appropriate level of protection may be determined on the basis of the level of protection reflected in the sanitary or phytosanitary measures in place" (p. 4). This is certainly a risky path to take, considering that some existing SPS measures may have been implemented many years ago, under different technological, agricultural and trading conditions and perhaps for reasons not exclusively related to SPS risk.<sup>16</sup> Far from advocating historically based policy, some

<sup>&</sup>lt;sup>16</sup> It also contradicts an earlier statement in the same guidelines that "[t]he determination of the appropriate level of protection is an element in the decision-making process which *logically precedes* the selection and use of one or

economists recommend periodic review of SPS measures (James and Anderson, 1998). Regular reviews of area freedom status and domestic quarantine and food safety policies will be needed to ensure methods of determining acceptable risk and measures to achieve it are beyond legal reproach and reflective of changing technology and risk conditions in the home country and abroad. Similarly, the Imported Food Control Act Review Committee recommended that legislation aimed at ensuring imported food meets Australian food safety standards be sufficiently flexible such that it can be compatible with changes in food production and processing technology, and any changes in Australian's own domestic food safety standards (Tanner 1999).

Economic analysis should become more prevalent in import risk analyses. A comprehensive review of current SPS barriers may reveal inefficiencies, if WTO challenges do not reveal them first. <sup>17</sup> The use of SPS barriers is typically seen as a scientific issue, and necessary to protect humans, animals and plants from health risks. But economists would see them as a resource issue as well, and hence amenable to economic analysis. The fact that SPS measures are different from standard trade barriers in that they can correct externalities does not mean they are always efficient, or that the externalities cannot be corrected in better ways. Using economic analysis, particularly in risk management decisions, will improve the efficiency of SPS policies, and promote the balance between achieving gains from trade reform and protecting human, plant and animal health.

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# 18

# **Environmental risk evaluation in quarantine** decision making

JOHN D. MUMFORD\*

Quarantine decisions affect the value of both cultivated and natural environments. While the economic principles governing these decisions are broadly similar, many specific issues are quite different in the two situations. There is no consensus on the value of the natural environment at risk from invasive species or how it can be determined. An appropriate level of spending on prevention and mitigation of losses from invasive species in the natural environment has not been explicitly agreed, nor has the way in which that cost should be allocated within society.

Few studies have determined either the overall value of a nation's natural environment or the potential economic loss to the environment due to invasive species. New Zealand has recently put a value of NZ\$46 billion/year on the indigenous natural environment (New Zealand Ministry of Environment 1998). In the US two recent estimates have been published on losses due to invasive species. One covers only some selected species (US Office of Technology Assessment 1993) while in the last year a more general estimate has been made, US\$138 billion/year lost due to all invasive species (Pimentel 2000; Pimentel *et al.* 1999), from over 50,000 species that have entered the USA. Concern about the often

<sup>\*</sup> Thanks to Megan Quinlan for help with background materials and experience with quarantine practices and Susana Mourato for discussions on environmental discounting issues.

irremediable loss of biodiversity is increasing and international agreements on biodiversity, trade and phytosanitary measures all require governments to take action. In the last year the US spent an estimated US\$590 million to prevent and control unwanted exotic organisms, raised from fees (US\$141 million) charged to users (importers, shippers, travellers, air carriers, etc) for inspections, with additional public funds allocated by Congress¹. However, as Pimentel *et al.* (1999) point out, overall the introduction of exotic species to the United States has made a positive contribution of US\$800 billion/year. International agreements require countries to undertake trade without unnecessary restriction. Therefore, a purely precautionary approach is inappropriate, and it has been discarded in the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement for anything other than a temporary measure².

There are three key issues to contemplate in including environmental considerations in quarantine decisions: prediction, evaluation and attribution. More specific issues are discussed in greater detail through the remainder of the chapter.

Prediction of impacts of invasion by exotic species in natural environments is, in general, even more difficult than in agricultural systems (Myers *et al.* 2000; US Office of Technology Assessment, 1993). The systems have greater ecological complexity, which affects both the prediction of the direct impacts and the management performance of any curative actions. It is also more difficult to anticipate the pathways of invasion, the range of possible invaders or the geographic boundaries of potential impacts. Public attitudes to environmental risks are diverse, as well, so it is more difficult to agree even on the time scales that might be appropriate to consider.

Stakeholders determine the value of environmental risk and its prevention through complex valuation criteria. But who is a stakeholder? How can these criteria be agreed and measured? How do we value conservation in a dynamic ecological community? Risk

<sup>&</sup>lt;sup>1</sup> USDA Budget 1999 estimated.

http://www.usda.gov/agency/obpa/Budget-Summary/2000/text.html#mrp

<sup>&</sup>lt;sup>2</sup> Article 5.7 of the SPS Agreement.

acceptance, even when the degree of risk is agreed, is a normative process dependent on the attitudes, interests and circumstances of each individual. Quarantine agencies must try to take actions that reflect a reasonable representation of that acceptance in the public. However, attitudes may vary much more on environmental issues than they do for commodity regulation, in which the relatively narrow business interests of fairly homogenous stakeholders are better focused (Perkins 1989; Kazmierczak 1996). Many people feel, at one extreme, that they have an obligation to protect the environment. At the other extreme there are those who put the environment, especially the unseen, distant or future environment, well below the day-to-day priorities of the here and now and their own struggles for families, work and homes (Stonehouse and Mumford 1994). Creating a consensus on even the dimensions of evaluation for environmental quarantine will inevitably be difficult.

The attribution of roles within a quarantine program with environmental relevance is also more difficult than for commodities. The responsibility for initiation, prevention, management and cost recovery does not always fall on the same group. Institutional divisions, for example between ministries of environment or interior and agriculture, as in the USA and UK, make it more difficult to initiate action or to take management decisions. President Clinton's decision in 1999 to establish an integrated interdepartmental approach in the USA3, New Zealand's earlier establishment of a Biosecurity Council, and similar efforts in South Africa, are steps towards resolving issues of responsibility. However, there remains a problem of what the role of "non-responsible" stakeholders is. Should a group that is not prepared to pay for management of an invasive species have as much, or any, say in the way that management is conducted - if they are not prepared to be responsible should they even be considered stakeholders? Should groups who will suffer costs or lost opportunities because of quarantine, and that have no choice but to bear the burden as a result, have limits put on their personal losses, when they are not necessarily responsible for the risk? Indeed is quarantine a

<sup>&</sup>lt;sup>3</sup> http://www.aphis.usda.gov/ppd/ead/eo13112.html

democratic issue in which all citizens and organisations are automatically stakeholders?

#### **Environmental risk evaluation**

#### What has value in the environment?

There are four components of value in the natural environment: use, existence, bequest and moral values. Use (or at least the option of use) is the easiest to measure. Recreation and amenity can be valued by estimating costs of travel, user fees, purchase of equipment associated with outdoor pursuits, etc. Indirect benefits arise from a value people place on the knowledge that a natural environment (or component of it) exists, that they can pass on this existence to future generations (at least to grandchildren, the limit of many people's thoughts), or that they have fulfilled a moral obligation in providing stewardship. Indirect values require measures of contingent valuation to express willingness to pay, which are fraught with difficulties of estimation. Two critical issues of contingent valuation are the lack of public awareness of what is in the environment to value in the first place - many species are unseen, far away, etc and the problem of valuing non-responses. The first tends to undervalue the environment, and the latter, if non-responses are ignored, may overvalue it.

