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INVASIVE ALIEN SPECIES

Report on existing international procedures, criteria and capacity for assessing risk from invasive alien species

Note by the Executive Secretary

1. The Executive Secretary is pleased to circulate herewith, for the information of participants in the sixth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) a report on existing international procedures, criteria and capacity for assessing risk from invasive alien species that has been prepared by a consultant commissioned by the Secretariat.

2. The report is being circulated in the form and language in which it was received by the Secretariat.

* UNEP/CBD/SBSTTA/6/1.

REPORT ON EXISTING INTERNATIONAL PROCEDURES, CRITERIA AND CAPACITIES FOR ASSESSING RISK FROM ALIEN INVASIVE SPECIES

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EXECUTIVE SUMMARY

The risk from alien invasive species is the combination of the probability of the entry and establishment of the invading species times the magnitude of the consequences. Factors of both probability and magnitude of the consequences are included in the concept of risk. In this concept, the consequences are the ramifications of the impact. For example if the impact is damage to an ecosystem, the ramifications may be lost income from farming or tourism, less pleasure in enjoyment of the location or the loss of a species that depended on a food source that was directly impacted.

The magnitude of the consequences, therefore, varies according to both the impact and the level of investment of stakeholders, as well as which stakeholders are taken into account. This investment may be economic or in terms of a societal value, such as biological diversity. Biological diversity is defined and therefore measured in various ways. Countries will clarify what they wish to protect, and how it can be measured, before successfully applying Risk Assessment to the problem of transboundary movement of alien invasive species.

Risk Assessment is used to estimate risk and to evaluate and choose Risk Management options in many disciplines. Environmental Impact Assessments (EIAs) involve similar methodologies. All of the methodologies are applied to a defined geographic area over a defined period of time. Although they cannot reflect the level of complexity involved with all variables existing in the natural world, these methods attempt to provide for the systematic evaluation of available information for the best possible decision making by regulators. The criteria used when identifying the hazard and assessing a risk will greatly influence the outcome.

There are no legally binding international guidelines for Risk Assessment of alien invasive species as a comprehensive category. Guidelines do exist for assessing the risk of introduction and spread of exotic animal disease and plant pests, including weeds. These Risk Assessment guidelines were prepared over the past ten years by the contracting parties to the International Plant Protection Convention (IPPC) and the Office of International Epizootics (OIE). New guidelines are under continual development, for example five years ago guidelines for aquatic animals were first published. With the advent of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) under the World Trade Organization (WTO), these guidelines have become binding for all WTO Member countries. Recommendations for control of species movement in ballast water have been developed under the International Maritime Organization, but are applied on a voluntary basis (except in countries that have their own binding legislation).

The Convention on Biological Diversity (CBD) does not explicitly require the use of Risk Assessment, but it does require the evaluation of threats that by their nature are subject to uncertainty. As Risk Assessment is a scientific process for determining uncertainty, then it is an essential tool in compliance with the CBD, and Article 8 (h) on control of alien invasive species in particular. The precautionary approach as stated in the Rio Declaration, and thus referenced in the CBD, is not a part of Risk Assessment. It comes within the decision making process of Risk Management. There is no conflict between the use of Risk Assessment for generating management options and the objectives of the Convention or its proposed ecosystem approach, as now defined.

Historically the IPPC and OIE Member countries that participate in the elaboration of international Risk Assessment guidelines have focused on impacts to cultivated/domesticated species. Similarity of the environment was the key consideration for the possibility of an invasive species becoming established and spreading in a new location. Important criteria for ecological aspects of survival and spread in a new territory, such as ability to be detected or the need for disturbance were not incorporated until recently,

and then only by a few countries. Impacts on species outside of cultivated areas were considered less critical in the past, based on the countries' focus on economic growth and poverty alleviation. With the increasing public demand for protection of the environment and recognition of its link to economic goals, there is a new drive to include broader criteria in the Risk Assessments conducted by national governments for trade purposes.

Although socioeconomic and ecological factors are already included in general terms in the SPS and in the specific Risk Assessment guidelines, additional guidance has been sought by Member countries and is encouraged by the CBD. This guidance appears in the form of guidelines for wildlife, wider recognition of environmental factors, use of screening processes for invasiveness and a call for supplemental standards to provide even greater detail on how to include these factors. Technical assistance and exchange of ideas supports the development of the Risk Assessment process. The gap in accessibility of information from and by the majority of countries hinders full development of representative tools and procedures. Many ecological factors require extensive research to understand. Such research is not presently budgeted for in regulatory agencies. Certain aspects of Risk Assessment remain weak, even in countries leading in its application. This includes the use of economics and the quantification of risk from alien invasive species, which is a vital addition to qualitative reviews.

Close coordination between members of the existing international organizations that set standards for the SPS Agreement and those working to implement the CBD is critical. This coordination needs to take place both internationally and within each country to support attempts to integrate more detailed guidance on ecological aspects of risk.

Currently most countries use of Risk Assessment does not explicitly address the broader aim of the Convention on Biological Diversity. This is because criteria related to conservation of biological diversity is not always included or given priority in Risk Assessment, data is lacking, relevant networks are still in their early stages and institutional depth is challenged by resource restrictions. Yet the technological and human resources existing under the current rights and responsibilities of international agreements can form the foundation for future expansion of Risk Assessment to include more environmentally oriented criteria. Those officials with an environmental mandate can learn from their colleagues about the range of uses of Risk Assessment. Those further developing the Risk Assessment process to meet trade requirements would benefit from the ecological perspective. National authorities face some confusion and burden on resources if the existing structure for evaluating risk and developing management options is supplanted rather than strengthened and complemented.

Risk Assessment appears to be a viable first step to compliance with Article 8 (h) of the CBD. As a methodology it has not reached its limits in application to alien invasive species and use for decision making on related issues. Governments must ask themselves and their citizens some challenging questions in order to enhance their efforts in conserving biological diversity. Risk Assessment would seem to be one way for finding answers to these questions.

REPORT

I. The Concepts of Risk and Biodiversity

This report is an initial review of what international risk assessment methods, guidelines and tools exist, often from agricultural situations, that may apply to the prevention and control of alien invasive species. Which are being applied, in what situations and by whom. What aspects of the methods are successful and what needs further development. Which capabilities of the agencies applying risk assessment appear adequate and which need to be enhanced. And the decisions to be made in response to the status of risk assessment given the rights and responsibilities of the various international agreements in place, in particular those stated in Article 8 (h) of the Convention on Biological Diversity[1] (CBD).

Risk Assessment is a process for estimating the probability of an event and the magnitude of the consequences. Characterization of uncertainty in the scientific information taken into account in a Risk Assessment is a critical step in the process. In fact, if uncertainty about a hazard did not exist, then there is no risk: there is only a known event (Griffin, 2000). Therefore, the Risk Assessment process is not incompatible with the precautionary approach as described in the Rio Declaration as Principle 15 (UNCED, 1992) and as reaffirmed in the CBD (as implied, see Glowka *et al.*, 1994). Even if the precautionary approach is applied in a manner beyond those described (Griffin, 2000), for example the emerging use of the term by the European Union, the approach appears as part of the Risk Management phase rather than within Risk Assessment (EC, 2000a). Because of this, the precautionary approach is not discussed in detail in this report.

Risk Assessment (referred to throughout this report as RA) is a required step for Risk Management to take place. However, RA can occur without Risk Management necessarily following. For example if a country is faced with a risk that it must accept and cannot directly mitigate, there may still be value in assessing the risk to determine the impacts. This report focuses on RA and the criteria included in the process when applied to alien invasive species.

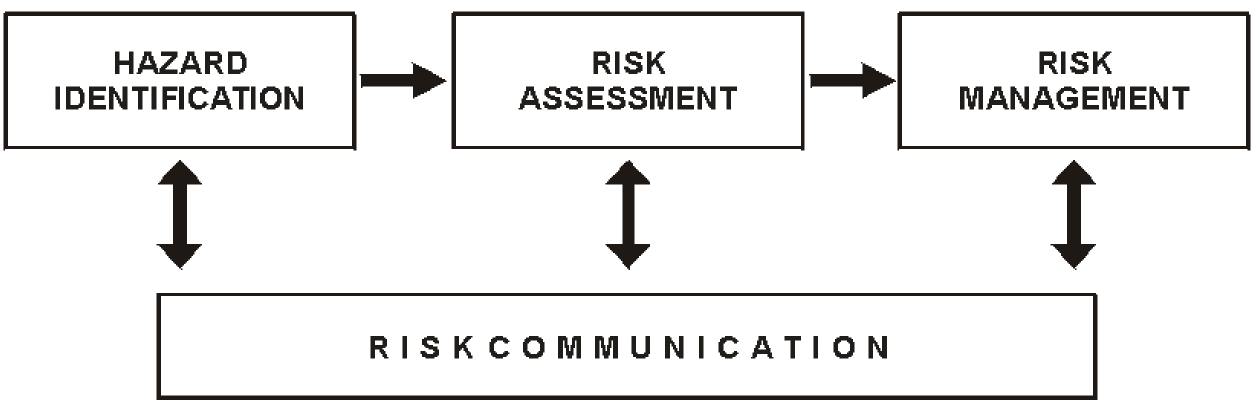

Figure 1. Steps in risk analysis (OIE, 2000b)

Other objectives of the CBD, such as biosafety and equitable sharing of benefits from genetic resources are not discussed here even though the process of Risk Assessment may apply. Regional and national guidelines for Risk Assessment of alien invasive species are not discussed systematically and are only mentioned to illustrate points made about the international procedures, criteria and capacities.

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[1] Article 8(h) states that "Each Contracting Party shall, as far as possible and as appropriate: Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;"..

Throughout the report, some statements are highlighted as summaries of important messages, possible points of action or recommendations. For easy reference, the Appendices include texts from some of the international agreements discussed in the report.

A. RISK AND BIOLOGICAL DIVERSITY

In this paper, the term "risk" means the probability of the entry and establishment of an alien invasive species to an area outside the species' normal distribution and the consequences of this introduction in terms of potential biological and socioeconomic impacts.

Factors of both the probability and the potential consequences are included in the concept of risk.

The definitions and usage of these terms by various organizations appear in their publications and standards (OIE, 2000b and 2000d; IPPC, 1999a). To apply RA, one must first consider the underlying question of what is at risk, what is biodiversity? The Convention on Biological Diversity (CBD) defines it in Article 2:

> **"*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.**

Presently 1.75 million species are formally listed (Stolzenberg, 2000). The range of diversity within each species is often not documented. Maintaining this diversity requires prevention of the destruction of the number of species and of the population level of each species (in order to provide for the intra-species diversity). Much of the recent work on conservation biology is asking how to maintain diversity through conservation of habitats, or prevention of habitat destruction. Although relying primarily on existing tools[2], the prevention and management of invasions from alien species across a wide range of taxa is a new discipline.

Even as new knowledge of invasion biology develops, there remains a gap in agreement on methods to maintain or even improve ecological health while obtaining human benefits from the same resources. The signatories of the CBD declared a two-fold objective of both conserving biodiversity and promoting its sustainable use (Article 1).

B. WHAT TO PROTECT?

Within the framework of a RA, the pragmatic question of what to protect is brought in at the regulatory level. This is done by defining the hazard or threat, and then identifying which species are potentially impacted by this threat. The assessment also defines the geographic area in which the threat is of concern, which may be limited by the area under the manager's jurisdiction. A decision is made as to the value of the species that may be impacted by the hazard before any further assessment is made. So ultimately (in the Risk Management phase) a value judgement is required to set priorities for protection of biodiversity.

One approach for prioritizing resources is to identify global centers of particular diversity, or centers of endemism, and focus protection on those areas. "Hotspots" have been defined as places where those species that are the most rare and that have the most geographically-restricted distribution occur (Stolzenberg, 2000) or as "exceptional concentrations of endemic species undergoing exceptional loss of habitat" (Myers *et al*., 2000). An assessment of the risk from an invading species in this scenario will focus heavily on habitat/ecosystem conservation. Recognizing that not all alien invaders are equally disruptive, an approach could be developed to assess the potential impact of the invasion of an alien species on the composition and functioning of the existing ecosystem before risk management recommendations are made. The complexity of such an approach is outside the ability of quick assessment techniques today. Management decisions based on the functioning of the ecosystem may

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[2] A report on existing tools and activities in prevention, early detection, eradication and control was prepared for the CBD in conjunction with this report (Murphy *et al.*, 2001).

become detached from species-specific considerations, and lose sight of what the programs were created to protect (Goldstein, 1999).

There are other problems with using "hotspots" concept to prioritize for protection against alien invasive species. In many areas biodiversity is not yet well surveyed and species are not yet known, which is the case for much of Brazil for example. Furthermore, Pimm and Raven (2000) explain how extinctions of species that are wider-ranging can exceed those of the rarer, narrow distribution species if vast areas of their habitat (humid tropical forests in that research example) are not preserved. Even with immediate protection of these hotspots from habitat destruction, approximately 18% of all their species will become extinct because of the forces already set into motion (Pimm and Raven, 2000). This is without factoring in the impact of new, alien species introductions into these areas and impacts on endemic species that alien species might cause. A prioritization scheme that does not factor in alien invasive species is only partially representing the threats to biological diversity of the area. The "hotspots" approach may work for global prioritization but not for national planning, particularly in countries that do not include any designated "hot spots."

Another approach to conserving biological diversity is at the national level through Biodiversity Action Plans, as laid out in Agenda 21. Under this model, each nation may choose to protect "typical" ecosystems important to their own cultural and social landscape. Plans for protection of biodiversity on the local (provincial, state or municipal) level may also be developed.

These approaches are from the perspective of environmental protection and are based on extensive research of ecosystems and individual species. In contrast, much of this report is from the perspective of regulators with other objectives, although environmental protection is included in their missions. In the pragmatic world of regulators, what can be protected: endemic or threatened species? Socially or economically important species? Or species that live in representational ecosystems or within protected areas?

Clarifying what it is we aim to protect will assist in determining the best criteria for assessing risks from alien invasive species.

Clarification of how we can determine if biodiversity is being conserved—by looking at economic damage, species extinction, change in the size or composition of populations of a species, or other quantifiable factors—is also necessary in order to properly select the best criteria for risk assessment.

II. Existing International Guidelines and Requirements[3]

A. Trade-Based International Guidelines and Requirements

The only international legally binding requirements for Risk Assessment (RA) related to alien invasive species are those of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures[4] (SPS), which does not cover all alien invasive species.

