

# PART 3

## AN OVERVIEW AND FRAMEWORK MANUAL FOR BIOSECURITY RISK ANALYSIS

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# INTRODUCTION

This manual presents a generic framework to structure and guide the application of risk analysis principles in biosecurity at the national level. It explores the processes and methods that are common to cross-sectoral biosecurity risk analysis and develops the position that coordinated action across sectors will inevitably result in improved outcomes and efficiencies. In this way, Part 3 gives effect to the recommendation of the FAO/WHO Technical Consultation on Biological Risk Management in Food and Agriculture (2003) that a more collaborative approach to risk analysis is an essential ingredient of a harmonized and integrated approach to biosecurity.

The manual is not intended to provide a rigid framework for application of risk analysis in different biosecurity settings at the national level, nor does it replicate detailed information on risk assessment that is widely available elsewhere. Rather, it focuses on those principles and guidelines that are “horizontal” in nature and advocates for their application in the development and implementation of a more harmonized and integrated approach to biosecurity at the national level.

It should be noted that principles and guidelines for risk analysis in different international biosecurity bodies were developed (and still are being developed) according to different contexts, timelines and standard-setting experiences. Hence there are significant differences in step-by-step terminology and processes but there are also strong underlying commonalities. The manual draws on these commonalities to work towards a common understanding of biosecurity risk analysis that will be useful at the national level. Differences in terminology and processes will inevitably remain between biosecurity sectors at the international level (e.g. what steps are entailed in “risk management”). However, national governments, especially in transitional and developing countries, will be able to utilize a common cross-sectoral understanding to improve their biosecurity, especially where resources are scarce.

## BIOSECURITY RISK ANALYSIS

The strategic and integrated approach to biosecurity that has been presented in Parts 1 and 2 draws heavily

on the discipline of risk analysis and this has its contemporary roots in the emerging global climate of “free trade” based on removal of barriers constituting unjustified protection of domestic economic advantage. Along with freeing up trade in the context of human, animal and plant protection, the global biosecurity community is increasingly sensitive to associated protection of the environment and conserving biodiversity as holistic goals.

This introductory chapter to the manual presents a brief narrative on biosecurity risk analysis as applied in different sectors and its potential role as a unifying discipline across biosecurity sectors, especially at the national level. As developed in Parts 1 and 2, the chapter reiterates the increasing application of risk analysis by international standard-setting organizations and bodies, as well as by national governments. It develops the position that coordinated action across sectors will inevitably result in improved biosecurity outcomes at the national level. Examples of the interdependence of biosecurity sectors in achieving shared goals are provided and the generic gains that can be expected from a harmonized and integrated approach to biosecurity are summarized.

## RISK ANALYSIS PROCESSES

Risk analysis processes are at the heart of contemporary approaches to biosecurity. International standard-setting organizations and bodies involved with human, animal and plant health and associated protection of the environment have embraced risk assessment as an essential tool to achieve their goals and competent authorities operating at the national level are bound by recent international agreements and instruments to similarly utilize risk assessment. Non-government stakeholder interest is fuelled by technological advances in detection of hazards that constitute potential threats, issues of transparency and equity in the establishment and implementation of biosecurity standards, and the unresolved scientific debate that often surrounds the ability of very low levels of hazards to cause adverse health and/or environmental impacts.

While developing the scientific capability to assess risks, competent authorities (and other stakeholders)

must properly employ other aspects of risk analysis (i.e. risk management and risk communication) if they are to effectively protect human, animal and plant health, and the environment. Risk management incorporates different processes to risk assessment, with the merging of science, policies and values often creating significant challenges for government. Effective risk communication relies on different processes again (e.g. appropriate participation of all stakeholders, including members of the public is a key aspect). Importantly, competent authorities must increasingly operate in a “seamless” domestic and import/export biosecurity environment when applying risk analysis to regulatory activities.

## CHANGES IN APPROACH TO BIOSECURITY AT THE NATIONAL LEVEL

**RISK ANALYSIS AS A VEHICLE THAT ENHANCES CROSS-SECTORAL BIOSECURITY ACTIVITIES**  
As described in Part 1, the emergence of risk analysis as a unifying discipline in biosecurity underpins many of the changes in approach that are happening at the national level (Box 3.1). There is great potential for risk

**Box 3.1.** Risk analysis as a discipline that enhances cross-sectoral biosecurity activities

- Risk analysis principles and frameworks have commonality across sectors.
- Risk analysis is an essential means to underpin a national biosecurity strategy.
- A risk analysis approach is essential to address some cross-sectoral biosecurity concerns (e.g. microbial resistance to antibiotics).
- Risk analysis skills can be shared between sectors to strengthen technical capability and capacity.
- Risk assessment facilitates cross-sectoral ranking and prioritization of national issues for risk management.
- Risk assessment is the primary methodology adopted by international organizations for standard-setting.
- Risk assessment modelling facilitates development and use of new and innovative control measures.
- Risk assessment methodology facilitates benefit cost analysis in case of competing priorities and/or lack of resources.
- Application of risk management frameworks foster consistency in decision-making across all jurisdictions of a competent authority(s).
- Risk communication processes provide a means to involve stakeholders in multiple biosecurity sectors

analysis to act as a vehicle to forge strong links between biosecurity sectors and embed integrated risk-based goals in national biosecurity strategies. Integration of risk analysis approaches and resources will also help in ensuring public confidence in overarching regulatory frameworks and assist in optimization of scarce biosecurity resources.

It should be recognized that effective application of risk analysis in biosecurity is fully dependent on an appropriate legislative base, infrastructure and regulatory system, as well as equitable stakeholder engagement. Risk analysis capability also is a key component of biosecurity capacity as indicated in Parts 1 and 2.

## PERFORMANCE OF THE COMPETENT AUTHORITY

With legal, structural and administrative changes to competent authorities, there is increasing interest in tracking the actual achievement of biosecurity goals. Risk analysis provides an important basis for evaluating the ongoing performance of a competent authority. Performance indicators measuring the actual health and life<sup>24</sup> outcomes required (e.g. expressed reduction in health risks over a particular time period) provide the “ultimate” measure of biosecurity performance. However, measuring such outcomes is often difficult in practice. Performance indicators measuring “intermediate outcomes” can provide an effective surrogate where risk analysis has established a sufficient link between the “intermediate outcomes” and the actual health and life outcomes required. Where this is impractical, measuring “direct outputs” may provide some indication of required performance but risk analysis is unlikely to establish a strong, quantified link between this third tier and actual health and life outcomes.

In the real world, it is likely that the performance of a competent authority will be best assessed using a combination of all three types of indicators (Box 3.2). Other aspects of performance may also be monitored on a periodic basis (e.g. decreasing compliance costs

<sup>24</sup> For the purposes of this manual, “life” is used as a generic term to cover impacts of biosecurity activities that are not easily categorized as health impacts. These can be diverse and often remain unquantified (e.g. in servicing the CBD, the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA) has noted that current means to determine the “value” of biological diversity and its components are inadequate). In ecological risk assessment, stakeholder involvement is essential to identifying and prioritizing valued ecological attributes so that appropriate risk assessment can proceed.

### Box 3.2. Measuring the performance of competent authorities

Measurement of “*ultimate outcomes*” (i.e. actual impacts on health and life caused by a prioritized list of hazards<sup>25</sup>) provide the most direct indicators of the performance of a competent authority.

Measurement of “*intermediate outcomes*” (e.g. level of reduction in priority hazards at particular steps in exposure pathways, level of uptake of a voluntary risk management option by industry during primary production) can be a sufficient indicator of performance if risk analysis has established a strong link to actual impacts on health and life.

Measurement of “*direct outputs*” that result from biosecurity activities (e.g. availability of new standards, level of industry compliance with a standard) are generally weakly linked by risk analysis to actual health and life impacts and therefore are only partial indicators of performance

for industry, improving the business efficiency of the competent authority, increasing technical capacity, providing regulatory flexibility and supporting technical innovation).

### IMPACT OF INTERNATIONAL FRAMEWORK ON BIOSECURITY RISK ANALYSIS

International legal instruments and agreements, particularly the SPS Agreement, the CBD and the Cartagena Protocol on Biosafety, and standard-setting organizations and bodies like the CAC, the OIE and the IPPC, have played a pivotal role in the progression to widespread application of risk analysis at the national level as elaborated in Part 1. The following sections describe the influence of some of the most relevant ones on biosecurity risk analysis. Agreements, organizations and bodies associated with biosecurity are presented in Annex 3.

#### WTO SPS AGREEMENT

The WTO SPS Agreement has played a fundamental role in promoting the use of risk analysis. A primary tenet of this Agreement is that SPS measures are to be

<sup>25</sup> The term “hazard” is used throughout this manual to cover all biosecurity sector descriptions of potential threats to health and life. In the case of environmental risk assessment, “stressors” such as climate change and natural disasters may be added to the impact of hazards such as invasive alien species.

### Box 3.3. Key provisions of the WTO SPS Agreement relating to risk analysis in biosecurity

- Provides a legal framework covering all sanitary and phytosanitary control measures which may directly or indirectly affect international trade.
- Requires that control measures be justified on the basis of science and risk assessment.<sup>26</sup>
- Decisions on acceptable levels of risk / appropriate levels of protection (ALOP) should be consistent and arbitrary decisions which result in unjustified restrictions avoided.
- Alternative control measures that deliver the same level of protection should be judged as equivalent.
- Countries should harmonize their biosecurity standards with those of international organizations to the greatest extent practicable

based on scientific evidence as elaborated through a risk assessment (see Box 3.3). The Agreement states that “Members shall ensure that their sanitary and 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”. Importantly, the legal framework established by the WTO also contains provision for legal recourse where Members encounter biosecurity restrictions on their trade which are not scientifically justified. Jurisprudence in this area has underlined the importance of getting right the risk assessments on which biosecurity measures are based.

The SPS Agreement has been successful in establishing a solid framework for establishing legitimate health protection barriers among countries. However, it has become apparent that countries lacking the resources to conduct risk assessments, carry out epidemiological surveillance and implement credible inspection and certification programmes have a decided trade disadvantage in terms of exploiting the provisions of this agreement.

#### CONVENTION ON BIOLOGICAL DIVERSITY

Biological diversity is closely linked to human interests. The CBD covers biodiversity protection and sustainable use of biological resources relative to the introduction and safe management of invasive alien

<sup>26</sup> In some circumstances, provisional controls that are not based on risk assessment can be implemented.

species and genotypes that threaten ecosystems, habitats or species. As with the WTO SPS Agreement, the CBD urges competent authorities to implement measures based on risk assessment. However, international agreement on methodologies remains a challenge. The provisions of the CBD are also having an increasing influence on managing and controlling the risks associated with the use and release of LMOs resulting from biotechnology.

#### **CARTAGENA PROTOCOL ON BIOSAFETY**

This Protocol to the CBD covers the safe transboundary movement, handling and use of LMOs that may have an adverse effect on biodiversity (including consideration of any risks to human health). The Protocol focuses primarily on LMOs intended to be introduced into the environment and that are capable of transferring or replicating genetic material (e.g. seeds, live animals and microorganisms). It also contains provisions for LMOs intended for use as food, animal feed or processing but only covers GM foods that meet the definition of an LMO. Risk assessment is a key discipline contributing to risk management of LMOs and their products but specific methodologies are still under development. As the primary focus of the Protocol is on biodiversity, guidelines for consideration of human health issues are very limited.

#### **INTERNATIONAL STANDARD-SETTING BODIES**

The WTO SPS Agreement recognizes the CAC, OIE and IPPC as the relevant international standard-setting organizations for health and life aspects of food safety, animal health and zoonoses, and plant health respectively. These organizations are actively developing principles and guidelines for application of risk analysis within their biosecurity sectors.

International standards for biosecurity are an important resource for countries that do not have the means to develop all of their own standards, especially where risk assessment is concerned. This is an important incentive for countries to fully participate in the activities of international standard-setting bodies and appropriately represent their interests. Availability of international standards also reduces the costs of doing business (e.g. risk of fraud and the costs of finding reliable trading partners) and is a pre-requisite for the operation of a well-functioning market. If standards are harmonized between countries, they

naturally facilitate trade (international and domestic) and trade itself is generally judged to promote economic development.

The scope of application of the IPPC is broad enough to include LMOs and their products (GMOs) that may directly or indirectly damage plants. As the mandate also covers wild plants and risks to the environment, IPPC also has guidelines for risk analysis relating to environmental risks (i.e. specific guidance on hazards (pests) that primarily affect other organisms, thereby causing deleterious effects on plants or plant health in ecosystems). While the role of the IPPC in relation to the CBD has recently been clarified, there are conceptual differences between pest risk analyses (PRAs) for LMOs compared with those for the environment.

Scientific activities associated with the CBD are supported by the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA). This Body has noted that it is unlikely that any one risk assessment method will ever be optimal and current means to determine the “value” of biological diversity and its components are inadequate.

#### **INTERPLAY BETWEEN BIOSECURITY SECTORS**

##### **HAZARDS CONFINED TO A BIOSECURITY SECTOR**

There are many examples where the direct adverse impact of hazards may be confined to a biosecurity sector but other impacts (e.g. economic, social and environmental) are expressed in multiple sectors. Foot and mouth disease (FMD) in animals provides a case study. The most recent outbreak in the United Kingdom occurred in 2001 and 2002. While the hazard itself does not cross biosecurity sector boundaries, the direct cost of the epidemic to the country in terms of losses to agriculture and the food chain has been estimated at 3.1 billion Pounds Sterling. Indirect costs to businesses (e.g. tourism) have been estimated to be a similar amount. Significant social losses (e.g. impact on rural communities), animal welfare issues (e.g. enforced movement restrictions and large numbers of animals awaiting slaughter) and environmental degradation from disposal of carcasses were other impacts. FMD virus can spread via a number of exposure pathways in addition to animal-to-animal transmission and a significant trade in illegal import of meat for

### Box 3.4. Examples of the interplay between biosecurity sectors

BSE in Canada is an example of an animal health problem that has had a significant non-health impact in other biosecurity sectors. Following the detection of a single case in a beef animal in Canada in 2003, impacts on different biosecurity sectors were profound.<sup>27</sup> In the animal health sector, highly significant financial, economic and social impacts on rural industries and communities were driven by perceived risks of presence and spread of the agent of BSE in the national bovine population. These impacts predominantly resulted from imposition of severe trading restrictions (on live animals and animal products) by importing countries, extensive loss of healthy livestock as a precautionary measure, sale of culled dairy cows into a depressed market, and ongoing loss of competitive market advantage due to costs of demonstrating "freedom". In the public health sector, extensive slaughter of healthy livestock as a precautionary measure resulted in changes in the food supply. Adverse consumer perceptions and animal welfare issues associated with farm disposal / potential mistreatment of surplus animals reduced demand for Canadian beef even though no human cases have been detected. Effective risk communication became a critical element in negating strong perceptions of human health risk. Disposal of stock also had environmental sector impacts that required management and there were spill-over economic impacts on the plant sector in terms of the animal feed industry. Wider Canadian society bore the cost of the financial compensation programme.

BSE in the United Kingdom is an example of an animal health problem that has had significant health and other impacts in multiple sectors. Many thousands of cattle were infected, either clinically or sub-clinically, over the period of

an epidemic that began in the mid-1980s. Highly significant impacts were experienced in all biosecurity sectors. In addition to destruction of clinically-affected animals and their cohorts, ongoing surveillance programmes imposed high costs and a carcass disposal burden. The emergence of variant Creutzfeldt-Jakob disease in people in the United Kingdom was a dramatic cross-sectoral consequence of the BSE agent in cattle. Epidemiological studies established consumption of bovine nervous tissue as the transmission pathway. This resulted in marked changes to the animal feed industry which flowed through to the global feed trade. The absence of a nationally-coordinated cross-sectoral management strategy in the early stages of the epidemic in cattle, including risk communication, hampered risk management. Huge financial impacts from lost international trade are still being felt.

Achieving safe and affordable food is an example of a biosecurity goal that depends on gains from effective risk management flowing between multiple biosecurity sectors. Where sector contributions are effective and appropriate, there will be efficient and sustainable production of affordable food to the benefit of stakeholders in all sectors (e.g. biodiversity confers health by providing a varied food supply, safeguarding against climatic and pestilent disasters which may affect one or more food sources, acting as a buffer to the spread of invasive plants and animals, and providing a source of medicinal material). Where sector contributions are ineffective, there may be significant adverse impacts, not only in terms of food safety and affordability, but also in terms of within-sector animal health, plant health and protection of the environment ■

human consumption illustrates the need for cross-sectoral strategies for prevention and control.<sup>28</sup>

#### HAZARDS INVOLVING

#### TWO OR MORE BIOSECURITY SECTORS

There also are many examples of the flow of hazards across biosecurity sectors that can result in adverse impacts in multiple sectors. Pandemic avian influenza is now accepted as a non-eradicable zoonosis that can have dramatic health, economic and social impacts. Further, adverse effects on the environment may be expressed through loss of native bird species. However, it is possible to recognize incipient pandemics through virus surveillance of poultry and respond accordingly. Along with effective emergency

preparedness and response (e.g. landfills ready for bird carcasses, ability to test for leachates), public awareness and education can do much to minimize cross-sectoral impacts.

#### SHARED BIOSECURITY GOALS

A third scenario is the improvement in biosecurity outcomes as a whole where risk management gains are made in separate sectors and these gains achieve a common biosecurity goal. Ensuring biodiversity and the use of pesticides according to integrated pest management practices<sup>29</sup> are examples of inputs in different sectors that contribute to the shared goal of safe and affordable food as discussed above.

#### MANAGING CROSS-SECTORAL ASPECTS OF BIOSECURITY

Effective management of cross-sectoral aspects of biosecurity obviously requires a coordinated approach,

<sup>27</sup> Canadian Animal Health Coalition. 2003. *Economic Implications of BSE in Canada, 2003. Final Report*. Calgary. November, 2003.

<sup>28</sup> Hartnett, E., Adkin, A., Seaman, M., Cooper, J., Watson, E., Coburn, H., England, T., Marooney, C., Cox, A. and Wooldridge, M. 2007. A quantitative assessment of the risks from illegally imported meat contaminated with foot and mouth disease virus to Great Britain. *Risk Analysis* 27 (1):187-201.

<sup>29</sup> Way, M. and van Emden, H. 2000. Integrated pest management in practice – pathways towards successful application. *Crop Protection* 19: 81-90.

**Figure 3.1. Safe and affordable food:**  
An example of the interplay between biosecurity sectors in achieving a common goal



whether in proactive mode (e.g. biosecurity strategies to achieve national gains) or reactive mode (e.g. emergency response to a disease incursion). National biosecurity strategies may be led by government (see Annexes 4 and 5) or government/industry consortiums (e.g. the Canadian Animal Health Coalition is a group of government and industry leaders that is committed to strategies and partnerships that will strengthen Canada's animal health system and have a positive impact on the Canadian economy, livestock trade, food safety, animal care and international market access). Emergency response is led by government but this is also a collective responsibility that requires partnerships between central government, competent authorities across all biosecurity sectors, industry and the general public. Policy documents

detailing joint roles and responsibilities in emergency situations are an essential requirement. Specific examples of the interplay between biosecurity sectors are given in Box 3.4.

#### ACHIEVING SAFE AND AFFORDABLE FOOD: AN EXAMPLE OF A CROSS-SECTORAL BIOSECURITY GOAL

The benefits of a cross-sectoral approach to biosecurity are well illustrated in the case of food safety. Vast amounts of food are traded every day and governments and international standard-setting organizations have a high level of involvement in protecting the interests of all stakeholders in an equitable manner. Consumers as the bearers of risk are vociferous in their demands for more stringent food

safety control measures whereas the food industry (as a significant part of the commercial base of most countries) often has legitimate benefit-cost concerns in implementing those measures.

Balancing the importance of protection of health and life in all biosecurity sectors while fostering a competitive and sustainable food sector is a holistic biosecurity challenge.<sup>30</sup> The interdependence of biosecurity sectors in achieving the shared goal of safe and affordable food is illustrated in Figure 3.1. Where biosecurity sector contributions are effective and appropriate, there will be efficient and sustainable production of affordable food to the benefit

of stakeholders in all sectors. In these cases, farming will also support a diverse rural community that contributes to national social goals and plays an important role in maintaining the environment in a healthy state.

Increased recognition of the potential for wide-scale food-borne threats to public health from acts of terrorism enacted in any biosecurity sector is a further consideration. Competent authorities need new tools such as “vulnerability assessments” to develop strategies to prevent, reduce or eliminate intentional contamination at the most vulnerable points in the food chain.

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<sup>30</sup> In this context, it is important to note that many of the factors that drive disease emergence need to be considered against a backdrop of intensification of agricultural food production on a global scale.