In commodity oriented quarantine decisions values are likely to be limited to, or at least dominated by, use. By contrast, non-use values (existence, bequest and moral) are likely to be the greater part of total environmental value. Of NZ\$46 billion/year (1994 values) value placed on indigenous biological diversity in New Zealand, only NZ\$9 billion/year is through direct environmental services to the national economy and the remainder is in indirect benefits (for example aesthetic and moral values) (New Zealand Ministry of Environment 1998). That report suggested it would be conservative to assume 5-10 per cent of the direct value would be at risk from all environmental change each year, but made no assumptions about losses to the much higher, but less tangible, indirect values.

The natural environment may face relatively low risks in terms of lost use value from introduced organisms. Many threats from exotic organisms are to individual species within an ecosystem, and this may not greatly affect recreation or amenity value, unless there is significant loss of a highly visible species or one particularly associated with certain cultural values. Furthermore, existence value is not lost in direct proportion to the area affected. Large areas could be lost completely, but as long as some is preserved much of the perceived existence value is maintained, though it may be more vulnerable to further loss in the future.

An alternative approach, considered by the EU in regard to environmental liability for a threat to the natural environment in protected areas (European Commission 2000), takes the cost of restoration to the original state or to an equivalent state as the starting point for a reasonable valuation of damage. However, the cost of restoration of an area does not have a direct relation to the actual lost value, which may be greater or less. This is particularly true in cases where only some parts of the environment are damaged, and so the existence and bequest value of the remaining areas continue, despite the loss of part of the area, or where use simply moves elsewhere.

# Where would the greatest impact in quarantine measures be?

Quarantine involves both preventative management of people, products and vessels entering the country, and subsequent mitigative management in the event of outbreaks. Risk to the natural environment could come from any form of entry, but seems more likely to come from diverse personal belongings, packaging materials and adventitious passage on ships and aircraft than from agricultural produce (which is more likely to harbour its own more specific pests). In terms of value the threat to forests and amenity trees appears to be greatest, due both to the relatively large area they occupy, and their high value in the case of amenity trees.

Of the US\$138 billion/year losses estimated by Pimentel *et al.* (1999) approximately US\$33 billion/year is more or less "environmental". Of these the greatest impact comes from the introduction of

carnivorous mammals, especially cats, followed by rats, molluscs and forest insects. The relative impact of future invasive species is likely to be much less for individual species, given the widespread presence of rats, cats and several molluscs already.

Various studies have indicated the extent of invasions into natural environments. Mooney and Drake (1989) reviewed several sets of data indicating very high levels of invasions amongst many major taxonomic groups, for example over half the 2000 flowering plant species in Hawaii are invaders. Wallner (1996) describes extensive invasions in forest communities in the United States. Smith *et al.* (1997) present a comprehensive list of over 250 designated quarantine insect and disease pests for Europe, many of which would attack natural environments.

#### Risk acceptability related to the environment

The standards for risk acceptability are different for the natural environment and for agriculture. Moral, bequest and existence values apply to the environment. Since these indirect values can be a substantial multiple of the direct value, the scale of risk may be greater in natural environments, but there is likely to be much less objective agreement on the level of that value. The natural environment is a universal property, so everyone is to some extent a stakeholder, but the degree of personal attachment is for the most part weaker than for commercial interests. There must be more reliance on public services to manage environmental risks than would be the case for commodities under private management, so the public has less opportunity to participate personally in decisions or subsequent actions. Finally, risk analysis involves a balance of benefits and losses, but there is little imperative to take a risk to improve or develop the environment, as there might be in agriculture, through the import of risky propagation materials, for example. As a result there is likely to be a more conservative approach to environmental risks.

# Demand for environmental risk evaluation in quarantine

Quarantine policy must be embodied in national legislation that complies with international obligations. This should reflect broad social values on the roles and rights of producers and importers, travellers, consumers, agriculture, fisheries and the natural environment. The quarantine process should be both effective in meeting the demands expressed and be economically efficient. Various approaches are taken, none of which are definitive. Some involve explicit economic evaluation of risks while others apply values implicitly, but "any decision implies evaluation" (Stonehouse and Mumford 1994). Explicit criteria are highly transparent, which is an important goal at both national and international levels. highlight However, explicit criteria may intrinsic differences on risk and values within and between nations.

#### National legislation

Economic criteria are not the only rationale established in law as a basis for quarantine. For example, the New Zealand Biosecurity Act 1993<sup>4</sup> provides several justifications for a Minister to notify a national pest management strategy to deal with an exotic pest organism: the Minister should be of the opinion that the benefits of action exceed the cost, it is better to act nationally than locally, and that there will be a "serious adverse and unintended effect" on either "economic wellbeing" or the "viability of species", "the survival and distribution of indigenous plants or animals, or the sustainability of natural and developed ecosystems, ecological processes, and biological diversity", soil or water quality, "human...enjoyment of the recreational value of the natural environment", and/or cultural values.

The US Council on Environmental Quality specifies environmental impact statements (EIS) in which cost/benefit analysis (CBA) may be a part of the process, along with qualitative environmental values, though no particular method is specified<sup>5</sup>.

<sup>&</sup>lt;sup>4</sup> Section 57

<sup>&</sup>lt;sup>5</sup> http://www.aphis.usda.gov/ppd/ead/g12

James and Anderson (1998) recommended that greater emphasis be placed on objective economic evaluation in Australian quarantine policy. Their concern is that quarantine actions are often a simplistic reaction to the relatively narrow interests of particular interest groups, either producers, consumers or environmental groups. Such decisions, particularly those resulting in exclusion of products, may not provide the most economically efficient outcome and do not reflect overall social values.

#### International agreements

The International Plant Protection Convention (IPPC) is working towards new guidelines that can operate in conjunction with the Convention on Biodiversity (CBD)<sup>6</sup> to reduce environmental risk from invasive organisms. These are not based on economic criteria but on an implied value in biodiversity. IPPC (2000) recognises "that under the IPPC's existing mandate, to take account of environmental concerns, further clarification should include consideration of the following five proposed points relating to potential environmental risks of plant pests:

- Reduction or elimination of endangered (or threatened) native plant species;
- Reduction or elimination of a keystone plant species (a species which plays a major role in the maintenance of an ecosystem);
- Reduction or elimination of a plant species which is a major component of a native ecosystem;
- Causing a change to plant biological diversity in such a way as to result in ecosystem destabilisation; and
- Resulting in control, eradication or management programs that would be needed if a quarantine pest were introduced, and impacts of such programs (e.g. pesticides or release of non-indigenous predators and parasites) on biological diversity."

<sup>6</sup> http://www.biodiv.org/

Within the CBD itself, economic factors are not specifically mentioned as part of the obligations for environmental assessments and where economic issues are mentioned they are in language that does not specify any particular methodology. The CBD has draft guiding principles for the prevention and mitigation of impacts of alien species (UNEP 2000). The first is precautionary, in which "Lack of scientific certainty about the environmental, social and economic risk posed by a potentially invasive alien species or by a potential pathway should not be used as a reason for not taking preventative action against the introduction of potentially invasive alien species."

The second states that prevention is cheaper than cure, and refers to later principles on how to respond when an outbreak has occurred: "The preferred response would be eradication at the earliest possible stage (Principle 13). In the event that eradication is not feasible or is not cost-effective, containment (Principle 14) and long-term control measures should be considered (Principle 15). Any examination of benefits and costs (both environmental and economical) should be done on a long-term basis."