The SPS Agreement relates to alien species of animal disease (including any form of pest or disease that affects terrestrial and aquatic animals) and plant pests (including plant disease, insects, plants that are weeds, and other taxa impacting plants) that cause significant economic damage. The Agreement generally does not cover mammals, birds, reptiles or other taxa that are pests in and of themselves. Only those species that are pests of plants or vectors of animal disease are included in this Agreement. For example, control of ticks that can spread animal disease may fall under the SPS while control of brown

[3] Regional guidelines and requirements are not covered by this report, although they are sometimes mentioned to illustrate a point.

[4] "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." Annex A Definitions, SPS.

snakes that do not transmit any disease to other species but do threaten native bird populations does not fall under the SPS. Therefore, some alien invasive species are not covered under the SPS.

The SPS is binding to all of the 140[5] Members of the WTO, whether they signed this agreement or not. The Agreement requires that a RA be conducted if a measure is enacted that (a) is not based directly on an international standard of a recognized reference setting organization, and (b) the measure may have impact on international trade. The specific requirements for RA under the SPS appear in Appendix V.

Environmental factors are not defined or clarified within the text, but are included with terms such as "relevant ecological and environmental conditions" or "potential biological consequences." The methods for factoring in ecological conditions, or for any other step in the RA, are not indicated in the text of the SPS.

The earlier WTO Agreement on Technical Barriers to Trade (TBT) utilizes a "Code of Good Practice for the Preparation, Adoption and Application of Standards," but indicates that a country will notify other members if there is a measure that either has no relevant international standard or if the country deviates from the standard. As with the SPS, national sovereignty is maintained in the parameters listed in Article 2.2 of the TBT:

> *For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.*

The TBT refers to risk without specifying any RA methodology. The disputes that have arisen under the WTO on "environmental" issues have all fallen under the TBT to date. These have been related to the method of production (e.g., dolphin-safe tuna, nets with turtle exclusion devices) of the countries of origin of the products. Because production processes and methods that do not affect the safety of the product are not covered under the TBT, the cases have resulted in apparently environmentally "unfriendly" decisions (as reported by Sampson, 1999, Haddock, 2000 and others). The role of the WTO and TBT in particular will be clarified with the implementation and first disputes under the Cartagena Protocol on Biosafety, in which the production method of biotechnology is at question (Anderson and Nielsen, 2001). Conclusions of this debate will not directly relate to regulation of alien invasive species, but may shed some light on the international application of the precautionary approach.

The SPS is the only WTO Agreement that names external standard setting bodies. The bodies named are: the Codex Alimentarius Commission, which covers human health issues and maintains a Secretariat under a joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) program[6]; the Office of International Epizootics (OIE), which covers animal health issues and is based in Paris; and the International Plant Protection Convention (IPPC), with its Secretariat in FAO Rome, which addresses the health of all plant resources. These organizations are discussed further in Section V on Institutional Aspects. Guidelines developed by these bodies are the standards employed under the SPS Agreement, although other relevant international organizations with membership open to all WTO member countries could be identified as sources of standards in the future.

Both the IPPC and the OIE have international standards, which provide guidance on topics such as RA. These are discussed in the report under Section III Criteria. Examples of standards appear in:

Appendix I. Risk assessment steps outlined in the International Animal Health Code.

Appendix II. Pest Risk Analysis for Quarantine Pests—A Draft Standard of the IPPC

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[5] There are 140 Member countries and 28 countries in negotiations to become members at the time this paper was written.

[6] Human disease and sanitation are not covered in this report (see Section IV on tools for some discussion of Codex methodologies).

Appendix III. Risk Assessment steps outlined in the Aquatic Animal Code

The approach of a harmonized risk assessment process in animal health and plant health (including weeds) is a relatively new idea. Only over the past decade has the OIE developed and refined harmonized animal health risk analysis methods (OIE, 2000a). The method for risk assessment of aquatic animal diseases was not approved within OIE until 1995. The IPPC member countries began work to harmonize methodologies in response to the pressures of the WTO/SPS a decade ago as well (NAPPO, 1993). Early attempts at creating a standard for applying this methodology to plant pests resulted in the original International Standard for Phytosanitary Measures (ISPM) No. 2 *Guidelines for Pest Risk Analysis* (IPPC, 1996a). This is slated for review in 2001 and is now considered to be too limited in its guidance (IPPC, 2000a).

Risk Assessment is the basis for justifying measures under the WTO/SPS guidelines but also is the basis for many national decisions. RA can provide useful information for decisions on prevention/exclusion, eradication, containment and other management options. This report focuses on the use of RA for prevention.

Other trade-based conventions may relate to alien invasive species. It is possible that some species under the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES), for example, could also be classed as invasive. Yet this Convention is designed to protect the endangered species rather than to prevent a its impact.

Another international organization related to trade is the International Maritime Organization (IMO), which is the international agreement on matters related to maritime shipping. Unlike the plant and animal health organizations, the IMO does not yet offer a harmonized guide to conducting RA. Individual IMO Member countries are starting to carry out RA, generally on the basis of pathways rather than individual species (see Murphy *et al.*, 2001 for examples).

Each of these international organizations, as well as others, provides guidelines for conducting RA in their subject field. These guidelines were developed by specialist commissions, expert panels or working groups, and approved for adoption by the entire member representational body. They were not developed by the Secretariats in isolation. These organizations have decades of experience translating their concepts and procedures into practice and can offer some insight into the effective implementation of the CBD.

B. CONSERVATION-BASED INTERNATIONAL GUIDELINES AND REQUIREMENTS

The CBD does not require Risk Assessment of alien invasive species, but it does require actions that will be based on some evaluation of the risks. The CBD directs its now 179 contracting parties to enact and impose (as far as possible and appropriate) Environmental Impact Assessment to any projects that may impact the environment (Article 14). EIA is not the same as RA as referred to in this report, however, nor was the apparent intention of the Article to alter the nature of EIA (Glowka *et al.*, 1994).

As discussed in the introduction of this report, there is nothing in the CBD in conflict with using RA for developing Risk Management options. Therefore, although not specifically indicated, RA is a useful process for achieving the objectives of Article 8 (h) of the CBD. Risk Assessment can be used for generating information for the management process being defined as the ecosystem approach. In fact, because RA is a method to identify and, to the degree possible, quantify uncertainties in scientific data relating to the system under review, RA is particularly appropriate as a tool for a dynamic system requiring regeneration of conclusions with each new discovery or piece of information. Properly conducted, a RA is one of the most efficient means for repeating analysis as new data is generated.

The United Nations Convention on the Law of the Sea refers to studies to assess the nature and extent of pollution, exposure to it, and its pathways, risks and remedies (Article 200). Article 196 binds contracting parties to "take all measures necessary to prevent, reduce or control…the intentional or accidental introduction of species, alien or new, to a particular part of the marine environment, which may cause significant and harmful changes thereto." This convention does not link the RA specifically to those measures or express pollution as inclusive of "biological pollution." Yet again, RA would be a useful process for determining the probability of an introduction of an alien species and for developing means to prevent, reduce or control this event.

There are no legally binding international requirements for Risk Assessment of alien invasive species as a whole. Risk Assessment is implicitly required under Article 8(h) in order to evaluate the threat to species and ecosystems and to develop Risk Management options.

Guidelines that exist under the title of alien invasive species provide principles and concepts, but do not fill in the details, even to the level of those trade-related guidelines. A number of species, ecosystem or geographic specific protocols propose guidelines for RA (USSD, 2000 and Shine *et al.,* 2000). These are either not international or not legally binding, and are therefore not covered in this brief report. A more complete discussion of these instruments appears in *A Guide to Designing Legal and Institutional Frameworks on Alien Invasive Species* (Shine *et al.*, 2000).

Before the articulation of "free, fair and safe" trade values in the Uruguay Round (Griffin, 1999), government regulatory agencies in plant and animal health were tasked only with the protection of their country's resources. The IPPC, OIE and Codex all existed for some years before being chosen as standard setting bodies under the SPS and all have mandates independent of the WTO. Therefore it is appropriate to return to these sources for conservation-based guidelines related to pests and animal disease. For example, protocols exist for intentional introduction of biological agents, often for the control of an invasive species that was already introduced without its predators or parasites and has caused economic damage as a result. The ISPM No. 3, *Code of Conduct for the Import and Release of Exotic Biological Control Agents* (IPPC, 1996b), was developed under FAO, before the existence of the IPPC Secretariat. It reflects years of experience in the introduction of species with a desire to improve their survival and spread rate. Although not legally-binding, the International Union on Conservation of Nature (IUCN, 1995) guidelines for the reintroduction of native species might also be considered in this context.

C. Environmental Impact Assessment and Risk Assessment

Perhaps the best known tool from the area of conservation is the Environmental Impact Assessment (EIA). In many countries, publicly funded large construction programs were the only activities originally submitted to this process. For some years, projects with international donor funding have required some type of EIA related to the donor's domestic requirements. These EIA generally involved local experts on a consulting basis and were reviewed by the host government (Quinlan and Krahl, 1996). Now the procedures for EIA have been enacted as legislation in some form in the majority of countries.

At this stage, countries are applying EIA to a wider range of activities, which are often listed in the legislation itself. Assessments of biological "pollutants" are far more rare. The international convention that would standardize the requirements for an EIA of transboundary activities (see Table 1) is not in force.

In Article 14, the CBD directs contracting parties to:

> *As far as possible and as appropriate…(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures*

Environmental impact assessment considers the direct and indirect potential impacts from a particular activity on a defined geographic area, at a defined time. Programmatic reviews analyze impacts from a program over time and are a step closer to the concept of cumulative assessment.

Cumulative impact assessment evaluates the combination of the effects of actions with other effects in a given location over a defined period of time. The impacts could be from various projects or policies, or it could be from relatively minor activities in an already degraded or otherwise fragile environment. This was a particularly useful advancement in countries where previously only impacts of publicly funded programs were subjected to review.

Table 1. Criteria included in reports on Environmental Impact Assessment (EIA)

INFORMATION TO BE INCLUDED IN THE ENVIRONMENTAL IMPACT ASSESSMENT DOCUMENTATION SHALL, AS A MINIMUM, CONTAIN IN ACCORDANCE WITH ARTICLE 4:

(a) A description of the proposed activity and its purpose;

(b) A description, where appropriate, of reasonable alternatives (for example, locational or technological) to the proposed activity and also the no-action alternative;

(c) A description of the environment likely to be significantly affected by the proposed activity and its alternatives;

(d) A description of the potential environmental impact of the proposed activity and its alternatives and an estimation of its significance;

(e) A description of mitigation measures to keep adverse environmental impact to a minimum;

(f) An explicit indication of predictive methods and underlying assumptions, as well as the relevant environmental data used;

(g) An identification of gaps in knowledge and uncertainties encountered in compiling the required information;

(h) Where appropriate, an outline for monitoring and management programmes and any plans for post-project analysis; and

(i) A non-technical summary including a visual presentation as appropriate (maps, graphs, etc.).

Source: CONVENTION ON ENVIRONMENTAL IMPACT ASSESSMENT IN A TRANSBOUNDARY CONTEXT (1991), APPENDIX II. This convention, also referred to as the Espoo Convention, is not in force.

Strategic Environmental Assessment is an attempt to integrate EIA into the decision making process more fully.

These are important tools developing from the environmental sciences. As designed in most legislation, the EIA process serves to identify and evaluate, often qualitatively, potential adverse impacts to the environment of a defined location over a specific time period. RA introduces the aspect of uncertainty by definition of risk, so that likelihood or probability of an impact is incorporated. While EIA inform decisions about use of the environment, RA informs decisions about uncertainty (Beer, 1996). Examples of use might be an EIA of the impact of factory emissions on air quality and a RA on the probable impact of reduced air quality on forest growth. Indirect impacts by their nature generally include some uncertainty, as would predictions of long-term impacts from global warming.

Biological criteria certainly may be included in an EIA, and would be critical for assessing the impact of, for example, a decision to introduce a biological control agent. In fact, RA can be used in evaluation of hazards identified in the EIA process. While complementary, these two processes of analysis – EIA and RA – serve somewhat different purposes and are distinct.

Existing and future developments of the Environmental Impact Assessment (EIA) and RA processes may be a source of ideas for integrated procedures. This is particularly the case for measuring those potential indirect impacts of alien invasive species from alteration of the environmental factors (e.g., the amount of water available to the species of concern).

The Organisation for Economic Co-operation and Development (OECD) is coordinating development and harmonization of environmental indicators for agriculture addressing issues such as biodiversity, wildlife habitats, socio-culture and greenhouse gases (OECD, 1999a). These indicators do not involve measurement of impacts from alien invasive species, but do include impacts on genetic diversity related to domesticated species. Such efforts will assist greatly in harmonizing data, which can feed into RA in the future.

D. THE BIOSAFETY PROTOCOL

The Contracting Parties to the Cartagena Protocol on Biosafety (the Protocol) will be required to apply RA to LMOs once the agreement has entered into force. Although LMOs are not the topic of this report, and the definition of LMOs is not equivalent to alien invasive species, LMOs with the potential to harm biodiversity may be considered a type of invasive organism.

Risk assessments undertaken pursuant to the Cartagena Protocol on Biosafety shall be carried out in a scientifically sound manner, in accordance with Annex III of the Protocol (see Appendix IV of this report) and taking into account recognized risk assessment techniques. The objective of risk assessment under this Protocol is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

III. Criteria in Risk Assessment

As discussed above, the outcome of a RA depends largely on the standards against which something is judged. Which questions are asked, and which stakeholders are consulted, will determine the impacts considered and resulting management options proposed. Therefore selection of criteria for RA is a critical aspect of the process. The evolution in lists of criteria has more to do with the changes in societal values than with the usefulness of the RA process per se.

An external review of protocols for agricultural regulators assessing risk of unplanned introductions compared some published guidelines at the time (Ruesink *et al.*, 1995) and found the following criteria:

Table 2. Criteria included in a comparison of risk assessment protocols for unplanned introductions (Ruesink *et al.*, 1995)

ESTABLISHMENT	SPREAD	IMPACTS
• Native range • Autecology (relationship between an individual organism and its environment) • Life cycle • Reproductive rate • Number of colonists • The need for disturbance (not included in any protocols for unplanned introductions reviewed)	• Mobility • Ability to hitchhike • Vector of other species • Asexual reproduction • Ability to be detected • Existence of effective control measures	• Diet breadth • Predators and/or competitors • Data on previous introductions • Related species' impacts • Economic damage • Environmental damage • Purpose of the introduction • Genetic change potential • Data from lab or field tests (not included in any protocols reviewed)

These same criteria were then checked against protocols for assessing risk of planned introductions. In this case, every criteria listed was included in at least one example protocol, but the coverage of this information was surprisingly sparse. The only examples reviewed for unplanned introductions were from plant health and a limited number of locations (the UK, the USA and North America). Five years ago, protocols for risk assessment of planned introductions of alien species that were reviewed related to introductions of fish, other marine species, research species, biocontrol agents, GMOs, and some specific to nematodes, plants and animals (Ruesink *et al.*, 1995). This summary is limited by its use of published descriptions of protocols rather than a direct review of international or country regulations or guidelines on risk assessment. Moreover, thought on risk assessment and its application has progressed significantly in the past five years and these changes have reached policy level in many countries.