# RISK ANALYSIS: SCIENCE, POLICY AND VALUES

Many aspects of biosecurity risk analysis are generic in nature and general principles can be readily formulated from those independently developed by different international standard-setting bodies and organizations. It is widely recognized that risk analysis encompasses three main components (risk assessment, risk management and risk communication), which must be applied within an established policy and organizational context. A risk analysis approach will only be successful if adequate biosecurity infrastructure and operations are in place and regulations are adequately enforced.

Risk assessment involves a scientific process to estimate risks to health and life that may be associated with a particular food, animal, plant, specific organism or environmental scenario. Prevention, reduction or elimination of those risks by risk management actions can take many forms. Both risk assessment and risk management should be wrapped in a “sea of communication” that includes all stakeholders as appropriate, and facilitates the iterative and ongoing nature of risk analysis.

A risk-based approach to biosecurity requires a pre-eminent role for science. Prior to the enactment of the WTO SPS Agreement, traditional biosecurity systems were not necessarily based on robust and transparent scientific inputs to standard-setting processes, especially in terms of risk assessment. The importance of “good” science<sup>31</sup> to modern biosecurity systems cannot be overemphasized and this places considerable technical demands on international standard-setting organizations and national competent authorities.

While good science is essential to risk assessment, risk management incorporates considerably different processes. Core decisions involve balancing scientific findings against questions of health and life expectations, likely economic, political and social impacts, and technical feasibility and cost-effectiveness of potential control measures. Merging of

policies and values with science in risk management presents considerable challenges and has different expression in different countries.

This chapter presents general aspects of biosecurity risk analysis. Although each biosecurity sector has developed a different history and usage of risk analysis, many aspects are common to all sectors and there is a clear incentive to identify commonalities and introduce the possibility of harmonizing approaches wherever possible and practical.<sup>32</sup> The objective is not only to align terminologies and processes to the extent practical, but also to use this alignment to promote cross-sectoral activities and enhance the achievement of shared biosecurity goals at the national level.

## THE ROLE OF COMPETENT AUTHORITIES

### PREREQUISITES FOR RISK ANALYSIS IN BIOSECURITY

Risk analysis cannot be undertaken in a vacuum. At the international level, the legal framework, infrastructure, organizational aspects and scientific capability are well established and are supported by government membership of standard-setting organizations such as the CAC, OIE and IPPC. At the national level, effective operation of biosecurity systems and programmes are prerequisites to the application of risk analysis. This should include a policy and legislative base that is efficient and dynamic, productive engagement with stakeholders other than government, and the ability to develop and implement appropriate standards (Box 3.5).

General aspects of infrastructure and operational requirements for an adequately-functioning biosecurity system are described in Parts 1 and 2. A key aspect is the operation of national inspection and audit systems in which infringements are subject to penalties and measures that are effective, proportionate and dissuasive.

<sup>31</sup> “Good” science is considered to be: objective and unbiased, appropriate to the context of the issue under consideration, comprehensive in terms of the scope of the issue, quantitative to the extent possible and practical, adequate to meet the test for sufficiency of scientific evidence, and inclusive of a description of uncertainty in analytical results where appropriate.

<sup>32</sup> Because of the current diversity in biosecurity risk analysis terminology, this manual utilizes international standard-setting organizations as the main source for developing cross-sectoral terms.

### Box 3.5. Prerequisites for effective risk analysis in biosecurity

#### International level

- International legal instruments
- Intergovernmental organizations
- Risk analysis policy
- Scientific capability
- Development of standards and guidelines
- Monitoring and surveillance using international reporting systems
- Information servicing

#### National level

- Policy and legislation
- National biosecurity strategy
- Infrastructure
- Scientific and research capability
- Development of standards and guidelines
- Implementation of standards
- Verification, audit and enforcement
- Emergency preparedness and response
- Monitoring and surveillance
- Certification
- Performance measurement
- Communication systems
- Training

jurisdictions to support cross-sectoral economic, social and environmental sustainability. Regulatory and non-regulatory actions to achieve sustainability goals should be coordinated across sectors and risk analysis is a key discipline in this respect. Regulatory aspects of a national biosecurity strategy will inevitably draw on opportunities and obligations inherent to international agreements and other legal instruments (see Annex 3).

A change in regulatory culture is an important part of the transition to a national biosecurity environment founded on science and risk assessment. The potential gains from applying a risk analysis approach will only be realized if there is an overall political, regulatory, industrial and social environment that values and supports this approach. Establishing this type of culture requires considerable efforts by international standard-setting organizations and national competent authorities. Unless the latter effectively communicate the benefits of risk analysis to industry, consumers and other stakeholders in the national setting, such a culture is unlikely to take root.

Currently, many countries have limited capacity to implement appropriate control measures for biosecurity and to properly monitor human, animal and plant health and protect the environment. Competent authorities must foster new strategic partnerships at both the national and international level if they are to combat the continuous emergence of new threats and achieve biosecurity objectives at source (e.g. primary production in exporting countries), at the border (e.g. port-of-entry inspection) and domestically. Further, developing countries with small economies can ill-afford traditional sector-orientated approaches to biosecurity. Capacity should be increased in a targeted manner, with integrated development of infrastructure and regulatory systems (see Part 2).

#### NATIONAL BIOSECURITY STRATEGY AND REGULATORY CULTURE

The concept of a national strategy for biosecurity has gained prominence in recent years in a number of countries. Such a strategy becomes a key vehicle for fully reaping the benefits of a cross-sectoral approach to risk analysis. This strategy should be developed in consultation with all stakeholder groups and incorporate a “whole of government” approach.

A national biosecurity strategy helps competent authorities operating within different biosecurity

#### INTERNATIONAL COMMUNICATION

##### NETWORKS AND LINKAGES

A particular need of a cross-sectoral approach to biosecurity is involvement in international communication networks and linkages. Formal and informal linkages and relationships greatly help governments to develop biosecurity strategies and establish control measures that are up-to-date and appropriate to the ever-changing global biosecurity environment. They give competent authorities early warning of the emergence or re-emergence of hazards in other parts of the globe (e.g. H5N1 avian influenza, BSE, Karnal bunt in wheat) and provide the same information to trading partners when these hazards emerge domestically. International connections also provide cutting edge information on new control measures that are being trialled offshore and which of those are ultimately effective. Bilateral or multilateral trade agreements that contain biosecurity provisions are influenced by the experience, knowledge and confidence in counterpart competent authorities that is gained from ongoing communication and technical linkages.

#### THE BASICS OF RISK ANALYSIS

Risk analysis constitutes a complex interplay of tasks. At the highest level of generality, risk analysis should determine:

- What can go wrong?
- How likely is it to go wrong?
- How serious would it be if it went wrong?
- What can be done to reduce the likelihood and/or seriousness of it going wrong?

#### GENERIC ASPECTS

Despite the use of different terminology and methodologies in each sector, many aspects of biosecurity risk analysis are generic in nature. There is a need to determine the risks that are faced in a given situation, decide on the required outcomes or level of acceptability of risk, and ensure that there is ongoing management to keep risks within acceptable levels.

Whatever the biosecurity issue, there should be:

- A strategic, organizational and operational context for risk analysis.
- A systematic and structured process for applying the components of risk analysis.

#### HAZARDS AND RISKS

There are various descriptions in the different biosecurity sectors as to what constitutes a potential threat to health or life and these have been presented in Part 1 (Box 1.4). For the purposes of this manual, the general term “hazard”<sup>33</sup> will be applied to cover all these sector descriptions. An agricultural product that can carry a biosecurity hazard is referred to as a “commodity”. Hazards can also be transported by other means (e.g. water pooling in used tyres, soil on agricultural machinery).

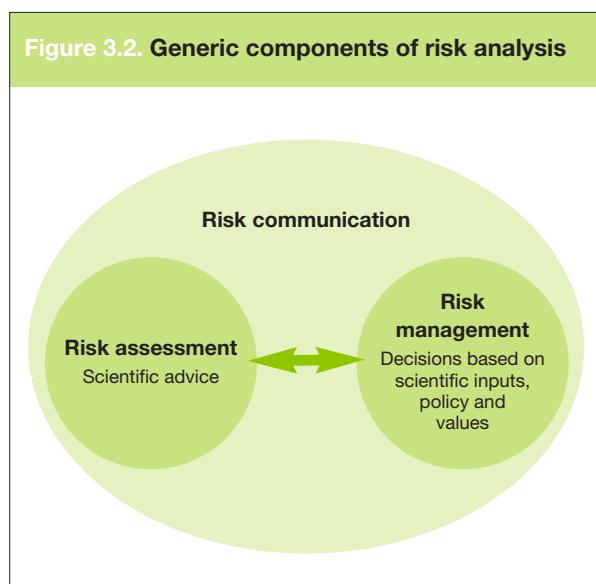
A clear understanding of the difference between the terms “hazard” and “risk” is fundamental to an understanding of biosecurity risk analysis. Control measures applied to reduce a hazard at a step in a biosecurity exposure pathway (or environmental setting) by a particular amount cannot be considered as “risk-based” unless there is reasonable knowledge of the likely decrease in risk that will occur.

The SPS Agreement establishes two “benchmarks” for risks:

- The likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences.

<sup>33</sup> IPPC does not usually use the term “hazard” but instead uses the term “pest”. For a pest to be subject to pest risk analysis (PRA), it has to satisfy the criteria for definition of a regulated pest.

**Figure 3.2. Generic components of risk analysis**



- Evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

#### COMPONENTS OF RISK ANALYSIS

Risk analysis is commonly recognized as having three components: risk assessment, risk management and risk communication (Figure 3.2).

Risk assessment generally involves a scientific process to identify and predict risks to health and life that may be associated with a particular biosecurity hazard or commodity. Management of those risks can take many forms and science is merged with values in making decisions and establishing control measures. Risk communication includes all stakeholders as appropriate, and facilitates the iterative and ongoing nature of risk analysis.

Although the availability of a risk assessment is generally presented as an intrinsic component of biosecurity risk analysis, competent authorities are often confronted with situations where risk assessments will be unavailable, or incomplete, in respect of specific hazard / exposure pathway scenarios. However, knowledge on risks can be derived from sources other than risk assessment to support risk management decisions (see chapter on risk communication).

#### RISK ASSESSMENT

Risk assessment in biosecurity can be described in general terms as characterization of the likely adverse

effects to health and life resulting from exposure to hazards over a specified time period. In the ideal situation, characterization of risks will include quantitative estimation of the probability and severity of adverse effects to health and life that result from exposure to a hazard in a particular circumstance.

All risk assessments are reliant on scientific data, and almost all include some degree of subjectivity. They may employ qualitative or quantitative approaches, or a mix of both. Constraints, uncertainties and assumptions should be considered at each step, together with a final description of uncertainty in the risk estimate.

Risk assessment methodologies are subject to variation, both within and between biosecurity sectors. Notwithstanding this, there are considerable opportunities for simplifying cross-sectoral terminology, harmonizing approaches and aligning methodologies. A detailed description of risk assessment in biosecurity is provided in the chapter on risk assessment.

#### **RISK MANAGEMENT**

Risk management in biosecurity can be described in general terms as the process of “weighing” control measure alternatives by government in consultation with interested stakeholders, taking into account scientific information on risks to health and life and legitimate values-based inputs, and then choosing and implementing control measures as appropriate.

Policies and values in risk management include political, legal, economic, social and environmental concerns. Criteria for their application are likely to be considerably different in different national settings. Where biosecurity commodities are moving in trade, the WTO SPS Agreement describes those factors that can be included in risk management decisions on international standards. Arriving at a global consensus on the weight that should be given to each of these factors when setting international standards is sometimes problematic. Where possible and practical, risk management will include a decision on an appropriate level of protection (ALOP).

Quantifying an ALOP when deciding on a specific control measure may not be an easy task. Surveillance systems are often inaccurate in attributing adverse health effects in a population to a particular hazard exposure pathway and in the case of import health standards for exotic hazards, the level of protection is usually predicted rather than expressed. As a consequence, ALOPs associated with a control

measure or group of measures range from the specific to the general, depending on the level of source attribution and other factors. In contrast to quantifying an ALOP, biosecurity goals incorporated in national biosecurity strategies are generally aimed at inspiring actions that will improve the future situation by a relative amount.

Risk managers ideally should know the degree of health and life protection they are aiming to achieve when deciding on risk management actions. The consequences of different levels of protection may be expressed in terms of health, economic, environmental or other impacts. The risk assessors will likely have examined the impact of different control measures on minimizing risks, thereby providing the risk managers with scientific information that allows them to more objectively reach decisions on the most appropriate control measures. An iterative process continues until one or more risk management options that achieve the desired level of protection are identified. The overriding objective of risk management is maximizing risk reduction while ensuring the efficiency and effectiveness of the control measure(s) that are employed. For products in trade, the measures that are chosen should satisfy the obligations of international trade agreements. A detailed description of risk management in biosecurity is available in the following chapter.

#### **RISK COMMUNICATION**

Risk communication can be described as the interactive exchange of information and opinions throughout the risk analysis process, with explicit consideration given to communicating the decision criteria applied in risk management.

Full documentation and transparency are important contributors to effective risk communication. Risk assessment outputs are often uncertain and incomplete. Further, technical inputs on the efficacy of different risk management options may be uncertain and incomplete in a particular biosecurity scenario. Full documentation allows risk communicators to make sure that differences between risk assessment and risk management inputs are not masked and the basis for decisions is clear to all.

Communication and consultation needs must be planned as early as possible in the risk analysis process and should be continually re-evaluated. Providing for adequate public participation in risk analysis must take into account resource needs and

time-spans. The effectiveness of risk communication with external stakeholder groups will depend on the transparency, inclusiveness, accuracy and timeliness with which they are informed. Cognisance should also be given to public perceptions of risk that can be very different to that of scientists. A detailed description of risk communication in biosecurity is provided later in this manual.

#### **IMPLEMENTATION OF CONTROL MEASURES**

A control measure is any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.<sup>34</sup> International standard-setting organizations establish standards but do not implement them. National competent authorities will implement standards either directly (e.g. regulatory border inspection) or indirectly (e.g. verification of standards that are implemented at farm level by industry).

Optimization of control measures is an important principle and involves implementation of measures at those steps in the hazard exposure pathway where risk reduction measures are most efficient and effective. A range of stakeholders may be involved and the measures that are chosen by risk managers may not necessarily be mandatory (e.g. quality assurance programmes administered by farmers, consumer education in safe food handling practices, public awareness and reporting of invasive alien species).

#### **RISK MANAGEMENT FRAMEWORK**

Application of a risk-based approach to biosecurity at the national level requires a systematic process. A generic risk management framework (RMF) provides the process whereby knowledge on risk, and evaluation of other factors relevant to health protection and the promotion of fair and equitable practices, are used to choose and implement appropriate control measures. It should be noted that principles and guidelines for risk analysis in different international biosecurity bodies were developed (and still are being developed) according to different contexts, timelines and standard-setting experiences. Hence there are significant differences in step-by-step terminology and

processes but there are also strong underlying commonalities. The manual draws on these commonalities to work towards a common understanding of biosecurity risk analysis that will be useful at the national level. Differences in terminology and processes will inevitably remain between biosecurity sectors at the international level (e.g. what steps are entailed in “risk management”). However, national governments, especially in transitional and developing countries, will be able to utilize a common cross-sectoral understanding to improve their biosecurity, especially where resources are scarce.

Application of a generic RMF allows decisions to be taken that are proportionate to the risks involved, facilitates innovation and flexibility in implementation of control measures, and allows due regard to be taken of costs as well as benefits in the broadest sense. Regulatory input to a proposed biosecurity programme at the national level should be broad enough to encompass all relevant components of the hazard exposure pathway and should ensure that control measures are applied where they will be most effective in reducing risks.

The components of a generic RMF for application at the national level are fully developed in the following chapter. In addition to managing individual issues, a RMF may be used for biosecurity resource allocation. It must be recognized that in order to successfully apply a RMF in a biosecurity sector, senior management in competent authorities needs to have a good understanding of risk analysis, and the support and participation of key stakeholders.

#### **PRECAUTION**

It is recognized that uncertainty is intrinsic to risk analysis and a precautionary approach is expressed in various ways during risk assessment and risk management. Many sources of uncertainty exist and they should be clearly identified as a risk analysis progresses. Precautionary positions may be intrinsic to risk assessment rules (e.g. use of safety factors in establishment of acceptable daily intakes for chemical residues in food) or may be introduced on a case-by-case basis (e.g. worst-case modelling scenarios where pathogens have a low infective dose and severe adverse health consequences). Precaution may also have qualitative expression (e.g. labelling guidelines for foods derived from modern biotechnology that provide for informed consumer (and government) choice).

<sup>34</sup> “Sanitary and phytosanitary measures” as described in the SPS Agreement have a very wide base. For practical purposes, a sanitary measure is any measure applied within the territory of a Member to protect human, animal or plant life or health, or to prevent or limit damage from the entry, establishment or spread of pests. This includes all relevant regulations, requirements, processes, procedures and tests.

## ROLE OF SCIENCE

### WHAT CONSTITUTES “GOOD SCIENCE”?

Competent authorities are increasingly recognizing the need for good science as a basis for risk-based standard-setting and regulatory action. However, the provision of that science can be a demanding exercise. In addition to sufficient scientific infrastructure and capability being available, the science itself must be robust, targeted and delivered in a timely manner. Advocacy of the WTO SPS Agreement for scientific justification of biosecurity control measures as a means to achieve the intent of the Agreement is an important driver of increasing resource needs in this area.

In the broadest sense, scientific information that is used as a basis for decision-making should be adequately evaluated as to its applicability to the particular biosecurity scenario in question. The information that is requested may be drawn from a single scientific study or from a wider body of scientific evidence. In either case, evaluation of the “strength of the scientific evidence” that is put forward should include evaluation of the type, quality and quantity of the studies involved.

Rating the strength of scientific evidence that is used to arrive at a risk estimate is greatly assisted when internationally-agreed scientific methodologies have been applied, especially if a single scientific study is the source of inputs to the risk assessment. Judgement of the sufficiency of the science can involve application of a number of criteria including: representativeness, reliability and accuracy of input data, model design, treatment of uncertainty and type of statistical analysis.

### RISK-BASED CONTROL MEASURES

Basing control measures on risk assessment is an important biosecurity goal but the lack of available risk assessment models means that the majority of measures will be based on other scientific knowledge in the short term.

Biosecurity decisions, standards and actions based on scientific knowledge of the likely level of reduction of hazards at a particular step in an exposure pathway can be described as hazard-based. In the general case, objective and verifiable scientific information on hazard prevention and control will be used to minimize exposure to the hazard in a particular biosecurity scenario, with the expectation that there will be a reduction in risks to health and life.

### Box 3.6. Working definitions for hazard-based and risk-based control measures

**Hazard-based.** A control measure that is based on quantified and verifiable information on the level of hazard control that is likely to be achieved but lacking quantitative knowledge of the level of protection that is likely to result.

**Risk-based.** A control measure that is based on quantified and verifiable information on the level of protection that is likely to be achieved

### Box 3.7. General principles of risk analysis in the context of biosecurity

- The primary goal of risk analysis should be protection of health and life.
- All aspects of risk analysis applied in a particular context should be documented, transparent, and available for independent scrutiny.
- Risk management should follow a structured and systematic process.
- Risk managers and risk assessors should engage in clear and iterative communication throughout the risk analysis process.
- There should be effective communication and consultation with all relevant stakeholder groups throughout the risk analysis process, with all information and opinion required for effective risk management being incorporated into the decision-making process.
- There should be functional separation of risk assessment and risk management to the extent practicable so as to preserve the scientific integrity of the risk assessment and avoid confusion over the roles of risk assessors and risk managers.
- Risk managers should clearly communicate the purpose, scope and form of the outputs when commissioning a risk assessment.
- A risk assessment should be fit for its intended purpose.
- Risk assessment should be based on sound science and take into account the whole hazard exposure pathway.
- Constraints, uncertainties and assumptions in risk assessment processes should be explicitly considered by risk managers making decisions.
- Where appropriate, risk managers should ask risk assessors to evaluate potential changes in risk resulting from different risk management options.
- Risk management should be a continuing process that takes into account newly generated data in the periodic re-evaluation and review of decisions.
- Risk analysis should be used where relevant to prioritize biosecurity issues for management

Where risk assessments are available, biosecurity decisions, standards and actions can be based on specific knowledge of the likely levels of risk that will result. Decisions on the acceptability of different levels

Table 3.1. General international terminology used for risk analysis in different biosecurity sectors

Food safety (CAC)	Animal health (OIE)	Plant health (IPPC)	Biodiversity and the environment (CBD)
Not applicable	Hazard identification	Initiation of the process (stage 1)	No specific terminology
Risk assessment (including hazard identification)	Risk assessment	Risk assessment (stage 2)	Risk assessment
Risk management	Risk management	Risk management (stage 3)	Risk management
Risk communication	Risk communication	Risk communication	Risk communication

of risk / appropriate levels of protection (ALOP) will drive the level of stringency of the control measure(s) that is chosen. Measures developed in this manner can be described as risk-based.