The CBD guidelines do not consider issues of distribution of costs and benefits, nor of time preferences for benefits or time periods to be covered in analyses. While the relative values of prevention and cure *a priori* are proverbial, they certainly bear close examination once some actual probabilities are available in specific cases.

A new draft International Standard on Phytosanitary Measures (IPPC 1999) was under consideration until August 2000. The portions particularly relevant to economic considerations of environmental evaluation in pest risk assessments are:

# "2.3.2 Analysis of economic consequences

# 2.3.2.1 *Time and place factors*

... economic consequences are expressed with time, and may concern one year, several years or an indeterminate period. The total economic consequences over more than one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

... The rate of spread may be estimated to be slow or rapid; ... Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading ... factors ... could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations will be required.

Analysis of commercial consequences [only commercial considerations]

Analytical techniques [related to producers/consumers]

#### 2.3.2.4 Non-commercial and environmental consequences

Some of the direct and indirect effects of a pest cannot be measured, or are inadequately measured, in terms of prices in established product or service markets. Examples include in particular environmental effects (ecosystem stability, biodiversity, amenity value) and social effects (employment, tourism). These impacts could be approximated with an appropriate non-market valuation method.

If quantitative measurement of such consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

# 2.3.3 Conclusion of the assessment of economic consequences

Wherever appropriate, the output of the assessment of economic consequences described in this step should be in terms of a monetary value. The economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms. Sources of information, assumptions and methods of analysis should be clearly specified.

The part of the PRA [pest risk analysis] area where presence of the pest will result in ecologically important loss should be identified as appropriate. This is needed to define the endangered area."

#### The environmental risk prevention problem

Quarantine changes the probabilities of particular environmental values occurring. The quarantine decision could be expressed as choosing between "with" and "without quarantine" probability distributions of environmental value, in which the "with quarantine" values were net of the cost of quarantine (including foregone opportunities associated with trade loss, etc). Kehlenbeck (1996) proposes such a model and Orden *et al.* (in Chapter 11) demonstrate the implications in two important case studies.

It should be recognised that it may not be possible to keep a natural environment free of unwanted organisms forever. As a result it is more appropriate to use the annual value of the environment, as expressed by access value or some measure of willingness to pay for its presence or maintenance, rather than its full asset value in estimating the benefits of management. This value is only maintained while the environment retains its quality and society maintains its appreciation or use of it. The value in relation to invasion by unwanted organisms is, therefore, only the value over the years between now and the next occasion on which that or another unwanted organism changes the value again, or simply as far ahead as each individual's horizon of thought extends. Thus, the cumulative present value up to the point at which some change occurs may be the key evaluator.

Agricultural commodities have an easily expressed annual value, so the value of preventing a probability of proportional loss for a year can be set against the cost of that prevention through quarantine. The natural environment may well have an annual value in terms of use, but its existence, bequest or moral value depends on its continued existence, and for many people this could extend over generations in time. For example, the bequest value of guaranteeing the existence of a natural environment for only one year is likely to be nil, and would presumably rise steadily over several generations, and then level off once grandchildren (or possibly great-grandchildren) had been considered. These longer-term indirect values are likely to exceed the simple annual use values. However, the cost of prevention of invasion during a given year can not be

readily set against the first year as a fraction of the long term nonuse value, since without an assurance of continued long term protection people may not perceive any long-term non-use value.

Unlike the case of quarantine for commodity protection, for environmental protection it may not be possible to look at comparisons of simple annual costs of prevention set against the benefit of that year's protection. An environmental quarantine protection program may need to be assessed as a long term (with inevitable political prevention measure uncertainties associated with the commitment to continue it) against a long term benefit that only has perceived value through maintaining its long term existence. An important issue in this case would therefore be how long existence of a natural environment or process must be maintained to give the public a sense of value, and how one expresses the uncertainty of continuing protection.

# Comparison with commodity oriented quarantine

Because of the huge number of potential quarantine risks each country faces it is appropriate to focus on either "key pests" or "key pathways" to make quarantine manageable (Orr *et al.* 1993). But will the "key pest" or "key pathway" approach work when protecting environmental value? Is there a "key value" in the environment to protect? In agriculture much of the risk is from pathways that can be self interested and self regulating to some degree (nursery stock, etc); whereas the natural environment is more at risk from adventitious hitchhikers and pests in packaging. As a result, it is more difficult to conduct pest risk analysis (PRA), and there is little option for self inspection and regulation, or a cooperative approach.

Pests of the natural environment are likely to attack or compete with common and widespread species, simply on the basis of probability of encounter. They are less likely to focus on rare species, although the impact on vulnerable rare species could be greater if they are attacked. There is a natural conflict between valuing rarity and diversity, whereas key impacts will focus on dominant and simple species.

The problem-solution paradigm of quarantine related to invasion of natural environments contains an inbuilt paradox. It is a complex problem, but must be managed through the specific solutions available to the quarantine system: Pest risk analyses on individual organisms, disinfestation or inspection of individual aircraft or passengers, etc.

Quarantine actions fall into several categories: prevention, through inspection and restriction of imports; surveillance for outbreaks or introductions; eradication or suppression following detection of outbreaks. The economic issues for environmental risks for each of these categories should be considered separately.

#### Prevention

The prohibition or special treatment of high-risk material is problematic for environmental risks since it is not always clear where the high risks are likely to arise, although wood and equipment that has been stored or used outdoors prior to shipment (for example, used cars) are particular problems. The value of controlling such imports can best be based on extrapolation from reported introductions elsewhere, for example instances of Asian gypsy moth arriving on used cars add to a probabilistic loss of broadleaf trees (Mumford 1999).

# Inspection

Inspection at entry ports is a broad risk reducing action that can be financed by user fees on passengers and shippers. This is a fair system and the role of reducing environmental risk can be an additional justification beyond that for commodity pests. There is clearly wide public acceptance of such inspection and it is a good example of a precautionary approach with very widely distributed and modest individual cost, which treats each source of risk equally.

Inspection beyond entry points, in the natural environment, is very difficult because of its scale, diversity and the lack of information about many native species. New organisms may spread in low numbers over many years and suddenly flare up in suitable climatic

conditions. Even for major agricultural pests there is considerable controversy over appropriate sampling methods to detect new introductions and ongoing infestations (eg Carey 1992).

#### Eradication and suppression

The control of invasive organisms in natural environments depends on the technical feasibility of management, the relative costs and benefits and their distribution and the organisational capacity to undertake control. Myers *et al.* (1998) reviewed the principles for the successful eradication of introduced insect species and some of the relevant economic issues. The potential for reinvasion/reintroduction is a significant factor that could make eradication uneconomic.

#### Evaluation framework relevant to environmental risk

A consistent analytical framework for plant health decision making is essential. Cost/benefit analysis (CBA) provides such a framework, classically by projecting a stream of predicted costs and benefits for management options, expressed in monetary terms, and setting present values on these streams. Further detailed analysis may consider the distribution of benefits in time and space, risk attitudes can be incorporated, and non-monetised elements can be incorporated either qualitatively or quantitatively. The aim is to provide a transparent and objective framework in which management options can be compared on common economic criteria, generally present monetary value.