It would be useful to conduct a comprehensive review of current examples of Risk Assessment guidelines or procedures in force on a national and regional level. This review should include a comparison of the criteria included, the definitions of these criteria and the manner in which each criteria is measured.

This more in-depth review would form the basis of discussion for future improvements and perhaps for international harmonization. This useful list of criteria from 1995 demonstrates the need for both biological criteria as well as management criteria. The availability of a tool for post-entry control, such as a chemical pesticide that would permit the eradication of an invasive species, is taken into account in current plant and animal health decisions. The availability of effective detection tools does not appear to be considered as consistently, despite the fact that the success of any post-entry control measures will depend upon the results of detection.

A. THE THREAT

This step is referred to in various ways including hazard identification, initiation, or hazard characterization. Guidelines divide these steps at different points so that comparison and use of terms may cause confusion. In the IPPC draft standard (IPPC, 2000b) which appears in part in Appendix II), for example, this section may cover both the initiation and the pest categorization step of the actual risk assessment.

(1) What is it?

The need for highly reliable taxonomic identification is paramount. This issue has been discussed by the Conference of Parties and is dealt with in other reports.

(2) Is it alien?

One of the first biological data needed in such a review is whether a species is truly alien to an area, or has been overlooked until some increase in either the population or its impact is observed. This may be particularly hard in the marine environment for which baseline biological surveys often do not exist (McEnnulty *et al.*, 2000).

All of the trade related guidelines on invasive species are based on prevention and management of species that are alien to the country, or a defined portion of the country, in question. The measures covered under the WTO/SPS, for example, are directed at control of quarantine plant pests (and more recently regulated non-quarantine pests) and exotic animal diseases moving across officially defined boundaries. By definition, this does not include a species that is a "naturally occurring" (e.g. IPPC, 1999a) component of an ecosystem, regardless of its invasiveness or damage caused[7]. Yet one country's native species is another country's exotic pest, so this does not necessarily limit the taxa of interest. It is also possible strictly by the definition that an alien pest that is not invasive would be covered by the IPPC, but most species that cause significant economic damage are invasive by nature.

A number of cosmopolitan (found throughout the world) animal diseases are not covered under the OIE, despite their serious impact. The choice of notifiable and actionable species of animal pathogens is far more harmonized than decisions on plant pests because, like humans, animals are more likely to be susceptible to the same diseases regardless of their external environment/location at the time of exposure.

The question "is it alien?" also arises for introduced species that have adapted to the new ecosystem either due to the length of time since its introduction or due to its evolution in a similar habitat before introduction. The brown trout (*Salmo trutta*) was introduced into New Zealand in 1867, for example, and has altered the functioning of the ecosystem it inhabits and possibly driven one endemic species (the grayling *Prototroctes oxyrhynchus*) to extinction (Townsend, 1996). Although the brown trout clearly is alien, efforts to eradicate the species in the hope of reversing the ecological impact would be misguided at this time because of the disruption it would cause to the now-adjusted ecosystem (Townsend, 1996).

(3) What are its normal living conditions? Do we know the limits for survival?

This step is related to a species' ability to establish in the new environment. If a species cannot survive and form a reproducing population in the country of import (or unintentional introduction), then no action is necessary and the risk assessment may stop here. Factors to review are presented in ecological studies in terms such as: diet preference, habitat usage, niche in ecosystem, life cycle and so forth. This step relies on the existence of some reliable data from published literature or other sources. The data collected to answer this question feeds into the assessment of risk and prediction of impacts.

Similarity of living conditions in the place of origin (either of original origin or just the origin of the shipment) with those in the place of import or introduction often has been used by regulators as an indication that establishment is probable.

A predictive framework was tested on alien cordgrass (*Spartina* spp), which has successfully invaded some Pacific estuaries in the USA. The presence of the native species of *S. foliosa*, and the absence of direct impact of waves but the presence of tidal action were the two indicators for identifying sites vulnerable to invasion. This prediction was then followed up with regular monitoring and immediate eradication of the alien species. Daehler and Strong (1996) discussed further refinement of this assessment method and hopes for more options in management. They acknowledge that changes in

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[7] Although the IPPC and OIE have mandates beyond trade issues, such as coordination of regional efforts to eradicate a migratory pest outbreak even if it is "native" to the area, the activities of these conventions that are disciplined under the WTO/SPS is limited to species against which some official control is in place. Furthermore, where a country does not have in place or terminates official control programs, the application of phytosanitary measures on imported articles is no longer justified under the SPS, even if the species is alien and invasive. In other words, if a country considers an alien species to be sufficiently injurous to merit import restrictions, the requirement of consistency under the WTO necessitates some action against this species when it may occur domestically as well.

hydrology or sediment accumulation are not taken into account in their method. This framework was used for state-level work plans.

(4) Is there evidence it will behave differently in other environmental conditions?

Is this species potentially invasive? The historic behavior of a species in its native environment, or in other places where it was introduced, is an important component of RA. There are many cases, however, in which a species either behaves differently in a new environment (e.g., expands host ranges, adapts to new microclimates outside the predicted climatic survival range, or hybridizes with a native population and alters its characteristics), or causes more severe consequences because of a difference in the environment itself (e.g., the presence of a crop not grown in the native area, differences in habitat management, or socioeconomic conditions that result in greater consequences). A recent well-publicized example is the Asian Longhorned beetle (*Anoplophora glabripennis*) that was not considered a threat to living trees until it was found to have invaded hundreds of them in Chicago and New York City. This case was a combination of change of behavior and simple ignorance of its behavior in its native range, since limited information was accessed from Chinese literature and official sources prior to these outbreaks.

Consideration of co-evolution, or long-term joint endemism, is not included in guidelines for RA, although some of the ramifications of this factor are picked up in review of the impacts from other historic introductions. Further study is needed to determine the usefulness of this factor. Goldstein is less enthusiastic about relying on joint-endemism to predict risk (Goldstein, 1999) and it is true that few ecosystems remain static or migrate as a whole and at the same rate naturally (Westman, 1990).

Although a change in behavior when put into a new environment cannot always be predicted, the evaluation of invasiveness has led to some conclusions regarding traits (e.g., rate and method of reproduction) that are more likely to be associated with successful invasion. Some ecologists question any attempt to label a species as more invasive, since all species could be invasive under the right conditions. Early colonizers tend to be more invasive in disturbed environments, but other conditions may set the stage for a population explosion of a species that was previously considered not to be invasive.

Several countries find it useful to impose a screening process based on potential invasiveness.

This tool appears to be gaining favor among regulators, particularly in the review of plants as potential weeds (AQIS, 2000; Tucker and Richardson, 1995; Reichard, 2000).

B. THE ENVIRONMENT

Risk Assessments are carried out within a defined geographic area designated and described in the documentation of the study. This may not always be an entire country. With the use of zonation for animal disease and the harmonized concept of pest-free areas (IPPC, 1996c), trading partners readily accept policy differences for subunits of a country with different situations. The environment also may be limited to terrestrial or waterways or other divisions, depending on the nature of the threat.

Some legislation is aimed at the protection of designated fragile areas, and requires RA only for those areas. Even the most recent and radical proposal on environmental liability in the European Union limits liability on biodiversity issues to damage to Natura 2000 areas, which will cover approximately 10% of the EC territory, based on the Habitats and the Wild Birds Directives. Anticipated damage is still from habitat destruction and non-point pollution rather than from alien invasive species (EC, 2000b).

Guidelines for RA methods for evaluation of plant pests and animal diseases include consideration of the impacted environment in terms of parameters that influence the probability of initial establishment, survival and spread of the exotic organism. This is based on the existing knowledge of the biology and behavior of the organism. Factors considered include climatic ones—the temperature range, rainfall amounts and timing; presence of hosts, predators or other control agents; and other known limits for the invading species.

(1) Climate and biogeography

Just as in Environmental Impact Assessment (EIA), RA describes the existing situation in the potentially impacted area. Rather than a baseline study, however, most RAs evaluate the potentially impacted species in the existing environment. This is a difference between the RA process used today by regulators and the EIA process.

Models on climate, such as CLIMEX and BioSYM, take some of these parameters into consideration and generate maps or tables of areas that appear sufficiently similar to the source of the species to have a high risk of establishment should the species arrive there. These models have been used by animal and plant health regulators in predictions of establishment of alien species (Dobesberger *et al.*, 2000), but they are well known to ecologists as well.

A private database being developed for use on RA of ballast water focuses on the compatibility of environments and the knowledge of key alien invasive species that could survive in similar environments (Det Norske Veritas, 2000). Key species are considered because at any given time there are 3,000 species of organisms carried in ballast water and as many as 10,000 species that can survive this pathway. Any species with a planktonic life stage can enter ballast water. The assumption that at least some of these that can survive are invasive and/or would be detrimental to the new environment seems sound without looking specifically at each species. The shipping industry's efforts are therefore on Risk Management and on reducing the transfer of species. (Pathway analysis is discussed further in Section IV.B).

(2) Hosts

Other factors considered are the presence of hosts for the introduced species. Hosts are those species that are capable of sustaining a specific pest or disease, for example by providing a food source and any necessary conditions for reproduction. This would include hosts in the ecosystem where the alien invasive species is introduced and alternative hosts or ecosystems that may be impacted if the introduced species spread. Even when livestock or a cultivated crop is the reason for a review of the risk from a proposed introduction, the presence of wild animals or plants susceptible to the pest or disease is included since wild hosts often serve as reservoirs for pests and disease, vectors, or the means for establishment and spread. From the environmental perspective, this can be turned around to ask what crops might introduce a pest that would then impact the native ecosystem or the species of concern.

For biological control agents introduced in order to control an unwanted species (possibly an alien invasive species that was previously introduced), the presence of a preferred host is obviously important or the agent could not survive. On the other hand, alternative hosts may suffer from the intentional introduction of a biocontrol agent. Thus regulators would consider the species' specificity of host in a RA, with the greatest specificity being an organism that is "only able to complete development on a single species or strain of its host" (IPPC, 1999a).

(3) Management practices in place

On the national governmental level, existing Risk Management practices are always taken into account but not often documented. Animal health community seems much more willing to officially review the credibility of the exporting country and its data (OIE, 1993). This factor must be taken into account in any RA, but some technical fields are reticent to document differences in credibility. It may be easier to do in animal health because of the centralized data collection point (the OIE) and the agreement on a limited number of diseases requiring notification.

On the level of an industry, a farm or a park, for example, the existence of other pests or disease in the host of concern and the measures used to control these are taken into account. For example, if citrus is the host of concern and the area already has external feeders, which require pesticide applications, then another similar pest may not be of as great a concern as one that would attack the roots. If a glass house operation has Western flower thrips (*Frankliniella occidentalis*) and has implemented integrated pest management then the addition of *Thrips palmi* has far less impact than its introduction to a system free of these species of more aggressive thrips.

Review of the management practices in place may be more important in the future as a combination of measures, referred to as a Systems Approach, is becoming more harmonized for quarantine regulation (IPPC, 1999b and c). This is an emerging option to achieve full reduction of risk. An example of the Systems Approach is the shipment of a potential host for a pest of concern from an area that has shown low prevalence with a trapping program in the field, combined with some special handling of the product such as screened in packing houses, plus inspection of sample lots on arrival. This combination might replace a single measure, such as fumigation, or outright prohibition that is more likely to lead to smuggling.

In the area of marine health, the Ballast Water Decision Support System in Australia is based on a list of target species of particular concern. The evaluation is whether ships will be arriving from areas that are likely to have these species. Although this is a national system, some Port Authorities have carried out their own RA. In work at twelve ports in Australia, approximately 80% of the species considered could be eliminated from priority actions due to the lower risk of their arrival and establishment in port. This permitted limited resources to be directed towards fewer concerns. Management plans are then developed aimed at those ships arriving from areas where the critical species exist (Raaymakers, 2000).

(4) Vulnerability[8] of the receiving environment

The probability of establishment has generally been assessed based on existing data on climate, biology of the pest, presence of hosts and existing management regimes. What has not been considered is any existing stress agents that may alter a particular species' or even individuals' vulnerability. (In human health, this can be the recognition that a population is more at risk due to its diet, health care, exposure to pollution, or conditions that suppress immunity.)

The CBD directs that biodiversity conservation efforts be aimed particularly at the more vulnerable species and ecosystems. When assessing risk to a protected area, the concept of vulnerability is already built in. The idea of a more vulnerable receiving environment is expressed as the protected area. Fragile areas or habitats are always ecosystem or habitat based, even if the reason that the habitat is protected is because of a rare species associated with it.

Other means of taking vulnerability into account are also used. The US Department of Agriculture is required to conduct additional reviews of policy decisions and programs to implement the National Environmental Policy Act. The US Government also requires reviews based on legislation to prevent greater impact on minority or low-income communities and on children. The vulnerability of individuals or subgroups is generally not considered in non-human populations. Many countries create pesticide regulation after evaluating the potential impact on children, the most vulnerable component of the public. These reviews have different objectives than the RA of alien invasive species, however, and do not constitute environmental considerations within the RA.

Ecological sciences tell us that habitat disturbance is usually helpful to invading plant species. The frequency and intensity of disturbances influence the degree to which the system is easily invaded. As many of the regulators applying RA have focused on continually disturbed environments, primarily through cultivation, it may be that this factor is intuitively included. Practitioners in agriculture are aware of these agents and possibly make decisions incorporating them, but the agents are not well-documented or represented in RA guidelines.

Natural phenomena can be one such stress agent. There are many examples of pest and disease entering an ecosystem or exploding in its population after a storm, fire or drought. The IUCN places this question in the context of Environmental Impact Assessment (EIA) (Appendix, UNEP, 1999):

> *What are the likely impacts of natural cycles of biological and climatic variability on the proposed introduction? (Fire, drought and flood can substantially affect the behaviour of alien plants.)*

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[8] Vulnerability is not a technical term in this case, but is related to the level (or lack) of resiliency of an ecosystem or species. Ecologists have varying definitions of ecological resilience, but guidance on this concept from the conceptual development of the ecosystem approach will relate to this section.