Working definitions for hazard-based and risk-based control measures are given in Box 3.6. International standard-setting organizations and national competent authorities will continue to increase the proportion of risk-based measures compared with hazard-based measures so as to reap the full benefits of a risk analysis approach to biosecurity. However, hazard-based standards are often sufficient to achieve biosecurity goals and they will continue to be used in many situations.

### GENERAL PRINCIPLES OF RISK ANALYSIS IN THE CONTEXT OF BIOSECURITY

Given an understanding of the components of risk analysis, a review of international documentation on application of risk analysis in different biosecurity sectors allows a number of general

principles to be identified (Box 3.7). Competent authorities should apply these principles when designing and implementing all risk-based biosecurity programmes.

### TERMINOLOGY USED IN DIFFERENT INTERNATIONAL BIOSECURITY SECTORS

General terminology for the main components of risk analysis as applied internationally in different biosecurity sectors is given in Table 3.1. Differences are inevitably significant and only broad comparisons can be drawn when working towards a common cross-sectoral understanding of biosecurity at the national level.

Hazard identification is incorporated as a step within risk assessment in the food safety sector but is regarded as a component unto itself of risk analysis for other sectors. Implications of this difference in regard to harmonizing terminology and processes across different biosecurity sectors will be discussed in the following chapters.

# A GENERIC RISK MANAGEMENT FRAMEWORK FOR BIOSECURITY

The concept of a generic process for managing risks is an important aspect of biosecurity at the national level. As well as facilitating consistent and systematic approaches to biosecurity within sectors, it provides for a more integrated approach across sectors. The central role of the risk manager in the generic process is implicit in risk analysis guidelines developed by international standard-setting organizations and other international bodies.

This chapter describes a generic risk management framework (RMF) that provides a simple four-step process to work through biosecurity issues as they arise at the national level. This RMF draws from all biosecurity sectors as well as wider disciplines such as finance and engineering. It provides an opportunity for harmonizing approaches across different biosecurity sectors and establishes a common basis for implementing national biosecurity strategies (Boxes 3.8 and 3.9). While there are some variations in the application of these generic steps in different sectors, these do not invalidate the RMF process described here.

The RMF emphasizes the generic roles of risk managers compared with risk assessors (and risk communicators) within an overarching process. It allows comparison of the different roles of employees working for competent authorities and illustrates how biosecurity risk analysis activities at the national level do not always correlate to those carried out at the international level.

The first step in the RMF, *preliminary risk management activities*, consists of a number of interconnected tasks including the commissioning of a risk assessment if deemed necessary by risk managers. *Identification and selection of risk management options* is the second step in the RMF process whereby potential control measures are identified and selected according to appropriate decision-making criteria. *Implementation of control measures* is the third step and this involves actions carried out by the competent authority, industry and other stakeholder groups. The last step is *monitoring and review* and this is the gathering and analysing of data so as to give an overview of the level of protection achieved, with review of risk management decisions where necessary.

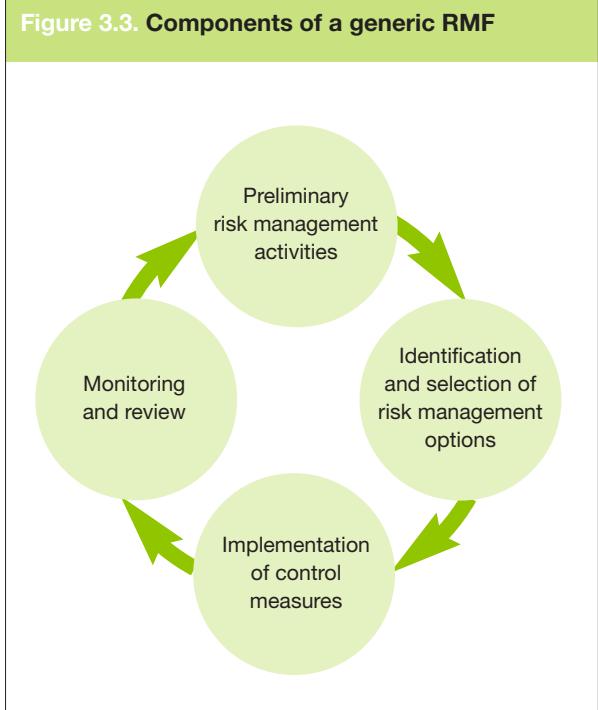
## Box 3.8. Benefits flowing from application of a generic RMF process at the international and national levels

- Improving understanding of risk analysis concepts, principles and processes by all stakeholders.
- Enhancing the ability to rank and prioritize biosecurity issues for risk management.
- Clarifying the roles of risk assessors and risk managers when evaluating a biosecurity issue and deciding on control measures.
- Facilitating systematic, transparent and consistent decisions on level of protection and associated regulatory and/or non-regulatory control measures.
- Facilitating innovation and flexibility in selection of control measures.
- Strengthening risk communication as a result of the participatory and iterative nature of the RMF process.
- Promoting a more harmonized and integrated approach to cross-sectoral biosecurity.
- Strengthening scientific capability due to sharing of experience and methodologies

## Box 3.9. Additional benefits flowing from application of a generic RMF at the national level

- Providing a systematic, flexible and credible science-based process for addressing all national biosecurity issues, even when risk assessment information is limited.
- Availability of a systematic means for incorporating international scientific information and standards into national biosecurity programmes.
- Providing a common cross-sectoral basis for developing national biosecurity strategies.
- Allowing systematic and consistent implementation of risk-based control measures.
- Promoting efficient allocation and sharing of scientific resources.
- Assisting measurement of the overall performance of a competent authority.
- Ensuring a better-informed and involved public.

At the national level, there are many forces competing for technical and operational resources within and between biosecurity sectors. A RMF approach can be used to help prioritize national issues and their resolution so that limited resources can be used in the most effective and efficient manner. Measuring the performance of a competent authority in

**Figure 3.3. Components of a generic RMF**

an overall sense also relies on systematic application of each component of the RMF to give quantitative expression to performance indicators.

## THE RMF

### COMPONENTS AND PROCESS

The generic RMF has four main components (Figure 3.3) and these will be explained in detail later in the chapter. Risk communication is continually played out as application of the RMF process progresses.

The process of applying the components of the RMF is cyclical, iterative and ongoing, with monitoring

and review likely to lead to new control measures over time. Availability of a RMF gives utility to the individual elements of risk analysis (risk assessment, risk management and risk communication) which are often described without reference to a process for practical application.

### SCOPE

A generic RMF must be capable of dealing with all biosecurity issues whether large or small, short-term or long-term. This requirement goes far beyond responding only to problems and emergencies. Competent authorities address issues associated with maintaining the biosecurity *status quo* (e.g. equivalence determinations for import health standards) and have to screen many more issues for their likely significance and need for action (e.g. international information networks continually identify new, emerging and re-emerging hazards). Competent authorities also have to constantly initiate projects to develop new regulatory standards and review old ones, often in institutional situations where there is a shortage of technical resources. Risk managers may have to manage the above scenarios in the absence of robust risk assessment.

The generic RMF provides the flexibility to achieve the above goals. In its entirety, it is cyclical, iterative and ongoing. Risk managers can initiate the RMF at any step in the process and carry out sequential activities to the extent relevant to the biosecurity issue at hand. Principles governing application of the RMF should ensure that whatever the series of activities commissioned, risk management decisions will be transparent, consistent and proportional to the risks involved.

**Table 3.2. Terminology used by different international organizations in relation to a generic RMF**

Generic RMF (Biosecurity)	Food safety (CAC)	Animal health (OIE)	Plant health (IPPC)	Biodiversity and the environment (CBD)
Preliminary risk management activities	Preliminary risk management activities	No specific terminology but would include hazard identification	Includes initiation of the process (stage 1) and risk assessment (stage 2)	No specific terminology
No specific terminology	No specific terminology	Risk evaluation*	No specific terminology	No specific terminology
Identification and selection of risk management options	Identification and selection of risk management options	Option evaluation	Risk management (stage 3) (the evaluation and selection of options)	No specific terminology
Implementation	Implementation	Implementation	Implementation (stage 3 and beyond)	Implementation
Monitoring and review	Monitoring and review	Monitoring and review	Monitoring and review (stage 3 and beyond)	Monitoring and review

\* Risk evaluation is the process of comparing the risk estimated in the risk assessment with the Member Country's ALOP

## CONCURRENCE OF THE GENERIC RMF WITH INTERNATIONAL TERMINOLOGY

An important goal of this chapter is to demonstrate that key parts of a generic RMF are already described in texts developed by international standard-setting bodies and organizations (Table 3.2) and these can be drawn together to form the components of a generic biosecurity risk analysis process for application at the national level. At the same time, creation of new terminology must be kept to a minimum. Those working within an international sector will continue according to their own terminology (and practices) for some time to come but a generic biosecurity RMF does offer the opportunity for harmonization of terms over time.

The degree of concurrence between the process described in the generic RMF and risk management processes described by international organizations is discussed in Box 3.10. Inevitably there is some cross-over between use of the term “risk management” in the RMF context (which emphasizes a complete risk analysis process administered by risk managers), compared to use of the term “risk management” in individual biosecurity sectors (which more reflects a component of risk analysis).

## FUNCTIONALITY OF THE RISK MANAGER

### GOVERNMENTS AS RISK MANAGERS

Although other stakeholders participate in risk analysis, government essentially is the risk manager in biosecurity. At the international level, risk management is the responsibility of government representatives participating in standard-setting and other normative activities. At the national level, it is the competent authority having jurisdiction that makes the final risk management decisions and has the overall responsibility for ensuring that control measures are properly implemented and complied with.

International organizations use a RMF process primarily to develop standards but they do not implement those standards. However, risk managers in national competent authorities have a functional role in all steps of the RMF process (Figure 3.4). They may implement control measures directly (e.g. import inspection of agricultural commodities by government inspectors) or they may verify control measures implemented by officially-accredited bodies or industry. When a selected risk management option does not

### Box 3.10. Concurrence of the generic RMF process with “risk management” processes described by international organizations

The generic RMF process described in this manual is very similar to that in a number of draft risk management documents currently being developed under the umbrella of the **CAC**. Within this overarching process, specific guidelines for risk management of different types of microbiological and chemical hazards are being developed by relevant Codex committees.

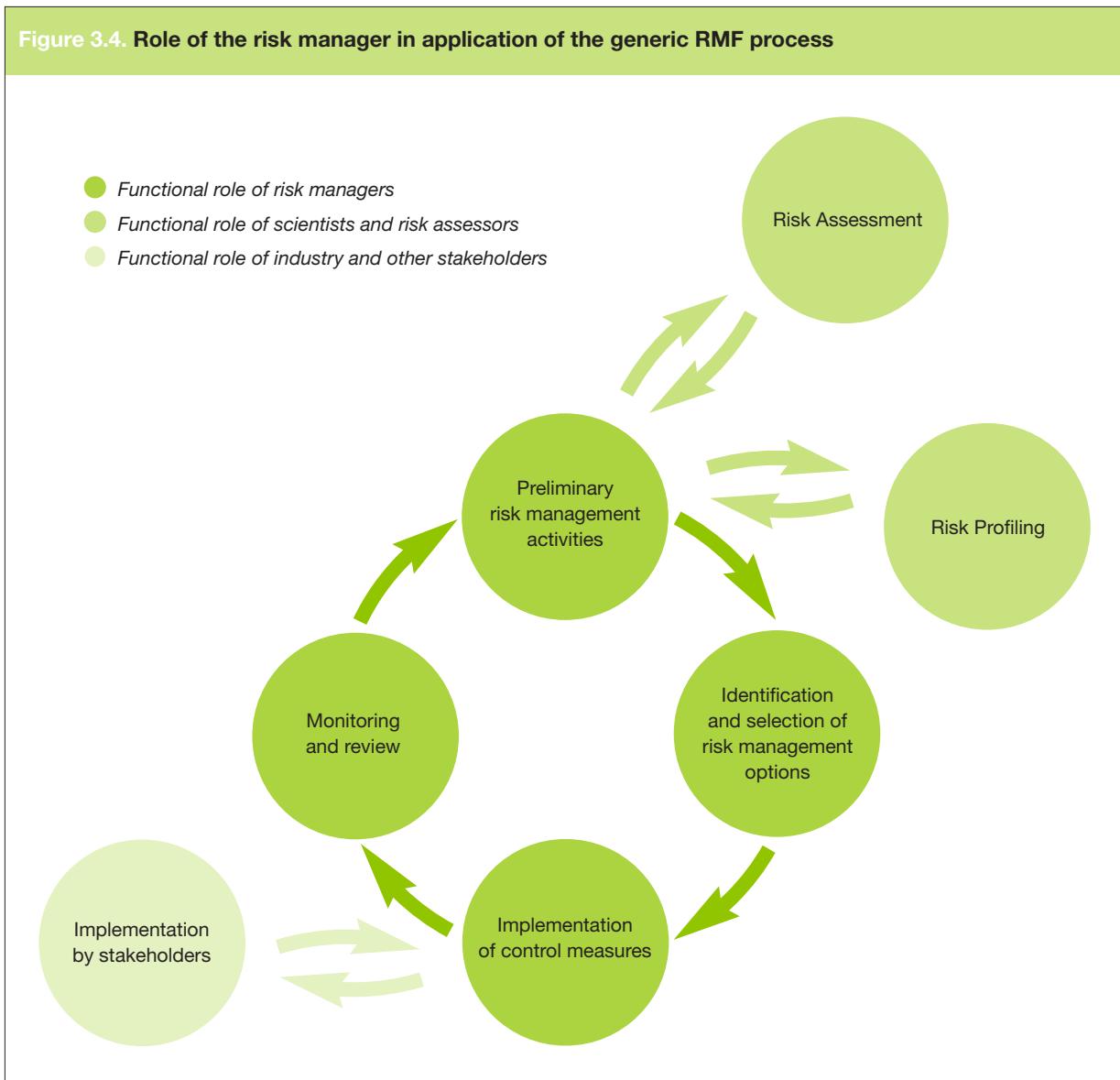
**OIE** describes risk management as the process of identifying, selecting and implementing measures to achieve the importing country's ALOP, while at the same time ensuring that negative effects on trade are minimized. The OIE risk management intent and process is congruent with the RMF described above (noting that “preliminary risk management activities” are not formally described as such). Only those OIE activities described as, and encompassed by, “risk evaluation” need to be specifically explained (see section on animal health risk assessment on page 78). Application of the generic RMF described here has been recommended by the OIE *Ad Hoc Group of Experts on Antimicrobial Resistance* for risk management of antimicrobial-resistant bacteria of animal origin.

**IPPC** emphasizes the need for a systematic process to gather, evaluate and document scientific and other information as the basis to technically justify phytosanitary measures but this is only addressed in general terms. In this respect, pest risk analysis (PRA) is described as consisting of three stages: initiation of the process for analysing risk (stage 1), assessing risk (stage 2), and managing risk (stage 3). Risk management is described as the evaluation and selection of options to reduce the risk of introduction and/or spread of a pest, implementation of controls, and monitoring and review. Thus the PRA process of the IPPC is congruent with the generic RMF process described above.

Risk management is described in the **CBD** as identification of measures that can be implemented to reduce or manage risks, taking into account socio-economic and cultural considerations. Different international sector organizations are involved in application of the CBD and this underscores the need for a generic RMF process. For invasive alien species, there is specific mention of the need to consider cross-sectoral policies on maintenance of ecosystems, recognizing that ecosystems are dynamic over time. For LMOs, competent authorities should apply a risk analysis process to determine that they do not present unacceptable risks to life or health (including risks to the environment) under the specific conditions of use in their country, before allowing them to be commercially deployed or offered for sale. It is noted that risk assessment as described in Annex III of the **Cartagena Protocol** includes “a recommendation as to whether or not the risks are acceptable or manageable”

involve regulation (e.g. implementation of a voluntary code of practice by industry), the competent authority may assist by providing implementation tools, training and education.

**Figure 3.4. Role of the risk manager in application of the generic RMF process**



**FUNCTIONAL SEPARATION OF RISK MANAGEMENT AND RISK ASSESSMENT**

Risk assessment is described in general terms as characterization of the probability and severity of adverse effects to health and life that result from exposure to a hazard in a particular circumstance. The scientific and objective nature of risk assessment clearly makes it distinct from the values-laden process of risk management.

Figure 3.4 presents the activity of risk assessment as external to the generic RMF process. The merits of separating out the functional role of the risk manager from that of the risk assessor were recognized by the United States National Academy of Sciences as early as 1983. A consensus has now developed that, to the extent practicable, risk assessment should be functionally separate from the regulatory standard-

setting process carried out by risk managers. The intent of this is to protect the integrity of risk assessment as a scientific, objective and unbiased activity. Where it is not possible in practice to have different personnel carrying out different functions (e.g. in small competent authorities in developing countries), risk management and risk assessment tasks should be carried out separately and documented as such. Several governments have reinforced this functional separation in new biosecurity organizational structures (see Part 1).

#### **STEP 1 IN THE RMF PROCESS: PRELIMINARY RISK MANAGEMENT ACTIVITIES**

Preliminary risk management activities in the RMF process consist of:

- Identification of biosecurity issues;
- Risk profiling;
- Establishing broad risk management goals;
- Setting risk assessment policy;
- Commissioning of a risk assessment;
- Considering the results of a risk assessment; and
- Ranking and prioritization.

#### **IDENTIFICATION OF ISSUES FOR POSSIBLE RISK MANAGEMENT**

Biosecurity issues that may require active risk management are raised in many different ways. Issues primarily arise from the ongoing activities of competent authorities such as inspection, monitoring of hazard exposure pathways, reviewing compliance records, surveillance, epidemiological studies, scientific research and market access negotiations.

Other stakeholders at the national level regularly present issues for consideration (e.g. application for importation of a new type of agricultural product, consumers notifying a food safety problem of concern, or a customs investigation). Issues for possible risk management also arise from international networks and linkages (e.g. emerging international health problems, a request for judgement of equivalence of control measures from a counterpart competent authority, developing control measures that satisfy the obligations of the WTO SPS Agreement).

The competent authority should have a qualitative system for aggregating and screening new issues as they arise. Several options are available for progressing an issue, including development of a risk profile.

#### **RISK PROFILING**

Risk profiling provides an opportunity to gather relevant information on an issue and it may take a number of forms. The main purpose is to assist risk managers in deciding on further action. Risk profiling is an established scientific practice in food safety risk analysis (Box 3.11). A risk profile should include available information on likely risks to health and life and identify significant gaps in scientific knowledge. It should detail regulatory requirements that already pertain to the issue and may contain an inventory of potential measures to further mitigate risk.

Although modern biosecurity strives to develop controls based on risk assessment, risk profiling may sometimes be used directly by risk managers to guide identification and selection of risk management options. These situations occur where rapid action is

**Box 3.11.** Information that may be included in a risk profile

- Description of the commodity, conveyance or environment involved.
- Description of the hazard exposure pathway.
- Assembly of scientific information on likely risks in relevant categories.
- Identification of data gaps in knowledge on risks.
- Distribution of likely risks (who produces, benefits from, and/or bears the risk).
- Documentation of current control measures pertaining to the issue.
- Documentation of risk management responses in other countries.
- Technical feasibility of mitigating risks.
- WTO SPS implications.
- Application of ranking criteria if risk profiles are used for this purpose ■

needed, profiling provides sufficient scientific information on a relatively simple issue, or there is insufficient data available to reasonably embark on a risk assessment. In some circumstances, scientific information on risks may be available from sources other than risk assessment (e.g. surveillance data from the target population or epidemiological studies).

#### **ESTABLISHING BROAD RISK MANAGEMENT GOALS**

Following the risk profile, risk managers need to decide on broad risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is feasible and necessary but must precede commissioning of a risk assessment. The broad risk management goals will help direct the scope and focus of the risk assessment and will likely be refined when the outputs of risk assessment are known.

#### **SETTING RISK ASSESSMENT POLICY**

When scientific uncertainty is encountered in the risk assessment process, inferential bridges are needed to allow the process to continue. Judgements made by scientists or risk assessors often entail a choice among several scientifically plausible options. Policy considerations inevitably affect, and perhaps determine, some of the choices. Thus gaps in scientific knowledge are bridged through a set of inferences that consist of default assumptions based on what is called “risk assessment policy”. Documentation of these default assumptions contributes to the transparency of the risk assessment.