CBA, as a principle, has been widely adopted as a guide for plant health decisions. It is a component of the risk management stage of pest risk analysis recommended by the IPPC (1996). Its use was recommended in the recent US plant resources safeguarding review (US National Plant Board 1999). In Australia it has been used and recommended, specifically (Hinchy and Fisher 1991) and as part of the risk management process (Nairn *et al.* 1996; Nunn 1997; James and Anderson 1998). The New Zealand *Biosecurity Act* 1993 specifies what is in effect a CBA to advise on quarantine decisions. It is also recommended as an approach to decisions on biodiversity damage

in the EC White Paper on Environmental Liability (European Commission 2000).

Several alternatives to CBA could also be used, but CBA is a fairly broad concept and other analyses are very similar in intention. Nairn et al. (1996) and Nunn (1997) discuss more subjective analyses that may be appropriate where scientific data is limited, for example "scenario trees" and semi-quantitative assessment. Cook (2000) used a method of break-even analysis, in a sense that inverts CBA, calculating the level of loss that would be needed for a CBA to show no net benefit and then considering the probability of that level being exceeded. The European Commission (2000) notes the cost and difficulty of conducting CBAs using contingent valuation and revealed preference techniques. It suggests the use of benefit transfer techniques (crudely, reference to costs, losses or benefits from a database of similar cases elsewhere, with modifications as appropriate where they can be justified) as a practical alternative. The EC Environmental Liability White Paper also suggests a "reasonableness test" as an alternative to CBA, which amounts to a subjective consensus that a management approach will be reasonable, given the information available at the time. This is proposed both as a cheaper alternative to a full CBA and in cases where there is inadequate quantified data. This may be particularly appropriate where rapid decisions are required before an outbreak spreads to an unmanageable size.

#### Quantitative valuation

The methodology applied by Pimentel (2000) to estimate losses to US agriculture and the environment is not fully explained, but is presumably based on extrapolation of individual consensus estimates of losses from particular types of invasive organisms on various crops and environments. The OTA study (US Office of Technology Assessment 1993) applied more specific consensus estimates but for only a selected list of pest species.

There is almost inevitably a lack of fully quantified data on the losses to expect from introduced pests that affect natural environments. Various contingent valuation techniques have been

used to determine the public willingness to pay for controlling such pests, for instance the gypsy moth in the northeastern USA (Jakus and Smith 1991; Miller and Lindsay 1993; Moeller *et al.* 1977). This is a particularly suitable pest for this method, since it is well recognised by the public and attacks amenity trees as well as forests.

The negative values associated with pest control programs need to be included in analyses. Mumford *et al.* (1996) modified a method used in the USA by Pimentel *et al.* (1993) to quantify the environmental effects of pesticides applied against cotton pests in Egypt. In both cases this involved applying a per unit environmental cost (made up of a predominant human health cost, with some additional impacts on bees and other wildlife) for each dollar of pesticide applied. In the US an environmental cost of \$19/kg active ingredient (ai) was estimated. In Egypt the figure used was \$5/kg active ingredient, based on lower GDP and costs in Egypt, but assuming more social and environmental contact because of the close proximity of agriculture to human and other populations and water.

# Time frame, discount rates

Time frames and discount rates are key elements of the valuation of quarantine risks. The longer the timeframe and the lower the discount rate the higher will be the apparent benefits of any risk prevention activity. Realistic figures must be agreed, which is likely to be more difficult for a multidimensional environmental valuation with diverse stakeholder interests than it will be for commodity protection. In commodity oriented quarantine/eradication studies relatively short time frames and high (commercial) discount rates have been used (Mumford 2000; Mumford *et al.* 2000). The short timescale reflects the relatively high likelihood of reinvasion and the fickleness of commitments to maintain quarantine efforts, even after major eradication efforts, such as Medfly in the USA (Mumford *et al.* 1995). A high discount rate (for example 8-15 per cent in the Middle East (Mumford and Knight 1996; Enkerlin and Mumford 1997), 6 per cent in the UK (Mumford *et al.* 2000) and 4 per cent for US decisions

on forest management<sup>7</sup>) reflects opportunity costs for what is, in effect, a commercial decision, even in the case of a public good. These same considerations could apply to the use element of environmental value, and would also apply to the future costs of quarantine or eradication efforts. With higher discount rates the timescale of benefits is less significant in determining present values since values beyond 15-20 years will be so heavily discounted that they will not add significantly to the total present value.

As discussed earlier, the time frame for environmental protection must be long to reflect existence, bequest and moral value. This is especially important since these values may represent much the greater part of the overall value. It has been suggested earlier that these values increase, up to a point, with time, probably with very little value for the first few years of protection. This poses a problem in relation to discounting. A commercial discount rate would render long term values negligible, and over-value short term benefits. A purely social discount rate of zero would give very high values for long term protection horizons, and would certainly over-value environmental protection compared to what people are likely to be prepared to pay in reality.

Two approaches could be used to create a more realistic value. One is to use a variable discount rate that falls with time, say up to the third generation. Another is to account for the increasing probability that protection will fail to be maintained successfully (due to variable political commitment, or simply bad luck), by applying a compounding "failure rate" [eg Future Value = Potential Value \* (1-Failure Rate)^Year]. There may be a threshold of probability below which people no longer accept that their bequest or moral obligation has been fulfilled, however. So, for example, once (1-Failure Rate)^Year was 50 per cent or less the future value may be deemed to be zero.

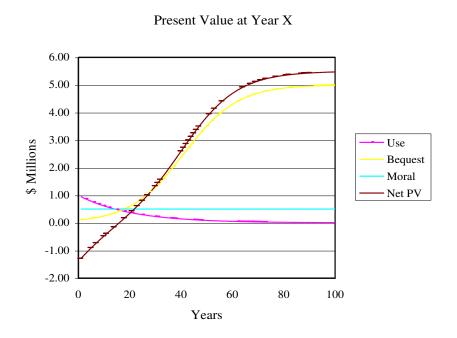
Moral obligation as an element of environmental value – the feeling that you have done something you really ought to have done – could be assumed to have a zero discount rate, a social value that

<sup>&</sup>lt;sup>7</sup> http://www.fs.fed.us/im/directives/fsh/1909.17/1909.17,10.txt

does not decline or increase with time. Experience suggests that the purely moral value put on environmental protection is relatively low compared to bequest or existence values; people see value accruing to themselves through existence or to their families as bequests.

Figure 18.1 illustrates an example of a 100-year time series of present values for three elements of environmental value (Use, potential value \$1 million/year, discount 5 per cent; Moral, potential value \$5 million/year, discount 0 per cent; Bequest, potential value \$5 million/year, discount declining from about 5000 per cent to 0 per cent over 100 years8; Cost; constant \$3 million/year). In this example there is an assumption that commitment to maintain quarantine effort would continue through to at least the years for which the cumulative values are shown.

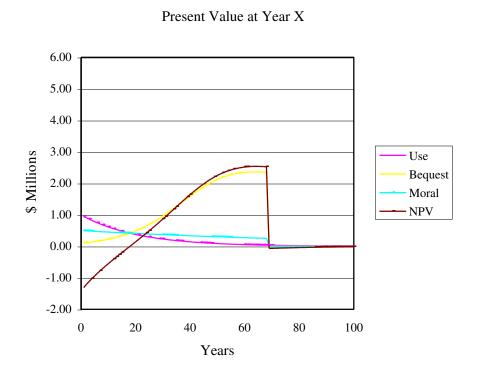
Figure 18.1: Environmental valuation over 100 years



 $<sup>^8</sup>$  In this example a dynamic discount rate is used for bequest values, in which the rate for each year  $D_{(t)}$  equals (A/(1+B)t), in which A and B are arbitrary variables equal to 0.1 and 50, respectively.