The impact of climate change has been studied in some cases and may become an important factor for longer-term policy decisions in certain countries. For example, in the UK, a country situated far north but with Gulf Stream tempered climate, the potential range of the Colorado potato beetle (*Leptinotarsa decemlineata*) could extend by 120% of its current range with the increase of temperature predicted from global warming. In this scenario the pest's range would cover 90% of the United Kingdom's ware and seed potato industry (Baker *et al.*, 1998) if it became established despite efforts to prevent its entry.

The impact of pollution on pest damage has been shown in the plant health field (e.g. Ashmore *et al.*, 1990 and Bell *et al.*, 1992) with some interesting results. These more general agents of stress that are not limited to protected areas might be considered in more complex RA, or as a trigger to re-evaluate RA results, for example after hurricane activity or drought.

Economic recession is an important factor to include in a RA. This has been documented regularly for animal health since the price of animals and animal products directly impacts health reporting and investment in care and often leads to slaughter of sick animals and unscrupulous trading (OIE, 2000a). Economic factors are frequently included in RA. It is less frequent that the regulators carrying out the economic portions of the RA are fully trained economists.

The impact of armed conflict or political instability is also not written into RA procedures. In reality, most countries in this situation are not conducting RA on alien invasive species. In this case, countries providing food aid or military assistance must take the responsibility of assessing the risk and put in place measures to prevent introductions at a particularly vulnerable time for the receiving country (CABI Bioscience, 2000).

Risk Assessment may fall short of other methodologies in determining any special vulnerability of the receiving environment. This occurs because factors of vulnerability are not included as criteria, not because of an inherent fault of the RA approach.

C. PROBABILITY OF ENTRY, SURVIVAL AND SPREAD OF INTRODUCED SPECIES

Information needed to determine the establishment potential of a plant pest, for example, is listed in ISPM 2 (IPPC, 1996a):

- availability, quantity and distribution of hosts in the PRA area
- environmental suitability in the PRA area
- potential for adaptation of the pest
- reproductive strategy of the pest
- method of pest survival

Once the information is collected on the species that poses the threat and on the factors that could lead to its survival in the new environment, some calculation of probability is made. Such techniques as the Monte Carlo simulation, in which models are run repeatedly with variations in the stochastic parameters (those governed by probability), can produce estimates of probability distributions for a range of outcomes, allowing sensitivity analysis. An example is to demonstrate the sensitivity of the rates of spread of a newly introduced pest.

Probability of establishment will depend on biological factors including the mode of sexual reproduction, since bisexually reproducing species will need a density of individuals sufficient for finding mates. Aggregation or coalescing behavior or circumstances will assist bisexually reproducing species, and so forth. Yamamura and Katsumata (1999) discuss the calculation of probability of an undesired introduction by category of larval spatial distribution (gregarious or solitary) and sexual reproduction mode. This is applied directly to a quarantine decision regarding use of a disinfestation treatment versus inspection of fruit with possible infestation by Mexican fruit fly (*Anastrepha ludens*). The model they propose will have implications for sampling techniques as well as quarantine measures.

Probability is also used for determining impacts. The US Department of Agriculture conducted a probabilistic RA on a new potential pathway of introduction of various diseases and insects, the shipment of citrus from Argentina. In this RA, not only are the probabilities of introduction of each of these species predicted, but also the economic and environmental impact (Cave *et al.*, 1997).

In both cases—probability of the establishment and spread and probability of the consequences—the uncertainty of the prediction is traditionally determined using sensitivity analysis. With this analysis, the uncertainty remains but it is more explicit and can be shown from different perspectives of risk acceptance. Uncertainty is not the equivalent to lack of knowledge on a subject, although the two may overlap. The respective probabilities of occurrence can be weighed in Cost Benefit Analysis to become useful as a Risk Management tool. Further discussion of these approaches appears in literature (e.g., Mumford *et al.*, 2000).

Probability is well developed as a tool for RA in plant and animal health fields. Many countries do not have adequately trained staff to conduct this vital step in the RA process.

D. IMPACTS AND CONSEQUENCES

(1) Determining impacts of management options

Guidelines indicate that management options for reducing risk should be presented in the documentation to policy makers. One option is always the option for no action. In this way, documentation includes predictions of the impact of the alien invasive species if nothing is done to prevent its entry or establishment. Management options may be taken into account without documenting the process, but understanding the original options and basis of decisions is important to the transparency of the RA. Transparency is not only a guiding principle under the WTO, it is important for creating institutional memory in the agency authoring the RA.

Potential impacts from the measures to prevent the arrival of a particular species are included in this analysis. Impacts from controlling or eradicating the species if it did arrive and become established are also considered. For example, programs aimed at maintaining the “natural” environment by eradication of alien species have highlighted the complexity of ecosystems in the US Park system. The policy was to remove exotic species, however reality of resources requires some prioritization. Falling to the temptation to remove those species that are easier to control would lead to ecosystems with more management-resistant exotics.

Furthermore, some alien species may play the same role in the ecosystem as a native species (e.g., erosion control), so that elimination of the new species would result in at least localized disruption to the ecosystem one is trying to protect. The theory that removing the invading species would allow the native one to regenerate may also be flawed given the state of disturbance that allowed an invasion in the first place (Westman, 1990). In a proper RA, all of these impacts are laid out for policy makers to consider in the decision making process.

(2) Determining the consequences

Different groups use terms differently. If one defines impacts as the direct injury to the species and ecosystem of the receiving environment, one can distinguish it from the concept of the consequences, which are the ramifications of this damage. For example, if the impact of an alien invasive species is the extinction of a native species, then the change in the flora and fauna of the area and reduction in tourism resulting in a loss of income to the area’s inhabitants are the consequences.

Frequently, direct consequences, such as the loss of income by farmers whose crops were damaged, are the only ones included in RA. Little guidance beyond this level is provided by the text of the SPS Agreement. Standards from the international organizations named in the SPS Agreement explicitly include indirect effects as criteria for study. Despite this, the indirect damage and indirect consequences are not well documented in many RAs at this time. This is due to a lack of resources and resulting priorities on the national level rather than to a flaw in the procedures. Figure 2 shows the current guidance from the IPPC on this question, from both the IPPC (Convention) as well as established and draft IPPC Standards for RA.

ISPM No. 2, Guidelines for Pest Risk Analysis, approved in 1995, included reference to ecological criteria. The concept is more fully developed in the draft ISPM on Pest Risk Analysis for Quarantine Pests (IPPC, 2000b), which is scheduled for final review and possible approval by the Interim Commission on Phytosanitary Measures (ICPM)[9] in April, 2001 (see Appendix II for an partial version of this draft).

Although this draft ISPM goes further in defining ecological criteria, the FAO member countries that attended the Exploratory Open-ended Working Group on Phytosanitary Aspects of GMOs, Biosafety and Invasive Species (June 2000) recommended that clarification of these criteria be elaborated even more, possibly as supplemental standards. This recommendation goes to the ICPM in April 2001 along with the

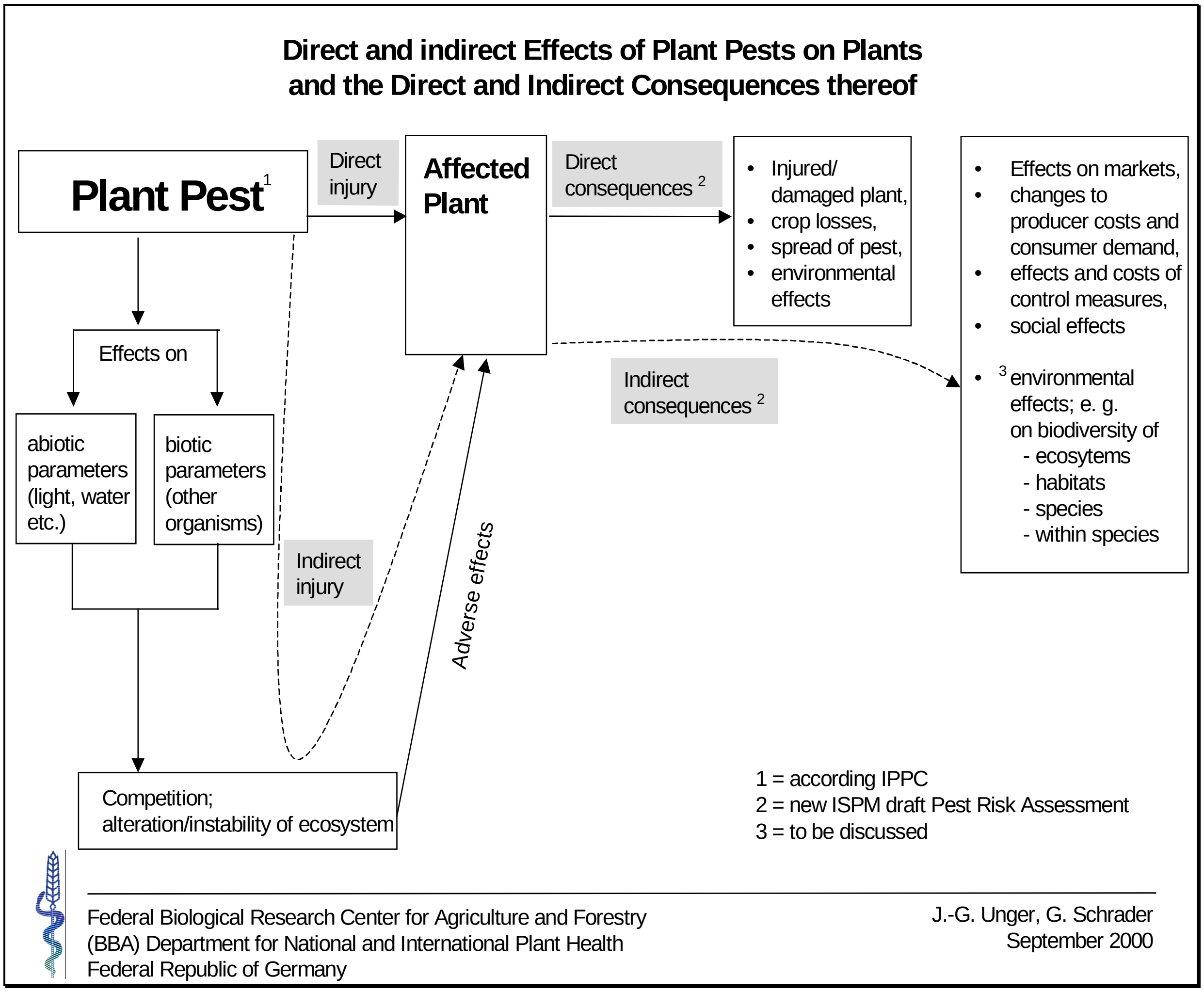

Figure 2. Direct and indirect effects of alien invasive species from the plant health perspective, showing which are included in standards for RA at this time.

[9] The ICPM consists of all FAO Members and Contracting Parties to the IPPC until the amendments adopted in 1997 come into force through acceptance by 2/3 of the Contracting Parties. At which time the Interim Commission becomes the Commission on Phytosanitary Measures and only those countries that are Contracting Parties to the IPPC will be Members.

draft ISPM. Other points in Figure 2 are items under discussion by Contracting Parties to the IPPC (as noted). Detailed ecological criteria are not yet enshrined in RA guidelines, particularly at the level of national legislation and programs. This is generally due to the national governments' decisions about the value of various sectors, or individual species or ecosystems, which are probably influenced by the lack of relevant ecological data readily available rather than lack of concern for the environment.

Risk can be reduced by reducing the probability of an invasion or by reducing the consequences. The magnitude of the consequences will be influenced by the stakeholders involved, their economic investment in the resources, and what is valued by society. Some of these factors are difficult to quantify. The trend is towards quantification of criteria, however, in order to allow comparison of measures and management options (both within a country and for equivalency debates between countries). There is also a need to define quantitatively an acceptable level of risk, as expressed in the SPS Agreement. This implies working with RA to design and evaluate various management options until the acceptable level of risk has been reached.

The level of risk is determined by estimating the probabilities of introduction and the magnitude of the consequences. A complete Risk Analysis also includes descriptions of the various options for measures to mitigate this risk and recommendations for the best alternatives. By quantifying the effect of each mitigative measure on the final level of risk, RA studies support greater precision and certainty for risk managers in policy decision-making.

Economics is as important as ecology when assessing the risk from the introduction of an alien invasive species and setting an acceptable level of risk from which to choose and design the best management practices.

A pathway analysis of risks from the importation of larch from Siberia and the Soviet Far East into North America was conducted (USDA, 1991). Regulators studied potential economic and ecological consequences if the invasive species associated with this timber in its country of origin were to become established in the importing country, where these pests were alien. Habitat modification, the role of environmental stress and climate change, and the ecological ramifications of the loss of forest trees were included in this review.

Few countries have the appropriate capacity (staff, expertise, methodologies, information) to fully develop this aspect of the RA process for the biological threat of alien invasive species.

E. SPECIAL CONSIDERATIONS

(1) Genetics of new strains, hybridization, or Living Modified Organisms

The OECD has published environmental indicators for agriculture which include some consideration of genetic diversity (OECD, 1999a, as mentioned in Section II, C on EIA and RA). Consideration of genetic strains within a species has appeared in plant health regulations in national or regional cases. For example, Europe already had endemic populations of the tobacco whitefly (*Bemisia tabaci*). These were not as aggressive as the biotype B which caused severe damage in California and, in addition to vectored disease, explains the European Union granting protected zone status for some countries that are not truly free of the species. New Zealand lists "strains of pests (when there is documented evidence of differences)" as a category under regulated organisms in their risk regulations (NZ Ministry of Agriculture and Forestry, 1997).

In recent discussions at an EPPO symposium, the consensus was that the IPPC guidelines do not cover the situation of LMOs (or alien species) escaping by hybridizing with wild plants that then successfully out-compete other plants. This level of genetic prediction is not explicit in current procedures.

Because of the concerns raised with genetic manipulation, RAs for GMOs/LMOs are more likely to consider hybridization or other means of genetic transfer. Living modified organisms are often not invasive, however, and should not be categorized as such automatically. The IUCN proposes including this factor for alien invasive species in the form of questions, which appeared under their Appendix on EIA (UNEP, 1999):

What is the potential for the alien species to genetically swamp or pollute the gene pool of native species through interbreeding?