Risk assessment policies are usually generic and are established by risk managers in consultation with risk assessors. They should preferably be established before a risk assessment commences. In the case of international standard-setting organizations, generic risk assessment policies are evident in many risk analysis guidance documents.

#### COMMISSIONING A RISK ASSESSMENT

If it is decided to commission a risk assessment, the risk manager should clearly define, in association with the risk assessor, the scope, purpose and expected outputs. The resources needed and the time to completion should also be agreed. Major risk assessments are often carried out by multidisciplinary teams but more simple projects can be undertaken by individuals. As risk assessment and risk management are iterative processes, the means of ongoing and effective communication between both parties will need to be established. The risk manager may have to contract scientific research to fill data gaps as the risk assessment proceeds.

#### CONSIDERING THE RESULTS OF RISK ASSESSMENT

Correct interpretation of the outputs of the risk assessment by the risk manager is a vital function. Risk assessors should clearly describe the uncertainty in a risk estimate and its origins. Decisions made by risk assessors in accordance with risk assessment policy should be clearly identifiable and the overall strengths and weaknesses of the risk assessment should be

discussed. The impact of biological variability on potential risk management options at different steps in the hazard exposure pathway should be well documented. Risk managers should engage with risk assessors to the extent necessary to fully understand the risk assessment and associated assumptions and uncertainties. Documentation should include a general summary that is easily understandable by stakeholders who are not experts on the subject.

#### RANKING AND PRIORITIZATION

Ranking and prioritization of biosecurity issues for risk management action (including commissioning of risk assessments) can take place at different stages during preliminary risk management activities (e.g. a series of risk profiles may provide a basis for commissioning of risk assessments according to national biosecurity priorities, or the outputs of risk assessments themselves may provide the information necessary for ranking issues according to likely adverse impacts).

As risks continue to present themselves in national settings, it is not feasible to identify and rank all potential risks that arise over a specific time period. An incremental approach that takes into account current work, risk management capability and strategic goals arising from national biosecurity policy is needed.

While ranking is essentially a scientific exercise, prioritization of issues is a management issue. New work may be prioritized according to drivers other than risks to health and life (e.g. disputes over international market access or political concerns). In other situations it will be necessary to move beyond preliminary risk management activities and consider the availability and practicality of control measures before prioritization of issues for risk management. Examples of criteria used for ranking and prioritizing biosecurity issues for risk management are illustrated below (Box 3.12).

Selecting priorities for risk management of invasive alien species is particularly difficult. Systematically aggregating ecological information in ways that allow risk managers to evaluate containment potential, costs and opportunity costs, as well as factoring in legal mandates (e.g. invasive species directly harmful to human health) and social considerations, is not currently feasible.

#### Box 3.12. Examples of criteria used for ranking and prioritization of biosecurity issues for risk management

##### Criteria related to risk assessment

- Prevalence of adverse health effects
- Severity of adverse health effects
- Economic impacts
- Environmental impacts
- Degree of uncertainty in the risk estimate
- Availability of validation data

##### Additional criteria related to risk management

- Regulatory jurisdiction
- Contribution to national biosecurity goals
- Likely social impact
- Feasibility and practicality of control measures
- International trade obligations
- Cost benefit analysis

#### TERMINOLOGY AND PROCESSES USED BY INTERNATIONAL STANDARD-SETTING ORGANIZATIONS

Box 3.13 describes the level of concurrence of the preliminary risk management activities as described in

the RMF process with similar activities described by international biosecurity organizations.

## STEP 2 IN THE RMF PROCESS: IDENTIFICATION AND SELECTION OF RISK MANAGEMENT OPTIONS

In the second step, potential risk management options are identified and then selected according to appropriate decision-making criteria. This will usually involve balancing risk mitigation expectations against the feasibility, cost and practicality of control measures. In effect, this is an iterative process that balances out the desire for the highest possible level of risk mitigation with the practical ability to achieve that goal.

### CONTROL MEASURES

Risk management options may range from single control measures to whole control programmes.<sup>35</sup> All stakeholders need to be involved in decision-making to some extent and they should be provided with a clear rationale for the final decisions taken. As a general principle, all parts of the exposure pathway should be taken into account in identification and selection of potential control measures. This concept is expressed to different degrees in different biosecurity sectors. In food safety, a number of countries have included this principle in law (e.g. the General Food Law of the European Union that was introduced in 2002). In animal and plant health, evaluation of biosecurity conditions in the country of origin as well as the importing country is intrinsic to risk management of imported commodities.

### EXPRESSIONS OF LEVEL OF PROTECTION/LEVEL OF RISK

While it is a common desire in all biosecurity sectors to quantify levels of protection/levels of risk,<sup>36</sup> there are many practical difficulties in doing so. A lack of precision in this area often leads to qualitative descriptions being put forward as expressions of a desired level of protection/acceptable level of risk.

<sup>35</sup> The WTO SPS Agreement describes sanitary or phytosanitary control measures as any control measure applied within the territory of a Member to protect human, animal or plant life or health, or to prevent or limit damage from the entry, establishment or spread of pests. This includes all relevant regulations, requirements, processes, procedures and tests.

<sup>36</sup> The WTO SPS Agreement uses the term “appropriate level of protection” (ALOP) but also notes the parallel use of the terminology “acceptable level of risk”. The latter term is often used preferentially at the national level.

**Box 3.13.** Concurrence of “preliminary risk management activities” as described in the generic RMF with similar activities described by international organizations

The **CAC** generally recommends the preliminary risk management activities described under Step 1.

Preliminary risk management activities are not specifically described as such in **OIE** guidelines. The formal process of risk management begins with a description of the commodity proposed for import and the likely annual quantity in trade. Risk managers may require a risk profiling exercise of some form or another to provide a context for risk analysis.<sup>37</sup> *Hazard identification* follows and feeds into risk assessment as described later in this manual. If a risk assessment is commissioned, the results will be subject to *Risk evaluation*, the process of “comparing the risk estimated in the risk assessment with the Member country’s ALOP”.

Preliminary risk management activities as described by the **IPPC** include *initiation* and *risk assessment*. The analysis may be initiated by identification of a potential pathway for a hazard/pest or by actual identification of a hazard/pest. The hazards/pests likely to follow the pathway are then listed and prioritized for risk assessment according to expert judgement; this is in effect a risk profiling and ranking process. Initiation may result from a number of situations (e.g. an emergency following discovery of an established infestation, interception of a new hazard/pest on an imported commodity, or a request made to import a commodity). A risk assessment will be commissioned depending on the outcome of the initiation stage to gather and evaluate information which will then be used to judge if risk management is needed.

Preliminary risk management activities are not formalized by the **CBD**. For protecting biodiversity and invasive alien species, competent authorities are urged to identify national needs and priorities. In the case of the first transboundary movement of a LMO for intentional introduction into the environment where there is a likelihood of adverse effects, an advance informed agreement procedure is necessary.<sup>38</sup> A decision by the competent authority responsible for transboundary movement can take the form of approval (with or without conditions), prohibition or request for further information ■■■

Examples of quantitative expression of the level of protection/level of risk are given in Box 3.14. However, many biosecurity threats will only be able to be described in qualitative terms (e.g. potential risks

<sup>37</sup> The OIE risk analysis process for antimicrobial resistance includes a “preliminary qualitative assessment (scoping study)” to advise on the necessity and feasibility of a quantitative risk assessment.

<sup>38</sup> This incorporates elements of preliminary risk management activities as well as identification and selection of risk management options. The notification to the appropriate competent authority should include: provision of accurate information on the identification and intended use of the LMO, the domestic classification (if any) of the “biosafety level” in the country of export, a risk assessment, the quantity to be transferred and suggested measures for safe handling, storage, transport and use.

**Box 3.14.** Some quantitative expressions of level of protection / level of risk

- Incidence of a disease in an entire population in a country per year.
- Public health risk per edible portion of a food.
- Animal health risk per import consignment of a commodity or conveyance.
- Animal health risk per total imports of a commodity or conveyance per year.
- Monetary human health valuation (e.g. costs and expenditures associated with disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs)).
- Economic impact of incursion and establishment of an animal or plant pathogen

**Box 3.15.** Some general approaches to decision-making on the level of health and life protection in domestic and/or international trade situations

- Direct comparison of risks (e.g. classification of animal diseases by OIE).
- Balancing approaches such as cost analysis (e.g. selecting measures to control *Campylobacter* in chickens in the Netherlands<sup>39</sup>) or as-low-as-reasonably-achievable (ALARA) approaches (e.g. inspection of plant commodities for freedom from a hazard to a specified tolerance).
- Procedural approaches where ALOP is determined by legal mandate, precedent or negotiation (e.g. full protection of endangered species or fragile protected areas, legal requirement to address weeds classified as noxious regardless of abundance or spread potential).
- Notional zero-risk determinations (e.g. amount of a food additive that can be ingested daily over a lifetime without appreciable health risk).
- Threshold approaches (e.g. no more than one additional case of disease above background per million target population)

associated with LMOs as identified in ISPM No. 11<sup>40</sup> include changes in adaptive characteristics which increase the potential for introduction or spread including invasiveness, adverse effects of gene flow or gene transfer, adverse effects on non-target organisms,

<sup>39</sup> Havelaar, A., Nauta, M., Mangen, M., de Koeijer, A., Bogaardt, M., Evers, E., Jacobs-Reitsma, W., van Pelt, W., de Wit, G. and van der Zee, H. 2005. *Costs and benefits of controlling Campylobacter in the Netherlands - integrating risk analysis, epidemiology and economics*. National Institute for Public Health and the Environment, Bilthoven. Report No. 250911009.

<sup>40</sup> FAO. 2004. *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms*. Secretariat of the International Plant Protection Convention, FAO. International Standards for Phytosanitary Measures (ISPM) Publication No. 11 (available at: <https://www.ippc.int/id/34163>).

genotypic and phenotypic instability, and other injurious effects). In other situations, risks associated with a biosecurity event may be cross-sectoral in nature (e.g. establishment of a new invasive species may involve a matrix of economic, public health and environmental impacts). While there is an expectation that these will be synthesized into an overall conclusion about the risk, such conclusions are beset by problems inherent to economic impact assessment, lack of a common currency for measuring changes, disagreement over what constitutes an adverse ecological impact, and difficulties in predicting the nature and size of impacts.

**DECISIONS ON AN ALOP/ACCEPTABLE LEVEL OF RISK**

“Zero risk” is rarely, if ever, attainable in biological systems. Further, attempting to achieve “zero risk” is seldom economically efficient; successive step reductions in risk usually become increasingly costly to achieve and will eventually add more costs than benefits.

During identification and selection of risk management options, risk managers will likely have asked the risk assessors to examine the impact of different control measures on minimising risks. This is usually an iterative process that continues until one or more risk management options that achieve the desired level of protection are chosen. Documentation of the basis for the final decision that is taken is essential and this must cover technical justification and the “weighting” given to other factors. In the general case, discussions on setting a level of protection are primarily informed by epidemiological information, whereas discussions on the relative effect of additional control measures are primarily informed by risk assessment.

Risk is generally described in terms of probability and severity of adverse effects. However, problems can arise when attempting to quantify these characteristics to inform a decision on level of protection/level of risk. The SPS Agreement does not contain explicit provisions which oblige a Member to determine its ALOP, although there is an implicit obligation to do so. Where an ALOP cannot be precisely expressed, the ALOP may be determined on the basis of the level of protection reflected in the control measures in place.<sup>41</sup>

<sup>41</sup> WTO. 2000. *Guidelines to further the practical application of Article 5.5. WTO Committee on Sanitary and Phytosanitary Measures*. G/SPS/15 (available at: <http://docsonline.wto.org/DDFDocuments/t/G/SPS/15.doc>).

A risk of low probability but high severity is not necessarily regarded by risk managers as having a similar ranking to a risk of high probability but low severity. In New Zealand, the Resource Management Act (1991) requires specific consideration of risks in the former category.

#### **General approaches**

Establishing the level of protection to be achieved by selected control measures is a core decision in the RMF process. Some general approaches used to arrive at a decision are given in Box 3.15. The basis for the final decision is first and foremost a negotiation with relevant stakeholders on the desired level of protection/acceptability of the risk. Decisions can be influenced by a wide range of economic, political, social and environmental factors (Box 3.16). The degree of influence of social and environmental values on risk management decisions at the national level varies according to the situation at hand and is often executed in the absence of objective criteria.

In international trade situations, the WTO SPS Agreement places specific constraints on factors that can be included in decisions on ALOP. Decisions should take into account the minimization of trade effects and ensure that selected control measures are not more restrictive than necessary to meet an ALOP. Competent authorities should also avoid unjustifiable or arbitrary distinctions in levels of ALOP chosen in different biosecurity situations.

#### **Box 3.16.** Values that may be incorporated in decision-making on the required level of health and life protection/acceptable level of risk

- Economic impact (e.g. cost/benefit, cost/effectiveness).
- Social impact (e.g. recreation, lifestyle and cultural values).
- Environmental impact (e.g. native and valued introduced flora and fauna, sustainability of ecosystems and biodiversity).
- Distribution of risks and benefits amongst different stakeholder groups.
- Irreversibility of impacts.
- Changes in circumstance (e.g. famine, climate change, war).
- Perceptions of risk (e.g. stakeholder values and perceptions in ecological risk assessment of national parks and sanctuaries).
- Ethics and religious beliefs (e.g. in relation to cloning of animals for food).

Where an ALOP in an international trade situation is not quantified, recent jurisprudence established by the WTO Appellate Body confirms that the results of risk assessment need to be reflected in the SPS measure applied (e.g. proportionality between the measure and the qualitative expression of risk<sup>42</sup>).

International standard-setting organizations include various expressions of ALOP in their standard-setting processes. The CAC incorporates a “notional zero risk” ALOP in standards for chemical hazards that are intentionally added to food. This is derived from the use of very precautionary safety factors but is not validated per se (see next chapter). OIE refers to a “very high level of protection, close to zero risk” when providing guidelines for import health standards and standards developed under the IPPC refer to appropriate level of protection, but these qualitative ALOPs also remain invalidated in most situations.

#### **Economic factors**

Economic factors provide a common thread in making decisions on biosecurity control measures. The WTO SPS Agreement states that in selecting measures to protect animal or plant health, governments shall take into account as relevant economic factors: costs of potential losses in production or sales, costs of control or eradication, and the relative cost-effectiveness of alternative measures. However, there is no consensus on how best to reflect socio-economic concerns and ecological risk assessment presents particular problems (e.g. non-market valuation of reductions in native species, loss of native genetic diversity and extinctions).

Costs and benefits associated with a risk management scenario in biosecurity need to be evaluated in an understandable and transparent manner. As well as economic analysis, the technical feasibility and practicality of available risk management options must be appropriately evaluated. This includes the availability and cost of technology and the ability to verify and enforce regulatory requirements that may be decided upon. Costs of compliance on individual stakeholder groups (e.g. farmers, fishermen, exporters) and society as a whole affect international trade competitiveness, innovation and sector growth.

<sup>42</sup> Gruszczynski, L. 2006. *The Role of Science in Risk Regulation under the SPS Agreement*. European University Institute Working Papers, LAW No. 2006/03. Badia Fiesolana, Italy (available at: <http://cadmus.iue.it/dspace/handle/1814/4085>).

**Box 3.17.** Difficulties of quantifying likely economic impacts as an input to decisions on level of protection/acceptability of risk

- The wide range of hazards and impacts to be considered.
- Gaps in information on likely economic effects.
- Dealing with uncertainty, especially in the case of long-term effects.
- Weighting irreversible effects.
- Quantifying the likely economic impact of a “median” impact (e.g. on the domestic and export agricultural sectors in the case of an outbreak of an exotic disease).
- Quantifying non-market effects.
- Controversy over utility matrixes (e.g. derivation of DALYs for food-borne risks to human health).
- Stakeholder preferences and attitudes to different types of risk

Cost-benefit analysis is widely considered to be the principal analytical tool for the evaluation of public expenditure. All significant effects, positive and negative, should be systematically identified and their relative magnitudes considered in decision-making. Qualitative or quantitative methods can be used to compare proposed expenditure and/or resource requirements with all significant outcomes and implications of risk management options.

Practical examples of the use of full cost-benefit analysis in biosecurity decision-making are very limited. Costs of implementation of control measures may be relatively easy to calculate but the valuation of benefits arising from the measures is a fundamental problem (Box 3.17). Consequently, cost-effectiveness analysis may have wider applicability e.g. determining the least-cost method of achieving a particular health target. Other methods that are narrower in scope can be employed (e.g. compliance cost analysis and economic impact assessment). The latter focuses only on the consequences of risk. When common units for costs and benefits cannot be found, techniques include identification of “significant” risks and risk ranking.

The extent to which the WTO SPS Agreement caters for socio-economic factors in decision-making currently lacks a body of jurisprudence in regard to WTO decisions. In comparison, the “ecosystem approach” incorporated in the CBD and its Cartagena Protocol deliberately aims to reconcile the need for environmental conservation with economic development. While the WTO does not appear to encompass socio-economic concerns (e.g. the risk

that exports of genetically engineered crops may replace traditional ones and undermine local cultures in the importing countries), the Cartagena Protocol directly refers to these. Factors to be taken into account when deciding on both import and domestic applications for LMOs include the potential for human well-being/achieving sustainable economic development compared with the possibility of inappropriate environmental release that would result in significant ecological damage. Adverse socio-economic and biodiversity impacts on indigenous people and traditional agriculture are extremely difficult to quantify on a case-by-case basis.

**PRECAUTION**

Uncertainty can exist at every level of a risk assessment and this is a key element in the choice of risk management options. Compounding this, different approaches to scientific uncertainty are taken in different political, social and economic contexts. As an example, developed countries may be more precautionary compared with developing countries when potential biosecurity benefits are high consequential to the import of new animal germ plasm or securing an affordable food supply. In the case of decisions for a number of exotic animal or plant pathogens, fear of a worst case reaction from international markets may drive national competent authorities to choose conservative import health standards so as to assure a very high level of protection. In other cases, consumer fears and distrust may drive regulatory bans (e.g. when the European Union banned the importation of hormone-treated beef irrespective of the lack of scientific certainty underlying those concerns). Uncertainty about associated environmental consequences (e.g. effect of the virus causing Newcastle disease on endangered native birds) may also drive a precautionary approach. Different legal contexts will influence the way scientific uncertainty is addressed and this is apparent when comparing the weight-of-evidence criteria used by individual competent authorities.

Incorporation of precaution into a risk management process for uncertain risks must be rational, practical and based on scientific principles. This is especially the case when risks are complex in their expression, there is considerable scientific uncertainty about the risks, and there is a need for timely preventative action. Risk management options are taken to prevent or limit exposure while more conclusive information is gained

**Box 3.18.** Concurrence of “identification and selection of risk management options” in the generic RMF with similar activities described by international organizations

The **CAC** deals with biological and chemical risks and the RMF process caters for both. Where there is a choice of introduction of chemical hazards to the food supply (e.g. for food additives and veterinary drugs), decisions on control measures are generally based on “nationally zero risk” approaches. In the case of unavoidable environmental contaminants, an ALARA risk approach is generally used. Biological hazards are inevitably present in the food supply and decisions on control measures will generally involve ALARA approaches. Economic analysis will be included on some level and countries can debate the implications that a draft standard may have for their economic interests at Step 8 of the standard elaboration process.<sup>43</sup> To date, the use of quantitative risk assessments to inform decisions on ALOP is rare.

**OIE** uses the term *Option evaluation* – the process of “identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation according to the importing country’s ALOP”. Economic impacts are key inputs to decisions on ALOP but criteria are not specifically developed. Potential control measures are incorporated into the risk assessment and the resulting level of risk is compared with that considered acceptable. For many of the standards listed in the OIE Codes, the recommended measures are not quantitatively linked to likely levels of health protection. Although described as a risk management function by OIE, option evaluation is generally carried out by risk assessors.

The guiding principle in **IPPC** when identifying and selecting risk management measures is 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” (ISPM 11). Factors that may be considered include biological effectiveness, cost/benefit of implementation, and commercial, social and environmental impacts). In deciding on controls, countries should apply the “minimum impact principle” (i.e. controls should be consistent with the risk involved and should represent the least restrictive measures available which result in the minimum impediment to the international movement of people, commodities and conveyances. ISPM 14<sup>44</sup> describes a “systems approach” which promotes selection of integrated measures (at least two of which act independently) that provide a cumulative effect in achieving an ALOP. ISPM 11 covers analysis of environmental risks and refers to impacts that can be approximated by using non-market valuation methods.

The provisions of the **CBD** and the Cartagena Protocol provide only general guidance on identification and selection of risk management options. Biodiversity conservation and the assessment of agricultural impacts on the environment requires the use of holistic models which are able to integrate multiple sources of information. Levels of protection may vary as goals range from sustaining ecosystem services to fully preserving endangered species or fragile protected areas. Links between environmental protection and human health also need to be considered (e.g. assessing risks of GM food in terms of safe release into the environment and safe use as a food for humans). No guidance is provided on reaching a decision on an “adequate” level of protection (e.g. while only those alien invasive species that are “unlikely” to threaten biological diversity should be permitted to be introduced, no guidance is offered on what constitutes “unlikely”)

on the actual risks faced and the control measures that are the most appropriate. Precautionary actions should be proportionate to the degree of scientific uncertainty, the severity of possible harm, the size and nature of the affected population or environment and the cost. For products in trade, there is an obligation under the WTO SPS Agreement to actively pursue additional scientific information, with timely review of interim control measures.

Article 5.7 of the WTO SPS Agreement is concerned with precaution and recourse to this Article has been the subject of considerable dispute in the WTO (e.g. EC-Hormones, Japan-Varietals). The degree of commonality inferred by the WTO SPS Agreement when managing human, animal and plant health may not be evident when managing environmental risks in a wider sense. The provisions of the CBD and its Cartagena Protocol in relation to transboundary risk

management of LMOs and invasive alien species provide more latitude in relation to precaution than the SPS Agreement. Constraints on measures that countries can take are not specified and as a competent authority may take action that is more protective than that called for in the Protocol (provided that such action is consistent with the objective and provisions of the Protocol), there is a need for effective communication between all stakeholders on conjoint issues. In this respect, the 1992 Rio Declaration at the United Nations Conference on the Environment and Development states that “Where there are threats of serious or irreversible damage, lack of full scientific uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”.

<sup>43</sup> FAO/WHO. 2006. *Codex Alimentarius Commission. Procedural Manual*. 16<sup>th</sup> Edition, page 24 (available at: [http://www.codexalimentarius.net/web/procedural\\_manual.jsp](http://www.codexalimentarius.net/web/procedural_manual.jsp)).

<sup>44</sup> FAO. 2002. *The Use of Integrated Measures in a Systems Approach for Pest Risk Management*. Secretariat of the International Plant Protection Convention, FAO. International Standards for Phytosanitary Measures (ISPM) Publication No. 14 (available at: <https://www.ippc.int/id/16210>).

At present, only a few GM foods are internationally traded and more comprehensive information on the potential for food-borne risks is needed if consumer perceptions are to be allayed. Conflicting risk assessments and incomplete substantiation of the benefits and risks of GM food have resulted in much controversy over their safe use and their safe release into the environment.

#### TERMINOLOGY AND PROCESSES USED BY INTERNATIONAL STANDARD-SETTING ORGANIZATIONS

There is a high level of concurrence between different international biosecurity sectors in application of the “identification and selection of risk management options” step in the generic RMF process for application at the national level (Box 3.18). Specification of decision-making approaches is highest for food safety and lowest for environmental protection. Within sectors, general approaches will largely be determined on a case-by-case basis.

#### STEP 3 IN THE RMF PROCESS: IMPLEMENTATION OF CONTROL MEASURES

This step of the RMF process enjoys many cross-sectoral commonalities. Risk management decisions may result in regulatory and/or non-regulatory control measures. Examples of the latter are quality assurance

programmes administered by farmers, consumer education in safe food handling practices, public awareness and reporting of invasive alien species.

#### IMPLEMENTATION

Control measures may be implemented by the competent authority itself (e.g. regulatory border inspection, certification), industry or other stakeholders. Flexibility in implementation of individual measures is desirable, as long as the biosecurity programme can be objectively shown to achieve stated goals. Competent authorities often develop implementation tools for industry and other stakeholder groups. Examples are generic codes of hygienic practice, guidelines on quality assurance systems, and accreditation systems for laboratories. Ongoing verification of control measures is an essential action.

#### REGULATORY “TARGETS”

Where hazards exist continuously in a biosecurity situation, risk-based control measures can benefit from the establishment of regulatory “targets”. In the case of microbiological hazards in foods, these are termed performance objectives (POs). The target level for control of specified hazards at a particular step in the food chain is quantitatively linked to the level of consumer protection required (e.g. a maximum of 100 *L. monocytogenes* per gram of ready-to-eat food at the point of final packaging and refrigeration) and this

#### Box 3.19. Guidance on “implementation” provided by international organizations

The **CAC** provides extensive guidance on implementation of control measures by stakeholders at the national level. This includes principles of risk analysis, generic codes of hygienic practice for different groups of food commodities, methods of analysis and sampling, designing HACCP plans, and establishing microbiological criteria. The CAC recognizes “the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers’ health”.

The **OIE** describes implementation as the process of “following through with the risk management decision and ensuring that the risk management measures are in place”. As with the CAC, OIE provides many implementation tools (e.g. guidelines on identification systems to achieve animal traceability). As an example of integrated guidance, OIE recommends that when serological tests prove positive for particular diseases during post-arrival quarantine, the subsequent response should be based on risk assessment of the likelihood of such animals posing an unacceptable biosecurity risk in the particular scenario.

The **IPPC** guidelines refer generally to implementation and individual ISPMs provide specific tools. ISPM 14 notes that if a “systems approach” to selection of control options is used, exporting and importing countries may consult and cooperate in the implementation of the system. As with animal health, implementation of control measures at the national level will be in two main areas: those aimed at prevention of the introduction (entry and establishment) of hazards/pests and those aimed at controlling the spread of hazards/pests that have become established.

The **CBD** addresses implementation of control measures to minimize the spread and impact of invasive alien species in very general terms (e.g. by taking an “ecosystem approach”). Priority is given to border and quarantine controls that will prevent introduction, rather than attempting to eradicate after introduction. Implementation of controls for LMOs subject to intentional transboundary movement will include those associated with handling, packaging and transporting according to conditions of safe use, and labelling according to intended use. Implementation tools are still being developed ■■■

allows the competent authority to monitor and verify food safety performance in an objective manner. POs also provide flexibility to industry in how they achieve the required level of hazard control (e.g. by limiting the level of the hazard at the farm level or at the processing level). As risk assessment models increase in number in all biosecurity sectors, it is likely that setting regulatory targets as a form of risk-based control measures will increase.

#### **TERMINOLOGY USED BY INTERNATIONAL STANDARD-SETTING ORGANIZATIONS**

All international standard-setting organizations recognize implementation of control measures as an integral step in a risk management process (Box 3.19). Although they provide implementation tools, actual implementation is done by stakeholders at the national level.

#### **STEP 4 IN THE RMF PROCESS: MONITORING AND REVIEW**

Recognition of monitoring and review as a formal component of a generic framework for managing biosecurity risks is relatively new.

##### **MONITORING**

Monitoring in biosecurity is variously described as either including or excluding “surveillance”. For the purposes of this manual, “monitoring” includes activities ascribed elsewhere to both “monitoring” and “surveillance” (Box 3.20).

The aim of monitoring is to gather and analyse data on the level of control of specific hazards throughout the exposure pathway and the level of protection/level of risk in the target population that is attributable to those hazards. This may be carried out ahead of implementation of control measures so as to establish baseline levels or it may follow their implementation.

Evaluating data on hazards and risks on a periodic basis provides risk managers with information on the effectiveness of their risk management decisions and actions. It should also help to identify new problems as they emerge. In some cases, competent authorities will monitor exposure pathways and levels of protection as a sentinel exercise in the absence of any specific control measures. Monitoring is also an essential activity to give effect to several provisions of the WTO SPS Agreement such as establishment and recognition of a pest- or disease-free area under Article 6. As an example, IPPC has developed standards covering

#### **Box 3.20. Working definitions associated with “monitoring and review”**

**Monitoring.** The ongoing collection and analysis of data on hazards at relevant steps throughout the exposure pathway.

**Surveillance.** The ongoing collection, analysis and dissemination of data on risks as expressed in living populations and the environment

requirements for establishment of pest-free areas, pest-free places of production and production sites, and areas of low pest prevalence.

For imported agricultural products or conveyances, it is not possible to check every unit or lot in a consignment for the presence of hazards. Official monitoring programmes in the country of origin are often imposed by importing countries as a means to improve the limited assurance that can be gained from sampling plans and procedures imposed at the border. Competent authorities in importing countries may require information from official surveillance programmes on the health status of live animal or plant populations in the exporting country.<sup>45</sup>

While competent authorities have overall responsibility for monitoring as the final step in the RMF process, monitoring of hazards at various steps in exposure pathways is often carried out by industry. This data may be made available to government so as to strengthen their knowledge or it may be kept confidential for commercial reasons. The recent increase in “private” voluntary standards (e.g. EurepGAP, a pre-farm gate private standard<sup>46</sup>) is an important trend in this respect. Compliance with private standards creates positive market access opportunities but it can become a choice between compliance or exit from the market (e.g. through high compliance costs or the inability of developing countries to comply at all). Further, the relationship between private voluntary standards and official SPS control measures is often blurred and differences relating to public health may go beyond what is scientifically justified by risk assessment<sup>47</sup>. On the

<sup>45</sup> Surveillance and monitoring of animal health in the exporting country are included in the OIE guidelines on risk analysis as an input to risk assessment.

<sup>46</sup> [www.eurepgap.org](http://www.eurepgap.org)

<sup>47</sup> WTO. 2007. *Private Standards and the SPS Agreement*. Note by the Secretariat. Committee on Sanitary and Phytosanitary Measures. G/SPS/GEN/746 (available at: <http://docsonline.wto.org/DDFDocuments/t/G/SPS/GEN746.doc>).

**Box 3.21.** Some reasons for review of biosecurity strategies and/or control measures

**Changes in monitoring outcomes**

- Changes in risks (prevalence and/or severity) identified.
- New hazards identified.
- Inadequate performance against risk reduction goals identified.

**Changes in the biosecurity situation**

- Change in type of commodity or conveyance in trade.
- Change in volume of trade.
- Change in environmental “stressors” (e.g. climate change).
- Availability of more effective and/or more efficient control measures.
- Inability to consistently comply with a control measure

positive side, monitoring as part of private voluntary standards often focuses on processes (i.e. direct outputs) rather than public health outcomes and this may ultimately assist competent authorities that focus on verification of the latter.

Monitoring may be enhanced by national networks incorporating genotyping of pathogens. As an example, FoodNet in the United States is a surveillance system where specific sites are used to seek out epidemiological information on food-borne illnesses identified by public health and regulatory laboratories. Data are collected into the PulseNet system that expedites comparison of pathogens to quickly spot related clusters of infections. BIOTRACER is a new European Union project that will use genomic and metabolomic methods for tracking microbial pathogens in food and feed.<sup>48</sup>

**REVIEW**

Where monitoring of hazards or risks indicates that biosecurity objectives are not being achieved, risk management strategies and/or control measures will need to be reviewed. Review may also be required when new information on hazards and/or risks arises. Review will be needed when there are changes in the biosecurity situation and risk assessment indicates that this change is likely to have significant impact on the current level of protection / acceptable level of risk (Box 3.21).

Integrated analysis of data on hazards in the exposure pathway and data on risks in exposed

populations and/or ecosystems is needed because information from either source is often limited.

Surveillance of adverse health impacts of chemical hazards is a difficult proposition in most situations. Causal relationships between specific chemical hazards and acute cases of toxicity can sometimes be established. However, chronic health risks potentially posed by long-term exposure to low levels of chemicals (e.g. in foods or in the environment) cannot usually be validated by surveillance data.

In some countries, regulatory impact analysis (RIA) is a formal process that is applied to new regulatory or legislative proposals to assess the associated costs and benefits. In addition to direct costs to commercial stakeholders, RIA has to take into account the transitional and ongoing costs of administration by the competent authority. RIA often depends on the availability of monitoring data that has established a baseline level of protection before application of proposed controls, with risk modelling to estimate the costs of achieving risk reduction goals.

**PERFORMANCE OF THE COMPETENT AUTHORITY**

Evaluation of the overall performance of a competent authority will draw heavily on full application of the RMF process. Performance indicators for measuring intermediate and ultimate outcomes (see page 44 and Box 3.2) will mostly be derived from monitoring data.

Monitoring the actual impacts on health and life caused by specific hazards provide the most direct indicators of performance although accurate measurement often presents practical difficulties. In other situations, the linkage between the control measures that are implemented and the level of health protection achieved may be largely theoretical (e.g. in the animal health sector, ALOPs such as limiting the risk of establishment of a hazard to less than one in a million may be embedded in risk management decisions on import controls but cannot generally be validated).

There are many opportunities to demonstrate that control measures have prevented the level of exposure to hazards from increasing, both within sectors and across sectors. In other situations, planned reduction in levels of exposure to specified hazards can be demonstrated. Monitoring programmes to demonstrate such outcomes depend on appropriate infrastructure and technical capacity and this can be provided by

<sup>48</sup> Improved bio-traceability of unintended micro-organisms and their substances in food and feed chains. European Union 6<sup>th</sup> Framework Project (available at: [www.biotracer.org](http://www.biotracer.org)).

### Box 3.22. Guidance on monitoring and review provided by international organizations

The **CAC** itself does not carry out a monitoring function. However, review of a standard can be prompted by monitoring data collected by competent authorities in national settings that suggest that a Codex standard is ineffective.

The **OIE** describes monitoring as ongoing programmes directed at detection of changes in the prevalence of a disease in a given population. Surveillance is described as the continuous investigation of a given population to detect the occurrence of disease for control purposes. Monitoring and review as an integral part of a RMF process is addressed in recent OIE standards (e.g. the standard for BSE states that surveillance strategies should be commensurate with the outcome of risk assessment and have two primary goals: to determine whether BSE is present in a country, and once it has been detected, monitor the development of the

epizootic, direct control measures and monitor their effectiveness).

The **IPPC** refers generally to monitoring and review and states in Article VII.2h “As conditions change, and as new facts become available, ensure that phytosanitary measures are promptly modified or removed...”. This is outlined in ISPM 1 as the principle of modification.

The **CBD** requires that a competent authority identify components of biological diversity important for conservation and sustainable use and monitors those components through sampling and other techniques. Monitoring systems should be capable of detecting any unexpected adverse public health or environmental effects associated with LMOs and their products.<sup>49</sup> Where possible, LMOs should have undergone an appropriate period of observation that is commensurate with the life-cycle or generation time, before being put to their intended use

competent authority, competent body and industry resources.

#### INTERNATIONAL COMMUNICATION

##### NETWORKS AND LINKAGES

Monitoring and review is greatly enhanced by effective communication networks and linkages, harmonized systems for data acquisition and analysis, and sharing of technical expertise. Formal and informal linkages with competent authorities in other countries provides data that significantly adds to the value of that collected in the domestic setting. Bilateral and multilateral agreements often contain obligations on monitoring and notification of new and emerging hazards. Membership of international organizations also has monitoring and reporting obligations. For example, OIE requires that member countries monitor the implementation of import controls and notify exotic disease outbreaks such as FMD. The latter activity has played a major role in shaping the world's meat trade.

Informal linkages assist competent authorities in keeping up to date with new risk management options and their effectiveness.

Where possible, competent authorities should link with international organizations which operate early warning systems for disease. For example, FAO, OIE and WHO have recently launched the Global Early Warning and Response System (GLEWS) to predict and respond to animal diseases, including zoonoses, worldwide. The Biosafety Clearing-House (BCH) is a cornerstone of the Cartagena Protocol in terms of a global monitoring resource.

#### MONITORING AND REVIEW BY INTERNATIONAL STANDARD-SETTING ORGANIZATIONS

All international standard-setting organizations recognize monitoring and review as an integral step in a risk management process (Box 3.22).

<sup>49</sup> Controls to minimize the unintentional transboundary movement of LMOs need to be taken in concert with specific controls related to intentional release of specific LMOs. Notification of potentially affected countries when an occurrence may lead to an unintentional transboundary movement is an obligation specified in the Cartagena Protocol.

# RISK ASSESSMENT

Risk assessment is at the heart of contemporary biosecurity risk analysis and has primarily evolved out of the necessity to make decisions on protection of health and life in the face of scientific uncertainty. Irrespective of some differences in terminology, risk assessment processes and methodologies are broadly congruent across biosecurity sectors and a generic set of principles can be used for guidance. Four general sets of activities (hazard identification, characterization of exposure, evaluation of likely adverse effects, and estimation of risk) are common across risk assessment in the sectors of biosecurity.

Risk assessments and their outputs can be qualitative or quantitative in nature. In food safety, different methodologies are used for estimating risks associated with chemical compared with biological hazards and quantitative risk assessment is an increasing trend. In animal health and plant health, risk assessment can be qualitative or quantitative with

## Box 3.23. General principles for risk assessment in the context of biosecurity

- Ensure an open exchange of ideas between risk assessors, risk managers and other stakeholders.
- Risk assessors should be objective in their scientific work and not subject to any conflict of interest.
- Each risk assessment should be fit for its intended purpose.
- The purpose, scope, questions to be answered and form of the risk assessment output should be clearly stated.
- Sufficient resources and time to carry out the work should be provided.
- Promote multidisciplinary involvement.
- The complete hazard exposure pathway should be taken into account.
- There should be explicit documentation of scientific judgements resulting from risk assessment policy.
- The risk assessment should be conducted in an iterative manner that allows refinement of the risk assessment questions, inputs and outputs where necessary.
- There should be explicit description of constraints, uncertainties and assumptions at each step in the risk assessment, including lack of scientific consensus if that occurs.
- The risk assessment should be peer reviewed.
- The reporting style should allow risk managers and other stakeholders to properly understand the risk assessment, its quality and its objectivity

potential economic impact estimated as the primary adverse effect. Risk assessments for invasive alien species and ecosystems are almost always qualitative in nature. Risk assessment for LMOs is the least well developed in terms of processes and methodologies.

Risk assessment should always be carried out in a structured, iterative and transparent manner. To the extent practicable, it should be separate and distinct from risk management so as to protect the integrity and objectivity of the risk assessment. A harmonized and integrated approach to risk assessment in biosecurity incorporates:

- common use of terminology to the extent possible;
- recognition of generic principles and a generic process;
- identification and acceptance of differences in process and methodology where necessary;
- shared understanding of ways to address uncertainty;
- shared understanding of ways to treat health, economic and other impacts when estimating risk;
- identification of differences in approach at the interface of risk assessment and risk management in different biosecurity sectors; and
- methodologies that will progress to a new generation of decision-support tools.

This chapter focuses on the processes and methodologies that are common to risk assessment in different sectors and identifies a generic approach. It further summarizes risk assessment methodologies recommended by international standard-setting organizations for each biosecurity sector. It should be noted that within a RMF applied at the national level, risk managers will commission a risk assessment and consider the results of that assessment, but the risk assessment itself is not carried out by risk managers.

## GENERIC ASPECTS OF RISK ASSESSMENT IN THE CONTEXT OF BIOSECURITY

### GENERAL PRINCIPLES

In addition to satisfying the general principles of biosecurity risk analysis outlined earlier, risk

assessment should be guided by a further set of principles (Box 3.23).

#### COMMISSIONING A RISK ASSESSMENT

Risk assessments are commissioned during “preliminary risk management activities” as described in the chapter on risk management. It is likely that a risk assessment will be commissioned when:

- the hazard exposure pathway is complex;
- data on the relative effectiveness of control measures are limited;
- the issue is of significant regulatory and/or stakeholder concern; or
- there is a mandatory regulatory requirement for a risk assessment.

Forming the risk assessment team will vary from case to case. A large-scale risk assessment will require assembly of a multidisciplinary team that is objective, balanced in terms of the required expertise and free from conflicts of interest. Small risk assessments may be undertaken by very small teams or even individuals. Risk managers, in association with the risk assessors, will formulate the questions to be answered.

#### A GENERIC RISK ASSESSMENT PROCESS

The simplest representation of biosecurity risk assessment is a process consisting of four steps as in Figure 3.5. Following identification of the hazard(s), the order in which these tasks can be carried out is not fixed. In most cases, risk assessment will be a highly iterative process involving risk assessors, risk managers and risk communicators. Where data on which to base model input variables is insufficient, expert opinion may be elicited. Where expert opinion is unavailable, risk assessors may default to best judgement in line with risk assessment policy. Such judgements should be clearly identified in the report of the risk assessment.

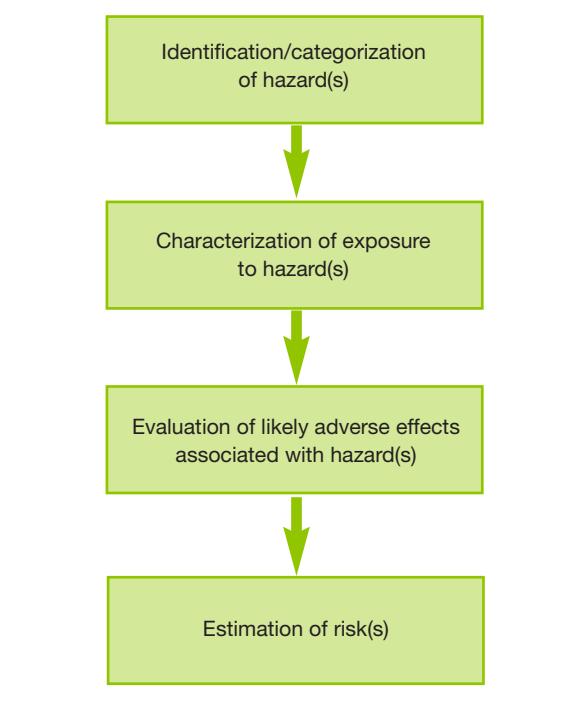
#### TRANSPARENCY

The risk assessment process must be transparent (Box 3.24).

#### DEALING WITH UNCERTAINTY

When data is lacking, uncertainty about the available scientific information can be represented in a risk assessment by using a range of possible data values. Uncertainty also arises from various conceptualisations of limitations imposed when modelling a biosecurity system. Risk assessors must ensure that risk

**Figure 3.5. A generic representation of steps involved in risk assessment in biosecurity**



**Box 3.24.** Characteristics of documentation that ensure transparency

- Scientific rationale and model structure is clearly presented.
- Any factors that impact on the risk assessment (e.g. resource constraints, non-representativeness of data inputs, data gaps) are identified.
- All scientific inputs are clearly and systematically described.
- Assumptions and uncertainties are identified and explained.
- An interpretive summary is provided for lay readers.
- Draft assessments are discussed with the public before finalization

managers understand the sources and degree of uncertainty in the risk assessment and the impact it has on risk estimates. Uncertainty (the quality of being unknown) should be clearly separated from variability (a characteristic of biological phenomena that differ from one observation to the next).

The risk assessment should describe how assumptions made in the face of uncertainty affect the results of the assessment. This should be distinguishable from the impact of biological variation that is inherent to any system. Where risk assessments

are qualitative in nature, characterizing the impact of uncertainty on the outputs becomes problematic.

When data is lacking, expert opinion can be used to address important questions and reduce uncertainty. A range of knowledge elicitation techniques are available. Experts may be unaccustomed to describing what they know or how they know it; knowledge elicitation techniques (e.g. Delphi method<sup>50</sup>) reveal expert knowledge and help to make expert opinions as evidence-based as possible.

Risk assessment will often raise levels of uncertainty that can only be mitigated by further research. After a core risk assessment has been completed, risk assessors may identify that they cannot properly answer the questions asked by risk managers until they have more scientific information.

#### ESTIMATES OF RISK

Risk assessments are described as qualitative or quantitative and outputs can be expressed in non-numerical or numerical terms (Box 3.25). “Semi-quantitative” risk assessments are sometimes described (e.g. assigning scores at each step in a hazard exposure pathway and expressing outputs as risk rankings).

To date, the majority of biosecurity risk assessments that have been undertaken are qualitative in nature. This is especially the case for plant quarantine and environmental risk assessments. Non-numerical risk estimates provide a less definitive base for decision-making on control measures relative to delivery of a specified level of health or life protection.

Where feasible and practical, probabilistic quantitative risk assessment is particularly useful because it:

- generates thousands of scenarios, thereby undertaking a probabilistic analysis that enhances representation of the real world;
- is an integrated response to problem solving and usually incorporates multidisciplinary inputs;
- focuses on quantification of uncertainty and thereby creates a good picture of what the community of experts know or do not know;
- presents risk estimates as probability distributions rather than point (deterministic) estimates; and

<sup>50</sup> The Delphi method is a technique for eliciting and refining group judgements. The objective is generally the reliable and creative exploration of ideas or the production of suitable information for decision making (further information on this method is available at: <http://www.iit.edu/~it/delphi.html>).

#### Box 3.25. Types of risk assessment outputs

A **qualitative** risk estimate is one where the likelihood and/or the magnitude of the consequences are expressed in qualitative terms such as high, medium or low.

A **quantitative** risk estimate is one where the likelihood and/or the magnitude of the consequences are expressed numerically and this should include a numerical description of uncertainty █

- allows direct comparison of different intervention strategies in terms of their impact on risks.

Despite the advantages, probabilistic risk assessment remains difficult. There are diverse opinions amongst scientists as to which probabilistic approaches are the most appropriate for complex biological situations. Further, the data necessary to fully model exposure and estimate risk for a particular biosecurity situation are rarely available.

#### SENSITIVITY ANALYSIS

Where a quantitative risk assessment is available, sensitivity analysis helps risk managers select those control measures that best achieve risk management objectives. Risk assessors can apply this analytical tool to a risk assessment to systematically investigate which input variables have the greatest influence on the outcomes of the risk assessment.

Probabilistic software programmes can perform sensitivity analysis by producing graphs or rank correlation statistics between input parameters and output parameters. This allows evaluation of the impact of each input distribution on the output distribution. Where the distribution in the data may be assigned to variation and uncertainty, a two-dimensional sensitivity analysis may be needed. Those input distributions where uncertainty has the greatest impact on the outcome can be identified, and this may illustrate a need for more research to reduce that uncertainty.

“What if” scenarios can be used to evaluate the impact of different assumptions and different ranges of input data on model outcomes. The results for each new “what if” scenario are compared to the baseline outcome to determine the degree of change.

#### VALIDATION

Model validation is the process whereby a simulation model is evaluated for its accuracy in representing a biosecurity system, for instance, by comparing model

Table 3.3. Terminology used by different international organizations to describe risk assessment activities

Generic risk assessment process	Food safety (CAC)	Animal health (OIE)	Plant health (IPPC)	Biodiversity and the environment (CBD)
Identification of hazards	Hazard identification	(Hazard identification identification has already been carried out as a stand-alone process)	Pest categorization	Characteristics of the invasive species. Identify novel characteristics of the LMO
Characterization of exposure to hazards	Exposure characterization	Release assessment. Exposure assessment	Assessment of probability of introduction and spread	No specific terminology
Evaluation of likely adverse effects associated with hazards	Hazard characterization (including dose/response if available)	Consequence assessment	Assessment of potential economic consequences	Evaluate consequences
Estimation of risks	Risk characterization	Risk estimate	Conclusion of risk assessment	Estimation of risks

predictions of disease with surveillance or epidemiological data, or comparing model predictions with survey data (or other data independent of the data used in the model construction) from an intermediate step in the hazard exposure pathway.

Recent food safety risk assessments performed by the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) provide examples of validation however these are more difficult to find in risk assessments from other biosecurity sectors. Validation of risk assessments for non-quarantine plant hazards/pests are possible as they are based on the hazard/pest already being present at some level in the control area and therefore subject to surveillance.

#### WTO JURISPRUDENCE ON BIOSECURITY RISK ASSESSMENTS

The WTO Appellate Body is establishing a body of jurisprudence on scientific justification of control measures under the WTO. In settling a dispute over Australia's ban on imports of fresh and frozen salmon in order to prevent entry of a number of fish-borne disease, the Appellate Body established a three-pronged test for what would qualify as an adequate risk assessment under the SPS Agreement:

- identification of the hazards and possible biological and economic consequences of their entry or spreading;
- evaluation of the likelihood of entry, establishment, or spreading; and
- evaluation of the impact of SPS measures on this likelihood.

Where an ALOP cannot be precisely expressed, it may be determined on the basis of the level of protection reflected in the control measures in place.<sup>51</sup>

Risks should be estimated according to the SPS measure that might be applied. Challenges to import restrictions that have been established in the absence of risk assessment based on SPS measures that might have been applied have generally been successful (such as control measures for fire blight on apples imported to Japan).<sup>52</sup>

#### CONCURRENCE OF THE GENERIC RISK ASSESSMENT PROCESS WITH SECTOR TERMINOLOGY AND PROCESSES

While terminology used by international biosecurity sector organizations differs somewhat, the key activities of the generic risk assessment process described in this chapter are common to all biosecurity sectors (Table 3.3).

#### FOOD SAFETY RISK ASSESSMENT

The CAC describes food safety risk assessment as "a scientifically-based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, risk characterization". Principles to guide food safety risk assessment are fully congruent with the generic biosecurity principles presented in Box 3.23.

<sup>51</sup> WTO. 2000. *Guidelines to further the practical application of Article 5.5*. WTO Committee on Sanitary and Phytosanitary Measures G/SPS/15 (available at: <http://docsonline.wto.org/DDFDocuments/t/G/SPS/15.doc>).

<sup>52</sup> WTO 2005. *Specific Trade Concerns. Note by the Secretariat*. WTO Committee on Sanitary and Phytosanitary Measures G/SPS/GEN/204/Rev.5 (available at: <http://docsonline.wto.org/DDFDocuments/t/G/SPS/GEN204R5.doc>).

### STEPS AS DESCRIBED BY CAC

Food safety risk assessment generally incorporates four steps:

- Hazard identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects.
- Exposure assessment:<sup>53</sup> The qualitative or quantitative evaluation of the likely intake of food-borne hazards, taking into account other exposure pathways where relevant.
- Hazard characterization: The qualitative or quantitative evaluation of the nature of the adverse health effects, and ideally including dose-response assessment.
- Risk characterization: The qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population.

### RISK ASSESSMENT FOR CHEMICAL HAZARDS

Adverse human health effects from exposure to chemical hazards are usually predicted for a lifetime of exposure. This is a fundamentally different process to estimating exposure in the case of biological hazards where the risk assessor is interested in a single exposure producing an acute adverse health effect.<sup>54</sup> Because long-term exposure is needed to induce a health effect, chemical risk assessment is unlikely to include consideration of individual variability in toxicological susceptibility.

Many quantitative standards have been established by Codex for allowable or “tolerable” levels of different classes of chemical hazards in foods. Data needs are well served by global data-gathering systems and other information sources specific to the class of hazard under consideration (e.g. national total diet surveys, industry registration packages for pesticides and veterinary drugs). The standards are usually set according to a deterministic “safety evaluation” process rather than a risk assessment *per se* and this generally employs a “worst case” exposure scenario.

Methylmercury in fish is an example of a chemical risk assessment that follows the generic RMF presented in this manual.<sup>55</sup>

<sup>53</sup> The order in which hazard characterization and exposure assessment is carried out is not fixed.

<sup>54</sup> Note that many natural toxins such as mycotoxins in grains and marine toxins in shellfish need insight into biology as well as chemistry for their risk assessment.

### “Safety evaluation”

Safety evaluation generally incorporates each of the steps in the generic risk assessment process for biosecurity. Hazard identification is the first task. Hazard characterization is usually represented by an animal model that is the most sensitive means of establishing adverse health effects associated with the particular chemical hazard. Exposure to the hazard is estimated by constructing an exposure pathway through different steps in the food chain and calculating likely dietary intake. Risk characterization correlates to estimation of an acceptable daily intake (ADI) for humans and this is extrapolated from a “no adverse effect level” as found in the animal model. The ADI represents an estimation of the maximum amount of hazard that can be absorbed daily by the consumer for a lifetime without risk to health; therefore it incorporates a pre-determined “notional zero risk” ALOP as a generic policy decision. The use of the chemical hazard in food or the level of unintended environmental contamination of the food so that the ADI will not be exceeded will incorporate appropriate risk management decisions (e.g. withholding times before harvesting of crops in the case of pesticides, restricting dietary exposure to particular foods).

In some cases, risk characterization will include consideration of different uses of chemical hazards, for instance, when a substance is used as both a veterinary drug for treatment of animals and a pesticide on plants, both pathways can be taken into account when setting an ADI for a type of food.

### “Safety factors”

Estimation of the ADI includes imposition of arbitrary “safety factors” as a way of mitigating uncertainty inherent in any animal model and its extrapolation to humans. Thus the ADI only correlates to a crude estimate of risk and the inherent uncertainty remains unquantified. Methods are now available for calculating reference doses for acute chemical toxicity if this is a potential adverse health effect.

### Maximum residue levels

Exposure characterization describes the exposure pathway for the hazard and predictions of dietary intake. This step is generally carried out in conjunction

<sup>55</sup> See Annex 2 of FAO/WHO. 2006. *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*. FAO Food and Nutrition Paper 87 (available at: [ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf](http://ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf)).

with estimation of the ADI and is usually composed of simple deterministic values for hazard levels at each step in the food chain. However, probabilistic models are emerging (e.g. for intake of pesticide residues). Maximum residue limits (MRLs) for chemical residues are established so that the theoretical maximum daily intake of residues is lower than that allowable by the ADI. If MRLs are likely to be exceeded when an agricultural chemical is used according to that described in the registration package, the risk manager will require a change (e.g. increased withholding times after use of a veterinary drug, longer time to harvesting of a crop after application of a pesticide).

For unavoidable environmental contaminants, Codex standards are often related to “permissible levels”, that is there is tacit acceptance that it is not economically or technically feasible to apply the same “notional zero risk” model that is applied to other chemicals in the food supply. However, the conservatism inherent to the safety evaluation process still has the effect of ensuring sufficient protection of human health.

#### **Quantitative risk assessment models**

Quantitative risk assessment modelling is rarely applied to chemical hazards, mainly because the “safety evaluation” of adverse health effects has generally been considered adequate. However, quantitative models are applied by some governments for characterizing non-threshold effects (e.g. for genotoxic carcinogens). These models utilize a biologically-appropriate mathematical extrapolation to fit observed animal data (usually derived at high doses) to the expected dose response at low levels. Data requirements for this approach are often difficult to meet and competent authorities in different countries may use different toxicological reference values and extrapolation models. This can lead to significant differences in cancer risk estimates.

#### **RISK ASSESSMENT FOR BIOLOGICAL HAZARDS**

Risk assessment for biological hazards in foods is a relatively recent development. Although bacteria, viruses, parasites and other biological agents may all be subjected to risk assessment, microbiological hazards have received the most attention to date. However, significant data gaps currently limit the ability to develop risk estimates with sufficient precision to allow risk-based regulatory targets to be set for defined hazard/food combinations.

*Listeria monocytogenes* in ready-to-eat foods is an example of a food safety microbiological risk assessment that follows the generic RMF presented in this manual.<sup>56</sup>

#### **Hazard identification**

This involves identification of a living agent or its toxin that may be present in a specific food. Recent epidemiological studies illustrate the value in identifying food-borne microbes to genotype level when assessing risks (e.g. multilocus sequence typing (MLST) of *Campylobacter* strains is showing that attributable risk varies significantly).

#### **Exposure characterization**

The likely intake of food-borne hazards in an edible portion of food is estimated from an exposure pathway model. This will depend on many factors including the extent of initial contamination of the raw food, the characteristics of the food and the food process in terms of survival, multiplication or death of the hazard, and the conditions of storage and preparation before eating.

#### **Hazard characterization**

This involves the qualitative or quantitative description of the severity and duration of adverse health effects that may result from ingestion of biological hazards or their toxins. Hazard characterization should ideally include quantitative dose-response information. A wide range of hazard factors (e.g. infectivity, virulence, antibiotic resistance) and host factors (e.g. physiological susceptibility, immune status, previous exposure history) are taken into consideration.

#### **Risk characterization**

Exposure and hazard characterization are used to generate estimates of risk. Risk estimates can be qualitative (e.g. high, medium or low rankings) or presented in quantitative terms (e.g. cumulative frequency distributions of risk per serving, risk in a population per annum or relative risks).

FAO and WHO have embarked on a series of microbiological risk assessments that represent an extensive and ongoing scientific commitment. This work is heavily dependent on QRAs already

<sup>56</sup> See Annex 3 of FAO/WHO. 2006. *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*. FAO Food and Nutrition Paper 87 (available at: [ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf](http://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf)).

commissioned by national governments. Topics include *Salmonella* spp. in broilers, *Salmonella* spp. in eggs, *Listeria monocytogenes* in ready-to-eat foods, *Campylobacter* spp. in poultry and *Vibrio haemolyticus* in seafood. These risk assessments inform both Codex and national competent authorities in the development of risk-based standards. The CAC is of the view that risk assessment should be used across biosecurity sectors to evaluate public health threats that may arise from antimicrobial resistant micro-organisms in food. A model to estimate the risk of human cases of campylobacteriosis caused by fluoroquinolone-resistant *Campylobacter* spp. transmitted by poultry meat in the United States established a highly linear relationship between the flock prevalence and food-borne risks.<sup>57</sup>

#### RISK ASSESSMENT OF FOODS

##### DERIVED FROM MODERN BIOTECHNOLOGY

Risk assessment principles have recently been elaborated by Codex for foods derived from modern biotechnology.<sup>58</sup> Potential adverse health effects of such foods include transfer of, or creation of new, toxins or allergens. The generic risk assessment approach described above can be applied but it has to be somewhat modified when applied to a whole food. This includes consideration of the characteristics of the donor and recipient organisms, the genes inserted and expressed, the extent of equivalence (compositional, nutritional, safety and agronomic) with appropriate comparators and the potential for dietary impact. A pre-market safety assessment should be carried out to compare the food derived from biotechnology with its conventional counterpart and safety must be assessed in ways on the basis of both intended and unintended changes in the food. Animal studies cannot readily be applied to testing the risks associated with whole foods, however, in particular cases properly designed animal studies can be requested. Specific risk assessment methodology has been developed for genetically-modified food crops and microorganisms,<sup>59</sup> and is being elaborated by Codex for genetically-modified animals.

<sup>57</sup> Bartholomew, M., Vose, D., Tollefson, L. and Travis, C. 2005. A linear model for managing the risk of antimicrobial resistance originating from food animals. *Risk Analysis* 25 (1): 99-108

<sup>58</sup> FAO/WHO. 2003. *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*. Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission. CAC/GL 44-2003 (available at: <http://www.fao.org/docrep/007/y5819e/y5819e02.htm>).

## ANIMAL HEALTH RISK ASSESSMENT

OIE describes risk assessment as “evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a hazard within the territory of an importing country”. Principles guiding animal health risk assessment are fully congruent with the generic biosecurity principles presented in Box 3.23. A risk assessment may be based on a commodity, an animal species (or similar group), or a particular disease (Box 3.26).

#### STEPS AS DESCRIBED BY OIE

Animal health risk assessment incorporates four steps:

- release assessment;
- exposure assessment;
- consequence assessment; and
- risk estimation.

Importantly, OIE describes hazard identification as an activity that is separate from risk assessment. However, the OIE activities involved in hazard identification clearly bridge to hazard identification described as the first step in the generic risk assessment process. Hazard identification includes identification of the pathogenic agents which could be present in the exporting country and that could potentially produce adverse animal health consequences in the importing country. It also includes identifying whether the hazard is already present in the importing country, and whether it is a notifiable disease or is subject to official control or eradication.

Evaluation of the veterinary services and their systems in the exporting country is an important input to assessing the likely presence of the hazard. This also confers confidence to the importing country in relation to factors such as veterinary certification, disease surveillance, animal health controls and diagnostic capability. Any OIE Member Country can request a visit to another country for the purpose of a formal evaluation of veterinary services.

<sup>59</sup> FAO/WHO. 2003. *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*. Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission. CAC/GL 45-2003 (available at: <http://www.fao.org/docrep/007/y5819e/y5819e03.htm#bm3>) and *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*. CAC/GL 46-2003 (available at: <http://www.fao.org/docrep/007/y5819e/y5819e04.htm#bm4>).

### Box 3.26. Example of cross-sectoral animal and public health risk assessment

Following the BSE epidemic in the UK in the late 1980s, a ban on the sale of beef from cattle over 30 months of age at slaughter was introduced in 1996. This was a response to a cross-sectoral biosecurity threat – strong evidence was emerging that variant Creutzfeldt-Jakob disease (vCJD) was caused by eating cattle with BSE. The infectivity of cattle increases with age. As the epidemic waned in cattle, a risk assessment was commissioned to establish the costs and benefits associated with continuation of the 30 month ban. This examined the potential increase in risks to human health if the ban was removed and replaced with the OIE-based BSE testing programme used in other European

Union countries. Exposure assessment was based on the amount of infectivity that had entered the food chain historically because of the BSE epidemic and the additional infectivity that would enter if the ban was lifted. Risks were estimated in terms of additional epidemic cases of vCJD. It was estimated that there would be about 0.5 new cases over a period of 60 years, with a worst case scenario of 2.5 cases, if the animal health control measure was changed. The UK Food Safety Authority recommended a change in control measures because of the very high economic cost to the agricultural industry versus the very small gain in public health protection

#### RISK ASSESSMENT PROCESS

Risk assessments under the OIE process are designed to answer the question “What is the likelihood of specified adverse consequences occurring as a result of exposure to a particular commodity or pathogen that came from a defined release source?” No single method of import risk assessment is recommended for all situations and special reference is drawn to the fact that risk increases with increasing volume of the animal commodity imported.

A risk assessment will only be commissioned where necessary. In some situations, an importing country may decide to permit imports of an animal product using the control measures recommended in the OIE Codes, thereby bypassing the need for a risk assessment.

#### Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to “release” hazards into a particular environment, and estimating the probability of that complete process occurring, either qualitatively or quantitatively. It includes a description of how the probability of “release” in terms of amount and timing may change as a result of various actions, events or measures (i.e. biological factors, country factors and commodity factors). Biological factors include species, age and breed of animal, agent predilection sites, and vaccination, testing, treatment and quarantine. Country factors include incidence/prevalence of the hazard, evaluation of veterinary services, and surveillance and control programmes in the exporting country. Commodity factors include quantity of commodity imported, ease of contamination, effect of processing, and effect of storage and transport.

The likelihood of release is directly proportional to the volume of trade.

#### Exposure assessment

This activity details the probability of animal (and/or human) exposure to the hazard via the identified biological pathway(s). (Release assessment and exposure assessment effectively combine to represent exposure characterization in the generic RMF process). The probability of exposure to the identified hazards is estimated for specific exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and characteristics of the animal and human populations exposed.

Outputs of exposure assessment can be described in quantitative (e.g. numbers of herds or animals likely to experience adverse health consequences over time) or qualitative terms.

#### Consequence assessment

Consequence assessment is the probability of specific exposures causing adverse impacts in terms of direct consequences (e.g. animal production losses and human health impacts) and indirect consequences (e.g. surveillance, control and compensation costs, potential trade losses, adverse environmental effects). Consequence assessment is congruent with evaluation of adverse impacts in the generic biosecurity risk assessment process.

Drafting of scenario trees is commonly used to depict the likelihood of each scenario and its consequences. Economic impacts include those from lost production, mortality, disease control and lost sales. The extent of each of these can change markedly in each biosecurity environment, depending on how the disease behaves epidemiologically and how national and international markets react. For instance, introduction of FMD would result in immediate loss of all agricultural export markets in the New Zealand situation with a devastating impact on the economy,

whereas other countries not so dependant on agricultural exports can sustain periodic outbreaks with much lesser economic concern. Valuation of non-market effects (e.g. threats to biodiversity and endangered species) is an important part of benefit-cost analysis and presents a number of challenges.

Stochastic modelling of production losses, costs of controls and their effectiveness in mitigating risk is a difficult proposition, and has yet to be widely applied as a means of ranking economic risks associated with different animal diseases.

#### ***Risk estimation***

Exposure assessment and consequence assessment are combined to estimate risk. Most animal health risk estimates are qualitative in nature and the results from release, exposure and consequence assessments are summarized to estimate whether or not the risk is "negligible". This initial judgement is made by the risk assessor and will be subjective to some degree. Quantification of the risk estimate itself is attempted in only a small proportion of import risk analyses and is inherently difficult for many of the same reasons found in food safety microbiological risk assessment.

The estimated risk in a given scenario will be compared with the Member Country's ALOP to determine if existing control measures are adequate.<sup>60</sup> Risk management is almost exclusively focused on selecting control measures that will reduce the likelihood of introduction of exotic diseases and organisms to a level that is considered acceptable.

#### **ZONING, REGIONALIZATION AND COMPARTMENTALISATION**

While these concepts are a shared concept in biosecurity risk assessment, they are especially important in animal (and plant) health. They allow definition of geographical areas of different animal health status within the territory of a country for the purposes of risk assessment and international trade. OIE stipulates the risk management options that are required for different diseases to assure the integrity of claims.

#### **PLANT HEALTH RISK ASSESSMENT**

For the IPPC, risk assessment is the second of the three stages of PRA, coming after initiation and before risk management. Risk assessment for quarantine hazards/pests is defined as "the evaluation of the probability of introduction and spread of a pest and of

the associated potential economic consequences".<sup>61</sup> Plants themselves can be hazards/pests to other plants when they are transferred to regions beyond their natural range. LMOs may present a phytosanitary risk and could warrant a PRA but it should be noted that other risks possibly associated with LMOs (e.g. social or human or animal health related) are not covered by the IPPC. Annex 3 of ISPM 11 helps to determine the potential for a LMO to be a hazard/pest and if it is determined to be so, the PRA framework of the IPPC can be applied. Principles guiding plant health risk assessment are fully congruent with the generic biosecurity principles presented in Box 3.23.

The IPPC is developing training materials specific to pest risk analysis, including a training course, workbook and teacher's manual.<sup>62</sup>

#### **STEPS AS DESCRIBED BY IPPC**

Plant health risk assessment generally incorporates four steps:

- hazard/pest categorization;
- assessment of the probability of introduction and spread;
- assessment of potential economic consequences; and
- conclusion (final output) of the risk assessment.

#### **RISK ASSESSMENT PROCESS**

IPPC guidelines are general in nature and plant health risk assessments are almost always qualitative. There are two main approaches to conducting a risk assessment; one focused on a pathway, the other focused on a particular pest associated with one or more pathways (Box 3.27).

#### ***Hazard/pest categorization***

For a quarantine risk assessment to proceed, hazards/pests have to satisfy the criteria for definition of a quarantine hazard/pest. Criteria include identification of the hazard/pest, confirmation of absence from the PRA area, regulatory status (i.e. under official control if

<sup>60</sup> This judgement is presented as part of the animal health risk assessment process whereas it would be undertaken by risk managers as part of identification and selection of risk management options in the generic RMF process.

<sup>61</sup> For the purposes of this document reference is made to PRA for quarantine pests. However, under the IPPC, the PRA process may also be applied to regulated non-quarantine pests. These two types of pests are jointly referred to as regulated pests.

<sup>62</sup> These materials will be available on the IPPC web site at: <https://www.ippc.int/id/186208?language=en>.

present but not widely distributed),<sup>63</sup> potential for establishment and spread according to biological parameters, and potential for unacceptable economic impact.<sup>64</sup> In some cases, countries may proceed to implement control measures even if the hazard/pest is not designated as a quarantine hazard/pest.

#### ***Assessment of the probability of introduction and spread***

This depends on: identification of all possible pathways from the exporting country, estimating the frequency and quantity of hazards/pests associated with the pathways at origin (spatially and/or temporally), and assessing the probability of the hazard/pest surviving transport, storage and existing control measures, and transferring to a suitable host. Assessment of the probability of establishment depends on the biological features of the hazard/pest such as availability of suitable hosts and vectors, suitability of the environment, crop cultivation practices, and control programmes and natural enemies. Assessment of the probability of spread after establishment also depends on a range of factors, including the potential for movement of the commodity and its intended end use.

#### ***Assessment of potential economic consequences***

In the general case, potential economic consequences should be estimated as monetary values. However, detailed analysis of economic consequences is not necessary if it is widely agreed that introduction of a hazard/pest will have “unacceptable” economic consequences (including environmental consequences). Here, the primary output of the risk assessment will be the probability of introduction and spread.

Economic factors need to be evaluated in appropriate detail (e.g. the uncertainty in the level of economic consequence, the need to assess the cost-benefit of exclusion or control) and these will vary on a case-by-case basis. Evaluation will include potential direct effects (e.g. type, amount and frequency of damage to known host plants, reduction of plant species that are major components of ecosystems) and

<sup>63</sup> If a plant pest is present in the PRA area but has not reached the limits of its ecological range, and is subject to official control, then the PRA is continued. If such limits have been reached, the PRA is discontinued.

<sup>64</sup> In other biosecurity sectors, an agent with *any potential* to cause adverse effects qualifies as a hazard.

#### ***Box 3.27. Example of a pest-initiated plant health risk assessment: Codling moth (*Lepidoptera: Tortricidae*) in cherries imported to Japan***

A probabilistic model was developed for the risk of codling moth being spread through the international trade in sweet cherries. The model was based on the recorded incidence of codling moths in sweet cherries, volumes of fruit in trade, and the estimated probability of survival during storage, transport to, and arrival in Japan. The quantitative model demonstrated that the probability of at least one male and one female surviving to adulthood from a consignment is extremely low in the case of cherries from New Zealand (less than  $8.5 \times 10^{-10}$  per consignment) and the United States (less than  $1.4 \times 10^{-6}$  per consignment), and therefore the need for specific quarantine measures is not scientifically justified.

C. H. Wearing, J. D. Hansen, C. Whyte, C. E. Miller and J. Brown. 2001. Potential for spread of codling moth (*Lepidoptera: Tortricidae*) via commercial sweet cherry fruit: a critical review and risk assessment. *Crop Protection* 20: 465-488

potential indirect effects (e.g. impacts on domestic and export markets, feasibility and cost of eradication or containment, significant changes in ecological processes, effects on human use). Analytical techniques may include partial budgeting, partial equilibrium approaches or general equilibrium approaches.

Potential non-commercial, social and environmental impacts are difficult to value in economic terms and will likely result only in qualitative inputs to assessment of economic consequences.

#### ***Final output of the risk assessment***

In the ideal situation, the risk estimate will be based on a quantitative or qualitative estimate of the probability of introduction of a hazard/pest and a corresponding estimate of economic consequences (including environmental and social impacts). For each hazard/pest being assessed, all or part of the PRA area may be identified as an endangered area.

This is followed by a qualitative judgement or recommendation by the risk assessor as to whether or not the hazard/pest has sufficient economic importance and introduction potential to justify specific control measures.<sup>65</sup> If the risk is deemed to be unacceptable, the PRA process may continue by

<sup>65</sup> This judgement is presented as part of the risk assessment process in plant health whereas it would be undertaken by risk managers as part of identification and selection of risk management options in the generic biosecurity RMF.

suggesting risk management options that will reduce the risk to an acceptable level.

PRA may constitute only a portion of the required overall risk analysis in some plant health situations. As an example, insect resistant GM crops have been developed by expression of a variety of insecticidal toxins from the bacterium *Bacillus thuringiensis* (Bt). Detrimental effect on beneficial insects or a faster induction of resistant insects have been considered in environmental risk assessment of a number of such insect-protected GM crops. Another example is outcrossing of transgenes from fields of commercially grown GM plants such as oilseed rape and sugar beet. This has the potential to transfer herbicide resistant genes to weeds creating new weed management problems.

Countries may require the assessment of risks to human or animal health or to the environment beyond that covered by IPPC. When a competent authority discovers potential for risks that are not phytosanitary it should notify the relevant authorities.

#### **Box 3.28.** Example of risk assessment of an invasive alien species: Importation of spiders associated with table grapes

A New Zealand study of the probability of introduction and establishment of spiders associated with table grapes showed that opportunities for infestation and pathways for introduction can be readily identified, along with a range of mitigation strategies (e.g. visual inspection and/or forced air fumigation either pre-shipment or post-shipment, packaging sanitation and security, and cold storage). Audit and certification requirements of competent authorities can also be specified. However, mitigation strategies cannot guarantee exclusion. For example, a 920 unit sample with a zero acceptance level provides 99 percent confidence that not more than 0.5 percent of the total units within the consignment are infested.

The likelihood of entry is low (but low-moderate for grapes from Chile). Risk of establishment is low to moderate, and risk of spread is moderate. Adverse health effects on humans were identified but discussion on the adverse impact on native species was speculative. It is noteworthy in this example the acceptable level of risk was defined as “the acceptable likelihood of entry given application of measures”.

The study also demonstrated the difficulty of establishing risks when the range of spiders that could infest the particular commodity in different countries of origin is substantial.

MAF. 2002. *MAF Biosecurity Pest Risk Assessment: Spiders associated with table grapes from the United States of America (State of California), Australia, Mexico and Chile*. New Zealand Ministry of Agriculture and Forestry (MAF). September 2002 (available at: <http://www.biosecurity.govt.nz/pests-diseases/plants/risk/spiders-grapes/spiders-grapes-ra.pdf>)

## RISK ASSESSMENT OF INVASIVE ALIEN SPECIES

The CBD focuses on biodiversity protection and sustainable use of biological resources, both of which are closely linked to human interests. It describes risk assessment for alien species as “an assessment of the consequences of the introduction and likelihood of establishment of an alien species using science based information”. Where the CBD describes principles to guide risk assessment, they are congruent with the generic biosecurity principles presented in Box 3.23.

Risk assessment steps themselves are only referred to in a general manner. Many aspects of hazard identification and evaluation of adverse effects are the primary responsibility of the applicant party (including relevant competent authorities). This is a different situation to risk assessment for food, animals and plants in international trade where the importing country bears the primary responsibility for risk assessment.

## RISK ASSESSMENT PROCESS

The risk assessment guidelines of several international legal instruments and organizations may be invoked in risk assessment of invasive alien species (Box 3.28). Specific risk assessment methodologies are still being developed.<sup>66</sup> The outputs of these risk assessments are almost always qualitative and include many subjective judgements.

Assessment, information and tools include:

- characteristics of the invasive species, the vulnerability of ecosystems and habitats, and the impact of climate change on these parameters;
- impact on biological diversity, at the species and genetic level;
- analysis of the importance of various pathways for introduction;
- social and economic impacts;
- development of control and eradication measures;
- costs and benefits of use of biocontrol agents; and
- criteria for assessing risks.

Clearly, there is a combination of risk assessment and risk management activities in the above. The burden of proof that a proposed introduction is unlikely to threaten biological diversity lies with the proposer for the introduction, or may be assigned as appropriate to the recipient country.

<sup>66</sup> Stohlgren, T. and Schnase, J. 2006. Risk analysis for biological hazards: What we need to know about invasive species. *Risk Analysis* 26 (1): 163-173.

Risk assessment endpoints associated with estimates of potential distribution, potential rate of spread and abundance are variable (e.g. reduction or replacement of native taxa, negative impacts on ecosystem components or processes, negative effects on human health). Costs associated with invading species may be environmental, economic (containment potential, costs and opportunity costs) or social (including risks to human health). Estimating monetary endpoints for risk assessment purposes may be attempted but quantifying reductions in native species, loss of native genetic diversity, and extinctions requires non-market valuations. Complications arise when estimating the influence of long lag times from introduction and establishment to successful invasion.

### RISK ASSESSMENT OF LMOs AND THEIR PRODUCTS

The Cartagena Protocol to the CBD describes risk assessment as “an assessment of the adverse effects of LMOs on the conservation and sustainable use of biological diversity, also taking into account risks to human health”.

#### STEPS AS DESCRIBED IN THE CARTAGENA PROTOCOL

Risk assessment of LMOs and their products incorporates the following steps:

- identify novel LMO genotypic or phenotypic characteristics that may cause adverse effects;
- evaluate the likelihood of these effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment;
- evaluate the consequences should these adverse effects be realized;
- estimate the overall risk based on likelihood and consequence;
- recommend as to whether or not the risks are acceptable or manageable, including where necessary, identification of strategies to manage these risks; and
- where there is uncertainty regarding the level of risk, consider the need for further information, or implement risk management strategies and/or monitoring in the receiving environment.

It is clear from the above that risk assessors are involved in risk management decisions as described in the generic biosecurity RMF.

### RISK ASSESSMENT PROCESS

As part of hazard identification, LMOs can be classified as being for: intentional introduction into the environment, direct use as food or feed, or use in processing. Risk assessment should take into account detection and identification methods for hazards, information relating to end use, and information relevant to the receiving environment. Detailed risk assessment methodologies are still being developed and a severe shortage of scientific information on possible environmental interactions makes quantitative risk assessment very difficult.

As with invasive alien species, the output of risk assessment for LMOs is almost always qualitative and includes many subjective judgements. Deliberate release of an LMO may have substantial benefits (e.g. sustainable development and more cost-effective food supplies). However, environmental release may initiate environmental risks in some situations. Potential risks can be expressed in a variety of ways. For instance, in the case of transgenic plants, risks may arise from increased “weediness”, transgene flow into related species, and development of new viruses with a wider host range on virus-resistant plants.

Regional effects are important. When a GM crop is subjected to risk assessment, contradictory findings for benefits and risks may be found and this reflects the impact of different agro-ecological conditions in different regions. As an example, the use of herbicide resistant crops and the consequent herbicide use could potentially be detrimental in a small-sized agricultural area which has extensive crop rotation and low levels of hazard/pest pressure. However, the moderate herbicide use related to these GM plants could be beneficial in other situations where it might actually represent a decrease in overall herbicide use.

The IPPC is developing guidelines on risk assessment of LMOs that qualify for PRA. Types of LMOs include modified plants for use in agriculture and horticulture, biological control agents modified to improve their performance, and pests modified to alter their pathogenic characteristics.

Risk assessment of LMOs under the Cartagena Protocol includes recommendations as to whether or not the risks are “acceptable or manageable”<sup>67</sup> and this remains a very subjective judgment.

<sup>67</sup> This is a decision for risk managers rather than risk assessors in the context of the generic RMF process.

# RISK COMMUNICATION

While risk analysis has emerged as a key discipline in biosecurity, the risk communication component has generally received much less attention than risk assessment and risk management. This has been to the detriment of risk analysis in some recent high-profile biosecurity events that have had global impacts (e.g. BSE and FMD outbreaks in Europe, contamination of the food supply with dioxins).

Ideally, a risk communication team should be deployed for all risk management projects that involve

## Box 3.29. Principles of risk communication in biosecurity

- Risk communication strategies and programmes should actively promote the understanding and involvement of all stakeholders in the risk analysis process.
- Risk communication should facilitate an open and interactive exchange of information, facts and opinions about risks amongst risk managers, risk assessors and other stakeholders.
- Management of each biosecurity issue involving a significant risk assessment should include a risk communication strategy and implementation plan.
- Variability, uncertainty and assumptions in risk models should be communicated to risk managers and external stakeholders in a user-friendly and understandable manner.
- Competent authorities should take into account knowledge, attitudes, values, practices and perceptions of stakeholders when communicating risk management options and decisions.
- A risk communication programme should ensure openness and transparency when arriving at and implementing risk management decisions.
- Risk communication should respect the legitimate concern to preserve confidentiality of scientific data where appropriate.
- Risk communication should improve the overall effectiveness and efficiency of the risk analysis process and strengthen the working relationship among participants.
- Risk communication should be carried out in a way that fosters public trust and confidence in regulatory decisions and control measures.
- Selection of risk management options that are non-regulatory in nature should be subject to a tailor-made risk communication programme.
- Competent authorities should develop specific risk communication strategies and implementation plans for emergency situations.
- Risk communication should include stakeholders in other countries and should service international reporting obligations

a significant risk assessment to identify relevant stakeholders, develop key messages, engage with stakeholder groups and monitor the effectiveness of communication. Stakeholder interests and responsibilities may be significantly affected by regulatory risk management decisions and consultation with external stakeholders throughout all phases of the generic RMF process is now recognized as critical to effective risk analysis.

National biosecurity strategies being put in place by competent authorities are placing much greater emphasis on risk communication and the provision of adequate resources for this purpose. Specialist training is becoming more widespread and a variety of methodologies are being used to communicate with the public. Active methods such as media-based information campaigns and telephone information services are increasingly being employed in risk events that are of high interest to industry and/or the public. A number of countries have established specialist consultative groups involving various parts of government, competent authorities, industry, consumers, environmental organizations and other groups to instil public confidence in the risk analysis process.

Competent authorities should provide general information on biosecurity-related hazards and their management as an ongoing public service. Risk communication needs in an emergency situation require a unique strategy and implementation plan.

## PRINCIPLES OF RISK COMMUNICATION IN BIOSECURITY

Historically, information flows associated with biosecurity regulatory actions have been non-participatory and “one-way” in respect of stakeholders external to government. Adoption of risk analysis as a discipline central to biosecurity has meant that “two-way” communication and consultation is now becoming the norm.

Generic principles of risk communication in biosecurity (Box 3.29) reflect this change, with a focus on public dialogue being expressed in many ways (e.g. engagement with a diverse range of public groups,

meeting extensive demands for scientific information, encouraging debate around “zero-risk” expectations, engaging in consultation on issues of ethics and social impacts of risk management decisions). However, it must be recognized that extensive risk communication will not compensate for poor application of RMFs and each of their components.

## RISK COMMUNICATION STRATEGIES AND IMPLEMENTATION PLANS

Risk communication encompasses a continuous and interactive exchange of information between all parties throughout the risk analysis process. The risk communication strategies and implementation plans of competent authorities should effectively service:

- provision of general information and advice on hazards and their management;
- standard-setting processes;
- emergencies as they arise; and
- international reporting obligations.

Those managing risk analysis processes should have an overarching risk communication strategy and implementation plan that properly engages with internal (e.g. administrators, risk assessors, risk communicators) and external stakeholders. The nature and urgency of the risk information to be conveyed will drive the implementation plan. This can range from predominantly one-way communication to the public to urgently advise or warn about a particular risk, to full two-way engagement with a number of stakeholder groups. In most cases competent authorities will need to transfer complex scientific information into understandable user-friendly messages and take into account industry views and public values and perceptions.

Routine risk communication activities are likely to involve a number of mechanisms to inform and educate stakeholders on current sector issues. Scheduled meetings with stakeholder representatives (e.g. six-monthly meetings with consumer advocates on current food safety issues) are a good means of proactively engaging stakeholders on upcoming problems. Routine publication of periodicals, pamphlets and technical reports by risk communicators is another means of improving public awareness and knowledge.

In many situations, risk communication strategies and implementation plans will need to span multiple biosecurity sectors. As an example, competent

authorities must clearly differentiate the likelihood of animal health impacts versus the likelihood of human health impacts when there is an epidemic of exotic disease such as “highly pathogenic” avian influenza. Even so, public reactions are unpredictable. In the recent outbreak of avian influenza in Southeast Asia, the Japanese government clearly informed their public that food-borne risks from imported poultry products were negligible but consumers still markedly reduced their purchase of chicken meat and eggs.

### ESTABLISH A RISK COMMUNICATION PERSON/TEAM

Each biosecurity issue that involves a significant risk assessment should have an individual risk communication strategy and implementation plan. The risk communication person/team should be appointed at the same time as risk managers are commissioning a risk assessment.

Successful risk communication requires expertise in conveying understandable and usable information to both internal and external stakeholders. The risk communication person/team is responsible for providing internal stakeholders with information on the concerns, perceptions and information needs of external stakeholder groups and will facilitate all ongoing communication.<sup>68</sup> The person/team needs to have sufficient expertise to effectively respond to the needs of very different audiences (e.g. other branches of government, the public, media and industry) and must ensure openness, transparency and flexibility in all communication activities. A cohesive team response, especially in terms of ensuring consistent messages, is a key function.

### PROFILE RISK COMMUNICATION NEEDS

The risk profile developed as part of the generic RMF process will be an important source of information for profiling of risk communication needs. Questions important to risk communicators include: how will potential risks be expressed, who generates and who bears the risks, what is the likely public response to risk management decisions, to what extent will public perceptions of risk influence decision-making?

Comparison with other risk analysis projects covering similar biosecurity issues will assist profiling.

<sup>68</sup> Notwithstanding this, it is likely that some communication activities (e.g. technical exchanges on import health standards between importing and exporting countries) will be the responsibility of persons not part of the risk communication team.

### Box 3.30. Questions that will assist in identifying relevant stakeholder groups

- Which branches of government(s) are officially involved in the applicable regulatory process?
- Who might be affected by the risk management decision?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who reasonably might be angered if not included? ■■■

This may provide clues on likely stakeholder responses and sensitivities (e.g. environmental issues associated with disposal of animal carcasses in an exotic disease outbreak may be more important to some stakeholders than the economic impact of the disease itself).

#### IDENTIFY RELEVANT STAKEHOLDERS

Before formulating risk communication messages, it is necessary to identify the various stakeholder groups that will be affected by a biosecurity issue or emergency and properly understand their motivations and opinions (Box 3.30). Risk communicators, risk managers and risk assessors should all contribute to this task.

Although identifying stakeholders takes time and effort, the results are very worthwhile. Countries are likely to have their own statutory or policy regulations concerning how and when stakeholders (including specific branches of government) can participate in public decision-making processes. Depending on the biosecurity issue, risk managers may need to solicit technical input from external stakeholder groups (e.g. in the development of a risk profile or in peer review of a risk assessment). The risk communication team should be involved in these tasks if there is potential for bias.

The nature and extent of stakeholder involvement (including competent authorities from other countries and other parties involved in trading situations) will depend on a number of factors including:

- the complexity, uncertainty and level of controversy underlying the decisions to be made;
- the scale of potential adverse effects;
- the urgency with which the problem must be addressed; and
- statutory obligations.

As risk communication is a highly iterative process, it is as important to seek out relevant information

sources and take heed of them as it is to identify those groups who need to receive information. If the final risk management decision is not really negotiable, stakeholders should be informed directly that they are unlikely to have a genuine influence on the decision.

#### DEVELOP KEY MESSAGES

The risk communication person/team will need to develop key messages targeted at particular stakeholder groups. These should address scientific, social and emotional aspects of risk management. National cultural and political norms dictate the need for different levels of information. It is the role of the risk communication team to ensure coordination with all stakeholder groups that have credible information related to the risk.

Public analysis of risks often differs from expert analysis and their judgement of benefits and risks is significantly affected by information flows. Thus it is necessary to identify the most appropriate media to disseminate information to, and communicate with, different types of stakeholders. If potential benefits are flagged as high, stakeholders tend to infer that risks are low. If risks are flagged as low, benefits tend to be inferred to be high. The opposite may occur if potential benefits are flagged as low (stakeholders infer that risks are high) or risk is flagged as high (stakeholders tend to infer that benefits are low).<sup>69</sup> Key messages must take into account distributional issues (e.g. who benefits and in what way, the importance of the benefit). Key messages must effectively communicate the degree and significance of uncertainty in the risk assessment.

#### ENGAGE WITH RELEVANT STAKEHOLDER GROUPS

Risk communication should involve a two-way dialogue wherever practicable. In most countries, communication mechanisms are generally in place. However, the degree to which controlling authorities are proactive in consulting different stakeholder groups rather than simply making information available, and the specific mechanisms they use to elicit and reflect the views of stakeholders, varies markedly.

Risk communicators should provide external stakeholders with clear and timely information about

<sup>69</sup> Finucane, M., Alhakami, A., Slovic, P. and Johnson, S. 2000. The affect heuristic in judgements of risks and benefits. *Journal of Behavioural Decision-Making*. 13: 1-7.

the risk and the options that are available to manage it. This information should be communicated in a way that stakeholders can easily understand and using a media that they can easily access. In addition, it is essential for risk communicators to solicit feedback from stakeholders and listen to their opinions in order to refine key messages and to fully and adequately address stakeholder concerns. The risk communication team should assess the optimal way to involve the various stakeholders at different stages of the risk analysis process (Box 3.31).

Stakeholder participation provides opportunities to bridge gaps in language, process, understanding, perceptions and values. It provides an opportunity for affected groups to hear, consider and respect the various opinions, ideas and recommendations about the risk in question. An honest exchange of information, ideas and opinions about risks and risk management options also enhances transparency. Risk assessments conducted with stakeholder involvement meet less opposition; stakeholders who have been able to review and comment on the risk assessment are more likely to understand and accept the results than those excluded from the process.

Engagement with stakeholder groups should involve risk assessors. They need to be able to explain the results of their assessment and the scientific data, assumptions and judgements upon which it is constructed. They must be able to clearly communicate what they know and what they do not know, and be able to explain the sources of uncertainty and how they were handled in the risk assessment process (Box 3.32).

#### BE A CREDIBLE SOURCE OF INFORMATION

Risk communication is not public relations; the essence is for all stakeholder groups to understand and appreciate the others perspective. Trust and credibility must be nurtured rather than eroded through ineffective or inappropriate communication. Stringent efforts should be made to provide accurate and timely technical information about the risk from sources that are viewed as trustworthy, fair and unbiased.

Disseminating consistent messages from multiple sources will reinforce the credibility of the message. Care must be taken to avoid exaggeration, omissions, distortion or self-serving statements. Above all, information should be disseminated as soon as possible, with frequent and ongoing updates, so that stakeholders do not become focused on the

#### Box 3.31. Examples of tactics to engage stakeholders

##### Meeting techniques

- Public hearings
- Public meetings
- Briefings
- Question and answer sessions
- Focus groups
- Workshops
- Inclusion of non-scientific stakeholder groups in scientific meetings

##### Non-Meeting techniques

- Interviews
- Hotlines and toll-free numbers
- Web sites
- Advertising and flyers
- Television and radio
- Reports, brochures and newsletters
- Booths, exhibits and displays
- Contests and events

#### Box 3.32. Key risk communication lessons emerging from two case studies in the United Kingdom: BSE and consumption of fish

- Stakeholders should be consulted on the framing of risk management questions to be answered, so as to avoid a focus on aspects of risk that might only be institutionally appropriate. For instance, as well as concern over risks to health from eating fish (dioxin and heavy metals), stakeholders were interested in cardiovascular benefits from eating oily fish and also the sustainability of fish stocks.
- Engagement should be broadened at different stages in the RMF process, particularly on issues of controversy or high uncertainty (e.g. BSE is a very sensitive biosecurity issue and special efforts need to be made to prevent the undue social amplification of risks when the results of risk assessment are presented).
- Things that matter the most to each individual audience should be clearly communicated.

The Royal Society and Food Standards Agency (UK). 2006. *Social science insights for risk assessment: findings of a workshop held by the Royal Society and the Food Standards Agency on 30 September 2005* (available at: <http://www.royalsoc.ac.uk/downloaddoc.asp?id=2797>)

suppression of facts rather than management of the risk itself.

#### MONITOR AND EVALUATE EFFECTIVENESS OF RISK COMMUNICATION

The clarity and impact of key messages for each stakeholder group should be monitored and evaluated

### Box 3.33. Examples of international disease reporting systems

- The FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH) provides a single access point for authorized official international and national information across the sectors of food safety, animal and plant health (<http://www.ipfsaph.org>).
- The Global Early Warning and Response System (GLEWS) established by FAO, OIE and WHO predicts and responds to animal diseases worldwide.
- The IPPC's International Phytosanitary Portal provides a forum for national reporting among the global phytosanitary community (<http://www.ippc.int>).
- The WHO Global Outbreak Alert and Response Network (GOARN) pools resources for the rapid identification, confirmation and response to human health outbreaks of international importance (<http://www.who.int/csr/outbreaknetwork/en/>).
- The Biosafety Clearing-House is an information exchange mechanism established by the Cartagena Protocol on Biosafety to facilitate sharing of information on LMOs (<http://bch.biodiv.org>) ■■■

to the extent practicable. Methodologies for determining the effectiveness of the key messages will depend on the nature and urgency of each biosecurity scenario, the extent of stakeholder involvement and the communication channels used.

Informal and formal means can be used to evaluate success. Where practical, performance measurement tools such as public opinion research can be used to gauge whether all appropriate target groups were reached and their level of understanding of key messages was adequate. Behaviour change as a result of risk communication can also be evaluated if appropriate. Reasoned involvement with stakeholders throughout a risk analysis process should help with acceptance of a final risk management decision even if the stakeholders are not in agreement.

Risk communication processes should be evaluated as to their transparency. While respecting legitimate concerns to preserve confidentiality (e.g. proprietary information or data), risk communicators must ensure that all relevant documentation is available for scrutiny by interested stakeholders.

#### INTERNATIONAL REPORTING OBLIGATIONS

Unlike risk communication plans to address national biosecurity issues as they arise, international reporting of disease outbreaks is a statutory requirement of international agreements, legal instruments and organizations. The transparency obligations of the WTO SPS Agreement also drive reporting. Global

systems greatly enhance emergency preparedness, rapid alert and response to threats to health and life at the national level.

Examples of international disease reporting systems are presented in Box 3.33 and a national biosecurity implementation plan should fully resource this risk communication function.

### RISK COMMUNICATION IN EMERGENCY SITUATIONS

Risk communication needs in emergency situations change markedly through the cycle of the crisis.

#### THE EMERGENCY BEGINS

As an emergency arises, the risk communication person/team should immediately begin to gather information, assess the situation, develop a communications plan and inform key stakeholders of potential impacts. Strong credible spokespeople should head implementation of the plan and deliver consistent key messages, even if the news is bad. Key media contacts should be appointed and the most trusted professional sources of information proactively deployed to put the science out in front of the public.

#### THE EMERGENCY UNFOLDS

As the likely nature and scale of the emergency unfolds, keeping stakeholders fully informed and up-to-date is vital. A number of communication channels can be used (e.g. free phones, dedicated web sites, media, press conferences and technical briefings). Biosecurity emergencies often involve more than one biosecurity sector and a joint communications strategy is needed to ensure that each competent authority puts forward credible spokespeople and consistent messages.

Notable media headlines set the tone as an emergency unfolds. Working with the news media so that they are allies in risk communication involves building on the track record, being available, providing full and honest access to breaking news, regular issuance of media advisories and routine technical briefings. Messages should also be shared with other stakeholders and key government representatives. Depending on the extent of the emergency, additional short-term staff may need to be hired to boost communication capability.

The communication team should meet regularly and often, with a close watch being kept for burn-out.

### Box 3.34. Factors that influence perception of risk

**Dread.** Hazards that provoke a risk that is perceived as dreadful tend to evoke stronger fears than something seen as less dreadful.

**Control.** When an individual feels as though she/he has some control over the process determining the risk faced, that risk usually seems smaller than if it was decided by a process over which the individual had no control.

**Natural or human-made.** Natural risks (e.g. sun radiation) are usually perceived as less worrying than human-made risks (e.g. anthropogenic sources of radiation) even when facts show that the former present greater risks.

**Choice.** A risk that an individual chooses usually seems less risky than a risk that is imposed.

**Children.** Research has shown that risks to children are perceived as worse than the same risk to adults.

**New or old.** A risk that is new tends to be more frightening than the same risk after people have lived with it for some time and have been able to put it into perspective.

**Awareness.** Greater awareness of a risk increases conscious concern about that risk.

**Personal exposure.** Any risk seems larger if an individual thinks they or someone they know could be a victim - this helps explain why statistical probability is often irrelevant to people and an ineffective form of risk communication.

**Risk-benefit trade-off.** When people perceive a benefit from a certain behaviour or choice, the risk associated with it seems smaller (e.g. the benefits of a vaccination are perceived to outweigh the risk of the side effects); if there is no perceived benefit, the risk seems larger.

**Trust.** Research has shown that the less people trust the institutions that are responsible for exposure to the risk or communication about the risk, the more they will be afraid.

Harvard Center for Risk Analysis. Risk in Perspective. June 2003. Volume 11, Issue 2 (available at: <http://www.hcra.harvard.edu/pdf/June2003.pdf>)

Assessing public reaction to the emergency and the risk communication plan should be ongoing as the emergency unfolds.

#### THE EMERGENCY WANES

As the emergency diminishes, the risk communication person/team should work with risk managers to communicate long-term decisions and general government responses to mitigate impacts. The team should also review actions taken and identify lessons learned. It is important to continue to communicate in the aftermath of the emergency so that stakeholders can gain a perspective of the complete emergency response.

#### PERCEPTION OF RISK

There is a large body of literature on how people perceive risk and how the risk communication activities of governments and non-government organizations can alter this response. Perception of risk is both analytical and emotional. Risk communication therefore

needs to consider technical or analytical dimensions of risk, as well as non-technical or emotional dimensions (e.g. outrage).

People do not generally respond to controversial risks on the basis of technical judgements. Non-technical information about the broader context of the risk – often emphasized by the media, industry or consumer groups – is often of most interest to the general public. Therefore, risk communication that addresses the emotional factors that underlie people's concerns, rather than dismissing such perceptions as “irrational” because they are not solely fact-based, is likely to be more successful in helping stakeholders make more informed choices about the risk they face.

Some of the factors that influence people's perception of risk are presented in Box 3.34. The perceived level of risk has an important effect on the extent of risk management considered necessary by public stakeholders to make risks acceptable. In general, the greater the perceived risk, the greater the desired reduction.

# CONCLUSIONS

Part 3 of the Biosecurity Toolkit has been developed to improve regulators' understanding of risk analysis and illustrate the potential for cross-sectoral use, especially in transitional and developing countries. The utility of risk analysis as a unifying discipline across different biosecurity sectors, both at the international and national levels, is clear and the gains that can be expected from application of risk analysis in a coordinated and mutually supportive manner at the national level are well illustrated throughout the Biosecurity Toolkit. The concept that risk analysis methodology provides an important tool with which to measure the performance of a competent authority in an overall sense is also introduced in this manual.

Although a range of stakeholders have inputs to risk analysis for biosecurity at the national level and will be involved in many ways in implementing risk management decisions, it is each competent authority having jurisdiction that makes the final decisions and has the overall responsibility for ensuring that regulation is properly implemented. For these reasons, this manual focuses on regulatory risk management and the application of a generic RMF for achieving biosecurity goals. As part of this, the manual illustrates the inextricable linkages between biosecurity control measures applied at the border and those applied in domestic settings.

A better understanding of risk analysis is driving the increasing attention that governments are now paying to international legal instruments and standard-setting organizations. In parallel, the latter are rapidly increasing the availability of risk-based standards and are improving guidelines on the practical application of risk analysis principles in national biosecurity settings. Accessing these technical resources should be a priority for developing countries contemplating change.

This manual has identified a generic RMF process that underpins management of all biosecurity risks (i.e. in food safety, zoonoses, animal health, plant health, invasive alien species, LMOs and their products, and sustainable use of the environment). It has also illustrated the generic nature of risk assessment and risk communication. The RMF clearly illustrates the different roles of people involved in risk assessment, risk management and risk communication when a

**Box 3.35.** Benefits gained from systematic application of a RMF process to biosecurity issues at the national level

- Consistency and fairness in biosecurity aspects of international trade as intended by the WTO SPS agreement.
- Consistency in decision-making across all jurisdictions of competent authorities.
- Gains in the effectiveness of biosecurity control measures for traded goods by shifting from country independence to interdependence.
- Collection and synthesis of global information on hazards and mitigation of associated risks.
- A better understanding of the "connectedness" of adverse impacts in different biosecurity sectors and their management.
- Cohesive development of national biosecurity strategies.
- Ability to consider complete hazard exposure pathways.
- Ranking of cross-sectoral biosecurity issues and prioritization of work.
- Cost-benefit and cost-effectiveness analysis of cross-sectoral impacts.
- Wide stakeholder participation in risk management decisions.
- Measurement of the performance of competent authorities.
- Sharing of risk analysis skills between sectors. ■

competent authority manages a biosecurity issue and it provides an opportunity to improve collaboration among diverse stakeholder groups. Recognition of the high level of commonality of the generic RMF process across all biosecurity sectors helps to achieve national biosecurity strategies in a mutually supportive manner (Box 3.35).

Comparison of international risk assessment processes in different biosecurity sectors shows that for some steps, there is a blurring of margins between the roles of risk assessors and risk managers. As international organizations strive to document and communicate scientific judgements as being distinct from the policy/value judgements that are part of risk management decisions, it is suggested that recommendations for sector risk analysis at the national level should increasingly reflect generic RMF principles.

Acceptance of the similarity of risk analysis processes and methodologies in different biosecurity sectors is leading to new opportunities in terms of alignment of training of competent authority personnel

and their structural groupings. Generic training materials and programmes that incorporate the most up-to-date experience in different biosecurity sectors can be prepared and this leads to greater cross-fertilization of ideas and techniques. Shared training opportunities are also likely to facilitate technical exchanges between countries and capacity building; the latter being particularly important for developing countries.

The interdependence of biosecurity sectors at the national level is extremely well illustrated by the profound influence that farming and nature exercise over each other. Farming has contributed over the centuries to creating and maintaining a variety of landscapes and valuable semi-natural habitats. It also supports diverse rural communities that play an essential role in maintaining the environment in a healthy state. Biodiversity conservation and the assessment of agricultural impacts on the environment requires the use of holistic models which are able to integrate multiple sources of information. Levels of protection may vary as goals range from sustaining agricultural production and ecosystem services to fully preserving endangered species or fragile protected areas. Links between environmental protection and human health also need to be considered, for example, when assessing risks of GM food in terms of safe release into the environment (e.g. in terms of unintended effects on non-target organisms, ecosystems and biodiversity) and safe use as a food for humans.

It is clear that the complexity of biosecurity issues demands careful problem formulation and interdisciplinary scientists and risk assessors working

closely with government agencies, NGOs and the public in estimating cross-sectoral biosecurity risks. Aggregating relevant information in ways that allow risk managers to systematically evaluate containment potential, costs, and opportunity costs and make reasonable trade-offs against legal mandates and social considerations will require a new generation of decision-support models.

With the increasing recognition that biosecurity is an interdependent partnership that requires participation from all biosecurity sectors at the international and national levels, significant benefits are now flowing from aligning approaches and sharing resources. Identifying and managing the interplay of impacts between different sectors in adverse biosecurity situations is greatly improved when competent authorities work effectively together. Recent national experiences of cross-sectoral impacts associated with BSE and FMD provide dramatic evidence of the need for effective national biosecurity strategies, sharing of resources and integrated responses to problems.

Achieving better biosecurity outcomes in an efficient and cost-effective manner, especially in transitional and developing countries, is a significant challenge. The emergence of risk analysis underpins many of the changes in approach that are happening within competent authorities around the world. It is predicted that administrative, structural and technical changes, together with cross-sectoral application of risk analysis principles, will greatly enhance the development of integrated biosecurity strategies and the achievement of broad biosecurity goals at the national level.