Figure 18.2 illustrates the same example, but with anticipated failure rate of 1 per cent per year (so all values are reduced to an expected value of Potential Value \* (1-Failure Rate)^Year) and assuming zero bequest and moral value once the cumulative failure rate exceeds 50 per cent (from year 69), while use value continues.

Figure 18.2: Environmental valuation over 100 years with some policy failure



#### Non-market values, alternative dimensions for value

Many environmental values, particularly associated with forests, involve either non-market values or indirect market values. Rosenberger and Smith (1997) reviewed the literature on non-market impacts of forest insect pests in the USA and methods used for measuring these: travel cost methods, hedonic pricing and contingent valuation. Values included recreational use, aesthetic attraction (sometimes revealed in tourism potential) and property prices. Travel cost methods measure the amount people spend to enjoy an environment, including costs of travel, special equipment,

time off work, etc. This tends to undervalue the resource, as some people live close by, and others may not visit because they could not meet the full cost of travel. Hedonic pricing relates impacts to their effects on prices of related marketable products, like house prices or hotel rates, and relies on a market existing and the ability to attribute changes in prices within that market to particular events. Contingent valuation is based on surveys of people who are questioned on their behaviour by accepting or rejecting values associated with an activity or resource, but it may also undervalue, particularly through fear that high charges may be imposed if respondents agree they would accept them. Despite concerns often expressed about any of these methods, they give reasonable quantitative guides to non-market values, which must in any event be coupled with similarly uncertain estimates of ecological impacts before quarantine decisions can be made. Because the effect on property prices is so tangible it can often outweigh all other values, as Clough (1997) found, estimating the potential impact of tussock moth in New Zealand (impacts on property values through defoliation of amenity trees in Auckland suburbs exceeded other national impacts).

# Institutional feasibility

In some cases the capacity for a quarantine agency to act effectively to prevent invasion may be inadequate to make quarantine technically feasible. For instance, in countries with extensive land borders where control of movement is difficult to enforce, it would be a moot issue to consider the economic benefits of partial quarantine. Many countries in Asia and Latin America cannot put quarantine inspections near to borders for fear of violence to inspectors. In other cases, even for island states, the number of entry points and the volume of trade and visitors would require excessive numbers of inspectors. The UK, for example, relies heavily on a system of inspection at points of delivery for predetermined high-risk products, in cooperation with the importers, and has only 90 inspectors as a result. Such systems make prevention of environmental risk from invasion very difficult.

Can an institution respond in the event that an outbreak occurs? If not, it is not an economic decision. The Ministry of Agriculture in Mauritius was faced with the decision of eradicating Oriental fruit fly in 1996, only because it already had a national campaign for suppression of several other similar species of fruit flies, making eradication a practical possibility<sup>9</sup>.

# Approaches to responsibility for environmental risk

#### Precautionary approach

A precautionary approach to quarantine would not be applicable if it interfered with trade and movement. However, it is widely argued that the irremediable nature of many introductions of exotic species, and the catastrophic nature of some, warrants this response (the Convention on Biodiversity "enshrines the precautionary approach as a principle of international environmental law"10). In any event, quarantine must represent a balance of risk and potential benefit from movement and introductions of foreign materials – which on the whole are positive to human welfare.

# Strict and unlimited liability

While strict liability has the appeal of imposing all the costs associated with prevention and mitigation of environmental loss onto the perpetrators, the polluter pays principle, the same shortcomings arise that plague all attempts to impose strict and unlimited liability. The scale of damages is often too great for any individual or even an industry to cover. Large commodity eradication programs such as Medfly in California can cost over US\$100 million. Damage may be too large for compensation to be covered where eradication may not be technically feasible, for instance the total annual value of the US forest related industries that could be damaged by Asian long-horned beetle is around US\$138 billion/year<sup>11</sup>. It is also difficult to prove liability for specific

<sup>&</sup>lt;sup>9</sup> Eradication was successfully achieved in this case.

 $<sup>^{10}\</sup> http://www.biodiv.org/biosafe/Protocol/Index.html$ 

<sup>11</sup> http://www.ars.usda.gov/is/np/mba/apr00/asian.htm

introductions. For example, while the entry path for Asian longhorn beetle into the USA through shipping pallets and wooden packing crates is well established it is not possible to trace the infestation to a particular shipment, or to attribute proportions of loss to outbreaks resulting from multiple introductions. When beetles are intercepted it would be difficult to charge a pro rata share of costs on the basis of detection incidence. There may be, for instance, potential bias in sampling – some entry paths may be particularly easy to detect (and so charge). However, they may also be easier to intercept and stop, and in any event may be less important than other less detectable pathways.

#### Shared liability

The US Safeguarding Review (US National Plant Board 1999) and Perrings (2000) propose systems in which funds are set up by government against which eradication costs could be drawn. These would be subject to suitable scientific expectations of effective control, economic justification and lack of other appropriate sources of funds (such as fines on those responsible for introduction or levies on expected beneficiaries). Participants in the risk would contribute to the bonds, and government may also share some of the risk. Such funds would be particularly useful for eradication programs aimed at restoring natural environments. There is a general lack of chargeable beneficiaries and it is difficult in most cases to recover sufficient funds from importers, either because it is impossible to prove responsibility or due to inadequate resources on the part of individual importers. An argument for shared liability with government as a contributor to the fund is that quarantine agencies may have failed to prevent an introduction, and that government represents beneficiaries, who should take some responsibility. A counter argument against such schemes, however, could be that they offer insurance without penalties for moral hazard, that is, risky behaviour by individuals or organisations.

# Budget limited approach

In many cases legislation, or appropriation, regardless of the needs that arise in a particular year predetermines the absolute national expenditure on plant health. So this is in effect the social value of plant health to the nation, as determined by the legislators. Priorities must be established up to the overall limit approved. While this may be a reasonable approach for directing routine preventative quarantine efforts it is less suitable for curative operations that follow introductions. Given the unpredictable arrival of invasive species, important and otherwise controllable outbreaks late in a financial year could, for instance, go unchecked if all funds had been allocated in earlier months. Underspending against an allocation for control of outbreaks, as a result of success at prevention or good luck in a particular year, could lead to diminished funding in following years, despite no real change in risk

# Cost recovery principles

Cost recovery is an increasingly important feature of quarantine services around the world, and is certainly a significant issue for Australian (Nairn *et al.* 1996) and US (US National Plant Board 1999) quarantine. While there appears to be general agreement and acceptance of inspection and certification charges, there is no consensus on charges for other aspects of plant health. In the UK recently there has been concern over the legal basis for charging for unsolicited inspections of premises receiving imported plant material, which resulted in the charging being dropped temporarily. Costs of surveillance outside of entry points is generally borne by government, but costs associated with subsequent eradication or control efforts may be met either by individual property owners who are required, for example, to destroy crops or by government, who may undertake area-wide control efforts (Mumford *et al.* 2000). The general principles are discussed below.