Could the alien species interbreed with a native species to produce a new species of aggressive polyploid invasive?

Determination of genetic susceptibility is an emerging option for humans to see if an individual is more likely to succumb to environmental illness, for example, as medical sciences understand further the genome and related tendencies. With humans, the fear is that this new knowledge can be used to discriminate against individuals or ethnic groups. For pests or disease, the individual level appears more significant when considering situations such as the development of resistance to antibiotics in a population that is primarily wiped out by its use, but regains strength from those few surviving individuals that are not destroyed. Development of a resistant population is a concern if eradication decisions are made based on the easiest alien species to remove from an invaded area (Westman, 1990). Genetic considerations in RA may arise in the future when the interpretation is more certain and the data more widely accessible.

(2) Critical social or cultural impacts

Socioeconomic impacts are required under RA guidelines laid out by the WTO. The CBD goes further by listing some of these impacts to consider due to social and cultural value, especially those criteria in the second paragraph (Annex I):

"Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;

Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species;"

Any of these factors could be included in the RA frameworks provided by the WTO standard setting bodies, if the significance of the species is somehow documented or quantified for inclusion in the RA.

(3) Reintroduction programs

In Article 9(c) the CBD states that countries shall: "Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;".

One area of concern for such programs is to avoid the introduction of an animal disease with the wildlife and to prevent the reintroduction of wildlife into an area with a disease that will devastate the new population. Issues in animal health of this nature are being addressed through new RA procedures developed by the Wildlife Committee of the OIE. These appear at a joint OIE, Canadian Cooperative Wildlife Health Centre web site (OIE, 2000c), along with an example of a RA for the importation of elk (*Cervus elaphus canadensis*) from Ontario to Saskatchewan. The web site recommends sources of information such as the IUCN site for its Species Survival Commission and the Commission's Specialist Group on Reintroduction. The IUCN Guidelines for Reintroduction include some factors unique to reintroduction programs, such as an evaluation of the previous causes of decline of the original population (IUCN, 1995).

(4) Co-evolved ecosystems

One factor that might improve the prediction of the change with change in environment is the evolutionary history and associations of the species. For example, trout whirling disease co-evolved with native brown trout in Europe, where it has a minor impact on the population. Thus impacts to related species that had apparently not been exposed to this disease before were not anticipated. What is occurring in the USA, however, is catastrophic. For example, an estimated 90% of rainbow trout in one river system in Montana were wiped out in 1999 when the disease first arrived to that area. The disease has spread to 22 states and into Canada since its arrival around 1955, when the disease probably was introduced through frozen fish imported to Pennsylvania from Denmark. Based on the situation in Europe, and the assumption that freezing would kill most disease, no one recognized this pathway as a threat (ProMED, 1999).

Consideration of co-evolution, or long-term joint endemism, is not included in guidelines for RA, although some of the ramifications of this factor are picked up in review of the impacts from other historic introductions. Further study or a review is needed to determine the usefulness of this factor. Goldstein is less enthusiastic about relying on joint-endemism to predict risk (Goldstein, 1999) and it is true that few ecosystems remain static or migrate as a whole and at the same rate naturally (Westman, 1990).

IV. Tools for Risk Management and Determining Socioeconomic and Environmental Impact

Tools for prevention, early detection, eradication and control of alien invasive species are discussed further in another report to the CBD Secretariat (Murphy *et al.*, 2001). This section mentions the highlights of tools employed in assessing risk and making Risk Management decisions.

A. Codes of Conduct, Best Practices and Other Technical Guidelines

Existing codes of conduct, best practices and other technical guidelines for RA are not analyzed in this report. These instruments are useful indications of the state of knowledge on any given objective or taxa. A listing of all of these instruments relevant to alien invasive species appears in Shine *et al.* (2000) and the US State Department (2000) complementary list. Although many of these do not strictly qualify as RA, they provide a possible step for inclusion in RA by evaluating the impact on risk if one follows the best practices.

B. Pathway Analysis

Many RA will be species specific and organism based, because the identity of the threat will be known. This will be the case when evaluating intentional introductions of biological control agents. In other situations, the threat may not be known.

The Global Invasive Species Program (GISP) *Toolkit* (GISP, 2000) recommends examination of pathways as a more comprehensive approach to prevention. The review of pathways of invasive species is also underway by GISP. The IPPC defines pathway as “any means that allows the entry or spread of a pest” (IPPC, 1999a). Despite the importance of this tool, few countries have a clear understanding of what pathways exist for introductions to their territory (GISP, 2000). Mistakes are easily recognized in retrospect, and retrospective analysis is useful in preventing future introductions. The most sophisticated of tools for this purpose is the genetic finger printing to determine the precise origin of an outbreak, for example in Florida with fruit fly outbreaks or with citrus canker disease.

There are many historic cases to demonstrate the importance of pathway analysis. Dutch elm disease was kept out of Ireland since 1929 when the first Act was passed prohibiting the import of elm trees. The disease struck in 1977, however, by means of a pathway regulators had ignored: the shipment of timber from elm trees. For marine, fresh water and coastal ecosystems, the introduction of species from aquarium is a significant pathway. This is generally done by the hobbyist public, but the example of the marine alga *Caulerpa taxifolia* being introduced into the Mediterranean Sea from the Oceanographic Museum in Monaco shows that even professional organizations need their awareness raised. This exotic species has spread from that first introduction in the early 1980s to the coastlines and sea floors of the entire Mediterranean (Meinesz, 1999). Other pathways for aquatic disease have been identified such as bait fish and whole fish imported through trade channels (MacDiarmid, 1994; Jones and Gibson, 1997).

Just as the human disease surveillance of military personnel is generally not integrated into national health networks (ProMed, March 28, 2000), the alien invasive species military might carry to new areas are also not covered by regular inspection programs.

C. Climatic Models

Climatic models for predicting probability of establishment and spread are widely used by regulators. Climate models may include temperature, evapotranspiration, rainfall, latitude and other factors. Worldwide, there are approximately 15,000 to 16,000 databases of meteorological parameters that can be used to define ecoregions of the world. The data is updated every ten years in most cases so that impact of global warming or other trends, including long term drought, will be picked up in this time frame (Dobegsberger *et al.*, 2000).

In addition to climate data, Canada has one of the most accessible and complete databases on soil type. Many other countries have this information, but it is not always easily accessible. Such data can be linked by Geographic Information Systems (GIS) to political units such as countries, states or provinces, or other areas for Risk Management. This data was used in a RA with an epidemiological approach to disease spread, focusing on the climatic conditions in which karnal bunt disease would spread in North America (NAPPO, 2000).

Microclimates may be important to take into account with some species that use burrowing, hibernation or other behavior to avoid the extremes of the prevailing climate. The UK plant health service attempts to include some of these factors and has done projections of Pest Risk Assessments with climate change. (See section on vulnerability of receiving environment.) Other factors including the presence of hosts must accompany any use of climate models. Also the elasticity of a species to adapt to new climates and/or hosts must be considered.

D. COST-BENEFIT ANALYSIS

Cost-Benefit Analysis (CBA) is a useful tool to strengthen the information on various management options presented for Risk Management decisions. This type of analysis is not specifically named in the SPS but is implied and CBA is recommended in country program reviews (Nairn *et al.*, 1996; National Plant Board, 1999; Mumford *et al.*, 2000). Table 3, adapted from the Economic Evaluation of the English Plant Health System, lists advantages and disadvantages of CBA when used for plant health decision making.

One challenge in the application of CBA has been the use of appropriate time lines given the nature of the organism, the rate of introductions, or the longevity of policies and funding. Many governments apply CBA over too short of a time frame (for example using a single year's worst case scenario). Each situation requires reconsideration of the appropriate time frame.

Cost-Benefit Analysis is essential in the implementation approach of the CBD to ascertain a worthwhile benefit to offset the risk of any introduction. The WTO approach is to have the least trade restrictive measures, based on a hopefully pre-determined acceptable level of risk, rather than aiming for a greater benefit than cost. Both approaches encompass CBA for decision making support.

E. TAKING TOOLS FROM OTHER FIELDS

The tools of epidemiology, primarily derived from the human health field, are clearly relevant to the introduction of a living organism, but must be adapted. Estimating the magnitude of risk is seen as one application of macroepidemiological approaches, in this case for animal health (Hueston and Walker, 1993). Statistical tools used for identifying a causal agent for very small numbers of cases, such as cancer clusters, might also be adapted for use with small numbers of a species detected.

Hazard Analysis and Critical Control Point (HACCP), a methodology increasingly used for reducing the risk of threat to human health from food borne illnesses, has some useful concepts for RA for alien invasive species. As the name implies, this process includes identification and analysis of hazards and the identification of critical control points. A control point, in this case to the safety of the food, is a step in a food manufacturing process at which control can be applied to reduce or eliminate a hazard. Further analysis determines which of these steps should be included in a food safety plan as critical control points.

Table 3. Advantages and disadvantages of Cost-Benefit Analysis for plant health decisions on reducing risk

The main advantages of CBA are: • the ability to aggregate impacts from various sources into one monetary measure of net benefits; • providing transparency and resulting accountability of policies; • provision of a consistent framework for data collection; and • identification of gaps and uncertainties in knowledge (Kopp *et al.*, 1997). Applying the method to all major quarantine policies would increase the transparency and robustness of the system and would facilitate the design of consistent and compatible actions between trade partners. However, CBA results in the context of plant health policy are bound to be incomplete and controversial given: • the considerable amount of information required, which can be hard to collect; • scientific uncertainty about the future impacts of pests; • difficulties associated with the monetary evaluation of the benefits of reducing pest risks and damages, which have a component of non-market public goods; and • more broadly focusing on one single criterion, that of efficiency, may be too narrow a means of achieving environmental targets. Taken from Mumford *et al*., 2000.

By focusing efforts to monitor and take preventive actions on these points in a process, the outcome is an acceptable level of risk. The level and nature of the hazards influence the points selected for control measures. The Systems Approach in plant health (IPPC, 1999b and c) has similarities to HACCP and can benefit from the discipline applied to food safety management.

The Microbiological Risk Assessment (MRA) work, mentioned in Section II.1, is providing the link between traditional RA in the field of food safety and HACCP, which is primarily aimed at microbial threats. Improvements in MRA will lead to improvements in Principle 3 of Table 4, the establishment of critical limits (Hogue, 2000). This may apply to assessment of risk to ecosystems from a variety of hazards or threats, or to the hazards posed by a single pathway or alien invasive species

V. Institutional Aspects

A. EXISTING STANDARDS SETTING AND RESOURCE ORGANIZATIONS

This report reiterates what has already been recognized by the Conference of Parties to the CBD. The existing institutions that were selected as standard setting bodies under the WTO/SPS have guidelines on RA that are relevant for the prevention and management decisions on alien invasive species. These organizations are also aware of the limitations of what is already approved by their membership and are actively engaged in expanding their guidelines to more explicitly address ecological concerns, in particular.

It is possible for a single international RA to be developed on food safety issues because the potential impact on humans is the same regardless of their country of residence. The Codex Alimentarius Commission has completed RA on several threats to human health of interest to its members. This has been done through joint programs by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) for more than a decade (WHO, 1987). Countries may use the Codex RA to justify their own policies (even before these RA become the basis for international standards) or adapt them with data on cultural practices unique to their own society, which may alter the level of risk. Most standards to

Table 4. Hazard Analysis and Critical Control Point (HACCP) Principles

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis

Principle 2: Determine the critical control points (CCPs)

Principle 3: Establish critical limits

Principle 4: Establish monitoring procedures

Principle 5: Establish corrective actions

Principle 6: Establish verification procedures

Principle 7: Establish record-keeping and documentation procedures

Source: U. S. Food and Drug Administration/U. S. Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods; Adopted August 14, 1997, accessed 11/00 at: http://vm.cfsan.fda.gov/~comm/nacmcfp.html#princ

date relate to food additives and contaminants, but a new program of FAO/WHO is conducting assessments of microbiological hazards (Codex, 2000; FAO, 2000).

Risk Assessment of alien invasive species must vary with the conditions of the receiving environment. The Secretariats of the IPPC and OIE do not conduct RA. Their member countries do. The IPPC offers and coordinates technical assistance on RA procedures, along with other topics. The OIE has been involved in some emergency program RA, generally to provide support until FAO programs can be put into place. A conference on RA for aquatic animals was organized by OIE to advance the procedures presented in the Aquatic Animal Health Code (OIE, 2000d, e).

Currently there is an externally-funded project called the Global Ballast Water Management Program, or Globallast, that will be providing support in baseline biological surveys and RA with six demonstration ports representing six regions: Dallan, China; Mumbai, India; Kharg Island, Iran; Cape Town, South Africa; Odessa, Ukraine; and Sepitiba, Brazil. The project is designed to support these regional teams to replicate the work throughout their regions. This is a three-year project ending in 2003 (Raaymakers, 2000). A joint national government/private sector effort to calculate risk from ballast is described in Section III.B.1.

Some of the criteria not well covered by current international guidelines or standards are the indirect consequences or injury that may occur from reduction of an ecosystem’s stability or resilience, competition with the species of concern, or indirect socioeconomic consequences. The issue of direct and indirect effects is illustrated in Figure 2 from the plant health perspective. The IPPC has existing or proposed standards covering some of these scenarios but not all of them. Indirect effects are mentioned in the guidelines, but any further information on what they mean is not.

These factors will be difficult but not impossible to measure. Currently few governments have the resources to develop tools for quantifying these issues or the data to utilize in such an exercise. Some of the criteria to be considered when developing more guidance on environmental factors in the context of the international plant health standards on risk analysis were proposed[10]:

Could this species cause:

- 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;
- a change to plant biological diversity in such a way as to result in ecosystem destabilization;
- ecosystem destabilization 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.

Another question not well addressed in existing international guidelines enshrined in binding agreements is the breadth of taxa that are included in the concept of alien invasive species. Ecologist and conservation biologists are developing methods for assessing risks from sources other than terrestrial agriculture and livestock. Yet many of these methods result from extensive research programs that are not practical for regulatory agencies in the current system of governments. Greater coordination is needed between researchers and regulators to create permanent links.

There should be close coordination between members of the existing international organizations that set standards under the WTO/SPS (e.g. the IPPC Member countries working on proposed wording for supplemental standards) and those participating in discussions in the CBD on implementation of the ecosystem approach. This coordination needs to occur both internationally and between the relevant ministries or agencies within each country to support attempts to integrate more detailed guidance on ecological aspects into the procedures for Risk Assessment of alien invasive species.

B. CAPACITY NEEDS ON A NATIONAL LEVEL

The evaluation of capacity in animal health is more institutionalized and harmonized as mentioned above. This approach allows for regular review of a country's status in terms of reporting and surveillance programs for specified animal diseases. Plant health and the responsibilities of each National Plant Protection Organization (NPPO) are discussed in the IPPC (IPPC, 1997). These mirror the CBD in stating the needs for capacity for Risk Assessment and Management of both alien invasive species and products of modern biotechnology.

There is a recent initiative in the IPPC to provide analytical tools for the self-evaluation of phytosanitary capacity by all of the world's NPPOs. At meetings in March and October 2000, an Informal Working Group of ICPM Members developed recommendations for the application of phytosanitary capacity evaluation methods by all IPPC members. A detailed list of over 500 questions for consideration by each country was developed by New Zealand and tested in six pilot countries. This list has been expanded, improved, and translated into Spanish. Further development and application is anticipated based on the high level of interest expressed by countries, in particular developing countries that plan to use the tool as the basis for formulating national strategies for capacity development and technical assistance.

The self-evaluation tool has been used in the South Pacific, South America, Canada and Australia. The evaluation is also being used in relevant Technical Cooperation Programmes of FAO[11]. Funding is being

[10] These recommendations come from a meeting of the Exploratory Open-ended Working Group on GMOs, Biosafety and Invasive Species, under the IPPC, FAO Rome in June 2000. These and other recommendations will be considered for adoption by the entire Interim Commission on Phytosanitary Measures in April 2001 and appear at: http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/PQ/En/Publ/ISPM/ispms.htm

[11] The Technical Cooperation Programme of the FAO is a small, flexible funding mechanism specifically for critical and urgent needs of member countries and is a complement to regular programme activities of the Organization.

sought for the further expansion and improvement of this evaluation tool for other countries. This assessment will be coordinated through the IPPC Secretariat. It will best answer the question on national capacity in anything related to plant health, including alien invasive species. Other branches of the agencies in charge of RA for other taxa of possible alien invasive species could be reviewed in a similar manner.

Australia expanded their internal discussions on improved application of economics for compliance with SPS by calling a meeting of experts in October 2000. This approach provided an international perspective on economics for quarantine decision-making (Anderson and Nielson, 2001).

C. JOINT EFFORTS IN RA

Joint efforts in conducting RA can reduce the demands on individual country staff and improve the quality of data and analysis. The structure of the European Union places final acceptance of RA and Risk Management conclusions at the regional level. The North American Plant Protection Organization has conducted joint RA on species of mutual concern, for example karnal bunt (NAPPO, 2000). This leveraging of country resources makes sense for many types of RA, particularly when the ecological regions can be formed and measures harmonized. There is increasing interest and some initiatives underway to divide Africa into ecological regions for plant health programs, for example.

In response to requests from developing countries, individual governments have supported workshops and training in RA. As mentioned above with Australia, all countries benefit from technical exchanges on new developments in RA. The WTO has worked towards an integrated framework for providing technical assistance among Member countries (WTO, 1997).

Private industry has an important role in preventing introduction of alien invasive species. Over the course of history, many introductions of plants should not have been allowed but were not regulated at the time. More recently RA may be conducted in some situations but not always on those of greatest risk. The landscape and nursery industry is becoming more aware of the need for some screening for invasiveness and are applying this voluntarily in some situations (Reichard, 2000). The seed industry has encouraged development of capacities in testing and screening by government organizations. Presently, the American Seed Trade Association is assisting by funding costs of travel for an initiative between the Governments of China and the USA to conduct RA of potential maize seed trade moving both directions. This joint effort may take advantage of the exhaustive RA carried out by the Government of Australia on the same species (Stevens, J. pers comm).

VI. Gaps and Opportunities

A. DATA

Complete, reliable, and up-to-date data is possibly the biggest problem for RA in any discipline and in particular for alien invasive species. This is because biological baseline data and information on economic impacts is lacking. Creating, maintaining and providing access to this data will take years and require a concerted effort by all nations and relevant organizations.

Even in the most resource-rich countries this is a problem. Disjointed programs may provide data that cannot be used to form a comprehensive picture of the situation. In the USA, a private foundation has recently reviewed the availability of data for biodiversity planning and found sectors such as coastal lacking in adequate data. There was also no uniformity for cross-sector studies (Heinz Foundation, 2000). The OECD continues to coordinate development of harmonized environmental indicators for agriculture in Europe that could guide all countries in standardizing data in that arena (OECD, 1999b).

The majority of materials quoted in this report were accessed either directly from the authors, by personally visiting the location where the RA was performed or the publication was sold, or by Internet. The opportunity for information collection through these means is extremely limited for the majority of professionals who will be conducting RAs.

A few countries are quoted repeatedly in any report of this nature: Australia, New Zealand, the USA, Canada, and increasingly South Africa. These countries are indeed leaders in the development and application of RA procedures and programs addressing alien invasive species. Yet other countries make equally significant contributions to global experience with Risk Assessment. The difference lies in the accessibility of the information from these countries noted above.

The gap in accessibility of information from and by the majority of countries hinders development of representative tools and procedures.

B. WHAT GETS CONSIDERED

With animal health, the primary gap appears to be what gets on the list of notifiable diseases in the first place. Once an animal disease is added to the list, it becomes part of the international reporting system, and becomes a topic for recommended diagnosis techniques and international networks. If a disease is not on the list, however, it may not receive any attention for some time.

In plant health, more guidance and more attention needs to be given to evaluating, capturing and documenting potential economic impacts. More explicit coverage of non-cultivated plants in IPPC standards is needed for more consistent consideration of these resources in national programs. “New” pests that do not fall within the plant health mandate, such as flat worms that are predators of native earthworms, or poisonous spiders, may be left unregulated until global movement of these species pass the point of useful intervention.

Current trade-based systems do not include comprehensive capacities in RA that address many taxa, yet the national agencies responsible are faced with establishing and enforcing legislation against introduction of these species.

C. INSTITUTIONAL MEMORY

Any country where the conditions of employment or quality of life for the technical expert or government official are poor faces the danger of training their human resources into a job with the private sector or even into a different country’s job pool. Other than rectifying the fundamental situation causing this flight of talent, organizations responsible for RA can ameliorate the problem by maintaining excellent documentation of:

- sources of information, methodologies used
- conclusions drawn from these sources (citations for each point made in the RA)
- assumptions made
- areas of uncertainty, the sources of uncertainty
- gaps in information, knowledge expertise, or data

With this, a new employee or policymaker can review a RA and easily see if new information or findings would alter the conclusions, or if new analyses would lead to a different result.

Involving technical experts at all levels of government in national, regional and international exchanges so that each person has his or her own network of peers is another way to prevent disaster from one individual leaving a position.

D. NETWORKS AND PARTNERSHIPS

Numerous partnerships exist within disciplines. There are specific examples of gaps within disciplines as well. The IMO has not linked well with FAO Fisheries or WHO on common concerns. There is no international organization with a clear lead on reducing transfers from the pathway of ship hull fouling (Raaymakers, 2000).

This paper highlights a need for greater coordination on the development of RA tools and procedures and the need for agreement on criteria. Because of the comprehensive coverage of taxa, the CBD is in a unique position to encourage, monitor and disseminate the results from such collaboration.

VII. Implications for Implementation of Article 8(h) and Questions to Consider on the National Level

Article 8(h) states that "Each Contracting Party shall, as far as possible and as appropriate:
Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;"

Risk Assessment alone cannot reflect the level of complexity that exists in the natural world nor answer some of the questions raised in alien invasive species programs (Hogue, 2000). Risk Assessment is an important process to support efforts for preventing the entry and establishment of unwanted alien species. Risk Assessment can also be used to generate recommendations for Risk Management, including for control and eradication programs. The criteria incorporated into the RA process will determine its usefulness in application to non-cultivated ecosystems and for protection of biological diversity.

National authorities exist and are in operation under already existing international standards that cover alien invasive species issue in part. For members of the WTO, these standards are legally binding and the dispute settlement process is available for challenging other countries to comply with these standards, when other forms of negotiation have failed. Some question the rule-based approach of the WTO system, and propose more complex analysis methods. Yet the authors of these same proposals acknowledge the lack of data to support more complex approaches (e.g., Haddock, 2000).

International organizations are already working to refine RA processes by being more explicit regarding environmental factors. The development of a separate RA process or insistence on some alternative methodology with even less guidance available would imply challenges to resource allocation at the national level. Many country officials are feeling confused regarding the relationship of similar or possibly conflicting rights and responsibilities under various international agreements (IPPC, 2000a).

Some questions must be answered at a national level, as well, in order to advance the international discussion on Risk Assessment as a tool for alien invasive species management. These include:

- What does biodiversity mean to our society?
- What specifically do we wish to protect?
- How will we know (using what parameters of measurement) that we have achieved this goal?
- How can we combine objectives of economic improvement under the WTO model with biodiversity protection under the CBD? How will this be reflected in the Risk Assessment approach and criteria we employ?
- What is our priority for long-term compliance with Article 8(h) of the CBD? What is the most urgent short-term threat?
- What capacities and resources exist throughout our government to conduct Risk Assessment of alien invasive species? What capacities are available from universities and the private sector?
- How will we address research needs and adapt tools to the unique situation of our country?
- How can we enhance limited resources for assessing risk? Are there strategic alliances within our region and/or other regions with similar climates and biogeography that we could form? Technical development or information exchange? Regulatory harmonization that would improve the efficiency of our programs?
- How can we best fulfill our responsibilities to other nations on these same issues?

All of these questions are under consideration through the CBD, GISP and other fora. The goal of this paper is to provide information regarding Risk Assessment in its current state for countries to evaluate in the larger framework of prevention and management of alien invasive species. Limits of budget and time restrict this report to an overview of international requirements, rather than a more in-depth analysis or a summary of all relevant regional or country situations. This should not prevent countries from taking these findings under advisement or requesting further research of particular aspects of the subject.

The primary points of this initial report are:

- Factors of both the probability and the potential consequences are included in the concept of risk.

- "*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.
- Clarifying what it is we aim to protect will assist in determining the best criteria for assessing risks from alien invasive species.
- The only international legally binding requirements for Risk Assessment related to alien invasive species are those of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which does not cover all alien invasive species.
- There are no legally binding international requirements for Risk Assessment of alien invasive species as a whole. Risk Assessment is implicitly required under Article 8(h) in order to evaluate the threat to species and ecosystems and to develop Risk Management options.
- Existing and future developments of the Environmental Impact Assessment (EIA) and Risk Assessment processes may be a source of ideas for integrated procedures. This is particularly the case for measuring those potential indirect impacts of alien invasive species such as the alteration of the environmental factors (e.g., the amount of water available to the species of concern).
- It would be useful to conduct a comprehensive review of current examples of Risk Assessment guidelines or procedures in force on a national and regional level. This review should include a comparison of the criteria included, the definitions of these criteria and the manner in which each criteria is measured.
- Similarity of living conditions in the place of origin (either of original origin or just the origin of the shipment) with those in the place of import or introduction often has been used by regulators as an indication that establishment is probable.
- Several countries find it useful to impose a screening process based on potential invasiveness.
- Economics is as important as ecology when assessing the risk from the introduction of an alien invasive species and setting an acceptable level of risk from which to choose and design the best management practices.
- Risk Assessment may fall short of other methodologies in determining any special vulnerability of the receiving environment. This occurs because factors of vulnerability are not included as criteria, not because of an inherent fault of the Risk Assessment approach.
- The gap in accessibility of information from and by the majority of countries hinders development of representative tools and procedures.
- There should be close coordination between members of the existing international organizations that set standards under the WTO/SPS (e.g. the IPPC Member countries working on proposed wording for supplemental standards) and those participating in discussions in the CBD on implementation of the ecosystem approach. This coordination needs to occur both internationally and between the relevant ministries or agencies within each country to support attempts to integrate more detailed guidance on ecological aspects into the procedures for Risk Assessment of alien invasive species.

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APPENDIX I. RISK ASSESSMENT STEPS OUTLINED IN THE INTERNATIONAL ANIMAL HEALTH CODE. VERSION 2000.

Article 1.3.2.4.

Risk assessment steps

1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to «release» (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the «release» of each of the potential hazards (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a) Biological factors
- species, age and breed of animals
- agent predilection sites
- vaccination, testing, treatment and quarantine.

b) Country factors
- incidence/prevalence
- evaluation of *Veterinary Services*, surveillance and control programmes and zoning systems of the *exporting country*.

c) Commodity factors
- quantity of commodity to be imported
- ease of contamination
- effect of processing
- effect of storage and transport.

If the release assessment demonstrates no significant risk, the risk assessment conclude.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the *importing country* to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors
- properties of the agent.

b) Country factors
   - presence of potential vectors
   - human and animal demographics
   - customs and cultural practices
   - geographical and environmental characteristics.

c) Commodity factors
   - quantity of commodity to be imported
   - intended use of the imported animals or products
   - disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. <u>Consequence assessment</u>

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

a) Direct consequences
   - animal infection, disease, and production losses
   - public health consequences.

b) Indirect consequences
   - surveillance and control costs
   - compensation costs
   - potential trade losses
   - adverse consequences to the environment.

4. <u>Risk estimation</u>

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

International Animal Health Code.
Accessed on 08 October 2000, website: www.oie.int

APPENDIX II. PEST RISK ANALYSIS FOR QUARANTINE PESTS – a draft standard of the IPPC

Selection from the:
DRAFT STANDARD FOR COUNTRY CONSULTATION
NOVEMBER 2000 version

INTRODUCTION

SCOPE
The standard provides details for the conduct of pest risk analysis (PRA) to determine if pests are quarantine pests. It describes the integrated processes to be used for risk assessment as well as the selection of risk management options.

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Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
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Requirements for the establishment of pest free areas, 1996. ISPM Pub. No. 4, FAO, Rome.
Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Requirements for the establishment of pest free places of production and pest-free production sites, 1999. ISPM No. 10, FAO, Rome.

DEFINITIONS, ABBREVIATIONS AND ACRONYMS
[Not included in this Appendix, see FAO web page directly for this section.]

OUTLINE OF REQUIREMENTS
The objectives of a PRA are, for a specified area, to identify pests and/or pathways of concern and evaluate their risk, to identify endangered areas, and, if appropriate, to identify risk management options. Pest risk analysis (PRA) for quarantine pests follows a process defined by three stages:

Stage 1 (initiating the process) involves identifying the pest(s) and pathways, which are of concern and should be considered for risk analysis, in relation to the identified PRA area.