# Polluter pays

Fairness implies that those who cause a problem should pay for it and much of the law on pollution control is predicated on this principle. Invasive species are sometimes described as 'biological pollutants' (for example, Wallner 1996), and as such it is suggested they be regulated similarly. However, polluter-pays regulation works most appropriately where the sources are readily identifiable

and the polluters are large enough entities to be able to afford to pay (for example, utility companies) or the pollution caused is modest per polluter (for example, engine exhaust). In the case of biological invaders, the source may not always be clear (in which case clear-cut introductions may be disadvantageously treated, while others are left to government) and the potential losses and mitigation costs are often large compared to the ability of individual importers to pay. Groups of importers/shippers could be required to take out insurance in aggregate to overcome the problem of not being able to attribute the source of invasions to any one individual (as proposed by Perrings 2000). However, this could reduce the incentive for responsibility for each subscriber, unless premiums were based on some proven risk contribution, or encourage smuggling to avoid payment.

#### Stakeholder pays

If the polluter cannot be found or made to pay, the fairest alternative is for beneficiaries of prevention or mitigation, the stakeholders, to pay. This is attractive where stakeholders are readily identifiable and organised in a way that allows levies to be imposed, for example relatively centralised agricultural industries. In principle, stakeholders will suffer most, through private costs or lost options as a result of unwanted organisms, and if it is more efficient for them to respond collectively this should be facilitated. However, for environmental protection, it is unlikely that suitable stakeholders could be identified or that they would be willing or able to pay the substantial costs of quarantine. Where stakeholders pay they should have representation in making decisions on how prevention and mitigation should be undertaken.

Two issues will arise with any stakeholder payment system. The first is the way a levy is raised – in effect a measure of the degree of stake held by each individual. (What is an appropriate measure to predict individual benefits from a range of uncertain introductions?) The second is the extent to which a corporate response reduces each individual's incentive to limit risk to themselves (for example, some parents do not risk vaccinating their own children once the general

level of vaccination rises to a high level). Both these problems must be dealt with by agreement of the stakeholders themselves.

#### Citizen pays

The last resort is for the citizen to pay, either through government action, private control efforts or lost amenity or opportunity? Quarantine is often described as a 'public good' (Nairn et al. 1996; US National Plant Board 1999) and as such the question eventually comes down to the relative efficiency of government funded quarantine activities. Even if polluters or stakeholders can be found who can/should pay are the transaction costs low enough to make it worthwhile collecting? Even for many agricultural quarantine situations this may not be the case, for damage to the environment it would certainly not be. However, the penalties for purposeful or accidental introductions of unwanted organisms should be set at levels that genuinely deter those responsible to protect the public from unnecessary expenditure. Adequate information, both for professional shippers and private travellers, would need to be provided to reduce the chances of people being victims of ignorance. Furthermore, the public should have some representation in the decisions on how prevention and mitigation are carried out, to ensure efficient and effective actions. This may be difficult, since knowledge of the technical aspects of the subject is generally limited to its practitioners. There may be a case for more international reviews of the efficiency and effectiveness of national responses to biological invasions

# Implications of change

A number of external factors will continue to drive the needs and opportunities for environmental aspects of plant health in the near future, both technical and institutional.

Technological change is likely to have a significant impact on prediction, evaluation and attribution capabilities. For example, low cost detection systems to identify any living material in sealed shipments and genetic identification of invasive organisms will contribute to tracing pathways and attributing responsibility for

introductions. Improved spatial modelling of spread related to climate, host and niche availability will allow much more accurate estimates of potential ecological impacts. There are also continuing improvements in environmental valuation techniques and the establishment of wider databases of reference values (for instance, the US Invasive Species Council's efforts to establish an information-sharing system on economic impacts). Together, these will allow much better prediction of economic consequences of introductions, which could alter the opportunities for cost recovery.

Institutional changes will also affect the impact of quarantine. Continual efforts to improve cost recovery may push quarantine services to focus on cases where responsibility can be attributed clearly to major importers or constituency groups who can afford to pay. This may mean greater attention to commodity based quarantine, at the expense of the natural environment. Some classes of environmental pests may also be more likely than others to be addressed - for instance timber pests from packing materials where shippers can be held responsible, rather than the types of organisms brought in by individual travellers. The greater vertical integration of supply chains and resulting traceability of produce through the food chain will make the analysis and management of risk pathways more direct and the clear responsibility for the operation of the regulation and cost make pathway will recovery more straightforward.

Accounting changes could open new opportunities for financing environmental quarantine operations. Companies are increasingly required to make environmental reports within their annual reports to shareholders and regulators, indicating the extent of the environmental liabilities they have and the financial provisions that have been set up to account for those liabilities<sup>12</sup>. The level of provision is open to scrutiny by regulators and tax authorities. Given the strict liability for environmental damage imposed in many jurisdictions, transport companies, importers, and exporters

<sup>&</sup>lt;sup>12</sup> For example, in the United Kingdom, Financial Reporting Standard 12. See for example: http://www.inlandrevenue.gov.uk/bulletins/tb40.htm or http://www.188e.com/kjsj/interacct/frs12.htm

may need to state any potential environmental risks to which they contribute (such as invasive organisms) and to make provisions, such as insurance or asset set-aside, to compensate for these sufficiently.

Some changes may have adverse effects, for example putting cost recovery and/or explicit cost benefit analysis into legislation can act against environmental risk protection. Such legislation in effect looks for a "constituency" for any problem, which in the case of invasions in natural environments may not readily exist. Even where an environmental constituency does exist it may be in competition with commodity oriented quarantine programs that can draw on more focussed resources and outcompete on estimated value of loss. Environmental quarantine may not reflect the true value society places on it because of the difficulty of mobilising the expression of that value.

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## PART V

# Conclusion

# 19

## Summing up

DAVID ROBERTSON

Acceptance of the SPS Agreement is increasing as its provisions and their implementation become familiar. In the three SPS cases so far taken to dispute settlement, however, little attention has been given to economic considerations, which allowed a legalistic approach to dominate proceedings. The debate on 'The Economics of Quarantine' is about reducing the imbalance between drawing on physical sciences, yet ignoring economic science in the application of the SPS Agreement.

The SPS Agreement mandates a scientific assessment of potential risks to human, animal and plant life or health associated with imported commodities. Public perceptions of these risks are often at variance with scientific assessments, which cause political tensions and complicate decisions about the 'appropriate level of protection' (ALOP). It is argued in the preceding chapters that risk assessments should include economic analysis and the trade effects of quarantine regulations (e.g., Chapter 3, by Nunn).

## The case for cost/benefit analysis (CBA)

By taking account of both benefits and costs, economists uses CBA to provide consistent assessments and to rank policy alternatives. The SPS Agreement in its present form is selective, neglecting consumer interests and other benefits from de-restricting trade, while focusing on the risks and costs from relaxing quarantine

protection. (The word 'benefits' does not appear anywhere in the SPS Agreement.)

The CBA approach to policy choice in SPS cases would probably not be welcomed by governments because it would cause political tensions with protected domestic producers. In Australia, for example, the Senate report on quarantine for salmon scarcely mentioned consumers or other producers affected by the 1999 changes (tuna and lobster aquacultures). Yet the authority of science in quarantine decisions need not be weakened by including economic considerations. Although only producers receiving quarantine protection appear to be consulted as 'stakeholders', SPS Article 4.6 does require that SPS measures should be 'not more trade-restrictive than required'. This suggests CBA could be applied to establish economy-wide interests, while still basing decisions on scientific evidence.

General equilibrium is the best approach to trade policy because it includes 'second round' and later effects of any changes. Several papers presented used partial analysis to good effect (Chapters 8 and 11, by Bigsby and Orden *et al.*), while others (Chapters 15 and 16 by Otsuki *et al.* and Anderson and Nielsen) adopted general equilibrium approaches. These studies contained excellent empirical work, which should be valuable in persuading governments to adopt a rational economic approach to quarantine regulation.

The costs of a pest or disease outbreak need not destroy a domestic industry. The costs of eradicating or isolating an outbreak are not always high, which should allow some SPS measures to be relaxed (Chapters 11 and 14 by Orden *et al.* and Forsythe *et al.*). Hence, quarantine effectiveness is not necessarily zero-sum.

An economy-wide approach should be promoted to overcome the narrow sectoral views familiar in the conventional trade protection debates. On the one hand, import-competing industries want quarantine protection because it provides valuable 'rents' and separation of rents from risk protection is difficult. On the other hand, export industries (two-thirds of Australia's agricultural output is exported) demand access to overseas markets, yet they do

not appear to make any connection with their country's own restrictive quarantine regime.<sup>1</sup>

Just as a tariff is a tax on exports (Clements and Sjaastad 1983), so quarantine restrictions that protect against diseases and pests raise domestic costs and reduce some exporters' competitiveness. As pointed out long ago by Haberler (1936), "The economic conflict over trade is between groups having different interests within each country."

Most governments follow cautious SPS policies, as described in Corden's 'conservative social welfare function', which suggests that any significant absolute reductions in real incomes of any significant section/group should be avoided (Corden 1974). This attaches low weights to income increases, high weights to income losses and makes income maintenance a policy target. By avoiding income redistribution, especially income 'losses', this policy downgrades growth and change. It is a risk-adverse strategy, which fairly describes political attitudes to quarantine by most governments, including Australia's, and by much of the public. This risk-averse strategy flows into the ALOP.

Two policy alternatives in many of the above chapters are either:

- adopt policy change if some are made better off, none worse off (conservative social welfare function); or
- ensure that the gainers pay compensation to losers, which is less precise but makes change possible.

The outcome will depend on the government's confidence in being able to persuade the community to accept change and economic adjustment.

<sup>&</sup>lt;sup>1</sup> Note the recent bilateral dispute where Australian quarantine restrictions on imported fruits effectively prevented access for Philippine fruits, which led the Philippine Government to impose quotas on their imports of Australian beef and live cattle.

## Is CBA consistent with SPS?

The central role of the SPS Agreement is to police foreign quarantine restrictions that unnecessarily restrict market access (i.e. provide protection). It requires consistent rules for risk assessment audits and risk management, but leaves the rules to be determined by national authorities. The SPS Agreement focuses on the cost of quarantine to foreign competitors and the potential losses to the protected industry from relaxation of SPS measures. There is no consideration of benefits to consumers or user industries.

In the WTO's dispute settlement cases involving the SPS Agreement, little attention has been given to economic questions by panels or the Appellate Body. Apparently economics is diminishing in the WTO, yet recognition that risk assessment and risk management are key considerations should raise the profile of economics in assessing the implementation of SPS measures.

Does the SPS Agreement allow for CBA? Economic factors are mentioned only three times in the SPS Agreement:

- Article 5.3. refers to 'relevant economic factors' but limits it to potential damage, that is, to production (sales) losses and to cost of eradication, while there is no mention of 'benefits';
- Articles 5.4 and 5.5. refer to 'minimising trade restrictive effects', that is, non-tariff import barriers should not be 'arbitrary or unjustified' as in GATT Article XX); and
- Article 5.6. states that 'measures are not more trade-restrictive than required', in addition, Annex A refers in paragraph 4 to 'economic consequences', but only in terms of assessing risk.

How committed are governments to the SPS Agreement? Opposition to changing quarantine measures is highly concentrated and vocal, and focuses on easily demonstrated 'costs' (usually couched in terms of the industry being destroyed!). Politicians are vulnerable to such lobbying, especially when prominent civil groups are implacably opposed to change. Nationalism carries more weight than CBA or other rational analysis.

Was the SPS Agreement included in the Uruguay Round just to prevent technical quarantine standards from replacing tariffs? Or was it included for the more pro-active purposes of reducing trade restrictions? CBA would be less welcome if the former, than if the latter.

## Should the SPS Agreement be modified to include CBA?

There is much official opposition to re-negotiating the SPS Agreement, although the European Commission and sympathetic NGOs would like to open up re-negotiation. The latter have three goals in mind:

- to introduce the precautionary principle (the EU version is included in the Cartagena Protocol), animal rights (included in the present WTO agricultural negotiations), and food safety standards;
- to strengthen environmental rules and to tighten global standards enforced with trade sanctions; and
- to clarify risk assessment processes and establish risk communication guidelines.

One course of action could be to seek more precise international standards (harmonisation according to SPS Article 2, using Codex, IPPC, etc). This brings 'one size fits all' problems where differences are crucial. (in climate, income/capita, social values, and so on). Moreover, there is a stock of existing quarantine regulations to be reviewed, and attempting to harmonise these would be a huge undertaking, and one that would have to be done by the international standards organisations, not the WTO.

Another suggestion, by Donna Roberts (see Chapter 2 above) is a 'WTO plus' approach. This could establish a new framework among a limited 'like-minded' group without changing the SPS Agreement. The US quarantine approach is science/cost based which appeals to many countries, and such a cluster could work to harmonise these countries' quarantine standards. By contrast, the EU adopts a sociopolitical, regulatory approach, in collaboration with European-based

NGOs. Bringing these disparate approaches together would be difficult, as recent SPS dispute cases have shown (e.g., the US-EU beef hormones case).

## ALOP - CBA interface

However presented, the 'appropriate level of protection' is a vague term. So far, SPS experience is limited to only a few cases. Many quarantine regulations are untested against ALOPs (see Chapter 7 by Gascoine). For human, plant and animal health, individual ALOPs may be defined, but for individual commodities this appears impossible (SPS Article 5.5).

The 'appropriate level of protection' is defined in the SPS Agreement as "The level of protection deemed appropriate by the (WTO) Member establishing a sanitary or phytosanitory measure to protect human, animal or plant life or health within its territory." This is deemed to be a matter of national sovereignty, but it should avoid "arbitrary or unjustifiable distinctions...if they result in discrimination as disguised restrictions on trade."

The ALOP (otherwise known as the acceptable level of risk) is central to any dispute about SPS measures. In practice, the ALOP is a subjective measure based on lobbying, public opinion, scientific evidence (as far as there is any) and nationalism, and is determined by an interaction between politicians and officials required to form a judgement. It is stated in broad terms because it has to be so comprehensive. In Australia, it is described as "high and very conservative, aimed at reducing risk to very low levels, but not zero risk" (see Chapter 5 by Goh and Ziegler).

In practice, no WTO Member has articulated its ALOP with precision because, unless it is set at zero, domestic industries facing any quarantine risks will complain. In this context CBA would seem to have a positive contribution to make to ALOP, by giving substance to an economy-wide approach. Each government is free to choose any approach and take account of any factors it considers relevant, as long as they are used consistently.

The above chapters express concern about the present framework for assessing an ALOP and the ambiguities in SPS Agreement. The differences between advocates of the present risk-formed approach and the more comprehensive CBA approach to policy decisions suggested a general model could be developed to explain the differences. This was written up for this volume by Snape and Orden (see Chapter 10 above). That chapter explains how the SPS Agreement is an exception to the GATT general rules, which are designed to facilitate reductions in trade barriers, because, unless there are scientific grounds for quarantine policies, they may not be used to restrict trade. The ALOP sets the acceptable level of risk and applies restrictions with discrimination by product or country. If the SPS Agreement required countries to adopt best-practice policies, all citizens would benefit and not just producers enjoying quarantine protection. But this would be a huge leap for political economy.

## **Developing countries**

The SPS Agreement's processes are too costly and too resource intensive for many developing countries. Non-OECD countries wish to include the SPS Agreement in the WTO's on-going agricultural negotiations, and to seek both special and differential treatment and technical assistance. The fascinating chapter on alfatoxins (Chapter 15 by Otsuki *et al.*) reveals how a small change in SPS measures can be used to severely restrict access to OECD markets for developing countries' exports. This is clear example of how OECD countries' rhetoric about helping developing countries falls short in practice. Financial assistance for dispute cases has failed to materialise too; and scientific SPS evidence is often expensive for developing countries to access.

## New technology and SPS measures

Technological advances alter the needs for SPS measures over time. There is a tendency to ignore the effects of new technologies. Similarly, steady-state assumptions for CBA are inappropriate. New technology can be the answer to many problems, including resistance to diseases and pests, advanced warning systems, etc.

Producers benefit from early warning systems and resistant varieties. Consumer attitudes do not adjust quickly, but benefits accrue anyway.

Can the SPS Agreement keep up with changing technology? How should disputes take account of new technology? There are new pathogens as well as new cures. Many health and food safety problems of today were not even known a few years ago.

## Conclusion

If the goal of the SPS Agreement is to prevent abuse of quarantine measure as replacement for other import barriers then harmonisation of standards would help. However, the restrictive wording of the SPS Articles and the lack of a consistent analytical framework raises concerns. Yet opening the SPS provisions to wider use, for example for environmental reasons, or for food safety, is actively sought by consumer and environmental lobbies.

Could introducing CBA strengthen the role of the SPS Agreement? The answer is probably yes, because CBA can clarify differences between policy options and rank alternative outcomes. However, it is doubtful that CBA will be adopted because of the revisions that would need to be made to SPS Articles, not to mention the political problems it would cause governments domestically. Moreover, there does not seem to be much meeting of minds among lawyers, scientists and economists.

A major constraint to reform of national quarantine regulations remains gaining community acceptance of risk analysis associated with a change. Public perceptions of risk attach higher risks to 'dreaded' outcomes and catastrophes than can be demonstrated statistically, and anecdotes tend to carry greater weight than scientific evidence. Overcoming such prejudices must be a first step in convincing the community that economic benefits can occur from using science-based quarantine measures that are no more restrictive than necessary.

To conclude, several areas for further research flow from the above chapters. They include the following:

- Valuable empirical chapters on ALOP and CBA have helped to clarify some issues, but more empirical evidence to establish the values of the CBA approach are needed to illustrate ways to make the SPS Agreement more effective. A vital step to offest the efforts of advocates for more regulation seekers is to expose the costs of excessive regulations. Investigating specific cases where data are available would help with this.
- According to the SPS Agreement, producers are regarded as bearing the costs of quarantine relaxation. In practice, of course, this is offset by gains to consumers and other users of the protected product. Empirical research to assess the gains from SPS reforms is needed to convince governments that relaxing quarantine measures brings economic benefits worth having, despite possible costs to some producers and the environment.
- What are the 'costs' of a conservative ALOP? Only when CBA is applied to the concept of ALOP will it be possible to assess this unique phenomenon.
- As trade in animals, plants and crops expands, quarantine authorities are collaborating to establish acceptable standards for those imports which minimise administrative delays. How could this experience be applied to ALOP?
- The primary requirement seems to be further analysis of the relationships between SPS procedures and CBA. The chapter by Snape and Orden is a welcome first step.

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## **APPENDIX**

The legal text of the SPS Agreement

Source: WTO (1995) *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts*, Geneva: WTO Secretariat

# AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

*Desiring* to improve the human health, animal health and phytosanitary situation in all Members;

*Noting* that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

*Recognizing* the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

*Desiring* therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)<sup>1</sup>;

<sup>&</sup>lt;sup>1</sup> In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

*Hereby agree* as follows:

#### Article 1

## General Provisions

- 1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
- 2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
- 3. The annexes are an integral part of this Agreement.
- 4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

## Article 2

## Basic Rights and Obligations

- 1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
- 2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
- 3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
- 4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

#### Harmonization

- 1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
- 2. Sanitary or phytosanitary 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 this Agreement and of GATT 1994.
- 3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.2 Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
- 4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.
- 5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

<sup>&</sup>lt;sup>2</sup> For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

## Equivalence

- 1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
- 2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

#### Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

- 1. Members shall ensure that their sanitary or phytosanitary 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.
- 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.
- 3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary 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.
- 4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
- 5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary 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. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

- 6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.<sup>3</sup>
- 7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
- 8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

### Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

<sup>&</sup>lt;sup>3</sup> For purposes of paragraph 6 of Article 5, a measure is not more traderestrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

- 1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area whether all of a country, part of a country, or all or parts of several countries from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
- 2. Members shall, in particular, recognize the concepts of pest- or diseasefree areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
- 3. Exporting Members claiming that areas within their territories are pestor disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

## Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

#### **Article 8**

## Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

#### Article 9

Technical Assistance

- 1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.
- 2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

## Special and Differential Treatment

- 1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
- 2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
- 3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
- 4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

#### Article 11

Consultations and Dispute Settlement

- 1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.
- 2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.
- 3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

#### **Administration**

- 1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.
- 2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.
- 3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.
- 4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international

standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

- 5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.
- 6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.
- 7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation.

## **Article 13**

## *Implementation*

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members

shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

#### Article 14

## Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

#### ANNEX A

## DEFINITIONS<sup>4</sup>

- 1. *Sanitary or phytosanitary measure -* Any measure applied:
  - (a) 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;
  - (b) to 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;
  - (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or

<sup>&</sup>lt;sup>4</sup> For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

- products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, 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.

- 2. *Harmonization* The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
- 3. International standards, guidelines and recommendations
  - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
  - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
  - (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
  - (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.
- 4. 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 sanitary or phytosanitary 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.
- 5. Appropriate level of sanitary or phytosanitary protection The level of protection deemed appropriate by the Member establishing a sanitary or

phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. Area of low pest or disease prevalence - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

#### ANNEX B

# TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

## Publication of regulations

- 1. Members shall ensure that all sanitary and phytosanitary regulations<sup>5</sup> which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
- 2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

## Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from

<sup>&</sup>lt;sup>5</sup> Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

interested Members as well as for the provision of relevant documents regarding:

- (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
- (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
- (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
- (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.
- 4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals<sup>6</sup> of the Member concerned.

## Notification procedures

- 5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:
  - (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
  - (b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

<sup>&</sup>lt;sup>6</sup> When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

- (c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
- (d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.
- 6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:
  - (a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
  - (b) provides, upon request, copies of the regulation to other Members;
  - (c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.
- 7. Notifications to the Secretariat shall be in English, French or Spanish.
- 8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.
- 9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.
- 10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

## General reservations

- 11. Nothing in this Agreement shall be construed as requiring:
  - (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

### **ANNEX C**

## CONTROL, INSPECTION AND APPROVAL PROCEDURES<sup>7</sup>

- 1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
  - (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
  - (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
  - (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
  - (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

<sup>&</sup>lt;sup>7</sup> Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.

- (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
- (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
- (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
- (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
- (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

- 2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.
- 3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.