Stage 2 (risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment, and spread, and of their potential economic consequences.

Stage 3 (risk management) involves identifying management options for reducing the risks identified at stage 2. These are evaluated for efficacy, feasibility, and impact in order to select those that are appropriate.

PEST RISK ANALYSIS FOR QUARANTINE PESTS

1. Stage 1: Initiation

The aim of the initiation stage is to identify the pest(s) and pathways which are of concern and should be considered for risk analysis in relation to the identified PRA area.

1.1. Initiation Point

The PRA process may be initiated as a result of:

- the identification of a pathway that presents a potential pest hazard
- the identification of a pest that may require phytosanitary measures
- the review or revision of phytosanitary policies and priorities.

1.1.1 PRA initiated by the identification of a pathway

The need for a new or revised PRA on a specific pathway may arise in the following situations:

- international trade is initiated in a commodity not previously imported into the country (usually a plant or plant product, including genetically altered plants) or a commodity from a new area or new country of origin;
- new plant species are imported for selection and scientific research purposes;
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, passenger baggage, etc.).

A list of pests likely to be associated with the pathway (e.g. carried by the commodity) may be generated by any combination of official sources, databases, sciencitific and other literature, or expert consultation. It is preferable to prioritize the listing, based on expert judgement on pest distribution and types of pests. If no potential quarantine pests are identified as likely to follow the pathway, the PRA may stop at this point.

1.1.2 PRA initiated by the identification of a pest

A requirement for a new or revised PRA on a specific pest may arise in the following situations:

- an emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area;
- an emergency arises on interception of a new pest on an imported commodity;
- a new pest risk is identified by scientific research;
- a pest is introduced into an area;
- a pest is reported to be more damaging in an area other than in its area of origin;
- a pest is repeatedly intercepted;
- a request is made to import an organism;
- an organism is identified as a vector for other pests;
- an organism is genetically altered in a way which clearly identifies its potential as a plant pest.

1.1.3 PRA initiated by the review or revision of a policy

A requirement for a new or revised PRA originating from policy concerns will most frequently arise in the following situations:

- a national decision is taken to review phytosanitary regulations, requirements or operations
- a proposal made by another country or by an international organization (RPPO, FAO) is reviewed
- a new treatment or loss of a treatment system, a new process, or a new information impacts on an earlier decision
- a dispute arises on phytosanitary measures
- the phytosanitary situation in a country changes, a new country is created, or political boundaries have changed.

1.2 Identification of PRA Area

The PRA area should be defined as precisely as possible in order to identify the area for which information is needed.

1.3 Information

Information gathering is an essential element of all stages of PRA. It is important at the initiation stage in order to clarify the identity of the pest(s), its/their present distribution and association with host plants, commodities, etc. Other information will be gathered as required to reach necessary decisions as the PRA continues.

Information for PRA may come from a variety of sources. The provision of official information regarding pest status is an obligation under the IPPC (Art. VIII.1c) facilitated by official contact points (Art. VIII.2).

1.3.1 Previous PRA

A check should also be made as to whether pathways, pests or policies have already been subjected to the PRA process, either nationally or internationally. If a PRA exists, its validity should be checked as circumstances and information may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for a new PRA, should also be investigated.

1.4 Conclusion of Initiation

At the end of Stage 1, the initiation point, the pests and pathways of concern and the PRA area will have been identified. Relevant information has been collected and pests have been identified as possible candidates for phytosanitary measures, either individually or in association with a pathway.

2. STAGE 2: PEST RISK ASSESSMENT

The process for pest risk assessment can be broadly divided into three interrelated steps:

- Pest categorization;
- Assessment of the probability of introduction and spread; and the
- Assessment of potential economic consequences (including environmental impacts).

In most cases, these steps will be applied sequentially in a PRA but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances. This standard allows a specific PRA to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination set out in ISPM No. 1, *Principles of plant quarantine as related to international trade* (FAO, 1995).

2.1 Pest Categorization

At the outset, it may not be clear which pest(s) identified in Stage 1 require a PRA. The categorization process examines for each pest whether the defining criteria in the definition for a quarantine pest are satisfied.

In the evaluation of a pathway associated with a commodity, a number of individual PRAs may be necessary for the various pests potentially associated with the pathway. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

An advantage of pest categorization is that it can be done with relatively little information, however information should be sufficient to adequately carry out the categorization.

2.1.1 Elements of categorization

The categorization of a pest as a quarantine pest includes the following primary elements:

- identity of the pest
- presence or absence in the PRA area

- regulatory status
- potential for establishment and spread in PRA area
- potential for economic consequences (including environmental consequences) in the PRA area

2.1.1.1 Identity of pest

The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible.

The taxonomic unit for the pest is generally species. The use of a higher or lower taxonomic level should be supported by scientifically sound rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status.

In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.

2.1.1.2 Presence or absence in PRA area

The pest should be absent from all or a defined part of the PRA area.

2.1.1.3 Regulatory status

If the pest is present but not widely distributed in the PRA area, it should be under official control or expected to be under official control.

2.1.1.4 Potential for establishment and spread in PRA area

Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest and where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area.

2.1.1.5 Potential for economic consequences in PRA area

There should be clear indications that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area.

2.1.2 Conclusion of Pest Categorization

If it has been determined that the pest has the characteristics of a quarantine pest, the PRA process should continue. If a pest does not fulfil all of the criteria for a quarantine pest, the PRA process for that pest may stop. In the absence of sufficient information, the uncertainties should be identified and the PRA process should continue.

2.2 Assessment Of The Probability Of Introduction And Spread

Pest introduction is comprised of both entry and establishment. Assessing the probability of introduction requires an analysis of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. In a PRA initiated by a specific pathway (usually an imported commodity), the probability of pest entry is evaluated for the pathway in question. The probabilities for pest entry associated with other pathways need to be investigated as well.

For risk analyses that have been initiated for a specific pest, with no particular commodity or pathway under consideration, the potential of all probable pathways should be considered.

The assessment of probability of spread is based primarily on biological considerations similar to those for entry and establishment.

2.2.1 Probability of entry of a pest

The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering by one of these pathways.

Documented pathways for the pest to enter new areas should be noted. Potential pathways, which may not currently exist, should be assessed. Pest interception data may provide evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage.

2.2.1.1 Identification of pathways for a PRA initiated by a pest

All relevant pathways should be considered. They can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures.

2.2.1.2 Probability of the pest being associated with the pathway at origin

The probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated. Factors to consider are:

- prevalence of the pest in the source area
- occurrence of the pest in a life-stage that would be associated with commodities, containers, or conveyances
- volume and frequency of movement along the pathway
- seasonal timing
- pest management, cultural and commercial procedures applied at the place of origin (application of plant protection products, handling, culling, roguing, grading).

2.2.1.3 Probability of survival during transport or storage

Example of factors to consider are:

- speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage
- vulnerability of the life-stages during transport or storage
- prevalence of pest likely to be associated with a consignment
- commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage.

2.2.1.4 Probability of pest surviving existing pest management procedures

Existing pest management procedures (including phytosanitary procedures) applied to consignments against other pests from origin to end-use, should be evaluated for effectiveness against the pest in question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

2.2.1.5 Probability of transfer to a suitable host

Factors to consider are:

- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host;

- whether the imported commodity is to be sent to a few or many destination points in the PRA area;
- proximity of entry, transit and destination points to suitable hosts;
- time of year at which import takes place;
- intended use of the commodity (e.g. for planting, processing and consumption).

Some uses are associated with a much higher probability of introduction (e.g. planting) than others (e.g. processing). The probability associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts should also be considered.

2.2.2 Probability of establishment

In order to estimate the probability of establishment of a pest, reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs (taking account also of protected environments) and expert judgement used to assess the probability of establishment. Case histories concerning comparable pests can be considered. Examples of the factors to consider are:

- availability, quantity and distribution of hosts in the PRA area
- environmental suitability in the PRA area
- potential for adaptation of the pest
- reproductive strategy of the pest
- method of pest survival
- cultural practices and control measures.

In considering probability of establishment, it should be noted that a transient pest (see ISPM No. 8, *Determination of pest status in an area*) may not be able to establish in the PRA area (e.g. because of unsuitable climatic conditions) but could still have unacceptable economic consequences (see IPPC Art. VII.3).

2.2.2.1 Availability of suitable hosts, alternate hosts and vectors in the PRA area

The following factors are among those that should be considered:

- whether hosts and alternate hosts are present and how abundant or widely distributed they may be;
- whether hosts and alternate hosts occur within sufficient geographic proximity to allow the pest to complete its life cycle;
- whether there are other plant species, which could prove to be suitable hosts in the absence of the usual host species;
- whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced;
- whether another vector species occurs in the PRA area.

The taxonomic level at which hosts are considered should normally be the "species". The use of higher or lower taxonomic levels should be justified by scientifically sound rationale.

2.2.2.2 Suitability of environment

Factors in the environment (e.g. suitability of climate, soil, pest and host competition) that are critical to the development of the pest, its host and if applicable its vector, and to their ability to survive periods of climatic stress and complete their life cycles, should be identified. It should be noted that the environment is likely to have different effects on the pest, its host and its vector. This needs to be recognized in determining whether the interaction between these organisms in the area of origin is maintained in the PRA area to the benefit or detriment of the pest. The probability of establishment in a protected environment, e.g. in glasshouses should also be considered.

Climatic modelling systems may be used to compare climatic data on the known distribution of a pest with that in the PRA area.

2.2.2.3 Cultural practices and control measures

Where applicable, practices employed during the cultivation/production of the host crops should be compared to determine if there are differences in such practices between the PRA area and the origin of the pest that may influence its ability to establish.

Pest control programs or natural enemies already in the PRA area which reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished. The availability (or lack) of suitable methods for eradication should also be considered.

2.2.2.4 Other characteristics of the pest affecting the probability of establishment

These include:

- reproductive strategy of the pests and method of pest survival. Characteristics, which enable the pest to reproduce effectively in the new environment, such as parthenogenesis/self-crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified.
- genetic adaptability. Whether the species is polymorphic and the degree to which the pest has demonstrated the ability to adapt to conditions like those in the PRA area should be considered, e.g., host-specific races or races adapted to a wider range of habitats or to new hosts. This genotypic (and phenotypic) variability facilitates a pest's ability to withstand environmental fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance.
- minimum population needed for establishment. If possible, the threshold population that is required for establishment should be estimated.

2.2.3 Probability of spread after establishment

A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment and/or eradication are more limited. In order to estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest currently occurs. The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the probability of spread. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

- suitability of the natural and/or managed environment for natural spread of the pest
- presence of natural barriers
- the potential for movement with commodities or conveyances
- intended use of the commodity
- potential vectors of the pest in the PRA area
- potential natural enemies of the pest in the PRA area.

The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

2.2.4 Conclusion on the probability of introduction and spread

The overall probability of introduction should be expressed in terms most suitable for the data, the methods used for analysis, and the intended audience. This may be quantitative or qualitative, since either output is in any case the result of a combination of both quantitative and qualitative information.

The probability of introduction may be expressed as a comparison with that obtained from PRAs on other pests.

2.2.4.1 Conclusion regarding endangered areas

The part of the PRA area where ecological factors favour the establishment of the pest should be identified as appropriate to define the endangered area. This may be the whole of the PRA area or a part of the area.

2.3 Assessment Of Potential Economic Consequences

Requirements described in this step indicate what information relative to the pest and its potential host plants should be assembled, and suggest levels of economic analysis that may be carried out using that information in order to assess all the effects of the pest, i.e. the potential economic consequences. Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data may also be used. Consultation with an economist may be useful.

In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, risk assessment will primarily focus on the probability of introduction and spread. It will, however, be necessary to examine economic factors in greater detail when the level of economic consequences is in question, or when the level of economic consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

2.3.1 Pest effects

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest occurs, naturally or has been introduced. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can usefully be considered. The effects considered may be direct or indirect.

2.3.1.1 Direct pest effects

For identification and characterization of the direct effects of the pest on each potential host in the PRA area, or those effects which are host-specific, the following are examples that could be considered:

- known or potential host plants (in the field, under protected cultivation, or in the wild)
- types, amount and frequency of damage
- crop losses, in yield and quality
- biotic and abiotic factors (climate, adaptability and virulence of the pest) affecting damage and losses
- rate of spread
- rate of reproduction
- control measures (including existing measures), their efficacy and cost
- effect on existing production practices
- environmental effects

For each of the potential hosts, the total area of the crop and area potentially endangered should be estimated in relation to the elements given above.

2.3.1.2 Indirect pest effects

For identification and characterization of the indirect effects of the pest in the PRA area, or those effects that are not host-specific, the following are examples that could be considered:

- effects on domestic and export markets, including in particular effects on export market access. The potential consequences for market access which may result if the pest becomes established, should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by trading partners.

- changes to producer costs or input demands, including control costs
- changes to domestic or foreign consumer demand for a product resulting from quality changes
- environmental and other undesired effects of control measures
- feasibility and cost of eradication or containment
- capacity to act as a vector for other pests
- resources needed for additional research and advice
- social and other effects (e.g. tourism).

2.3.2 Analysis of economic consequences

2.3.2.1 Time and place factors

Estimations made in the previous section related to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences (per year) in the PRA area. In practice, however, economic consequences are expressed with time, and may concern one year, several years or an indeterminate period. Various scenarios should be considered. The total economic consequences over more that one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

Other scenarios could concern whether the pest occurs at one, few or many points in the PRA area and the expression of potential economic consequences will depend on the rate and manner of spread in the PRA area. The rate of spread may be envisaged to be slow or rapid; in some cases, it may be supposed that spread can be prevented. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations will be required.

2.3.2.2 Analysis of commercial consequences

As determined above, most of the direct effects of a pest, and some of the indirect effects will be of a commercial nature, or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified. The following may usefully be considered:

- effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices
- effect of pest-induced changes in quantities demanded or prices paid for commodities by domestic and international consumers. This could include quality changes in products and/or quarantine-related trade restrictions resulting from a pest introduction.

2.3.2.3 Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects of a quarantine pest. These should incorporate all of the effects that have been identified. These techniques may include:

- *partial budgeting*: This will be adequate, if the economic effects induced by the action of the pest to producer profits are generally limited to producers and are considered to be relatively minor.
- *partial equilibrium*: This is recommended if, under point 2.3.2.2, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial

equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers.

- *general equilibrium*: If the economic changes are significant to a national economy, and could cause changes to factors such as wages, interest rates or exchange rates, then general equilibrium analysis could be used to establish the full range of economic effects.

The use of analytical techniques is often limited by lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be provided.

2.3.2.4 Non-commercial and environmental consequences

Some of the direct and indirect effects of a pest determined in 2.3.1.1 and 2.3.1.2 will be of an economic nature, or affect some type of value, but not have an existing market which can be easily identified. As a result, the effects may not be adequately 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.

2.3.3.1 Endangered area

The part of the PRA area where presence of the pest will result in economically important loss should be identified as appropriate. This is needed to define the endangered area.

2.4 Degree of Uncertainty

Estimation of the probability of introduction of pests and of its economic consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest occurs to the hypothetical situation in the PRA area. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

2.5 Conclusion of the Pest Risk Assessment Stage

As a result of the pest risk assessment, all or part of the PRA area may be identified as an endangered area. A quantitative or qualitative estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences (including environmental consequences), have been obtained and documented or an overall rating could have been assigned. These estimates, with associated uncertainties, are utilized in the pest risk management stage of the PRA

3. STAGE 3: PEST RISK MANAGEMENT

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used. Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. Pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options. The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.

3.1 Level of Risk

The principle of "managed risk" (ISPM No. 1) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures". In implementing this principle, countries should decide what level of risk is acceptable to them.

The acceptable level of risk may be expressed in a number of ways, such as:

- reference to existing phytosanitary requirements;
- indexed to estimated economic losses;
- expressed on a scale of risk tolerance;
- compared with the level of risk accepted by other countries.

3.2 Technical Information Required

The decision to be made in the pest risk management process will be based on the information collected during the preceding stages of PRA. This information will be composed of:

- reasons for initiating the process;
- estimation of the probability of introduction to the PRA area;
- evaluation of potential economic consequences in the PRA area.

3.3 Acceptability of Risk

Overall risk is determined by the examination of the outputs of the assessments of the probability of introduction and the economic impact. If the risk is found to be unacceptable, then the first step in risk management is to identify possible phytosanitary measures that will reduce the risk to, or below an acceptable level. Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread). Countries may decide that a low level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

3.4 Identification and Selection of Appropriate Risk Management Options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on the following considerations, which include several of the *Principles of Plant Quarantine as related to International Trade* (ISPM No. 1):

phytosanitary measures shown to be cost-effective and feasible. The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.

- principle of "minimal impact". Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- reassessment of previous requirements. No additional measures should be imposed if existing measures are effective.
- principle of "equivalence". If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- principle of "non-discrimination". If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the risk of introduction with other types of pathways (e.g, packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

The measures listed below are examples of those that are most commonly applied to traded commodities. They are applied to pathways, usually consignments of a host, from a specific origin. The measures should be as precise as possible as to consignment type (hosts, parts of plants) and origin so as not to act as barriers to trade by limiting the import of products where this is not justified. Combinations of two or more measures may be needed in order to reduce the risk to an acceptable level. The available measures can be classified into broad categories which relate to the pest status of the pathway in the country of origin. These include measures:

- applied to the consignment;
- applied to prevent or reduce original infestation in the crop;
- to ensure the area or place of production is free from the pest;
- concerning the prohibition of commodities.

Other options may arise in the PRA area (restrictions on the use of a commodity), control measures, introduction of a biological control agent, eradication, and containment. Such options should also be evaluated and will apply in particular if the pest is already present but not widely distributed in the PRA area.

3.4.1 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a pest or to a specified pest tolerance. Sample size should be adequate to give an acceptable probability of detecting the pest
- prohibition of parts of the host
- a pre-entry or post-entry quarantine system. This could be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available. This system may be the only option for certain pests not detectable on entry
- specified conditions of preparation of the consignment (e.g. handling to prevent infestation or reinfestation)
- specified treatment of the consignment. Such treatments are applied post-harvest and could include chemical, thermal, irradiation or other physical methods
- restrictions on end use, distribution and periods of entry of the commodity.

Measures may also be applied to restrict the import of consignments of pests.

3.4.2 Options preventing or reducing original infestation in the crop

Measures may include:

- treatment of the crop, field, or place of production.
- restriction of the composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species.
- growing plants under specially protected conditions (glasshouse, isolation).
- harvesting of plants at a certain age or a specified time of year.
- production in a certification scheme. An officially monitored plant production scheme usually involves a number of carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

3.4.3 Options ensuring that the area, place or site of production is free from the pest

Measures may include:

- pest-free area. Requirements for pest-free area status are described in *Requirements for the Establishment of Pest Free Areas* (ISPM No. 4).
- pest free place of production or pest-free production site. Requirements are described in *Requirements for the establishment of pest free places of production and pest-free production sites (ISPM No. 10).*

3.4.4 Options for Other Types of Pathways
For many types of pathways, the measures considered above for plants and plant products to detect the pest in the consignment or to prevent infection of the consginment, may also be used or adapted. For certain types of pathways, the following factors should be considered:

- Natural spread of a pest includes movement of the pest by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the pest is entering the PRA area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect. Control measures applied in the area or origin or containment or eradication in the PRA area after entry of the pest could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.

Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestation

3.4.5 Options within the importing country
Certain measures applied within the importing country may also be used. These could include careful surveillance to try and detect the entry of the pest as early as possible, eradication programmes to eliminate any foci of infection and/or containment action to limit spread.

3.4.6 Prohibition of commodities
If no satisfactory measure to reduce risk to an acceptable level can be found, the final option may be to prohibit importation of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

3.5 Phytosanitary Certificates and other Compliance Measures
Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification (see ISPM No. 7). The issuance of phytosanitary certificates (see *Guidelines for Phytosanitary Certificates*) provides official assurance that a consignment is "considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party". It thus confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other compliance measures may be used subject to bilateral or multilateral agreement.

3.6 Conclusion of Pest Risk Management
The result of the pest risk management procedure will be the selection of one or more management options that have been found to lower the risk associated with the pest(s) to an acceptable level. These management options form the basis of phytosanitary regulations or requirements.

The application and maintenance of such regulations is subject to certain obligations, in the case of contracting parties to the IPPC.

3.6.1 Monitoring and review of phytosanitary measures

The principle of "modification" states: "As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary" (ISPM No. 1, *Principles of plant quarantine as related to international trade*).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring during use. This is often achieved by inspection of the commodity on arrival, noting any interceptions or any entries of the pest to the PRA area. The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

4. DOCUMENTATION OF PEST RISK ANALYSIS

4.1 Documentation requirements

The IPPC and the principle of "transparency" (ISPM No. 1) require that countries should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest risk management should be sufficiently documented so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, pest list, pathways, PRA area, endangered area
- sources of information
- categorized pest list
- conclusions of risk assessment
    - probability
    - consequences
- risk management
    - options identified
    - options selected

APPENDIX III. RISK ASSESSMENT STEPS OUTLINED IN THE AQUATIC ANIMAL HEALTH CODE. VERSION 1997 WITH UPDATES INCORPORATED UP TO 2000.

CHAPTER 1.4.2.

GUIDELINES FOR RISK ASSESSMENT

Article 1.4.2.1.

Estimation of the probability of an adverse event

In the risk assessment of an importation, the risk associated with one or more disease agents may have to be considered. The importing country should elaborate the scenarios that could be involved in the introduction of a disease agent in an imported commodity and its subsequent exposure and transmission to aquatic animals and humans.

In constructing a scenario by which a disease agent might be introduced into the importing country, some or all of the following factors (and other factors) need to be considered:

1. the probability of the disease agent being present in aquatic animal populations in the water of origin;
2. the probability of the disease agent being present in the particular aquatic organism;
3. the risk of flesh becoming contaminated during processing;
4. the probability of the disease agent being present in the particular tissues imported;
5. the probability of infected or contaminated aquatic animals, gametes, embryos or product passing diagnostic screening, inspection or grading procedures;
6. the probability of the disease agent surviving at an infectious dose during processing, transport or storage of the aquatic animals, gametes, embryos or products under consideration;
7. the probability of the disease agent coming into contact with susceptible hosts in the importing country at a suitable dose and by a suitable route to cause infection;
8. the risk of disease spreading from the index case and establishing in host populations in the importing country;
9. risk mitigation by optimising detection of pathogens and minimising their likelihood of survival (see Risk reduction factors).

Each scenario would comprise a set of factors that should be identified for the estimation of the likelihood of some risk. In these guidelines, the factors are loosely grouped into four categories, namely country factors, commodity factors, exposure factors and risk reduction factors. Depending on the commodity and the disease agent, any number of these factors may be used to estimate the probability of an adverse event for the importing country. Point estimates or probability distributions are employed to represent the values associated with each factor.

The number of aquatic animal import units being imported significantly influences the risk assessment. The aquatic animals for import must be fully described and aquatic animal products may be further described as to processing times, temperature, pH and storage conditions.

Article 1.4.2.2.

Country factors

Country factors principally reflect the prevalence of the disease agent in the aquatic population of the exporting country. The aquatic population represents the origin or parent population of the commodity. This population must be defined as it may comprise all aquatic animals in aquaculture establishments and/or wild aquatic animals within the exporting country or some sub-population therein. The latter may include aquatic animals in a particular body of water or other geographically defined area.

In the absence of quantitative data, a prevalence may be assigned to the occurrence of diseases notifiable to the OIE and other significant diseases as reported to the OIE in the categories of exceptional, low sporadic, enzootic and high. Where the data are uncertain, it is essential that the risk analysis be made as transparent as possible and all assumptions made explicit. Assumptions must be supported with available scientific information on the prevalence of the disease agent in aquatic animal populations. An evaluation of the Competent Authority of the exporting country will be necessary when considering the other country factors.

Other country factors include:
- level of surveillance and monitoring
- disease zoning
- degree of contact between farmed and wild aquatic animals and vice versa
- import controls on aquatic animals and aquatic animal products.

Commodity factors
The commodity factors are parameters specific to a particular commodity that affect the probability of disease agent presence and survival in the commodity at the time of entry into the importing country.

Some of the following factors may be involved:
- species and life-stage of aquatic animal
- water source where reared
- water salinity and temperature in the period prior to export
- disease agent predilection sites
- ease of disease agent contamination
- pH
- temperature and duration of heat processing
- temperature and duration of freezing
- other processing procedures
- temperature and duration of storage
- transit temperature and duration
- additives and treatments.

The scientific literature on agent isolation and disease transmission should be the source of information for these determinants of disease agent presence and survival. The species determinant is evaluated on the basis of information on the hosts of the disease agent. Where the literature is deficient, the available information may be supplemented by specific studies.

Exposure factors
Exposure factors are parameters specific to the use and distribution of the commodity in the importing country that affect the probability that susceptible host species will be exposed and infected with a disease agent. Exposure of a particular infected commodity to aquatic animals and humans in such a way as to result in infection of one or more species may depend on a number of factors including:
- nature of the disease agent
- intended commodity use and distribution
- calendar period of importation
- distribution of the primary, secondary and intermediate hosts of the disease agent
- nature of the commodity
- mode of transmission of the disease
- customs and cultural practices
- aquatic animal health legislation and compliance
- disposal practices for unused commodity or contaminated material.

Risk reduction factors
For many aquatic organisms there is a dearth of information relating to the prevalence of disease in the source population and available diagnostic tests may be of
limited use. In such cases, the analysis must pay particular attention to factors that reduce risks. Risk reduction factors are parameters specific to measures that are
applied to reduce the probability that a disease agent will be introduced into the importing country, exposed to and/or transmitted to an aquatic or human population.

Options that exist to reduce risk associated with a particular importation include:

- choice of the origin of the commodity
- restricting the destination
- pre- and post-shipment quarantine
- diagnostic testing
- vaccination
- processing, maturation and storage for a specified time and temperature
- treatments, e.g. heat treatment for a specified time and temperature, use of antibiotics and chemotherapeutics, disinfection procedures,
- manipulation of salinity or pH, etc.
- limiting the size and the frequency of importation.

When a series of risk-reducing measures is applied to an importation, it may be possible to demonstrate that the extent to which risk is reduced is sufficiently great that an accurate estimate of the initial unrestricted risk is unnecessary.

Specific risk reduction methods for particular diseases are described in each chapter of the Code. If information on the probability of the presence or survival of a particular disease agent following application of a risk reduction option is not available, documented experience is an acceptable source of information.

Article 1.4.2.3.

Consequences
The adverse consequences affecting aquatic animal health, human health, aquatic ecology and ecosystems and the environment must be described and quantified. The scope of the adverse effects to wild populations could entail a whole range from minor to irreversible alteration to the aquatic environment and ecology.

APPENDIX IV. RISK ASSESSMENT GUIDELINES IN THE BIOSAFETY PROTOCOL

Cartagena Protocol on Biosafety:

Annex III
RISK ASSESSMENT
Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

APPENDIX V. GUIDANCE AND REQUIREMENTS FOR RISK ASSESSMENT IN THE SPS AGREEMENT OF THE WTO

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES (the SPS Agreement of the WTO)

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 co-operate 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.[12]

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.

[12] 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.

Appendix VI. Abbreviations and Acronyms

APHIS	Animal and Plant Health Inspection Service
AQIS	Australian Quarantine and Inspection Service
CABI	CAB International (CABI Bioscience is a division of CABI)
CBA	Cost-Benefit Analysis
CBD	Convention on Biological Diversity
CCPs	Critical control points
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
EIA	Environmental Impact Assessment
EC	European Commission
EPPO	European and Mediterranean Plant Protection Organisation
FAO	Food and Agriculture Organization
GIS	Geographic Information Systems
GISP	Global Invasive Species Program (see CABI, IUCN, SCOPE and UNEP)
GMO	Genetically modified organism
HACCP	Hazard analysis and critical control point
IMO	International Maritime Organization
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures (IPPC)
IUCN	International Union for the Conservation of Nature
LMO	Living Modified Organism
MRA	Microbiological Risk Assessment
NAPPO	North American Plant Protection Organization
NPPO	National Plant Protection Organization
OIE	Office of International Epizootics
PRA	Pest Risk Analysis
RA	Risk Assessment; in other papers this may refer to Risk Analysis. To avoid confusion, Risk Analysis is spelled out any time it is used in this document.
RPPO	Regional Plant Protection Organization
SCOPE	Scientific Committee on Problems of the Environment
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UK	United Kingdom
UNEP	United Nations Environment Programme
US	United States
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization