FAO BIOSECURITY TOOLKIT

FAO BIOSECURITY TOOLKIT

Food and Agriculture Organization of the United Nations
Rome, 2007

ISBN XX-X-XXXXXXX-X

For further information, please contact:
Biosecurity Priority Area for Interdisciplinary Action (PAIA)
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153, Rome, Italy
Fax: (+39) 06 57054593
E-mail: biosecurity@fao.org
Web site: www.fao.org/biosecurity/
www.fao.org/ag/agn/agns/foodcontrol_biosecurity_en.asp

CONTENTS

LIST OF FIGURES, BOXES, TABLES

FIGURES

BOXES

TABLES

ABBREVIATIONS

ADI	Acceptable Daily Intake
ALARA	As Low as Reasonably Achievable
ALOP	Appropriate Levels of Protection
APFSWG	Animal Production Food Safety Working Group, OIE
BCH	Biosafety Clearing-House
BSE	Bovine Spongioform Encephalopathy
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CPM	Commission on Phytosanitary Measures
DALY	Disability Adjusted Life Years
EU	European Union
EVIRA	Finnish Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
FMD	Foot and Mouth Disease
GAINS	Global Avian Influenza Network for Surveillance
GAP	Good Agricultural Practice
GEF	Global Environment Facility
GHP	Good Hygienic Practice
GLEWS	Global Early Warning and Response System for Animal Diseases
GM	Genetically Modified
GMO	Genetically Modified Organism
GOARN	Global Outreach Alert and Response Network
HACCP	Hazard Analysis and Critical Control Point
IICA	Inter-American Institute for Cooperation on Agriculture
IHR	International Health Regulations
INFOSAN	International Food Safety Authorities Network
INGO	International Non-Governmental Organization
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
IPFSAPH	International Portal on Food Safety, Animal and Plant Health
ISNAR	International Service for National Agricultural Research
ISPM	International Standard for Phytosanitary Measures
JECFA	Joint FAO/WHO Expert Committee on Food additives
JEMRA	Joint Expert Meeting on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LMO	Living Modified Organism
MDG	Millennium Development Goals
MRL	Maximum Residue Limit
NGO	Non-Governmental Organization
NPPO	National Plant Protection Organization
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effects Level
OECD	Organization for Economic Cooperation and Development
OIE	World Organisation for Animal Health
PO	Performance Objective
PRA	Pest Risk Analysis
PCE	Phytosanitary Capacity Evaluation Tool
QA	Quality Assurance
RIA	Regulatory Impact Analysis
RMF	Risk Management Framework
RPPO	Regional Plant Protection Organization
SPS	Sanitary and Phytosanitary Measures
SARS	Severe Acute Respiratory Syndrome
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice to the Convention on Biological Diversity
STDF	Standards and Trade Development Facility
SWOT	Strengths, weaknesses, opportunities and threats
TBT	Technical Barriers to Trade
UNDP	United Nations Development Programme
UNEP	United National Environment Programme
WHO	World Health Organization
WTO	World Trade Organization

ACKNOWLEDGEMENTS

FAO would like to express its appreciation to the many people who provided advice and guidance during the preparation of this toolkit. In particular, FAO would like to recognize the role of Steve Hathaway, New Zealand Food Safety Authority in developing the Overview and Framework Manual for Biosecurity Risk Analysis, and Marlynne Hopper in producing the Guide to Assess Biosecurity Capacity. Thanks are due to Keren Bar-Yaacov, Norwegian Food Safety Authority and Gunnar Hagen, Ministry of Agriculture and Food, Norway for their work on the case study describing implementation of a biosecurity approach in Norway.

A number of experts in various aspects of biosecurity from different parts of the world provided valuable support to the development of the toolkit through a peer review process. This included an expert meeting at FAO Headquarters in Rome from 2 to 4 November 2005, which was attended by the following experts: Michael de Shield, Belize Agricultural Health Authority; Steve Hathaway, New Zealand Food Safety Authority; Chagema Kedera, Kenya Plant Health Inspectorate Service; Randall Morley, Canadian Food Inspection Agency; Eric Schoonejans, Ministère de l'Ecologie et du Développement Durable, France; and Alfonso Torres, College of Veterinary Medicine, Cornell University, United States of America. In addition, Jörgen Schlundt, World Health Organization and Lee Ann Jackson, World Trade Organization participated in the peer review meeting. Written comments were received from Ruth Frampton, New Zealand on Parts 1 and 2, and from Bill Roberts, Biosecurity Australia on Part 3. FAO is grateful to all these persons for their interest and commitment to participate in the peer review process, and for their valuable contributions to improve the toolkit.

Useful comments were provided by FAO staff in different technical units and their inputs are gratefully acknowledged. FAO would also like to recognize the contribution of Niek Van Der Graaff, former Chief of the Plant Protection Service in the Plant Production and Protection Division, in chairing the FAO inter-departmental biosecurity working group during the initial stage of development of this toolkit. Last, but not least, FAO would like to thank the Government of Norway, which provided financial support for the development and publication of this toolkit under the FAO Norway Partnership Programme.

FOREWORD

Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life[1] and health and associated risks to the environment. Interest in biosecurity has risen considerably over the last decade in parallel with increasing trade in food, plant and animal products, more international travel, new outbreaks of transboundary disease affecting animals, plants and people, heightened awareness of biological diversity and greater attention to the environment and the impact of agriculture on environmental sustainability. Growing membership of the World Trade Organization (WTO) and the need to comply with global agreements governing the trade in agricultural and food products – particularly the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and, to some extent, the Agreement on Technical Barriers to Trade (TBT Agreement) – have heightened the focus on biosecurity. At the same time, changes in the way food, plants and animals are produced, processed and distributed, and the use of new technologies, have introduced new concerns about the health of plants and animals, as well as food safety and agricultural and environmental sustainability. Improved coordination is being sought among national bodies responsible for setting and enforcing sanitary[2] and phytosanitary measures to better protect human, animal and plant life and health without creating unnecessary technical barriers to trade.

During the past decade, some governments have moved towards an integrated approach to biosecurity that harmonizes and rationalizes policy, legislation and core roles and responsibilities as a means to better manage relevant risks in food and agriculture. However, most countries continue to manage biosecurity along traditional, sector-oriented lines, resulting in a lack of strategic focus, inefficient use of scarce resources and less than optimal results.

The Technical Consultation on Biological Risk Management in Food and Agriculture, organized by FAO in Bangkok, Thailand in January 2003, acknowledged the advantages of a more integrated approach to biosecurity to take advantage of synergies across sectors at the national and international levels, and recognized the efforts under way in some countries to adopt such an approach. It noted that several countries, including developing and transition countries, were revising their biosecurity arrangements and stressed the importance of external support in this context. It noted, in particular, the need for FAO to provide the necessary guidance and tools to assist developing countries in their efforts to move towards a more coherent and holistic approach to biosecurity.

This toolkit, which comprises three parts, has been developed by FAO in this context with support from the Government of Norway. The first document in the set, *Biosecurity Principles and Components*, is an introductory text providing a contemporary context for the development and implementation of a harmonized and integrated biosecurity approach across all sectors. The second part is a *Guide to Assess Biosecurity Capacity*, which offers a process for assessing dimensions of biosecurity capacity across all sectors and sector organizations. The third part of the toolkit, *An Overview and Framework Manual for Biosecurity Risk Analysis*, presents a generic framework to structure and guide the application of risk analysis principles in biosecurity.

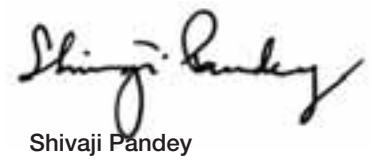
1 For the purpose of this toolkit, "life" is used as a generic term to cover impacts of biosecurity activities that are not easily categorized as health impacts.

2 For the purpose of this toolkit, "sanitary" refers to humans and animals (zoosanitary).

Respectful of variations in conditions across countries, biosecurity sectors and sector organizations, the toolkit fully acknowledges that there is no universally acceptable or standard policy or infrastructure that should govern national biosecurity systems. It offers countries guidance to develop and implement national biosecurity systems in accordance with their international obligations and based on their particular needs. It seeks to increase knowledge on the broader development and implementation of biosecurity policies and frameworks at the national level. This includes enhancement of biosecurity capacity through the assessment of needs and the generic application of risk analysis principles as an essential element of biosecurity. Indeed, the toolkit develops the thesis that risk analysis provides a common foundation for biosecurity.

We welcome comments and feedback on this toolkit as part of our ongoing commitment to support member countries to better manage biosecurity as a means to protect public health, agricultural production and the environment, and promote economic development through enhanced compliance with international agreements focused on sanitary and phytosanitary measures.

Ezzeddine Boutrif
Director
Nutrition and Consumer
Protection Division



Shivaji Pandey
Director
Plant Production
and Protection Division

INTRODUCTION

Biosecurity is emerging as one of the most pressing issues facing developed, developing and transition countries. Globalization, the increased movement of people, agricultural and food products across borders, greater attention to biodiversity and the environment, the emergence and spread of transboundary diseases, changes in the way food, plants and animals are produced, processed and distributed, uncertainties surrounding new technologies, as well as international legal obligations are some of the trends driving this growing interest, and highlighting the importance of adequate biosecurity capacity.

Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life[3] and health, and associated risks to the environment. It is based on recognition of the critical linkages between sectors. Biosecurity hazards[4] of various types exist in each sector and have high potential to move between sectors. For that reason, inadequate controls in one sector can have far-reaching consequences for other sectors.

Harmonizing and integrating national biosecurity systems and controls whenever possible provides a means to take advantage of the synergies that exist across sectors. This will considerably enhance the capability of countries to protect human health, agricultural production systems, and the people and industries that depend on them. In addition, there are likely to be other benefits. A harmonized and integrated approach to biosecurity will help to safeguard the environment and protect against the uncertainties associated with new technologies. It will further enhance the capacity of countries to meet obligations under relevant international agreements and to take full advantage of opportunities associated with the global trade in food and other agricultural products.

PURPOSE AND SCOPE

This toolkit provides practical guidance and support to develop and implement national biosecurity frameworks at the country level. It presents the benefits of a harmonized and integrated approach to biosecurity and illustrates the experiences of countries, including Belize, Norway and New Zealand, which have adopted such an approach in recent times.

By providing a framework to identify cross-cutting biosecurity capacity needs based on an integrated approach, this toolkit addresses the gaps inherent in a purely sectoral approach to biosecurity. The purpose is to support governments to better manage biosecurity as a means to protect public health, agricultural production and the environment. At the same time, this will enhance the ability of countries to comply with international agreements, regulations and requirements focused on sanitary and phytosanitary measures, contributing to economic development and trade.

The toolkit comprises three separate but linked documents. All three documents are developed on the premise that biosecurity concerns different parts of

3 As indicated in footnote 1, above, “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. For instance, in servicing the Convention on Biological Diversity (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.

4 The term “hazard” is used in this document in relation to all biosecurity sectors, however, the International Plant Protection Convention (IPPC) generally uses the term “pest” rather than the term “hazard”.

government, that biosecurity risks are interrelated, and that the best way to manage the risks faced is through coordinated action across the relevant sectors, contributing to improved outcomes and efficiencies.

Part 1: Biosecurity Principles and Components

The first part of the toolkit provides a broad introduction to biosecurity and outlines the contemporary context for development and implementation of a harmonized and integrated biosecurity approach across all sectors. It shows how such an approach can enhance the protection of human, animal and plant life and health and the environment by taking advantage of synergies across sectors, as well as generating a number of other tangible benefits.

Part 2: Guide to Assess Biosecurity Capacity

The second part of the toolkit provides guidance on how to assess dimensions of biosecurity capacity across all sectors and sector organizations in accordance with the requirements of an integrated biosecurity approach as presented in Part 1. Use of this guide will enable governments to increase awareness of the synergies and interdependencies that exist across biosecurity sectors. It will further help to generate an understanding of existing biosecurity capacity and performance, a medium-term vision for national biosecurity, and a strategy and action plan to enhance biosecurity capacity based on an identification of capacity needs.

Part 3: An Overview and Framework Manual for Biosecurity Risk Analysis

The third part of the toolkit presents a generic framework to structure and guide the application of risk analysis principles in biosecurity. Risk analysis is at the heart of modern approaches and is rapidly emerging as a unifying discipline across all biosecurity sectors. International standard-setting organizations and bodies have embraced risk assessment as an essential tool to achieve their goals and national competent authorities are obliged by international agreements to similarly utilize risk assessment wherever possible and practical. Part 3 of the toolkit explores the processes and methods common to cross-sectoral risk analysis and illustrates the role of this discipline in forging better linkages and promoting more efficient use of technical resources.

TARGET AUDIENCE

Government officials involved in biosecurity or a particular biosecurity sector are the main target audience. This group will include officials involved in food safety and public health, animal and plant life and health, and protection of the environment, at both the policy and/or operational level. In addition, development agencies, consultants and trainers supporting biosecurity activities and programmes will find the toolkit useful.

Part 1
Biosecurity
principles and components

Introduction

WHAT IS BIOSECURITY?

Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment. Biosecurity covers food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g. genetically modified organisms or GMOs), and the introduction and management of invasive alien species. Thus biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, and wide-ranging aspects of public health and protection of the environment, including biological diversity.

The overarching goal of biosecurity is to prevent, control and/or manage risks to life and health as appropriate to the particular biosecurity sector (Figure 1.1). In doing so, biosecurity is an essential element of sustainable agricultural development.

This toolkit advocates a strategic and integrated approach to biosecurity as a holistic concept that is of direct relevance in meeting consumer expectations in relation to the safety of their food supply, preventing and controlling zoonotic aspects of public health, ensuring the sustainability of agriculture, safeguarding terrestrial, freshwater and marine environments, and protecting biodiversity. Biosecurity may also include measures to ensure security of the food supply in terms of counter-terrorism. Terms related to biosecurity that are used in this toolkit are included in the glossary in Annex 1.

Box 1.1. Some factors influencing biosecurity

- Globalization
- New agricultural production and food processing technologies
- Increased trade in food and agricultural products
- Legal obligations for signatories of relevant international agreements
- Increasing travel and movement of people across borders
- Advances in communications and global access to biosecurity information
- Greater public attention to biodiversity, the environment and the impact of agriculture on both
- Shift from country independence to country interdependence for effective biosecurity
- Scarcity of technical and operational resources
- High dependence of some countries on food imports

THE CONTEXT OF MODERN BIOSECURITY

Biosecurity issues have an ever-increasing profile on a global basis due to a range of factors (Box 1.1). The increasing diversity and volume of international trade in animals, plants and their products is a key contributor in the spread of recognized diseases from region to region. Changing agricultural practices are resulting in new hazards to health that are readily able to cross borders. Changing human ecology and behaviour also contribute to the greater incidence and spread of hazards of public, animal and plant health importance. New technologies add a further dimension, for instance organisms and products derived from biotechnology need to be evaluated for any potential risks to health.

Figure 1.1. Sector goals of biosecurity

With increasing public awareness of the impact of adverse biosecurity events and interventions, political and social demands on government regulatory agencies are resulting in considerable infrastructural change. Stakeholder interest is fuelled by technological advances in detection and management of hazards to life and health, together with the often unresolved scientific debate that surrounds the potential of very low levels of hazards to result in adverse health or environmental impacts.

WHO IS INVOLVED?

National stakeholders

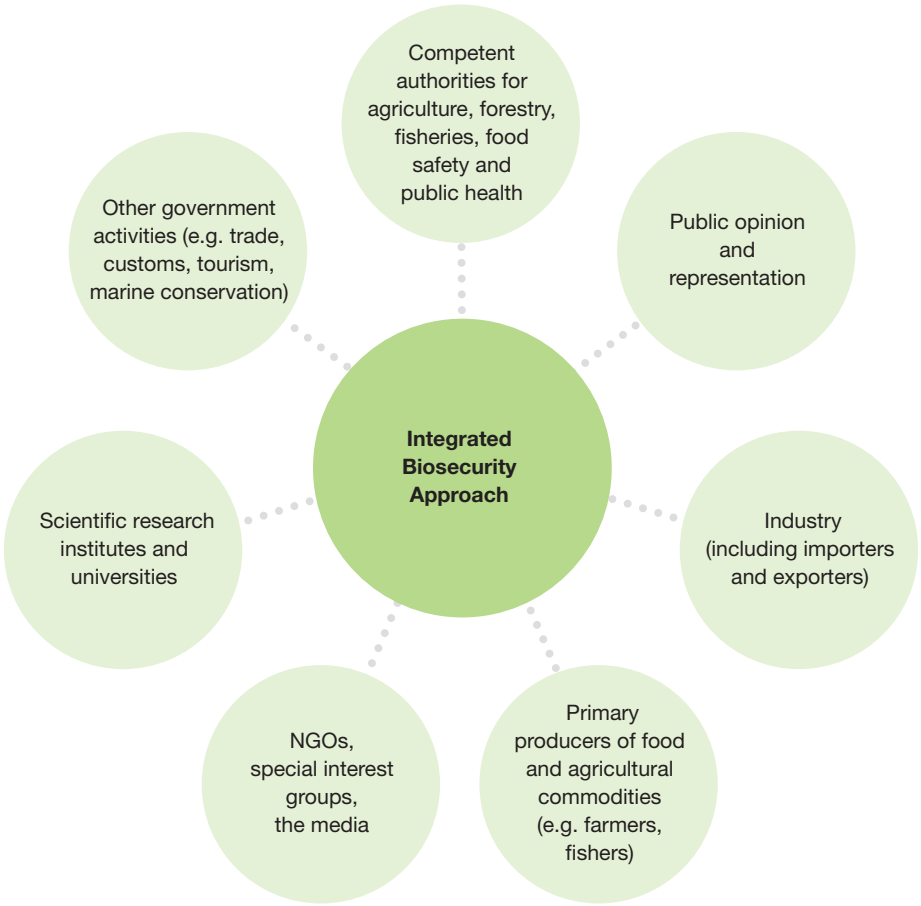
Biosecurity involves many different kinds of stakeholders at the national level. Government agencies have a primary interest but industry, scientific research institutes, specialist interest groups, non-governmental organizations (NGOs) and the general public all have a vital role to play.

Several branches of government, at both the national and sub-national levels, are involved. The competent authorities responsible for the sectors usually associated with biosecurity – food safety, public health, agriculture, forestry, fisheries and the environment – play the primary role in a contemporary integrated approach to biosecurity. However, other parts of government responsible for sectors such as trade, customs, transport, finance and tourism can also play a role depending on national circumstances (see Figure 1.2 and Annex 2). In addition, "third party" organizations are often contracted by competent authorities to deliver a range of core biosecurity functions including surveillance programmes, incursion response activities and laboratory diagnostic services.

International stakeholders

At the global level, international standard-setting organizations, international bodies and international

Figure 1.2. Sector interests that are important to an integrated approach to biosecurity



legal instruments and agreements play important and complementary roles in biosecurity.

International standard-setting organizations and bodies like the Codex Alimentarius Commission (CAC), the World Organisation for Animal Health (OIE) and the Commission on Phytosanitary Measures (CPM)[5] develop standards[6] for different biosecurity sectors in accordance with their mandates. While international standards are not legally binding in and of themselves, they have become international reference points through the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which adopted them in 1995 as the benchmark for all international sanitary and phytosanitary measures.

Responsibilities for sectors of biosecurity at the international level are shared among a number of organizations and bodies. Reflecting its mandate and competencies, FAO plays a leading role in normative work and technical assistance, at the both the national and international levels, to support the implementation of a biosecurity approach. Related activities include the organization of expert and technical consultations on biosecurity, the development of tools to assist countries to apply a biosecurity approach and support capacity building, and the development and operation of the International Portal on Food Safety, Animal and Plant Health[7] to facilitate the exchange of relevant information. FAO hosts the Secretariat for the Codex Alimentarius Commission, under the Joint FAO/WHO Food Standards Programme, as well as the Secretariat for the International Plant Protection Convention (IPPC). In addition, FAO's participation in the Standards and Trade Development Facility (STDF) aims to enhance collaboration between the three SPS-recognized standard-setting bodies and FAO, the World Bank, the World Health Organization (WHO) and WTO.

WHO supports countries to prevent, detect, verify rapidly and respond appropriately to epidemic-prone and emerging disease threats when they arise to minimize their impact on the health and economy of the world's population. This includes prevention, alert and response operations, laboratory and epidemiological strengthening, preparedness for deliberate epidemics, support for the Global Outbreak Alert and Response Network, and the revised International Health Regulations, referred to as IHR (2005).[8] Under IHR (2005), WHO has the mandate to collaborate with States Parties to evaluate their public health capacities, facilitate technical cooperation, logistical support and the mobilization of financial resources for building capacity in prevention, surveillance and response.

In addition to the standards and related texts developed by the CAC, the OIE and the CPM, several other international legal instruments, agreements and texts are relevant to biosecurity. These include the SPS Agreement and, to some extent, the Agreement on Technical Barriers to Trade (TBT Agreement), the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety[9], and the International Health Regulations. These generally have a single sector perspective (e.g. food safety, human/animal/plant health, protection of the environment, biosafety, biological diversity, nature conservation, wetland protection, marine resources). However, they share certain common characteristics including risk analysis principles, notification procedures and information exchange. International legal instruments, agreements, texts, organizations and bodies associated with biosecurity are listed in Annex 3.

---

5 The Commission on Phytosanitary Measures (CPM) governs the IPPC (an international treaty to secure action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control) and adopts International Standards for Phytosanitary Measures (ISPMs).

6 For the purposes of this toolkit, use of the word "standard" as an output of international standard-setting organizations and bodies is taken to include "standards, guidelines and other recommendations". It is noteworthy that the WTO considers that the SPS Agreement does not differentiate between these terms and they would each be applied according to their substantive content rather than their category. Joint FAO/WHO Food Standards Programme. CAC. Report of the 23rd Session. Rome, 28 June to 3 July 1999. ALINORM 99/33 (available at: http://www.codexalimentarius.net/web/archives.jsp?year=99).

7 Available at: www.ipfsaph.org

8 A revision of the International Health Regulations was unanimously adopted on 23 May 2005 by the World Health Assembly and these Regulations entered into force in June 2007. See Annex 3 for further information.

9 Biosafety is defined as: "Means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health." UNEP/CBD. 1992. Convention on Biological Diversity: Article 8(g).

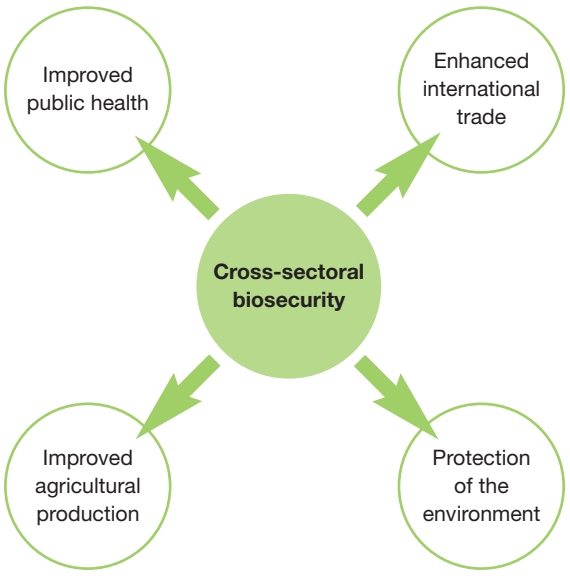
Rationale for a harmonized and integrated approach to biosecurity

In a modern biosecurity environment, considerable importance is placed on a holistic approach. Countries are encouraged to base their controls, as far as possible, on international standards where they exist. Harmonization at the national level can occur in terms of generic approaches to biosecurity and/or in terms of biosecurity standards themselves. At the national level and internationally, there are likely to be significant benefits in integrating biosecurity activities to the extent practical (Figure 1.3).

BIOSECURITY LINKAGES

Human, animal and plant life and health and protection of the environment are inextricably linked and this is the fundamental rationale for an integrated approach to biosecurity at the national level. Biosecurity hazards[10] of various types exist in each sector and have high potential to move between sectors (e.g. many animal pathogens readily infect humans; animal feed may be contaminated with mycotoxins and plant toxins). While transfer of pests of plants between biosecurity sectors may occur on a lesser scale, inadequate control can have impacts well beyond plant health.

Figure 1.3. Potential benefits associated with a cross-sectoral approach to biosecurity



In respect of food chains, hazards can be introduced anywhere from production to consumption and a breakdown in security at any point can result in adverse health consequences to individual or multiple biosecurity sectors. As examples, pesticide residues in plant foods and veterinary drug residues in animal foods can have negative impacts on human health, and the emergence of variant Creutzfeldt-Jakob disease in people in the United Kingdom has intensified concerns about the contribution of contaminated animal feed to food-borne illnesses in humans. The size and scope of the global trade in animal feed and animal feed ingredients is one example of the immense potential for biosecurity hazards to move between and within countries.

Changes in the environment, such as the loss of biological diversity and contamination of food and water sources, sometimes result in significant risks to human and animal health. It has been reported that 10 percent of all preventable human diseases are due to the deterioration of the environment, and the principal causes of these diseases include a lack of sanitary measures, contamination of water sources and unsafe food.

RISK ANALYSIS

Many aspects of a risk-based approach to biosecurity are shared by the different sectors concerned and this provides an essential impetus to risk analysis as a unifying discipline in biosecurity. Risk analysis is composed of three distinct but closely connected components – risk assessment, risk management and risk communication – which are explained in detail in the Overview and Framework Manual for Biosecurity Risk Analysis (Part 3 of this toolkit).

International standard-setting organizations and bodies involved with different components of biosecurity have embraced risk assessment as an essential tool to achieve their goals. Biosecurity risk assessment involves a scientific process to estimate risks to life and health that may be associated with a

[10] There are various descriptions in different biosecurity sectors as to what constitutes a hazard. These are described in Box 1.4 and further discussed in Part 3.

particular food, animal, plant or specific organism. Prevention, reduction or elimination of those risks can take many forms. Prior to the enactment of the SPS Agreement, biosecurity systems were not necessarily based on robust and transparent scientific inputs to standard-setting processes, especially those for traded agricultural goods. Now, the importance of good science and risk assessment to biosecurity cannot be overemphasized and this places considerable technical demands on relevant stakeholders.

Biosecurity risk management incorporates considerably different processes to risk assessment. Core decisions involve the balancing of scientific findings against questions of life and health expectations, likely economic and social impacts, and the technical feasibility and cost-effectiveness of controls. The merging of policies and values with science in biosecurity risk management presents considerable challenges and has different expression in different countries.

Both risk assessment and risk management should be wrapped in a "sea of communication" that includes all stakeholders as appropriate. Successful risk communication is a prerequisite for effective risk assessment and risk management, and facilitates the iterative and ongoing nature of risk analysis.

PRIMARY DRIVERS FOR CHANGE

Moves towards a harmonized and integrated approach to biosecurity at the national level are being driven by a number of interconnected factors. Greater awareness of the consequences of a breakdown in security at one point in the food chain for the rest of the chain (as discussed above) is a core driver. This is particularly relevant at a time when production systems are ever more specialized, concentrated and connected, increasing numbers of people, animals and goods are crossing borders, the global food trade is continuing to expand, and the general public is taking more interest in sanitary and phytosanitary issues.

The increasing number and stringency of sanitary and phytosanitary requirements, the recognition of the high cost of regulation and acknowledgement of limited public resources are other drivers of change. On top of this, there are increasing demands from industry for better cost-effectiveness of biosecurity systems and greater accommodation of new technologies.

In this context, many governments are asking how national competent authorities can perform their roles more effectively. In the broadest sense, a harmonized and integrated approach to biosecurity will significantly enhance the ability of national competent authorities to achieve their mandates (Box 1.2). Achieving these mandates requires a proactive and dynamic response to ever-changing biosecurity challenges and national priorities.

The desire to avoid an increase in potentially significant adverse health impacts in all biosecurity sectors and the associated negative repercussions, including economic ones, is another important driver of change (Box 1.3).

Box 1.2. Generic mandate of biosecurity at the national level

- Protect human health and consumer confidence in agricultural and food products.
- Protect the agricultural, forestry and fisheries production systems, and the people and industries that depend on them.
- Protect the environment including indigenous plants and animals.
- Take advantage of trade opportunities and demonstrate to importing countries that agricultural and food exports meet their expectations in terms of appropriate levels of protection (ALOPs).
- Efficiently utilize limited resources across the areas of food safety, animal and plant health.
- Provide cost-effective and efficient government services to private sector producers and processors.
- Meet obligations under international agreements.
- Protect against uncertainties associated with new technologies

Box 1.3. Moving towards a biosecurity approach to minimize potentially adverse impacts

A harmonized and integrated approach to biosecurity can help to minimize potentially adverse health, economic and other impacts such as:

- Incidence and range of food-borne risks to consumers.
- Cross-border spread of new and emerging diseases among humans, domestic and native animals, plants and fish.
- Introduction of alien plant, animal and aquatic species.
- Loss of biodiversity and unwanted changes to ecosystems.
- Disruption of the livelihoods and earning potential of rural communities and agricultural industries.
- Loss of consumer trust in government, food industry and the food supply following major transboundary biosecurity incidents.
- Disruptions to trade whether scientifically justified on the basis of health risks or not

Further, international events may superimpose requirements for more integrated approaches (e.g. increased recognition of the potential for wide-scale food-borne threats to public or animal health from acts of terrorism is a new consideration in modern biosecurity systems).

The increasing convergence of human, animal, plant and environmental health issues is motivating some governments to:

- share scarce biosecurity technical resources;
- recognize and apply generic approaches to risk analysis;
- develop nationally integrated responses to biosecurity problems;
- promote nationwide access to biosecurity information and improve stakeholder awareness;
- develop new international strategic alliances; and/or
- shift from country independence to interdependence in complying with international agreements and instruments and ensure consistency in their application.

Biosecurity in a modern world

What constitutes a biosecurity hazard?

Biosecurity systems are primarily concerned with preventing, controlling or managing hazards to life and health. There are various descriptions in the different biosecurity sectors as to what constitutes a hazard, as illustrated in Box 1.4.

Sector changes in biosecurity

Food safety

Biosecurity systems for food safety must control hazards of biological, chemical and physical origin in imported food, food produced domestically and food that is exported. This is a different scenario to other biosecurity sectors where controls are developed primarily for biological hazards alone.

Earlier approaches to food safety were established in a time of limited knowledge about the relationship between the presence and level of hazards in the food chain and the level of risk to the consumer. Nevertheless, systems based on empirical knowledge of food safety have served government, industry and consumers well in limiting exposure to hazards of public health concern. Food controls based on good hygienic practice (GHP) remain the foundation of modern food safety systems.

While earlier controls were applied primarily to production and transport of bulk food commodities, the last few decades have seen remarkable changes in the global food supply. Along with the increasing volume of trade, the geographical origins, nature, range, preservation requirements and intended end-uses of foods are now vastly expanded. This places ever-increasing demands on available resources, especially in terms of evaluating food safety issues associated with changing agricultural practices and new processing technologies, and applying appropriate controls.

In this increasingly complex food safety environment (Box 1.5), three “waves of change” have been evident. The early 1990s saw more rigorous science being applied in review of traditional GHP-based controls. The mid-1990s brought more targeted food safety systems, particularly Hazard Analysis and

Box 1.4. Definitions of a hazard as applicable to different biosecurity sectors

Food safety	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (CAC).
Zoonoses	A biological agent that can be transmitted naturally between wild or domestic animals and humans (OIE).
Animal health	Any pathogenic agent that could produce adverse consequences on the importation of a commodity (OIE).
Plant health	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products (IPPC).*
Plant health quarantine	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (IPPC).
“Biosafety” in relation to plants and animals	A living modified organism (LMO) that possesses a novel combination of genetic material obtained through the use of modern biotechnology that is likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Cartagena Protocol on Biosafety).
“Biosafety” in relation to food	A recombinant DNA organism directly effecting or remaining in a food that could have an adverse effect on human health (Cartagena Protocol on Biosafety).
Invasive alien species	An invasive alien species outside its natural past or present distribution whose introduction and/or spread threatens biodiversity (CBD).

** 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 quarantine pest*

Box 1.5. New influences on food safety biosecurity systems

- Adoption of HACCP and a risk-based approach.
- Documentation of high levels of food-borne disease.
- Significant changes in food production and processing on a global scale.
- Shift in primary responsibility for food safety from the competent authority to industry with government assuming an oversight role.
- Development of controls based on "production-to-consumption" considerations.
- More vociferous involvement of consumers.
- Consumer perceptions and fears reflected in more stringent regulatory requirements, including labelling

Critical Control Point (HACCP), and challenging of standards based on control of hazards to levels that were "as-low-as-reasonably-achievable" (ALARA). The late 1990s saw the need for risk-based controls emerge as a global goal, even though in many cases there is still insufficient scientific data to promulgate regulatory standards on this basis.

Despite considerable investment by governments in food safety, illnesses arising from biological hazards in the global food supply are still common. It is estimated that up to one third of people are affected by microbial food-borne diseases each year, with the majority of the pathogens involved being zoonotic. The occurrence of some of these seems to have increased significantly in recent years.

Zoonoses

The term zoonosis refers to infectious diseases that can be transmitted naturally between wild or domestic animals and humans. There are a number of possible means of transmission but food and water are by far the most common vehicles (Box 1.6).

Emerging zoonoses are those that have newly appeared in a population or are rapidly increasing in incidence and/or range. Recent examples are haemolytic uraemic syndrome caused by *Escherichia coli* O157:H7, acute diarrhoea caused by *Campylobacter spp.*, severe acute respiratory syndrome and avian influenza. The latter two hazards are unlikely to be spread by food and represent examples of significant microbial adaptation and epidemiological change.

Many factors contribute to the expression of emerging food-borne zoonoses in human populations. As one example, changing animal feeding practices, variable animal surveillance systems, variable measures to remove certain "high-risk" materials from the food chain and advanced meat recovery systems may all contribute to food safety aspects of bovine spongiform encephalopathy (BSE) and its geographical expression in humans.

Emerging zoonoses illustrate the recent convergence of biosecurity aspects of animal and human health and this is likely to lead to marked changes in the roles, partnerships and regulatory activities of competent authorities collectively involved in their control.

Animal health

Animal health biosecurity is concerned with import, domestic and export health controls. Veterinary administrations have generally been the sole competent authority responsible for animal health and, in many cases, have also been responsible for food safety aspects of the slaughter of animals up until the end of primary processing. Import controls are primarily designed to prevent the introduction of hazards pathogenic to animals during trade in animals, animal genetic material, animal products, feedstuffs and biological products. Competent authorities in the domestic setting, besides being responsible for control and eradication of endemic diseases of animals, are often responsible for implementing controls that prevent the introduction of unacceptable

Box 1.6. Some new, emerging and "re-emerging" zoonoses of public health importance

Food-borne

- Enterohaemorrhagic *E. coli* from mammals
- BSE from cattle
- Norovirus from seafood
- *Campylobacter* from poultry
- *Salmonella* from poultry and eggs
- *Cryptosporidium* from ruminants

Other

- Avian influenza from poultry
- Bovine tuberculosis from mammals
- Monkeypoxvirus from pets
- West Nile virus from birds
- Rift Valley Fever from ruminants
- Rabies and related Lyssavirus infections from mammals
- Lyme borreliosis from small mammals and birds
- Nipah virus infection from pigs
- Hantavirus from rodents

levels of chemical hazards to the food chain (e.g. residues of veterinary drugs and pesticides). Recently, concern has arisen over antibiotic resistant bacteria being conveyed by animals and animal products to humans via food. Competent authorities responsible for animal health are also commonly involved with control of zoonoses as described above but do not carry out human health risk assessments *per se*.

As with food safety, drivers of animal health biosecurity have undergone significant change over the last two decades (Box 1.7). Trade in animal commodities crossing borders is now very different, especially in terms of the volume, range and complexity of animal products. The increasing availability of animal genetic material has meant a decrease in the international trading of breeding animals, however, the economics of the global food supply is driving an increasing trade in export of live animals for slaughter. In this context, there is a rapid expansion of consumption of animal products in developing countries, especially in Asia. Livestock production is increasing to meet this need and there is a commensurate increase in animal health risks. The close proximity of people and animals, especially poultry, adds to these risks.

Partly in response to the above drivers, new and emerging diseases of animal health importance are increasing in incidence and geographical range. This is forcing competent authorities to strengthen their biosecurity systems if they are to adequately meet stakeholder needs. A specific response to the inevitability of new and emerging diseases is the establishment of "disease-free" geographical compartments within countries or regions ("regionalization") so that animals and their products can still be traded.

Where zoonoses are concerned, it is clear that there is often an overlap between animal health and public health biosecurity objectives. Veterinary competence can be shared in these circumstances and a number of countries are exploring such synergies in the reform of legislative systems.

Plant health

Application of regulatory controls to protect plant health is an important biosecurity domain. This also covers threats to wild plants. Plant health can be adversely affected by different types of pests (i.e. plants themselves, and animals or pathogenic organisms which are injurious to plants or plant products). Management of pathways and vectors is an important aspect of plant health biosecurity.

Establishment and spread of a pest often depends directly on biological factors such as availability of suitable plant hosts and vectors, crop cultivation practices, suitability of the environment and natural enemies. As with animal health biosecurity, adverse plant health impacts are usually evaluated in direct economic terms.

Approaches to plant health biosecurity are undergoing changes similar to those in other biosecurity sectors (Box 1.8). With an increasing interest in environmental issues, competent authorities responsible for plant health must also manage environmental pests that primarily affect other organisms, thereby causing harmful effects on plants

Box 1.7. New influences on animal health biosecurity systems

- Adoption of a risk-based approach.
- Increasing number of new and emerging pathogens.
- Increasing availability of sophisticated diagnostic tools for epidemiological surveillance.
- More attention to zoonoses associated with asymptomatic animal carriage of enteric pathogens.
- More attention to traceability systems.
- Greater focus on emergency preparedness and response.
- Increasing attention to marine and freshwater biosecurity.
- Changing epidemiology of disease due to confluence of animals and people in intensive farming situations

Box 1.8. New influences on plant health biosecurity systems

- Adoption of a risk-based approach.
- Improvements in taxonomic knowledge and diagnostics.
- More attention to non-agricultural pests and safeguarding the environment.
- Adoption of "systems approaches" which integrate controls in a defined manner throughout the complete hazard exposure pathway.
- Higher levels of public participation needed in implementation of controls.
- Greater urbanization resulting in less public empathy with controls.
- Increasing requirements to protect specific geographical sites.
- Forestry as a plant health biosecurity sector of increasing significance

and plant ecosystems. Organisms produced by modern biotechnology also may threaten the plant environment such as by out-crossing to create more aggressive weeds or wild relatives that upset the ecological balance and decrease biodiversity.

While competent authorities can be proactive in preventing import of pests, risk management programmes are needed to control pests that have become established within the borders of a country. As with animal health, "pest-free" geographical compartments can be established within countries or regions so that plants and their products can continue to be traded.

Living modified organisms and their products

Biosafety has been defined as the "means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."[11] As such, biosafety does not represent an individual biosecurity sector as it is cross-cutting in scope (Box 1.9).

LMOs are increasingly being released on a world-wide basis. While they may have potential benefits for human well-being and achieving sustainable economic development, their proliferation could have unintended adverse effects on the environment, including destruction of native flora and fauna, as well as adverse effects on human health. This could be especially significant in developing countries that do not have the capacity to track releases of these organisms and therefore cannot adequately safeguard national interests.

Regulatory requirements covering the safe transfer, handling and use of LMOs resulting from modern biotechnology are a new focus point in biosecurity and are triggering strong cross-sectoral interest in more holistic approaches to their management. However, controls on trans-boundary movements currently vary considerably between countries in terms of their development, importation, field testing or release. Food may also be derived from (or traits introduced) by modern biotechnology. Although international guidelines on assessment of the safety of foods derived from GMOs are being developed, the adequacy of current processes is a continuing issue of public concern.

As with plant biotechnology in the early 1990s, animal biotechnology has reached a point where developers are beginning to market products derived in this manner. This may, in the near future, include agri-food applications. As an example, transgenic animals derived from recombinant DNA technology or by cloning (somatic cell nuclear transfer) is a means to generate animals with preferred traits. These animals and/or their products are likely to trigger regulatory requirements in most countries but guidance on safety assessment is still at the developmental stage.

Box 1.9. New influences on biosafety aspects of biosecurity systems

- Adoption of a risk-based approach.
- Rapid proliferation of new gene technologies.
- Emphasis on rapid establishment of credible and effective controls for LMOs and GMOs so as to maximize the benefits of biotechnology while minimizing associated risks.
- Development of detailed national strategies for conservation and protection of the environment.
- Increasing "public good" regulation for sustainable use of biological resources.
- Greater inclusion of indigenous and local communities in decision-making

Invasive alien species

Protection of biodiversity in terms of the variability among living organisms from all sources includes the introduction, control or eradication of invasive species that threaten ecosystems, habitats or other species (Box 1.10). Strategic emphasis is placed on prevention

Box 1.10. New influences on invasive alien species aspects of biosecurity

- Adoption of a risk-based approach.
- Intensification of broader aspects of biosecurity (e.g. border inspection of people and products).
- Development of detailed national strategies for conservation and protection of the environment.
- "Ecosystem approaches" to minimizing spread.
- Increasing "public good" regulation for sustainable use of biological resources.
- Demands for cross-sector cooperation between environmentalists and agriculturalists at both the government and private sector level

11 UNEP/CBD. 1992. Convention on Biological Diversity: Article 8(g).

of introductions, rather than eradication, mitigation or containment once an invasive alien species is established. Although there are calls from governments and other stakeholder groups (e.g. special interest groups, NGOs) in many countries for much more diligence in protecting biodiversity and the environment, equitable management of biodiversity presents many challenges.

Environmental protection

Environmental protection in a broad sense is also a biosecurity activity. While not excluding any aspects of the above sectors, specific biosecurity cross-sectoral environmental initiatives may be undertaken by competent authorities, especially in the management of biological resources to ensure sustainable agriculture while maintaining full biological diversity of genetic resources.

Harmonization and integration of approaches to biosecurity

"Traditional" approaches to biosecurity are under challenge on a worldwide basis. The scope of biosecurity is constantly expanding and national competent authorities are incorporating considerable legislative, institutional and infrastructural change as a response.

In any biosecurity environment, there is a plethora of policies, systems and controls. However, there is widespread opportunity to enhance biosecurity by developing integrated national policies and implementing harmonized approaches to biosecurity systems and standards.

CHANGING APPROACHES TO BIOSECURITY

Biosecurity at the national level can be approached on a continuum that progresses from complete separation (and fragmentation) of sectors to high levels of harmonization and integration. In a traditional system, biosecurity is managed on a sector basis through the development and implementation of separate policy and legislative frameworks (e.g. for animal and plant life and health, food safety and environmental protection). Sector agencies organize their work without much attention to the other sectors. Limited if any attention is paid to the interdisciplinary nature of biosecurity. Moreover, in some cases, roles and responsibilities within a biosecurity sector may not be under the same legislative jurisdiction and this further creates fragmented biosecurity.

In a modern national system, there is a more harmonized and integrated approach, with competent authorities responsible for different sectors and components of biosecurity working together towards common goals. Sector policies, laws and regulations can be harmonized to avoid contradictions, overlaps and/or gaps. Sector agencies can better coordinate their work and actively seek to take advantage of the synergies and complementarities in their roles and responsibilities. This encompasses the joint setting of biosecurity priorities and allocation of resources, joint planning and implementation of activities, and integrated systems for monitoring and review of outcomes. In the future in some countries, this may lead to a single competent authority responsible for biosecurity.

There is a growing recognition that biosecurity will profit from these changes. During the past decade, some governments have moved to harmonize and rationalize policies, legislation and core roles as a means to improve overall efficiency and outcomes. Models to rationalize regulatory operations among sectors in the quest for improved effectiveness and efficiency have appeared in a number of countries. For example, New Zealand has had a Biosecurity Act since 1993[12]; the first Biosecurity Minister was appointed to Cabinet in 1996 and a Biosecurity Council was established in early 1997. In Belize a single authority, the Belize Agricultural and Health Authority, was created to cover food safety, animal and plant quarantine, and environmental issues (see Annex 4). Norway has reorganized its national food safety administration and adopted a modernized biosecurity framework (see Annex 5). In Canada, the creation of the Canadian Food Inspection Agency in 1997 brought together all federal inspection and enforcement in one

Box 1.11. A competent authority structure that facilitates biosecurity as a holistic concept

The newly formed Finnish Food Safety Authority (EVIRA) arguably represents the most holistic example of national efforts to facilitate cross-sectoral harmonization and integration. Departments within EVIRA comprise Agricultural Production Control (including plant protection), Food and Veterinary Control (including food hygiene and animal health), Animal Diseases and Food Safety Research, and Administrative Services. Risk assessment and communications departments operate directly under the Director General. The Ministry of Trade and Industry and the Ministry of Social Affairs and Health make policy inputs to EVIRA, and cooperative partnerships with other national and regional authorities and agencies are in place. Together, these arrangements deliver the integrated biosecurity goal of EVIRA to "create prerequisites for the safeguarding of human and animal health as well as the environment, for agriculture, forestry and food economy, and for high consumer protection". Further information is available on the EVIRA web site (www.evira.fi)

[12] The New Zealand Biosecurity Act does not cover food safety.

agency responsible for safeguarding not just the food supply but also the plants and animals upon which safe and high-quality food depends. Similar changes have recently been made in Finland (Box 1.11).

REQUIREMENTS FOR A HARMONIZED AND INTEGRATED APPROACH TO BIOSECURITY

The successful implementation of a harmonized and integrated biosecurity approach requires a clear policy and legal framework, an institutional framework that defines the roles and responsibilities of relevant stakeholders, adequate technical and scientific capability (including use of risk analysis), a well-functioning infrastructure, and a system for communication and information exchange.

The Guide to Assess Biosecurity Capacity (Part 2) provides a process for assessing biosecurity capacity needs across all sectors and all sector organizations, which will help to identify requirements to pursue a harmonized and integrated biosecurity approach.

Policy framework

A biosecurity policy framework sets out a broad course of action to address biosecurity risks in food and agriculture. It is based on appropriate public goals and a set of beliefs about the best way of achieving those goals. It provides a common basis for assessing biosecurity risks and priorities for action and gives direction and guidance to all the parties concerned.

Legal framework

Sound biosecurity legislation (encompassing laws and regulations) is necessary to create an enabling environment of predictability and certainty through good governance and respect for the rule of law. Law clarifies the roles, responsibilities and rights of different stakeholders, including those parts of government with policy and delivery roles for biosecurity outcomes and programmes, in order to ensure consistency and accountability. It also defines appropriate powers to act, which is essential for enforcement.

Institutional framework

A clear institutional framework within which to manage biosecurity is an important part of a more harmonized and integrated approach to biosecurity. The institutional framework identifies the competent authority or authorities responsible for establishing biosecurity controls and ensuring their implementation, as well as any other stakeholders involved. It also sets out the rules and procedures governing their roles and defines the mechanisms through which they work towards shared goals. The choice of institutional framework will be determined by factors which are specific to a country and biosecurity context (e.g. historical traditions, political orientation, financial and other resources).

Communication and information exchange

The complexity inherent in managing biosecurity requires communication and information exchange among a wide range of national stakeholders including government agencies, the private sector (agricultural producers, processors, enterprises, importers/exporters, etc.), the scientific and research community, and the general public.

Transparency obligations under international agreements such as the SPS Agreement require governments to ensure transparency in the adoption of their sanitary and phytosanitary rules. This includes publishing proposed rules in advance and allowing time for comments from the public, as well as the establishment of enquiry points for consultations on rules and inspection and control procedures applicable to imports and exports. They also must open to scrutiny how they apply their food safety and animal and plant health regulations. National, regional and global networks all contribute to meeting the information needs of an integrated biosecurity system.

Risk analysis

Risk analysis processes and methodologies are at the heart of a harmonized and integrated approach to biosecurity. The move to risk-based sanitary and phytosanitary measures at the international level has placed new responsibilities and accountabilities on national competent authorities.

The application of good science and risk analysis in biosecurity is fully dependent on an effective biosecurity infrastructure and appropriate technical capability (see below). As an example, implementation of a risk-based regulatory programme cannot be effective unless there is an appropriate legislative base, sufficient scientific capacity to develop appropriate regulatory controls, robust regulatory systems for verifying compliance, equitable stakeholder engagement and on-going monitoring of overall performance.

The Overview and Framework Manual for Biosecurity Risk Analysis (Part 3 of this toolkit) presents a generic framework to structure and guide the application of risk analysis principles in biosecurity.

Competent authorities with adequate technical and scientific capability and infrastructure

Establishing biosecurity controls and ensuring their implementation is the core responsibility of competent authorities. They should have appropriate policies and regulations in place, as well as operational principles, procedures and capacity, and adequate resources. They should have, or have access to, adequate technical and scientific knowledge and skills, and should have adequate infrastructure.

Implementing national biosecurity mandates demands human resources with adequate technical capability. This includes personnel with specialized scientific knowledge and skills to carry out biosecurity functions (e.g. provision of scientific research and advice, inspection, verification and enforcement, diagnostic analysis, quarantine and certification, risk profiling and priority setting, standard setting and implementation, monitoring and surveillance, and emergency preparedness and response), based on a risk analysis approach wherever possible and practical.

Technical resources in several of these areas may be shared across public agencies and the private sector. For instance, inspection activities may be carried out at any step in the hazard exposure pathway by the competent authority or by officially-recognized bodies. Similarly, diagnostic laboratories may be owned and operated by the public or private sector, or as a public-private partnership.

Emergency preparedness and response in the event of a disease outbreak are key elements of biosecurity systems and need for this capability is illustrated by recent disease outbreaks in many parts of the world. Emergency preparedness and response is a collective responsibility that requires partnerships between central government, competent authorities across all biosecurity sectors, industry and the public. Policy documents detailing joint roles and responsibilities, as well as decision-making and funding procedures in emergency situations are required, along with a series of standards and procedures governing monitoring and surveillance.

Modern biosecurity concepts can only be applied if there is an effective infrastructure at the national level. Necessary infrastructure includes diagnostic laboratories with functioning equipment and supplies, facilities for storage and containment of samples and suspect consignments at checkpoints, as well as sanitation equipment, quarantine yards, inspection equipment, vehicles, and computers and communication equipment for the operation of monitoring, surveillance and emergency preparedness systems.

Willingness to explore new approaches

New approaches to biosecurity can be achieved in different ways depending on the particular circumstances and needs at the country level. There is not one single or best model. Generally, an integrated approach is pursued by merging services and functions. However, the extent of consolidation varies. For example, in New Zealand, policies and planning affecting different biosecurity sectors are more inclusive than in countries like Canada and Australia. In countries like France where there has been less consolidation, cooperation is pursued by means of formal and informal mechanisms of interaction, exchange and coordination among relevant bodies.

It is important to note that an integrated approach does not mean that all of the roles and responsibilities of the competent authorities involved should be harmonized. They often have distinct and sometimes separate roles, and contribute to biosecurity in different ways (e.g. a quarantine function presents a front line of defence against all hazards whereas a forestry management function may focus more on monitoring and remedial risk management of pests in either natural forests or plantations). Moreover, the situation is not static (e.g. rapid growth of aquaculture and technical breakthroughs in fish transgenics presents different biosecurity policy and functional needs compared with forestry). However, a common thread in all sectors is the increasing reliance on systematic risk analysis.

National biosecurity strategy

A national biosecurity strategy can provide an impetus and unifying force to support the achievement of a harmonized and integrated approach to biosecurity. This concept has gained prominence in a number of countries in recent years. A national biosecurity strategy translates high level policy into objectives to achieve specific outputs and outcomes (Box 1.12). It gives

direction and guidance to all the parties concerned with the implementation of biosecurity measures.

A national biosecurity strategy should be developed in consultation with all stakeholder groups and incorporate a "whole of government" approach. It should also include reference to the international regulatory environment.

ENHANCING SPECIFIC ASPECTS OF BIOSECURITY THROUGH A HARMONIZED AND INTEGRATED APPROACH

Better risk analysis

There are considerable advantages from a harmonized and integrated approach to risk analysis at the national level. While international risk assessment processes differ in part between sectors, many aspects are common (e.g. recognition of the benefits of probabilistic modelling of hazard pathways to better represent and describe the complexity of real-world situations). Utilization of the expertise and experience gained in all biosecurity situations has the potential to improve risk analysis both within and between sectors, provide for consistency in approaches and outputs, and facilitate better uptake and understanding by competent authorities and other stakeholders. A more integrated and holistic approach will help in ensuring public confidence in overarching regulatory frameworks and assist in optimization of scarce biosecurity resources in developing countries.

Expanded uptake of risk assessment methodologies by competent authorities and more systematic risk management processes will result in enhanced implementation of integrated national biosecurity goals. If a national biosecurity strategy has been developed, an integrated risk management approach enables the overall use of government resources to be prioritized according to a broad ranking of biosecurity issues.

Improved biosecurity capability

National level

A harmonized and integrated biosecurity approach considerably improves the ability of competent authorities to achieve their mandates. Taking advantage of the interdependencies of competent authorities is increasingly reflected in shared technical capability. The resulting improvements in biosecurity capacity may be manifest in many ways (Box 1.13) and include the opportunity to develop a national strategy for biosecurity.

Restructuring of competent authorities and consolidation of multiple legislative and functional

Box 1.12. Components of a national biosecurity strategy

- A "national vision" for biosecurity that is agreed upon by all stakeholder groups.
- Availability of sufficient financial and technical resources.
- Mechanisms for establishing national risk-based priorities.
- Coordination between competent authorities working within and between biosecurity sectors.
- A culture of collaboration between competent authorities, especially in areas where control structures are decentralized and local and national priorities are different.
- Recognition of international biosecurity obligations.
- Participation in international standard-setting organizations and bodies, and effective representation of national interests

Box 1.13. Improved national biosecurity capability resulting from increasing interdependence of competent authorities and convergence of biosecurity issues

- Simplification of legislation and condensing of biosecurity jurisdictions.
- Development of a national biosecurity strategy and establishment of cross-sectoral priorities.
- Better use of resources (e.g. sharing of methodologies, sharing of border inspection systems, training).
- Rationalization of controls (e.g. opportunity to develop a single import health standard for an agricultural product that meets all biosecurity needs).
- Shared certification where appropriate.
- Improved data acquisition and quality.
- Improved emergency preparedness and response (including contingency planning).
- Integrated response to new and emerging diseases (e.g. combining veterinary, public health and food safety aspects of zoonoses).
- Integrated pest management (IPM) programmes (e.g. appropriate use of pesticides to achieve pest control goals while ensuring human health, protection of the environment and sustainability of agriculture).
- Integrated surveillance (e.g. systems capable of detecting any unexpected adverse public health or environmental effects that may be associated with LMOs).
- Integrated traceability systems.
- Greater acceptance of privatization of some biosecurity services

Box 1.14. Restructuring of competent authorities as expressions of improved biosecurity capability

- In Canada, a new regulatory initiative is the consolidation and modernization of biosecurity inspection and enforcement activities in the areas of food, agricultural and aquatic commodities, agricultural inputs (e.g. seed, feed, fertiliser), animals and plants. This will result in a more consistent and comprehensive approach to the Canadian Food Inspection Agency's inspection, compliance and enforcement activities. Inspectors will be able to move freely from one food and agricultural commodity to another, thereby improving the effectiveness and efficiency of regulatory systems.
- In the newly-established Biosecurity New Zealand, the Pre-Clearance Directorate manages all biosecurity hazards (other than food safety hazards) up to the point where goods receive biosecurity clearance; the Post-Clearance Directorate manages all biosecurity hazards (other than food safety hazards) that are "residual" in nature (i.e. still present after border clearance) or are already present in the country

Box 1.15. Improved global biosecurity capability resulting from increasing interdependence of countries and convergence of biosecurity issues

- Harmonization of approaches in areas of mutual SPS interest (e.g. standard-setting, determination of equivalence, traceability, laboratory compliance and audit, laboratory accreditation).
- Strengthening of biosecurity infrastructure in exporting countries because of the need for reliable health assurances and certification.
- Sharing of scientific data, risk assessments, other methodologies and technical resources, especially with developing countries.
- Improving exchange of information.
- Jointly addressing security risks in international trade.
- Enhancing and integrating emergency preparedness, rapid alert and response.
- Improving regional and sub-regional diagnostic resources (e.g. sharing of laboratory equipment and facilities, laboratory referral testing systems).
- Promoting harmonized administrative technology such as electronic certification that increases effectiveness and reduces fraud.
- Understanding and combatting new and emerging diseases.*
- Promoting capacity building according to regional and international perspectives.

* A WHO Consultation on emerging zoonoses in 2004 concluded that "for WHO, together with FAO and OIE, the next step forward is to mobilize political awareness and support for the implementation of a public and animal health infrastructure" (consultation recommendations available at: http://www.who.int/mediacentre/news/briefings/2004/mb3/en/index.html)

activities that were previously spread over several jurisdictions is progressing in different ways in different countries (Box 1.14).

International level

The rapidly accelerating volumes and diversity of food and other agricultural commodities in international trade is contributing to the ever-increasing interdependence of competent authorities operating in different countries and illustrates the convergence of sector issues.[13] This is significantly influencing biosecurity strategies and processes to the advantage of the global community (Box 1.15).

Ability to consider complete exposure pathways

The ability to consider and implement controls at those points in the complete hazard exposure pathway where they will be most effective is a distinct biosecurity advantage. In recent years, implementation of this concept has also been given international expression under regional trading block agreements such as those of the European Union, Asia (South Asia Free Trade Agreement), Australia and New Zealand (Trans-Tasman Mutual Recognition Agreement) and North America (North American Free Trade Agreement).

In the European Union, single legislation covering official feed and food safety controls was introduced in 2004 (Regulation 882/2004/EC) with the aim of ensuring common compliance with feed and food law, animal health and animal welfare rules (Box 1.16).

In the emerging globalized biosecurity environment, it is often more efficient to achieve biosecurity objectives at origin in exporting countries, rather than relying on controls at point-of-entry to the importing country. This provides a clear incentive to promote and support the role of competent authorities in developing countries that may have limited capability.

Opportunity for integrated approaches to emerging cross-sectoral problems

There are a number of emerging biosecurity issues that are cross-sectoral in nature and that can benefit from increasingly integrated approaches, especially in terms of risk management. Antibiotic resistance arising from

[13] Examples are: emerging zoonoses that impact on animal and human health; production of affordable food that is safe and wholesome being partially reliant on protection of the environment and maintaining biodiversity.

Box 1.16. Food chain biosecurity – an example of a "complete exposure pathway" legal framework in the European Community

- General Food Law (Regulation 178/2002[EC]) providing general principles and requirements for food safety.
- Regulation 854/2004(EC) laying down specific rules for organization of official controls.
- Specific feed and food laws covering areas such as medicated feeding stuffs, feed and food hygiene, zoonones, animal by-products, residues and contaminants, control of zoonotic diseases in animals, genetically-modifed foods.
- Regulation 882/2004(EC) on regulatory controls to ensure verification and compliance with feed and food law, animal health, and animal welfare rules

use of antimicrobials in agriculture and veterinary practice (including aquaculture) is a good example and it is recognized that a multidisciplinary and multi-agency response is needed. New agricultural commodities derived from biotechnology (e.g. transgenic animals) presents another example where multi-sector experience will improve risk management.

Improved training

Harmonization of approaches to biosecurity is leading to new opportunities in terms of alignment of training of competent authority personnel. Common biosecurity concerns and methodologies mean that training materials and programmes can be shared and there is increasing cross-fertilization of ideas. Shared training opportunities also arise in technical exchanges between countries and capacity building; the latter being particularly important for developing countries.

Enhanced linkages for international standard setting

Linkages between international bodies are increasingly being created so as to harmonize and enhance cross-sectoral standard-setting processes where there is specific need (Box 1.17). It is noteworthy that the SPS Agreement provides for a common approach in that it applies to all sanitary and phytosanitary controls that may affect international trade.

Increased access to international biosecurity information

Exchange of, and access to biosecurity information is an obligation of signatories that is common to all international instruments. This is essential to risk analysis, especially in developing countries where scientific information is scarce, and is a vital component of enhanced global biosecurity capability.

Better international servicing of biosecurity information is being achieved by increased networking capacity of international standard-setting

Box 1.17. Linkages between international bodies that are enhancing development of international biosecurity standards

- Current discussion on broader interpretation of health risks in the International Health Regulations may result in wider international powers and conditions for zoonoses quarantine.
- The strategic framework of the CAC for 2003-2007 has an objective to "promote linkages between Codex and other multilateral regulatory instruments and conventions" and considers it important to avoid duplication of effort in new areas of activity such as biotechnology. Similarly, the new CAC strategic plan for 2008-2013 continues this drive for better linkages.
- The OIE Fourth Strategic Plan 2006–2010 aims to "provide a better guarantee of the safety of food of animal origin" and has established the Animal Production Food Safety Working Group (APFSWG) to help achieve this (see http://www.oie.int/downld/Good_Governance/3.2.13.1.pdf). OIE is particularly interested in identifying the duality of public health and animal health objectives throughout the food chain and the need for conjoint epidemiological surveillance.
- CAC/OIE have agreed to collaborate in the areas of food safety, animal feeding, use of veterinary drugs, aquaculture and controls for BSE throughout the complete hazard exposure pathway.
- OIE has now concluded cooperative agreements with FAO, WHO, WTO and the European Union (EU).
- Regional Plant Protection Organizations (RPPOs) coordinate activities of the IPPC at the regional level and promote regional cooperation, harmonization of controls and information gathering and dissemination.
- There is considerable overlap between the provisions of the IPPC and CBD (even though the latter is non-executing in that it requires implementing legislation at the national level); cooperation is increasing between the two secretariats so as to avoid duplication and inconsistencies in implementation.
- The Cartagena Protocol to the CBD calls for greater cooperation with the CAC in developing standards for the identification and labelling of foods derived from biotechnology.
- The Standards and Trade Development Facility (STDF), established by FAO, OIE, the World Bank, WHO and WTO, is a global programme to address the capacity building and technical assistance needs of developing countries in relation to trade and SPS measures (http://www.standardsfacility.org/)

Box 1.18. Examples of systems for improving international biosecurity networking

- The International Portal on Food Safety, Animal and Plant Health (IPFSAPH) developed by FAO in association with the organizations responsible for international standard setting in sanitary and phytosanitary matters, provides a single access point for authorized official international and national information across the sectors of food safety, animal and plant health (www.ipfsaph.org).
- The International Food Safety Authorities Network INFOSAN (which includes an emergency component, INFOSAN Emergency) has been developed by WHO in cooperation with FAO to promote the exchange of food safety information and to improve collaboration among food safety authorities at national and international levels (http://www.who.int/foodsafety/fs_management/infosan/en/).
- The Global Early Warning and Response System (GLEWS) was established by FAO, OIE and WHO to predict and respond to animal diseases including zoonoses worldwide.
- The International Phytosanitary Portal serves as the official web site for the IPPC and provides a forum for national IPPC reporting and the exchange of more general information among the phytosanitary community (http://www.ippc.int).
- The WHO Global Outbreak Alert and Response Network (GOARN) is a technical collaboration of existing institutions and networks which pool human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance (http://www.who.int/csr/outbreaknetwork/en/).
- The Biosafety Clearing-House (BCH) is an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, LMOs (http://bch.biodiv.org/default.aspx).
- The Global Avian Influenza Network for Surveillance (GAINS) was established to expand operational field capabilities, improve the understanding of viral strains and transmission of influenza viruses in wild birds, and to disseminate information to all concerned stakeholders (www.gains.org)

organizations and bodies, and more systematic involvement of competent authorities in different countries (Box 1.18).

CONCLUSIONS

Improved health and well-being of human populations are the ultimate outcomes of well-functioning biosecurity systems. These outcomes are strongly influenced by society and the environment and, in this context, agriculture and health are linked in many ways. Agriculture produces the world's food, fibre and materials for shelter, and is an important source of livelihoods. At the same time, agriculture can lead to poor health, especially in the form of infectious disease and malnutrition.[14]

The benefits of a more harmonized and integrated approach to biosecurity are already apparent in specific national situations. While the multi-sectoral character of biosecurity and the diverse range of interests involved make each national situation different, there are likely to be significant improvements in biosecurity systems and outputs if more coherent national and international approaches are applied. Benefits include improved regulatory and policy frameworks for human health (particularly food safety), improved animal and plant health, greater efficiencies in the use of human and financial resources, better understanding of potential risks (within and between sectors) and appropriate measures to manage them, and improved protection and sustainable use of the environment. Moreover, a more holistic approach to biosecurity will enable these benefits to be achieved in a manner that avoids inconsistencies, fills gaps, and prevents the creation of unnecessary barriers to trade.

[14] C. Hawkes and M. Ruel. 2006. The links between agriculture and health: an intersectoral opportunity to improve the health and livelihoods of the poor. *Bulletin of the World Health Organization*, 84 (12), 2006 (available at: http://www.who.int/bulletin/volumes/84/12/05-025650.pdf).

Part 2
Guide to assess biosecurity capacity

Introduction

Biosecurity is emerging as a critical issue for developed, developing and transition countries, however, many countries have inadequate biosecurity capacity. This lack of capacity jeopardizes their ability to protect the health and well-being of their population, animals, and plants and ensure protection against associated risks to the environment, threatens economic interests and trade, and compromises their ability to meet international legal commitments.

FAO and other international organizations have recognized this situation and, during recent years, developed a variety of sectoral tools to assess capacity needs (Box 2.1) as a means to support the development and delivery of sound policies and programmes in the various areas of biosecurity. This guide has been produced to complement these sector-specific tools. It may be used in connection with or independently of existing sectoral tools as appropriate. For instance, some countries may already have applied one or more of the existing sectoral tools before deciding to use this guide to address issues that cut across the various sectors. Other countries may decide to focus on cross-cutting biosecurity capacity needs before getting more involved in sectoral capacity building activities. The most fitting approach will depend on national circumstances.

Box 2.1. Relevant sector-specific capacity assessment tools

- FAO. 2006. *Strengthening national food control systems: Guidelines to assess capacity building needs* (available at: ftp://ftp.fao.org/docrep/fao/009/a0601e/a0601e00.pdf).
- FAO. 2007. *Strengthening national food control systems: A quick guide to assess capacity building needs* (available at: ftp://ftp.fao.org/docrep/fao/010/a1142e/a1142e00.pdf).
- IPPC. 2003. *Phytosanitary Capacity Evaluation Tool* (User's Guide available at: www.ippc.int/IPP/En/default.jsp).
- ISNAR/FAO. 2003. *Decision Support Toolbox for Biosafety Implementation* (available at: www.isnar.cgiar.org/ibs/biosafety/).
- UNEP/GEF. *Biosafety Framework Development Toolkit* (available at: http://www.unep.ch/biosafety/resources.htm).
- IICA/OIE. 2005. *Performance Vision and Strategy (PVS) for National Veterinary Services* (available at: www.oie.int/downld/Prep_conf_Avian_inf/A_Final_PVS.pdf)

CONTENTS AND STRUCTURE

The Guide to Assess Biosecurity Capacity offers a systematic, seven-step process to examine critically the nature and performance of an existing biosecurity system, pinpoint areas for improvement and identify the means to achieve a future vision of biosecurity.

It is developed on the premise that biosecurity concerns different parts of government, that biosecurity goals are interrelated, and that the best way to manage the risks faced is through coordinated action across the relevant sectors, thereby contributing to improved outcomes and efficiencies. By providing a process to identify cross-cutting biosecurity capacity needs, the guide addresses the gaps inherent in a purely sectoral approach.

Circumstances and needs differ substantially between countries and there is no universal model for either biosecurity or capacity development. This guide acknowledges that different countries and sectors are at varying stages in their ability to address biosecurity issues, and is sensitive to the need to proceed accordingly. Similarly, it recognizes that a harmonized and integrated approach to biosecurity is a flexible undertaking and there is no off-the-shelf strategy that can be applied universally. The approach presented in this guide can take different forms and need not entail extensive institutional restructuring or the merging of sector competent authorities or other agencies.

The methodology presented is inter-disciplinary and participatory. It offers a framework for different groups and individuals to work together on common tasks, thereby serving as a mechanism for inter-agency collaboration and cross-sectoral decision-making on various aspects of biosecurity. Options to improve biosecurity capacity are introduced, as well as examples from countries implementing the principles discussed in Part 1 of this toolkit.

The guide examines biosecurity capacity needs at the various interfaces between human, animal and plant health and life, and associated aspects of

environmental protection. Attention therefore focuses on dimensions of capacity that cut across the sectors of biosecurity. While the guide addresses related elements of capacity within the competent authorities responsible for core biosecurity functions, existing sector-specific tools should be used as required to obtain a more detailed assessment of capacity needs within the individual sectors.

EXPECTED OUTPUTS

Use of this guide will enable governments to increase awareness about the interdependencies and synergies of biosecurity, and the benefits to be achieved through a more harmonized and integrated approach. It will produce an assessment of existing biosecurity capacity, a medium-term vision of biosecurity, a gap analysis and an assessment of the options and actions needed to close the gaps. The combination of these outputs amounts to an assessment of capacity needs in the biosecurity area.

Systematic assessment of biosecurity capacity needs will assist countries to develop harmonized and integrated biosecurity frameworks, enabling them to reap the benefits described in Part 1. This will directly result in improved decision and policy making, enhanced resource allocation, better risk analysis, and improved ability to comply with the requirements of international agreements governing trade in food and agricultural products. By demonstrating a national commitment to biosecurity to the international community and trading partners, a capacity needs assessment will also help to attract new sources of funding for biosecurity activities.

An integrated biosecurity approach and the assessment of capacity needs

WHY ASSESS BIOSECURITY CAPACITY NEEDS?

Biosecurity has traditionally been managed on a sectoral basis through the development and implementation of legislation and regulations related to human, animal and plant life and health and associated protection of the environment. Responsibilities tend to be spread across various agencies with varying approaches, resources, capability and performance. More recently, new issues related to biotechnology and the introduction of living modified organisms (LMOs) and their products (e.g. genetically modified organisms or GMOs) have expanded the range of sectoral interests in biosecurity. While a fragmented, sector-based approach may have been sufficient to manage known biosecurity risks in the past, recent and emerging trends indicate that such an approach will not meet today's needs. As a result, countries that want to improve biosecurity, demonstrate compliance with international obligations and commitments and/or take advantage of new trade opportunities, are asking what is required to realize the benefits of a harmonized and integrated biosecurity approach (Box 2.2).

A needs assessment is an essential initial step in the process of improving biosecurity capacity. It provides a means to identify country level requirements and priorities and exploit trade opportunities. It will ensure that activities to improve biosecurity capacity are demand-driven and tailored to the specific circumstances and requirements that exist at the country level. By assessing needs, governments will be better able to set priorities and organize their work, improve the use of available resources and raise additional resources for unmet needs.

Assessing needs can help to raise awareness among different parts of government about the synergies and interdependencies that exist across the sectors of biosecurity, and the benefits to be achieved through a more harmonized approach. This avoids duplication of effort and helps to build the foundation for improved cross-sectoral information exchange, dialogue and collaboration. At the same time, the needs assessment process will enable staff of the agencies involved to obtain new insights and skills, contributing to organizational learning.

Box 2.2. What motivates countries to assess biosecurity capacity needs?

Governments may decide to carry out an assessment of biosecurity capacity needs for a variety of reasons. For instance, they may wish to:

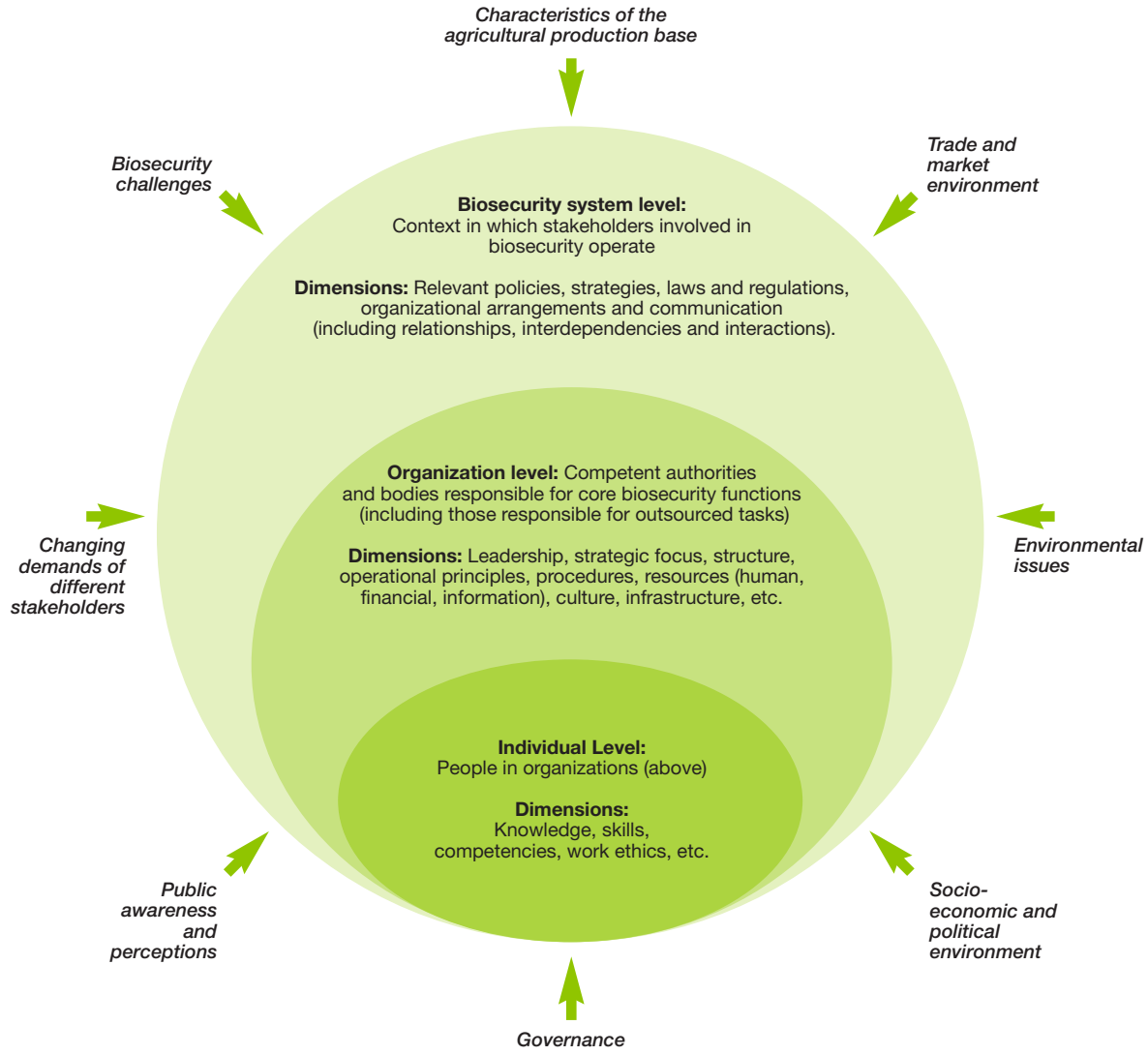
- determine how to improve the safety of food and agricultural products for human consumption;
- identify ways to better protect animal and plant life and health, and the environment;
- clarify the biosecurity roles and responsibilities of different government agencies so as to avoid duplication of effort and/or improve the quality of government services;
- support the development of a national biosecurity strategy and/or sector strategies;
- demonstrate compliance with international agreements and treaties related to human, animal and plant life and health and associated protection of the environment;
- respond to an challenging event (e.g. spread of transboundary disease, ban on a food or agricultural export) that has had negative impacts on public health, trade or the overall economy; or
- take advantage of trade opportunities, such as to access a new market or to consolidate a market position

WHAT DOES BIOSECURITY CAPACITY ENCOMPASS?

Capacity can be considered as "the ability of individuals, organizations and systems to perform functions effectively, efficiently and sustainably"[15]. Biosecurity capacity relates to the ability of relevant organizations to perform appropriate functions effectively, efficiently and sustainably in order to protect human, animal and plant life and health, and associated aspects of the environment.

[15] UNDP. 1998. *Capacity assessment and development in a systems and strategic management context*. Technical Advisory Paper No. 3. January 1998. Bureau for Development Policy, United Nations Development Programme (UNDP).

Figure 2.1. Levels and dimensions of biosecurity capacity[16]



As illustrated in Figure 2.1, biosecurity capacity encompasses:

i. An enabling system underpinning the various aspects of biosecurity through the provision of sound policies, laws and regulations, adequate resources, a mechanism to facilitate inter-agency collaboration on cross-cutting issues and effective communication channels.
ii. Organizations (competent authorities and competent bodies[17]) with the mandate and ability to perform the core functions required to adequately identify, manage and prevent biosecurity risks in all sectors.
iii. Individuals with skills and expertise in biosecurity and its sectors, and the ability to apply these attributes to effectively manage the risks faced in accordance with their roles and responsibilities.

Assessing biosecurity holistically examines the contribution and performance of each of the levels (the system level, the organization level, and individual level) as shown in Figure 2.1.

ANALYTICAL FRAMEWORK TO ASSESS BIOSECURITY CAPACITY NEEDS

Existing methodologies to assess capacity needs in biosecurity are based on a sectoral approach. This

16 Figure developed based on concept of capacity within a systems context. UNDP, 1998.

17 An officially-recognized body acting under the supervision and control of a competent authority.

Table 2.1. **Levels of analysis**

Level of analysis	Dimensions of Capacity
System Level	Policy framework
	Legal framework
	Organizational arrangements (including coordination)
	Communication
Sectors of biosecurity / Organization Level	Mandate, roles and responsibilities of sector competent authorities and competent bodies
	Core biosecurity functions (deliverables)
	Operational principles and procedures
	Resources (human, financial, infrastructure, information, other)
	Linkages and interdependencies

Table 2.2. **Core biosecurity functions based on a risk analysis approach**

Risk Assessment	Risk Management	Risk Communication
Scientific research and advice		Risk communication
Diagnostic services	Risk profiling and priority setting	
	Assessing and responding to biosecurity needs	
	Standard setting and implementation	
	Quarantine and certification	
	Inspection, verification and enforcement	
	Emergency preparedness and response	
Monitoring and surveillance		

serves the purpose for which these tools were developed. However, the lack of attention to cross-cutting functions and issues makes it difficult to use these sectoral tools to generate a comprehensive assessment of cross-sectoral biosecurity capacity in a contemporary setting.

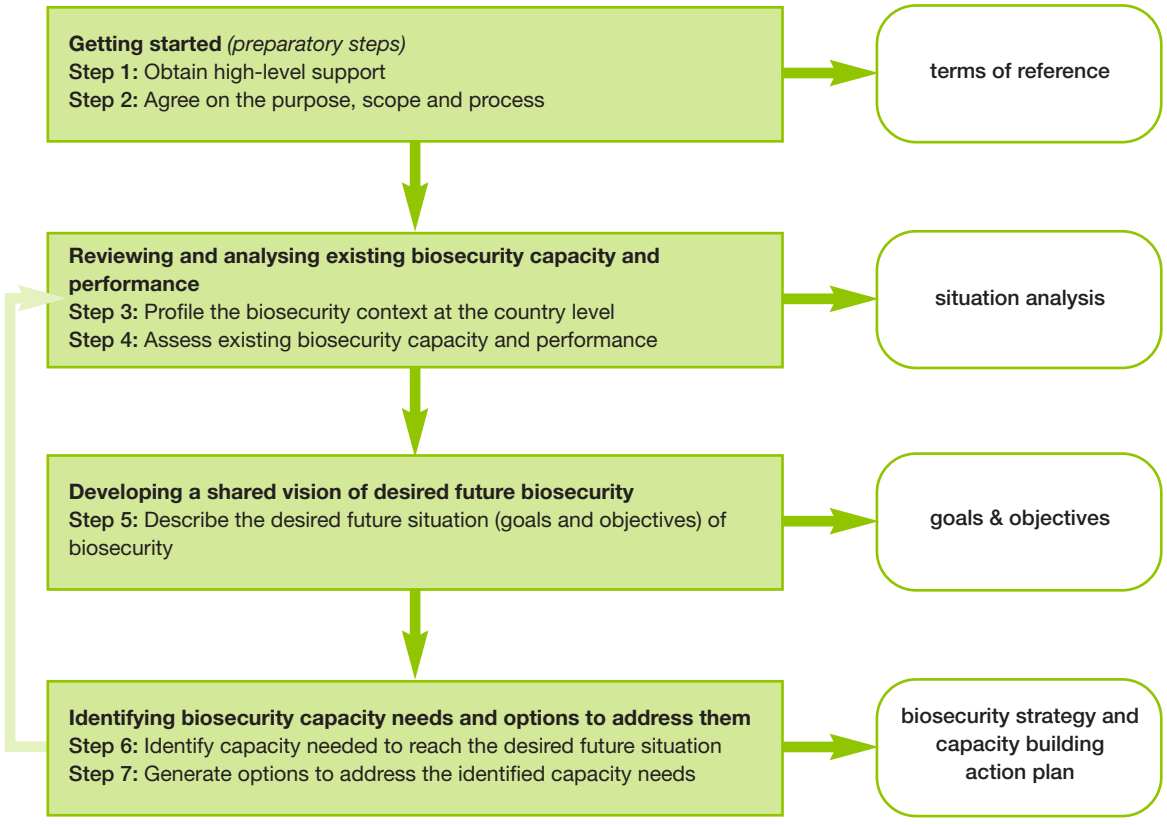
The analytical framework in Table 2.1 provides guidance to assess capacity needs across the entire biosecurity arena. The focus is on dimensions of capacity that cut across the sectors of biosecurity and their respective organizations. This encompasses dimensions of capacity in:

- the overall biosecurity system (including policy framework, legal framework, organizational arrangements, communications); and
- the competent authorities and competent bodies responsible for core normative and technical functions that are necessary for biosecurity.

Looking at the system level in more detail:

- The ***policy framework*** defines a country's overarching biosecurity goals and objectives, as well as the broad course of action to be followed. Policy frameworks vary in accordance with specific national (or sub-national) needs and circumstances.
- The ***legal framework*** delimits general and specific rights and obligations of stakeholders involved in biosecurity including those parts of government with responsibility for the delivery of core biosecurity functions. It defines a system of enforcement, penalties and appeal.
- The ***organizational arrangements*** refer to the type of mechanism through which stakeholders collaborate in the planning, budgeting, delivery and monitoring of core biosecurity functions, and the interdependencies and relationships between them. The definition and division of these core functions provides the link between the system level and the organizational level, by defining how normative and technical roles and responsibilities are distributed among specific government agencies and/or through sub-contracts to other stakeholders (third parties).
- ***Communication*** encompasses the information flows and dialogue between the stakeholders involved in biosecurity.

Figure 2.2. Process to assess biosecurity capacity



At the sectoral/organizational level, this guide examines the capability of relevant competent authorities (in terms of their mandate, structure, processes, resources, infrastructure, etc.) to deliver core normative and technical functions of biosecurity based on a risk analysis[18] approach. Table 2.2 broadly categorizes these functions in terms of the three components of risk analysis (risk assessment, risk management and risk communication). These functions may be provided by the public and/or private sector, and planned, funded, delivered and/or monitored in different ways. In some cases, countries may utilize external resources in particular situations (e.g. risk assessments carried out by other national governments or international bodies, diagnostic services in another country) rather than perform the function themselves.

The scope of this analysis is limited to capacity for relevant cross-sectoral tasks. Existing sector-specific tools (Box 2.1) should be used to obtain a more in-depth assessment of specific capacity needs within biosecurity sectors as required.

PROCESS TO ASSESS BIOSECURITY CAPACITY NEEDS

A process to assess biosecurity capacity is illustrated in Figure 2.2. This process provides a systematic and analytical means to critically examine the nature and performance of the existing biosecurity system, pinpoint areas for improvement and identify options to address these needs:

- The first two steps encompass a number of simple preparatory steps to clarify why the assessment is being undertaken, and ensure broad sponsorship, legitimacy and resources. It should be anchored in national biosecurity policy or strategy documents where these exist.
- The following two steps (3 and 4) evaluate existing sector-based arrangements for human, animal and plant life and health and associated protection of

[18] Part 3, *An Overview and Framework Manual for Biosecurity Risk Analysis*, provides detailed guidance on the use of risk analysis in biosecurity.

the environment, and assess their capability to identify, prevent and manage biosecurity risks.

- The fifth step generates a national vision (goals and objectives) of desired future biosecurity.
- The final steps (6 and 7) identify biosecurity capacity needs on the basis of identified gaps between "what is" (the present) and "what should be" (the goals and objectives) and considers options to address them as a means to generate a biosecurity strategy and capacity building action plan.

Although presented here in a linear sequence, the actual order in which the first five steps are tackled is less important than the fact that they are addressed. In practice, some or all of the actions may take place simultaneously and there may be different entry points depending on the situation. In some settings, time and information constraints may make it impossible to fully comply with all the steps. In such cases, the methodology should be adapted to fit the local circumstances without abandoning the approach.

The way in which this process is used will vary according to the characteristics of the country in question (including its type of government and political structure), the resources available internally (human, financial, time, etc.) and access to external assistance. The information required can be collected and analysed in different ways. Some countries may obtain information through expert technical papers reviewing available information on the current situation, including existing sector-specific capacity assessments. Other countries may generate new information with the use of surveys, focus group discussions, meetings and workshops. In some cases, work carried out through ongoing development projects may feed into the assessment.

This guide includes a number of broad questions to support information collection and analysis, and help create understanding about the issues among the stakeholders involved. It offers tips and practical guidance to facilitate the planning and delivery of the capacity needs assessment process.

A participatory and consultative process will generally help to build consensus and foster ownership of the identified capacity needs, which should increase acceptance of any proposed changes and contribute to sustainability. Financial resources will be required to facilitate information collection and analysis, including the hiring of experts and the organization of meetings and workshops. Good facilitation will be important to the success of the assessment process. Support from experienced, external and impartial facilitators may be useful, especially when the process encounters complex decisions.

Finally, it is important to realize that capacity needs and priorities change over time. Assessing these needs is therefore part of an ongoing process of capacity building.

Seven steps to assess biosecurity capacity needs

STEP 1: OBTAIN HIGH-LEVEL SUPPORT

Since biosecurity cuts across the authority and statutory responsibility of different competent authorities, the process of assessing and developing biosecurity capacity demands cross-sectoral collaboration. Clear political commitment and high-level backing is essential to establish the basis for this collaboration and ensure the meaningful participation of different parts of government. Government leaders should visibly endorse an integrated biosecurity approach that bridges sectors and organizations, and recognize the role of a capacity assessment in moving towards this goal. Without high-level political commitment, maintained over the longer term, capacity building efforts are likely to be unsuccessful, regardless of the quality of their design and implementation.

Ensuring high-level commitment for biosecurity and reaching agreement on the need for a biosecurity capacity assessment may take time. Politicians and government leaders will need to be convinced that biosecurity is important (e.g. for public health, agricultural and environmental sustainability, the economy and trade). These efforts will be most effective when they relate biosecurity to national priorities and goals, the challenges faced, the potential costs of not taking action and the benefits (for instance cost savings, enhanced efficiency of results, improved management of risks) to be gained through a harmonized and integrated biosecurity approach.

Recent or current crises can act as a major stimulus to achieve this kind of awareness. A focus on trade agreements, regional sanitary and phytosanitary programmes, the International Health Regulations[19] or Millennium Development Goals[20] may provide an important impetus. The "champions" or actors driving forward the needs assessment process may differ. For instance, the catalyst may come from a national development agency or high-level committee (such as a congressional committee or a working group attached to the prime minister's office) with the mandate to review biosecurity or one of its sectors.

Tips

- Given the numerous challenges and resource constraints facing governments, it will be necessary to make a strong case in support of biosecurity if it is to be endorsed by leaders. In addition, in order to ensure that biosecurity remains a priority even with a change in government, attention may need to be given to obtaining broad-based political support. Linking biosecurity to the International Health Regulations or Millennium Development Goals, or developing a biosecurity policy or act and passing it through the appropriate national bodies, can serve to increase the visibility of biosecurity to all stakeholders and establish it as a national priority. The appointment of a new senior manager or leader to a relevant government portfolio may provide an opportunity to seek high-level support.

STEP 2: AGREE ON THE PURPOSE, SCOPE AND PROCESS

Before beginning to identify biosecurity capacity needs, it is essential to have clear agreement on the purpose and scope of the assessment, as well as the process to be followed. This is important to make the best use of the available resources and get the most out of the assessment. It will also contribute to transparency and reduce the possibility of misunderstanding among the agencies involved.

Defining the ***purpose*** of the assessment is important to ensure clarity among the participants about why the assessment is undertaken and what it seeks to achieve. Identifying the hoped-for results of the assessment will clarify the purpose statement (see Tips below).

Discussing the ***scope*** is necessary to reach consensus on the substantive reach of the assessment.

---

19 The purpose and scope of the IHR (2005) are to "prevent, protect against, control and provide a public health response to the international spread of disease and which avoid unnecessary interference with international traffic and trade". See Annex 3 for further information.

20 In September 2000, at the United Nations Millennium Summit, world leaders agreed to a set of time-bound and measurable goals and targets for development. These eight goals are referred to as the Millennium Development Goals (MDGs). For further information, see: http://www.un.org/millenniumgoals/

Preferably this should encompass all biosecurity sectors. However, in some countries it may not be feasible or possible to focus simultaneously on the whole biosecurity arena, and the scope may need to be adjusted somewhat according to local circumstances. The participation of stakeholders is related to the scope. Several different parts of government (including sector competent authorities, and national committees or contact points representing SPS, CAC, IPPC, OIE, etc.), scientific and research institutes, consumer groups and industry are relevant for biosecurity and may be involved and/or consulted. At the beginning, it will be useful to define the respective roles of these groups in the assessment process.

Reviewing the following key questions can help to clarify the scope:

- Which sectors of biosecurity will be included?
- Which government agencies or committees will be involved and what will their exact roles and responsibilities be?
- Which other stakeholders (e.g. competent bodies, general public, consumer groups, industry groups, academic and research institutes, interest groups, will be involved and how?
- Which international stakeholders (e.g. FAO, WHO, OIE, regional organizations) will be involved and how?

Finally, agreement on the ***process*** to be followed is important to ensure the smooth implementation of the assessment and enhance the outcomes achieved. Here, participants need to discuss and reach agreement on the following:

- What data gathering is needed and how will it be carried out?
- How will consultation with stakeholders be carried out?
- Will external facilitators/consultants be used and, if so, how will they be expected to contribute?
- What is the expected time frame?
- What resources (financial, human) are required and available? If there is a shortfall, how will it be met?
- How will the findings be documented and shared?
- How will coordination be ensured?
- What will be done to encourage consensus?

Tips

- One practical method to facilitate inter-agency participation in the process is to establish a small team to apply the Guide to Assess Biosecurity Capacity. For instance, depending on the country, those parts of government that are responsible for human animal and plant life and health and associated protection of the environment as well as national committees or contact points representing SPS, CAC, IPPC, OIE or other international committees, may have a role. Other parts of government (e.g. finance, trade, etc.) that make decisions with consequences for biosecurity programmes may be involved. In addition, depending on national circumstances, scientific and research institutes, consumer groups, industry and/or NGOs will likely need to be consulted. However, it will be important to balance participation with manageability to ensure that the size of the team does not become unmanageable.
- In addition to engaging the appropriate stakeholder groups, it is important to ensure that the right people (i.e. with the relevant professional background, subject knowledge, status and personal skills) are involved, and that they have sufficient time to devote to the assessment.
- Documenting the decisions taken during this step in a short purpose statement, which would serve as terms of reference for the team, will enhance transparency.
- It is wise to identify as many possible sources of funding (internal and external) for follow-up to the capacity assessment as early as possible in the process. An effectively carried out assessment will come to nothing unless resources are available for capacity building activities. Informing potential donors that the assessment is being carried out is a useful first step. They may be interested in supporting and/or participating in the assessment process. Indeed, in some cases, they may be more likely to support the findings and provide resources for follow-up activities if they have been actively involved from the outset.

STEP 3: PROFILE THE BIOSECURITY CONTEXT AT THE COUNTRY LEVEL

The third and fourth steps in the capacity assessment process ask: What is the current situation of biosecurity capacity and performance? They seek to understand the context for biosecurity at the country level, and to identify the resources available, the stakeholders involved and the outcomes currently achieved. This analysis will provide a good understanding of the baseline or current situation. It

will reveal to what extent there is a consistent and coordinated approach to biosecurity, which will be useful in identifying the capacity needs to move towards a harmonized and integrated approach.

Step 3 examines the context for biosecurity at the national level. It considers the issues and general needs that are relevant in the country including the prevailing challenges and opportunities. Understanding these factors is important because they profoundly shape and influence biosecurity related goals, programmes and activities, and provide the drivers of, and constraints to, change.

The following key questions can be used to help generate a profile of the biosecurity context in the country:

- ***What structural factors influence biosecurity?***
  Structural factors that have a major influence on biosecurity are beyond the influence of the stakeholders involved. These include geography, natural resources, regional influences, economy, trade, etc.
- ***Which trends in the production, processing and distribution (including import and export) of food and agricultural products are relevant for biosecurity?***
  Trends in the production, processing and distribution of food and agricultural products – such as HACCP, cold chain in perishable products, increased production and export of value-added products, the introduction of research and development programmes related to biotechnology or the use of pesticides or veterinary drugs – can influence risks to human, animal and plant life and health and associated risks to the environment, and are therefore relevant for biosecurity.
- ***What are the pathways through which biosecurity hazards/diseases emerge and spread?***
  Biosecurity hazards/diseases can emerge within national borders or be introduced from other countries. Pathways through which exotic pests or diseases can enter a country include animals, plants and agricultural products, packaging materials, containers, luggage and vehicles. In addition, biosecurity hazards/diseases can emanate from well-intentioned changes in production or processing, which can have negative or unexpected impacts.
- ***What cultural perceptions and practices are relevant for biosecurity?***
  Regulatory culture is embedded in socio-economic settings. Countries and people perceive biosecurity and related risks in different ways. For instance, countries may be more or less ready to accept any potential risks that may emerge from biotechnology. Understanding local cultural perceptions and practices is therefore important.

The profile that emerges from this step will describe the various contextual factors that are relevant for biosecurity in the country. It will vary across countries. For instance, the profile of the biosecurity context in a small island state with an active fishery sector but limited animal or plant production will be different from that in a land-locked country whose agricultural production system is dominated by a few crops. The issues of importance to a country that relies heavily on food and agricultural exports to generate foreign exchange earnings may be different from those of a country dependent on food imports for a large share of its domestic food consumption needs. Understanding these characteristics is essential to ensure that biosecurity capacity building activities are appropriately planned and delivered.

STEP 4: ASSESS EXISTING BIOSECURITY CAPACITY AND PERFORMANCE

Understanding existing biosecurity capacity is essential to be able to identify capacity needs accurately and to ensure that the needs identified, and any capacity building activities subsequently developed, fully reflect local circumstances.

Existing biosecurity capacity and performance can be analysed through a situation analysis. Based on the framework presented in Table 2.1, this analysis should focus on:

i. the overall biosecurity system encompassing the policy, legal and regulatory framework, organizational arrangements (including the substantive and financial division of core biosecurity functions as well as coordination), and communication;
ii. the delivery and performance of core functions (based on a risk analysis approach) that are necessary for biosecurity; and
iii. linkages and interdependencies across biosecurity sectors.

Broad areas of interest for this review and analysis are outlined in Table 2.3, which offers a starting point for discussions to take stock of existing capacity and help

Table 2.3. **Broad questions to take stock of existing biosecurity capacity and performance**

Policy framework	• Have any relevant policy reviews been carried out in the last five years? What were the key recommendations? What is the status of their implementation? • Which existing policies contain goals and objectives, and/or establish priorities of relevance to biosecurity? • Which stakeholders have been involved in the formulation of these policies? How have they been involved (e.g. as planners, implementers, enforcers, monitors, providers of funding, etc.)? • Do existing policies: - identify appropriate levels of protection (ALOPs)[21] in biosecurity areas? - clearly define goals and objectives for biosecurity? - seek to ensure interaction, consistency and synergy across the sectors involved in biosecurity? - enable resources to be prioritized across the sectors involved in biosecurity? - facilitate choices between competing fiscal priorities?
Legal and regulatory framework	• Which existing sector-specific laws or regulations (at the central, regional and/or local levels) are relevant for biosecurity? • How are stakeholders' roles, responsibilities and rights defined in these laws? What accountabilities are legally defined with respect to the delivery of core biosecurity functions? • Is legislation comprehensive, consistent and up-to-date? Where are there any gaps or overlaps? • Does legislation adequately cover locally produced, imported and exported food and agricultural products? • Do those involved in delivering biosecurity functions have adequate powers to perform effectively? • Are relevant national regulations harmonized with international norms, guidelines and recommendations? • Are risk analysis principles incorporated in policies, laws and regulations? • Has a risk analysis approach been adequately utilized in establishing and implementing standards?
Organizational arrangements	• Which government agencies serve as competent authorities with responsibility for: - making policy decisions related to biosecurity? - planning and implementing programmes and activities related to biosecurity? - providing technical and financial resources for programmes and activities related to biosecurity? - providing advice, policies and support to international functions and coordination related to biosecurity? • Which other government and non-government stakeholders are involved in biosecurity, and how (e.g. role in the formulation of national development plans or priorities, resource allocation, compliance with policies and regulations, etc.)? • Which government agencies serve as official contact points for CAC, IPPC/CPM, OIE, CBD and Cartagena Protocol, the WTO SPS and TBT Committees? Who are the members of any such national committees (if existing)? • Which competent bodies (if any) are contracted to deliver core biosecurity functions? What services do they provide? • Do any inter-agency processes, groups or other coordination mechanisms focused on biosecurity exist? If existing, what is the purpose (e.g. plan or prioritize activities, resource allocation decisions)? How do they operate and what are the strengths and weaknesses? • Does a preliminary evaluation identify any overlaps or gaps in the delivery of core biosecurity functions?
Communication	• How do competent authorities and competent bodies involved in biosecurity communicate and share information with: - each other? - relevant national stakeholders (e.g. industry, scientific institutes, interest groups, consumers)? - other national governments, international organizations (e.g. CAC, FAO, OIE, IPPC/CPM, WHO) and international committees (e.g. WTO SPS Committee)? • How is communication of cross-cutting issues related to biosecurity handled? • How do official contact points and committees (where they exist) related to the WTO SPS Agreement, Codex, IPPC/CPM and OIE communicate with each other and work together? • What have been the experiences to date with communication on matters related to biosecurity (e.g. national response to an emergency)?
Sectors of biosecurity / Risk analysis functions	• What core biosecurity functions are provided by competent authorities or bodies? • What established policies, rules and regulations govern the delivery of these functions? • Which stakeholders are involved in the delivery of these functions? What are their respective roles and responsibilities? • What operational principles and procedures (e.g. guidelines, manuals, standard operating procedures) guide the delivery of these functions? • What resources (human, financial, infrastructure, diagnostic, information, other, etc.) are available for the provision of these functions? How are they allocated? • Do competent authorities and/or competent bodies responsible for the delivery of biosecurity functions interact with relevant stakeholders? If so, how? • What relevant external resources (e.g. risk assessments, diagnostic laboratories, international standards, etc.) are available and used by sector agencies? What have been the experiences in this regard? *(see Annex 6 for more detailed questions on core biosecurity functions)*

[21] An appropriate level of protection is defined as in the WTO SPS Agreement as "The level of protection deemed appropriate by the Member [country of WTO] establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." This concept is also referred to as the acceptable level of risk.

create understanding about the issues among those involved. These questions may be posed to stakeholders during focus group discussions or individual interviews. They are illustrative of the types of inquiries that should be made, and should be adapted as required based on the particular circumstances in the country (including the specificities highlighted in the country profile and the number and type of stakeholders concerned). Where available, the main findings and conclusions of sector-specific capacity evaluations should be examined and considered as part of this analysis.

By critically examining the overall framework for biosecurity and assessing the outputs achieved by the competent authorities and bodies involved in delivering core functions, it will be possible to generate a picture of current biosecurity capacity. This analysis will reveal strengths and weaknesses that cut across the sectors of biosecurity, as well as those within the sectors of biosecurity. In particular, the information and insights generated through this process will help policy and decision makers determine to what extent:

- existing policies and legislation related to biosecurity are effective, and where there are weaknesses;
- organizational arrangements for biosecurity and communication among the concerned stakeholders are effective;
- the capabilities of the competent authorities and bodies tasked with core biosecurity functions are adequate in the context of the risks faced;
- the outcomes and outputs achieved are satisfactory, both on a sectoral and cross-sectoral basis; and
- cross-sectoral aspects of biosecurity are recognized and addressed in a system in which different stakeholders are involved.

The assessment of existing biosecurity capacity and performance may yield a great deal of information, which will be important to identify biosecurity capacity needs. The findings will provide a measure or baseline on which to monitor progress in the future, and should be clearly documented. In addition, it may be useful to synthesize and summarize the findings in a way that is easily communicated to officials in key leadership positions.

Tips

- Taking stock of relevant sectoral assessments and evaluations will build on previous work, save time and enhance the use of resources. Several countries have already applied one or more of the existing sectoral tools to assess capacity needs in particular aspects of biosecurity. Where relevant reports and assessments exist, it makes sense to incorporate their findings wherever possible.
- Different techniques can be used to support information collection and analysis. For instance, conducting a stakeholder analysis provides a means to: i) identify the government agencies (and any organizations contracted by them) responsible for core biosecurity functions; ii) characterize and assess the relative importance of their roles; and iii) understand the relationships between them (see Annex 7). Preparing a Venn diagram[22] is a useful way of illustrating the relationships between the competent authorities, bodies and other organizations involved in biosecurity, and the extent to which they have overlapping roles and/or interact with each other. Conducting a SWOT analysis,[23] with the support of the questions in Table 2.3, will help to arrive at a common understanding of reality among those involved in the assessment (see Annex 8 for an illustrative SWOT analysis scenario for biosecurity).
- Thinking about the shortcomings in recent incursion responses and/or the biosecurity issues that have gained media or political attention in recent years will be useful to inform the review and analysis of existing biosecurity capacity and performance.
- The public and other stakeholder groups may have diverging views and perceptions of the existing biosecurity situation and its adequacy. Asking various people the same questions helps to confirm the accuracy of information collected.

STEP 5: DESCRIBE THE DESIRED FUTURE SITUATION (GOALS AND OBJECTIVES) OF BIOSECURITY

Developing a shared vision of desired future biosecurity is crucial to identifying capacity needs and actions to effectively respond to these needs. This

22 Venn diagrams are used to illustrate the relationships between different groups of stakeholders. They are made up of a variety of circles representing different stakeholders. The location and size of these circles depicts how the concerned stakeholders interact with each other.

23 SWOT analysis is a strategic planning tool that can be used to identify and assess strengths and weaknesses, as well as the range of opportunities and threats faced.

stage of the process provides a means through which those involved can begin to move towards a more coherent approach on both a sectoral and cross-sectoral level. One of the outputs will be the development of a set of national goals and objectives for biosecurity that are supported by key stakeholders.

Defining the desired future situation of biosecurity permits the concerned government agencies and other stakeholders to discuss and reach consensus on the goals, objectives and desired outcomes of biosecurity in the medium term (some period beyond the next 12 to 18 months, consistent with national planning and/or budgetary processes). It offers an opportunity to think beyond day-to-day issues and crises in order to foster, develop and sustain cooperation, collaboration and partnerships. The vision that emerges will map out a strategic direction for biosecurity that cuts across sectoral interests and effectively guides policy and decision-makers.

A description of the desired future situation of biosecurity can be developed through discussions and brainstorming sessions involving competent authorities and bodies. Some countries may decide to involve other groups (such as industry, academic or scientific institutes) given their contribution to biosecurity, for instance through compliance with regulations or their creation and provision of scientific knowledge. Whatever the case, the process will be iterative and should be flexible and sensitive to national needs and conditions. Similarly, while the vision, goals and objectives that emerge from these discussions should be forward-looking and ambitious, to be feasible, they should also be based on an honest and realistic understanding of the existing capacity and resources available.

The following key questions will provide focus to discussions on the future situation:

- What outcomes are expected of the biosecurity system?
- How should biosecurity outcomes be enhanced in the future?
- What would the biosecurity system achieve as a whole if it worked effectively and maximized potential cross-sectoral gains?

By evaluating responses to these questions, it will be possible to define the outcomes that are desired in the future. Examples of generic outcomes include:

- Biosecurity system is able to protect the public from zoonotic and pest-borne diseases.
- Border controls are able to effectively control the entry and exit of unwanted pests and diseases.
- Biodiversity is protected from damaging diseases, pests and invasive alien species.
- Plant and/or animal agricultural production is thriving.
- Consumers and other stakeholders trust that biosecurity risks are managed effectively and transparently.
- Food and agricultural exports meet sanitary and phytosanitary requirements of trading partners.

Such outcomes will set out a clear direction for national biosecurity and provide a solid basis on which to develop concrete actions as part of a capacity building action plan. They should be translated into a vision or policy statement and supporting goals and objectives, which will express in clear and, where possible, measurable terms what the country seeks to achieve. An example of the vision for biosecurity developed by New Zealand, after an extensive consultation process, is presented in Box 2.3 as an illustration.

Tips

- There are different ways to define the desired future situation of biosecurity depending on the country situation and the resources available. It can be generated by a few people during meetings and brainstorming sessions that extend over a whole or half day. In other circumstances, more extensive consultation can be carried out with stakeholders, which will require more time and/or resources.
- In situations where a number of stakeholders with different backgrounds and perspectives are involved, or when there is limited knowledge about biosecurity or the benefits of a coherent approach, it may take time to reach a vision of the desired future of biosecurity. In such cases, increasing awareness about a biosecurity approach and/or involving an external facilitator may be useful.
- The vision, goals and objectives defined during this step should be ambitious but also realistic based on an understanding of the present level of capacity and resources available. They should also be reviewed periodically to take into account technical progress, policy development or other changes in the biosecurity context.
- Reaching decisions on ALOPs for different hazards of human, animal and plant health importance (i.e. health outcomes) and ensuring that biosecurity measures achieve ALOPs on an on-going basis presents a considerable challenge. As a

Box 2.3. Our vision – New Zealand's biosecurity in 2010

"New Zealanders, our unique natural resources, our plants and animals are all kept safe and secure from damaging pests and diseases"

In 2010 …New Zealand has a high performing, integrated system for managing biosecurity risks to the economy, environment and human health. New Zealanders understand and have confidence in the biosecurity system; committed and playing their vital role, from pre-border through to pest management.

Biosecurity is making a significant contribution to achieving a range of goals for the economy, environment and human health, including:

- Protecting marine and terrestrial primary industries and facilitating exports and tourism;
- Protecting New Zealand's indigenous biodiversity – our native species, natural habitats, ecosystems and landscapes;
- Enabling sustainable use of natural resources and protection of the natural environment;
- Maintaining the relationship between Maori and their culture and traditions with ancestral lands, waters, sites, waahi tapu and taonga;
- Protecting the health of New Zealanders from zoonotic and pest-borne diseases and from venomous species; and
- Reducing the damage caused by pests and diseases introduced in the past.

New Zealand's biosecurity system is providing evolving protection as risks are identified and change. Decisions are made on a case-by-case basis within a consistent, transparent decision-making framework. Cooperating agencies are clearly accountable and reporting on performance. A comprehensive review of the Biosecurity Strategy has just been completed, with refined goals and adjustments to programmes agreed.

New Zealanders have confidence in the management of biosecurity risks and are satisfied there is strong leadership and commitment at all levels. The biosecurity system is well organized, information is shared and efforts are well coordinated and focused.

Decisions are founded on good information, based on quality science, taking into account the full range of values at stake and with transparent tradeoffs. There is efficient use of the biosecurity budget and biosecurity risk management (from pre-border to pest management) provides an appropriate and sustainable level of protection for New Zealand.

Source: Reproduced from: *Protect New Zealand. The Biosecurity Strategy for New Zealand*. August 2003. (available at: http://www.biosecurity.govt.nz/bio-strategy/biostrategy.pdf)

consequence, it will be necessary to include outputs as well as outcomes when formulating objectives of the biosecurity system. Examples of outputs are: level of compliance with regulatory standards, competencies achieved by inspection staff, level of understanding achieved by the public in risk communication programmes, etc.

STEP 6: IDENTIFY CAPACITY NEEDED TO REACH THE DESIRED FUTURE SITUATION

Following the analysis of existing capacity and performance and the development of a vision of the improved future situation, the final two steps in the capacity assessment process focus on the diagnosis and analysis of needs and options to address them. In biosecurity, as elsewhere, one size clearly does not fit all. Although competent authorities responsible for biosecurity in different countries may face similar issues and perform comparable functions, the individual circumstances, operating environments, competencies, resource availability and goals may vary greatly. As such, it is essential that actions to develop capacity are based on an accurate and comprehensive diagnosis of needs.

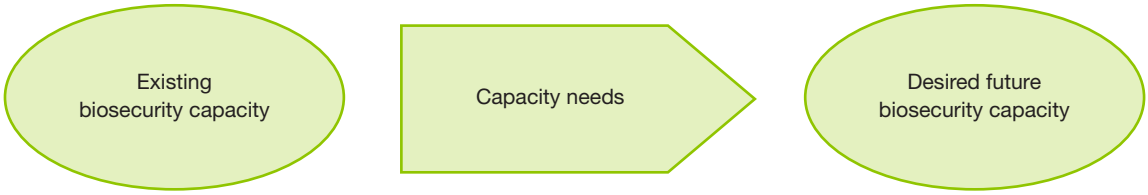
Step 6 is critical to be able to effectively identify the requirements to develop and implement a harmonized and integrated biosecurity approach. It focuses on the identification of capacity needs at the various interfaces between human, animal and plant life and health, and associated environmental protection, in terms of opportunities to take advantage of cross-sectoral synergies and/or to reduce overlaps. The needs identified may be related to the biosecurity policy framework, legislation, organizational arrangements, communication, and/or the delivery of core biosecurity functions (e.g. scientific research and advice, diagnostic services, quarantine, inspection, etc.) based on a risk analysis approach.

Given the variations in country circumstances, understanding biosecurity capacity needs will demand an honest and introspective analysis of the present situation vis-à-vis the goals and objectives. The gaps in biosecurity capacity can be identified by comparing the existing capacity and performance with the desired future situation as illustrated in Figure 2.3. The nature and scope of the gaps in turn allows the identification of capacity needs.

The following key questions offer a starting point for discussions to identify biosecurity capacity needs.

- What is required to move from the current situation to the desired future situation?
- What minimum level of capacity is necessary to perform core biosecurity functions, ensure cross-

Figure 2.3. Identification of biosecurity capacity needs



cutting aspects of biosecurity are addressed effectively, and achieve the goals and objectives describing the future situation?

- What maximum level of capacity could be properly utilized?
- What are the critical capacity needs (i.e. those that should be addressed first)?

Annex 9 reviews and summarizes the questions asked during the previous steps and may be useful to help organize discussions about the identification of capacity needs and ways to address them.

Sometimes the needs identified will be numerous and impossible to address at once. Therefore, it will be important to differentiate between what is essential and what is simply desirable, and to prioritize the identified needs by focusing on the areas, resources and capabilities considered most important, as well as the time it takes to implement activities including the most appropriate sequencing of activities. Identifying needs which when acted upon will result in measurable achievements is important to the success of strengthening biosecurity capacity.

Tips

- A participatory and inclusive approach to needs identification will increase acceptance of any proposed changes and enhance implementation and sustainability. Non-governmental stakeholders such as scientific institutes and academia, industry, interest groups, etc. can make a useful contribution.
- Using facilitated workshops is one way to enable concerned stakeholders to participate in the identification of needs, and ensure that a range of opinions is heard and taken into account.
- Capacity needs may change over time. Therefore, capacity assessment should be an ongoing process that is reviewed periodically.

STEP 7: GENERATE OPTIONS TO ADDRESS THE IDENTIFIED CAPACITY NEEDS

Assessing biosecurity capacity needs provides a means to identify a range of ways to strengthen national capacity to manage biosecurity risks. Once there is a good sense of the country's biosecurity needs and goals, identifying and considering possible options to achieve the goals and objectives is the final step in the assessment process. This step seeks to determine which actions and activities would be most effective to achieve the desired future situation in terms of expected biosecurity gains, costs and benefits, feasibility, affordability, legitimacy and timeliness. On the basis of the selected courses of action, concrete capacity building strategies and a plan of action can be elaborated.

Of the many options available to address the identified biosecurity capacity needs, different options will suit different countries. Factors such as the nature of the existing arrangements for sectors of biosecurity, historical and political considerations, the expected financial cost or time required, the level of support among sector competent authorities (including leaders and staff) and/or the human resources available, will influence the selection and feasibility of courses of action toward a more coherent biosecurity approach. Depending on these factors, the options pursued may reflect a radically different approach or more conventional, incremental changes. No particular approach or course of action is inherently better than another.

Some of the possible options to address biosecurity capacity needs are indicated in Table 2.4. These options offer alternative strategies to achieve the identified goals. Several of them can be pursued simultaneously and they are not therefore mutually exclusive. Annex 10 discusses the options outlined

Table 2.4. **Possible options to address biosecurity capacity needs with a focus on cross-sectoral potential**

Options to strengthen the biosecurity policy framework	*Option 1*: Align and harmonize existing sectoral policies related to biosecurity *Option 2*: Formulate a new national biosecurity policy *Option 3*: Involve stakeholders in the policy process to reflect the multi-sectoral nature of biosecurity *Option 4*: Develop/adopt a regional approach to policy formulation
Options to strengthen biosecurity legislation	*Option 1*: Review and improve existing laws and regulations related to biosecurity *Option 2*: Create a new biosecurity law and supporting regulations
Options to streamline organizational arrangements for biosecurity	*Option 1*: Coordinated multi-agency system *Option 2*: Lead agency approach *Option 3*: Independent biosecurity agency
Options to facilitate biosecurity communication	*Option 1*: Regulate risk communication through legislation *Option 2*: Creation of memoranda of understanding defining roles and mechanisms for multi-stakeholder communication *Option 3*: Establish stakeholder advisory groups *Option 4*: Develop biosecurity information systems
Options to improve biosecurity functions	*Option 1*: Involve competent bodies and/or other third parties in the provision of some biosecurity functions *Option 2*: Apply a cost-recovery model for services provided *Option 3*: Use shared infrastructure and technical expertise *Option 4*: Develop shared information systems for specific technical areas *Option 5*: Utilize risk analysis to prioritize risks and guide biosecurity decision-making *Option 6*: Develop shared training materials and programmes

above in greater detail and includes illustrations from countries that have adopted a harmonized and integrated approach to biosecurity.

In order to determine the most appropriate course of action, and enhance legitimacy and ownership of any changes proposed, the options considered should be evaluated at a policy and strategic level in terms of their expected impact, feasibility, affordability, legitimacy, timeliness and cultural acceptability. Ideally, this should include an analysis of costs and benefits to different types of stakeholders. Such a review will generate information that can be used to select the most valuable options and help to reduce uncertainty during decision making.

Once the options have been considered and a decision reached on the most appropriate course of action, the recommendations can be documented in a national biosecurity strategy and capacity building action plan.

- A ***biosecurity strategy*** translates high level policy into goals and objectives to achieve a specific course of action. It provides a bridge from the biosecurity vision (goals) to medium-term targets and short-term actions, establishes concrete linkages between the sectors of biosecurity to ensure a harmonized and integrated approach and presents a framework for collaboration with stakeholders.
- A ***biosecurity capacity building action plan*** clearly describes what needs to be done, and when and how to do it. In particular, it addresses the incremental actions required to apply a new harmonized and integrated approach to biosecurity, roles and responsibilities, the timeframe and resources required, and indicators to monitor and evaluate progress.

The biosecurity strategy and biosecurity capacity building action plan will be the key outputs of the capacity assessment process. They will also: i) demonstrate to the international community and trading partners the country's commitment to biosecurity; ii) provide a useful tool for mobilizing support (including resources) for specific follow-up activities; and iii) enhance accountability. By clearly defining roles and responsibilities, they will support cross-sectoral coordination for improved biosecurity outcomes.

The development of a biosecurity strategy and capacity building action plan will be an iterative process, with the assessment of biosecurity capacity needs and the ability of government and other stakeholders to meet those needs dictating the extent of the biosecurity strategy. Both the biosecurity strategy and action plan that result from this step should be reviewed regularly during implementation.

Tips

- As far as possible, it is advisable to consider the main options available in terms of:
  i. expected impact (e.g. level of health or environmental protection, savings in regulatory/enforcement costs, implementation costs, new trade opportunities) from the perspective of different stakeholders;
  ii) feasibility (e.g. financial and human resources available, time required, level of support among agencies concerned, ease of implementation, political acceptability);
  iii. affordability (e.g. capital/recurrent costs, economic returns to investment, cost recovery opportunities, overall economic viability);
  iv. efficiency (e.g. rapid and successful response to a food safety emergency or cross-border pest incursion);
  v. legitimacy (e.g. consistent with national development goals and priorities, international recommendations, expert opinion and scientific knowledge, etc.); and
  vi. timeliness.
- While the exact contents of a biosecurity capacity building action plan will depend on the goals and capacity needs identified, it will generally include the following elements:
  i. a clear link to the goals and objectives of the national biosecurity strategy;
  ii. a statement of the overall purpose for biosecurity capacity building that clearly sets out the overall goals and objectives;
  iii. a list of the key actors involved and their roles, the guiding principles and approaches to be used;
  iv. a description of the activities required to achieve the goals set and address the priority needs that specifies the expected outputs, the time frame, the specific roles and responsibilities of the organizations involved (including processes for coordination and communication between those concerned);
  v. a statement that clarifies the financial and other resources required to carry the capacity building activities, the resources already available for this purpose, outstanding needs and ways to address them;
  vi. criteria and performance indicators to monitor progress in implementation so that changes can be made if necessary; and
  vii. a performance monitoring programme to ensure that the biosecurity goals and objectives are being achieved on an on-going basis.
- It is important to keep track of reality while drawing up a capacity building action plan. Attempting to do too much too soon may be less effective and less sustainable than a more incremental approach.
- Considering how other countries have applied a biosecurity approach may provide useful experiences and lessons. Where resources are available, experts from such countries could be invited to share their guidance, or study trips organized.

Part 3
An overview and framework manual for biosecurity risk analysis

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 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.

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

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[24] 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

[24] 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[25]) 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

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.[26]
- 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

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 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

[25] 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.

[26] 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 Stirling. 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.[27] 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.[28]

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[29] 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,

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

28 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.

29 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.[30] 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.

30 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[31] 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.[32] 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.

---

31 "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.

32 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

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 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.

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

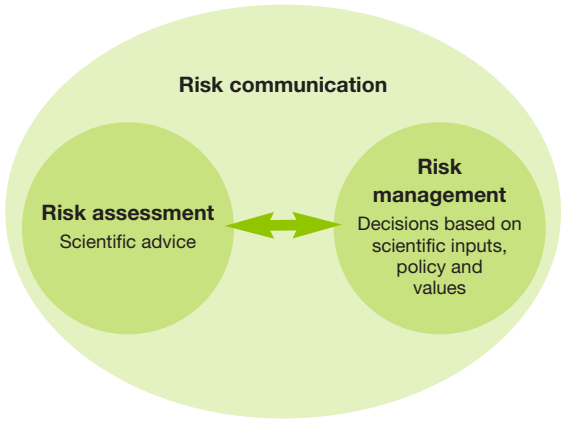
There are various descriptions in the different biosecurity sectors as to what constitutes a potential threat to health or life and these have been presented in Part 1 (Box 1.4). For the purposes of this manual, the general term "hazard"[33] will be applied to cover all these sector descriptions. An 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.
- 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.

Figure 3.2. Generic components of risk analysis



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

[33] 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.

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.[34] 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).

---

34 "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

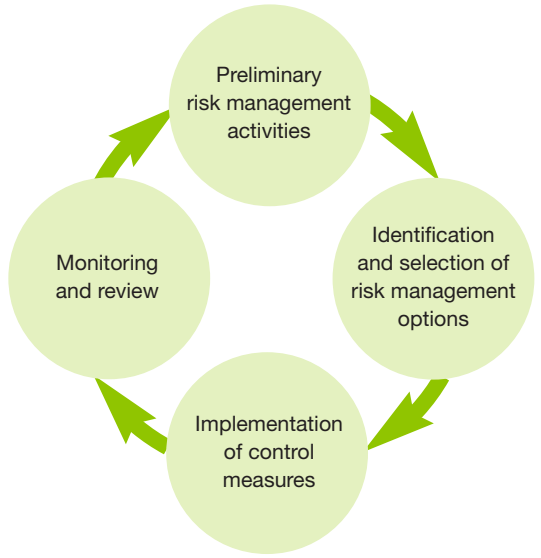
- Improving understanding of risk analysis concepts, principles and processes by all stakeholders.
- Enhancing the ability to rank and prioritize biosecurity issues for risk management.
- Clarifying the roles of risk assessors and risk managers when evaluating a biosecurity issue and deciding on control 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 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 andreview	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 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.

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

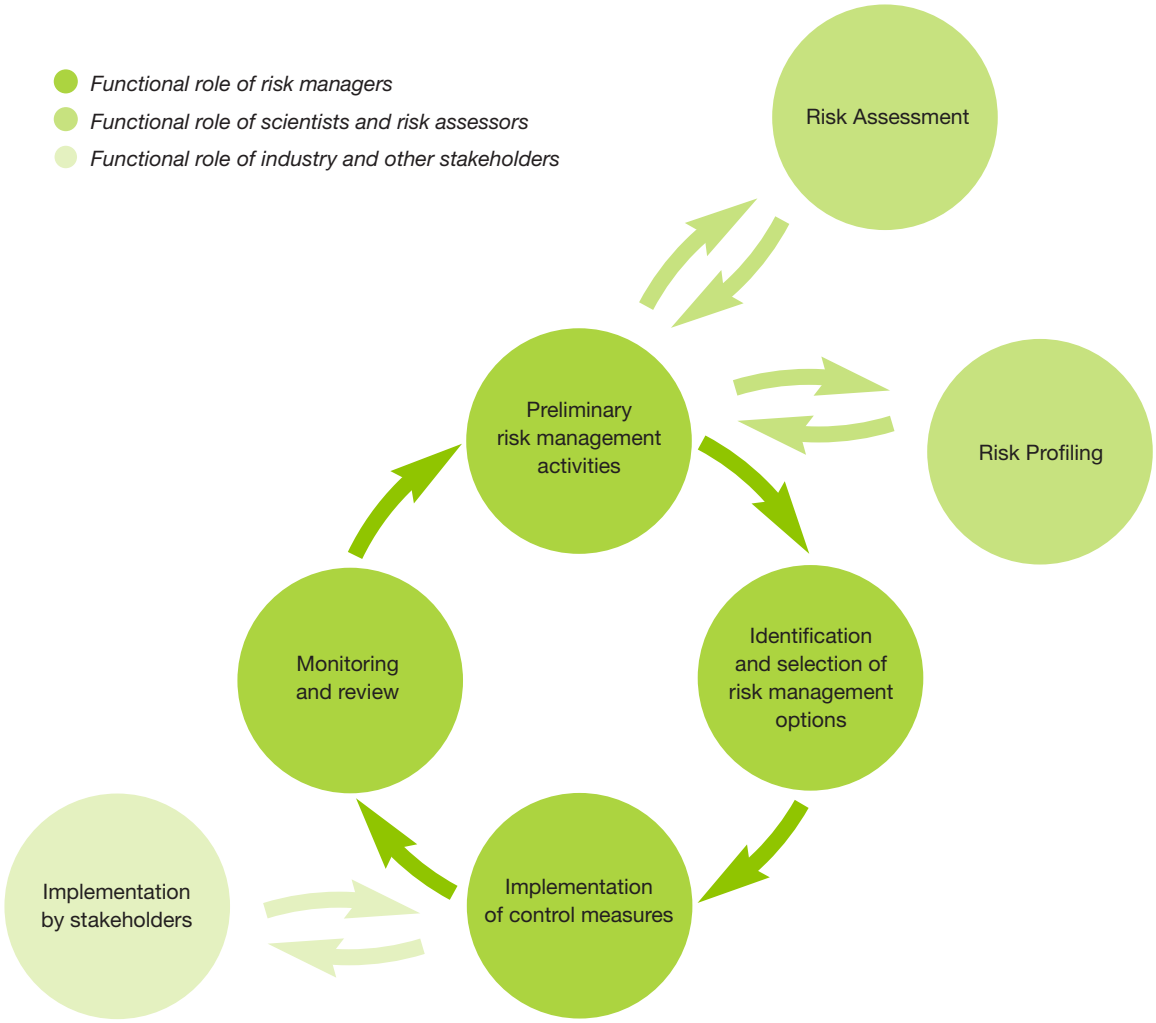
The generic RMF process described in this manual is very similar to that in a number of draft risk management documents currently being developed under the umbrella of the **CAC**. Within this overarching process, specific guidelines for risk management of different types of microbiological and chemical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

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 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).

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

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.

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

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.

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.[35] 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,[36] 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.

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.[37] *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.[38] 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

35 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.

36 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.

37 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.

38 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[39]) 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[40] 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, 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.[41]

---

39 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.

40 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).

41 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[42]).

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.

---

42 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 "notionally 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.[43] 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[44] 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".

43 FAO/WHO. 2006. *Codex Alimentarius Commission. Procedural Manual*. 16th Edition, page 24 (available at: http://www.codexalimentarius.net/ web/procedural_manual.jsp).

44 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".

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.

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

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

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.[45]

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[46]) 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[47]. On the

45 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.

46 www.eurepgap.org

47 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.[48]

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

[48] Improved bio-traceability of unintended micro-organisms and their substances in food and feed chains. European Union 6th Framework Project (available at: 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.[49] 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).

[49] 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 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.

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

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:

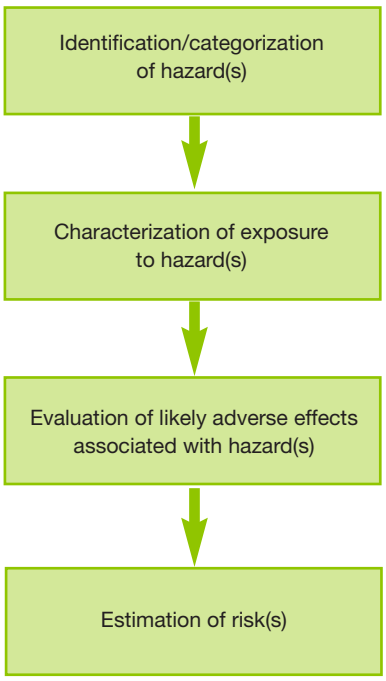
- the hazard exposure pathway is complex;
- data on the relative effectiveness of control measures are limited;
- the issue is of significant regulatory and/or stakeholder concern; or
- there is a mandatory regulatory requirement for a risk assessment.

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.

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

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 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[50]) 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
- 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.

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

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

[50] 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).

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:
i) identification of the hazards and possible biological and economic consequences of their entry or spreading; ii) evaluation of the likelihood of entry, establishment, or spreading; and iii) 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.[51] 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).[52]

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.

---

51 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).

52 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:[53] 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.[54] 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.[55]

"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

---

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

54 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.

55 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).

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.[56]

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

[56] 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).

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.[57]

Risk assessment of foods derived from modern biotechnology

Risk assessment principles have recently been elaborated by Codex for foods derived from modern biotechnology.[58] 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,[59] and is being elaborated by Codex for genetically-modified animals.

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.

---

57 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

58 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).

59 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.[60] 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".[61] 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.[62]

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

---

60 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.

61 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 at regulated pests.

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

present but not widely distributed),[63] potential for establishment and spread according to biological parameters, and potential for unacceptable economic impact.[64] 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 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.[65] If the risk is deemed to be unacceptable, the PRA process may continue by

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 x 10-10 per consignment) and the United States (less than 1.4 x 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

63 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.

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

65 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 asessment 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.[66] 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.

[66] 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"[67] and this remains a very subjective judgment.

[67] 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 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.

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

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.[68] 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.

---

[68] 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).[69] 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

[69] 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 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 3.31. 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)

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 that 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 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).

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.

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 decisison-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.

Annexes

1. GLOSSARY

Acceptable daily intake. An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis that can be ingested daily over a lifetime without appreciable risk.

Animal. For the purposes of this toolkit, animal includes mammals, birds, fish and bees.

Audit. A systematic and functionally independent examination to determine whether control activities and results comply with documented objectives.

Biodiversity. The variability among living organisms from all sources, including diversity within species, between species and of ecosystems.

Biosafety. This term is widely used in biosecurity and a general working description is "the safe use for human, animal and plant health, and the environment, of new biotechnologies." In the Convention on Biological Diversity and Cartagena Protocol, biosafety is defined as the "means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health (UNEP/CBD. 1992. Article 8(g)).

Biosecurity. Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment.

Competent authority. The official authority charged by the government with sector control of biosecurity, including setting and enforcing of regulatory requirements.

Competent body. An officially-recognized body acting under the supervision and control of the competent authority.

Control measure. Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

Emerging zoonosis. A zoonosis that is newly recognized or newly evolved, or that has occurred previously but shows an increase in incidence or expansion in geographic, host or vector range.

Equivalence. The capability of different biosecurity controls to achieve the same health objectives.

Food-borne zoonosis. An infection transmitted through food to humans when the source of the infection is an animal.

Harmonization. The establishment, recognition and application by different countries of biosecurity controls based on common standards.

Hazard-based. Decisions and actions in biosecurity control programmes that are based on objective and verifiable information on hazards.

Input. Any information that is fed into a risk assessment model.

Invasive alien species. An invasive alien species outside its natural past or present distribution whose introduction and/or spread threatens biodiversity.

Maximum residue limit. The maximum concentration of residue resulting from the use of a chemical during primary production that is acceptable in or on a food.

Model. A simplified representation of the real world.

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

Performance objective (in relation to food safety)**.** The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a food safety objective or appropriate level of protection (ALOP), as applicable.

Quality assurance. All the planned and systematic activities implemented within a quality system that provide confidence that an entity will fulfil requirements for quality.

Risk. A function of the probability of an adverse effects on health or life in a biosecurity setting and the severity of those effects.

Risk assessment. A scientifically-based process that is used to identify hazards, characterize their adverse health impacts, evaluate the level of exposure of a given population to those hazards, and estimate the risk.

Risk assessment policy. Guidelines on the availability and choice of default assumptions at scientifically-uncertain decision points in risk assessment.

Risk-based. Decisions and actions in biosecurity control programmes that are based on specific knowledge of risks to health or life.

Risk communication. The interactive exchange of information and opinions on risk, risk management issues and risk perceptions.

Risk management. The process undertaken by the competent authority of weighing risk assessments, policy alternatives and stakeholder views relative to health protection, and selecting any controls needed.

Risk profile. A description of the context and potential risks associated with a biosecurity issue that will help in guiding further action.

Sensitivity analysis. A method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs.

Stakeholder. "Internal" stakeholders are risk assessors, risk managers and risk communicators employed by the competent authority; "external" stakeholders are other branches of government and foreign governments, competent bodies, industry, academic communities and public interest groups.

Surveillance. Active and ongoing collection, analysis and dissemination of data on risks to life and health.

Validation. Objective demonstration that biosecurity controls are effective in achieving stated outcomes.

Verification. Activities that are performed, in addition to monitoring, to determine whether a biosecurity control(s) is or has been operating as intended.

Zoonoses. Infectious diseases that can be transmitted naturally between wild or domestic animals and humans.

2. TYPICAL SECTOR ROLES OF COMPETENT AUTHORITIES IN BIOSECURITY[70]

Agriculture / Forestry

- Formulation and implementation of legislation and policies (e.g. transboundary diseases and pests, zoonoses, food-borne diseases and invasive alien species)
- Development of the agriculture and food sectors including agri-food exports
- Risk analysis
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities, etc.
- Certification of products
- Participation in international organizations and bodies involved in agriculture (e.g. FAO, OIE, Codex, CPM/IPPC)

Fisheries

- Formulation and implementation of legislation and policies (e.g. transboundary diseases, invasive alien species).
- Development of the fisheries sector including fisheries exports
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities
- Certification of products
- Participation in international organizations and bodies involved in agriculture (e.g. FAO, OIE, Codex)

Public Health

- Formulation and implementation of public health legislation and policies,
- Prevention and control of illnesses, including food-borne diseases, zoonoses, transboundary diseases
- Prevention of malnutrition
- Participation in international organizations and bodies (e.g. WHO, Codex, WHA)

Environment

- Formulation and implementation of legislation and policies (e.g. invasive alien species, biosafety)
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities
- Participation in international organizations (e.g. UNEP) and conventions (e.g. CBD)

Trade and Economics

- Regulation of imports and exports including provision of trade permits
- Export promotion and development
- Regulating movement/trade in potential alien invasive species
- Certification of agri-food exports

Justice

- Development and enforcement of laws, rules and regulations

Customs

- Enforcement of government regulations on the import and export of agricultural and related products

Transport

- Safe and documented transportation and storage of food and other agricultural imports, exports, and inputs to agriculture (e.g. chemicals, pharmaceuticals)

Foreign Affairs

- Coordination of international aspects of biosecurity
- Participation in international organizations and bodies (e.g. WTO, Codex, OIE, CPM), international agreements (e.g. GATT, SPS, TBT) and conventions (e.g. IPPC, CBD)

Finance

- Budgetary allocations for biosecurity

Planning and Development

- Formulation of national development strategies and implementation plans

Tourism

- Monitoring effect of tourism on the environment

70 Note that competent bodies, acting under the supervision and control of the competent authority, also implement biosecurity standards.

3. INTERNATIONAL LEGAL INSTRUMENTS, AGREEMENTS, TEXTS, ORGANIZATIONS AND BODIES ASSOCIATED WITH BIOSECURITY[71]

Given the broad scope of biosecurity, several international organizations and bodies are associated with biosecurity and numerous global and regional agreements and soft-law instruments are potentially important. Some of the most relevant are introduced (in alphabetical order) below.

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

The SPS Agreement sets out the basic rules in the WTO on how governments (Members) can apply food safety and animal and plant health measures (sanitary and phytosanitary or SPS measures). Under the SPS Agreement, Members are permitted to set their own standards, but they must be based on science and applied only to the extent necessary to protect human, animal or plant life or health. Members are encouraged to use international standards, guidelines and recommendations where they exist, however, they may use measures which result in higher levels of protection if there is scientific justification. The text of the agreement and other information is available on the WTO web site (www.wto.org/english/tratop_e/ sps_e/sps_e.htm).

Agreement on Technical Barriers to Trade (TBT Agreement)

The TBT Agreement seeks to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. It states that the procedures used to decide whether a product conforms with relevant standards have to be fair and equitable, and discourages any methods that would give domestically produced goods an unfair advantage. The text of the agreement and other information is available on the WTO web site (www.wto.org/english/tratop_e/tbt_e/tbt_e.htm).

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety, negotiated under the framework of the Convention on Biological Diversity (CBD) and adopted in January 2000 (entered into force in September 2003), is the first global instrument on biosafety. It sets out a comprehensive regulatory system to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from any modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on transboundary movements. More information is available on the Internet (www.biodiv.org/biosafety).

Codex Alimentarius Commission and the Codex Alimentarius

The Codex Alimentarius Commission (CAC) was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts. The Codex Alimentarius constitutes a collection of internationally adopted food standards, guidelines and recommendations, developed by the CAC. Although Codex standards and related texts in and of themselves are not binding, they have become international reference points through the SPS Agreement, which adopted them in 1995 as the benchmark for all international food standards. More information is available on the Internet (www.codexalimentarius.net/web/index_en.jsp).

Convention on Biological Diversity (CBD)

Adopted in 1992, under the auspices of the United Nations Environment Programme (UNEP), the Convention on Biological Diversity (CBD) is the first global treaty to provide a comprehensive framework that addresses all aspects of biodiversity (i.e. ecosystems, species and genetic diversity). It explicitly addresses animal and plant life and health as well as the management of risks associated with living modified organisms (LMOs) resulting from biotechnology and the management of risks associated with alien species. There is considerable overlap between the the provisions

[71] Derived from the indicated web sites and the following paper: Ingrassia, A. International and Regional Regulatory Frameworks Relevant to Biosecurity for Food and Agriculture. Background paper commissioned by FAO for the FAO Technical Consultation on Biosecurity in Food and Agriculture, Bangkok, Thailand, 13-17 January 2003.

of the CBD and IPPC. For more information, see the CBD web site (www.biodiv.org/convention/default.shtml).

Food and Agriculture Organization of the United Nations (FAO)

FAO leads international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy. FAO is also a source of knowledge and information, and provides technical assistance to modernize and improve agriculture, forestry and fisheries practices and ensure good nutrition for all in developing and transition countries. As such, FAO is actively involved in normative work and technical assistance, at the both the national and international levels, to support the effective implementation of biosecurity at the national level. More information is available on the FAO web site (www.fao.org and www.fao.org/biosecurity/).

General Agreement on Tariffs and Trade (GATT 1947)

GATT 1947 potentially covers areas not addressed by the SPS Agreement and remains relevant to biosecurity even after the formation of the WTO in 1995. Article XX sets out the General Exceptions to the Agreement as follows:

> *"Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:*
>
> *(*b) *necessary to protect human, animal or plant life or health;"*

More information is available on the WTO web site (http://www.wto.org/english/docs_e/legal_e/legal_e.htm#gatt47).

International Health Regulations (IHR)

A revision of the International Health Regulations was unanimously adopted on 23 May 2005 by the World Health Assembly and these Regulations entered into force in June 2007 for all WHO Member States. The purpose and scope of the IHR (2005) are to "prevent, protect against, control and provide a public health response to the international spread of disease and which avoid unnecessary interference with international traffic and trade". Further information about IHR is available on the WHO web site (http://www.who.int/csr/ihr/en/).

International Plant Protection Convention (IPPC) and the Commission on Phytosanitary Measures (CPM)

The IPPC entered into force in 1952 to regulate plant pests, as well as any organism, object or material capable of harbouring or spreading pests that affect plants or plant products in order to prevent the spread and introduction of these pests and promote measures for their control. It formalizes procedures for standard setting and outlines modern phytosanitary concepts. The New Revised Text of the IPPC was approved in 1997. Revision was undertaken to reflect contemporary phytosanitary concepts and the role of the IPPC in relation to the Uruguay Round Agreements of the World Trade Organization, particularly the SPS Agreement. The New Revised Text provides for the establishment of a Commission on Phytosanitary Measures (CPM) that will serve as the global agreement's new governing body; the members of the CPM are the contracting parties to the Convention. The CPM adopts International Standards for Phytosanitary Measures (ISPMs), which are recognized by the WTO as reference international phytosanitary rules. More information is available on the International Phytosanitary Portal (www.ippc.int).

International Maritime Organization (IMO)

The IMO provides support for national marine biosecurity programmes in several areas (e.g. marine pest surveillance, risk assessment and biofouling management). More information is available on the IMO web site (www.imo.org/).

Organisation for Economic Cooperation and Development (OECD)

OECD contributes to cross-sectoral biosecurity activities in a number of ways. The OECD Environment, Health and Safety Programme fosters international cooperation in the area of chemical safety by harmonizing policies and instruments (e.g. pesticide registration programmes) for use in the protection of health and the environment. It also sponsors economic evaluation of agricultural systems e.g. research into the costs and benefits of private sector standards (G/SPS/GEN/763), works to minimize non-tariff barriers to trade, and develops economic policies and

instruments for use by countries in the management of biodiversity. More information is available on the OECD web site (www.oecd.org).

World Health Organization (WHO)
WHO specializes in human health. Although not directly involved in setting international standards for biosecurity aspects of human health (food safety and zoonoses), it actively contributes to global databases on these topics and assists governments, civil society, industry and consumers in gaining up-to-date scientific information on new and emerging hazards. Regarding food safety, WHO helps in integrating and strengthening surveillance systems for food-borne disease on a world-wide basis and is promoting a multidisciplinary response to emerging food safety issues. WHO is actively involved in normative work and technical assistance, at the both the national and international levels, to support the effective prevention of and response to international spread of zoonotic diseases. WHO hosts the joint WHO/FAO International Food Safety Authorities Network (INFOSAN), which includes a food safety emergency component. The International Health Regulations (2005), which entered into force in June 2007 for all WHO Member States, cover international public health events related to animal and food transport over borders (see above). Further information is available on the WHO web site (www.who.org).

World Organisation for Animal Health (OIE)
The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from animal (including fish and bees) diseases and zoonoses, without setting up unjustified sanitary barriers. These texts include the International Animal Health Code, the Manual of Standards for Diagnostic Test and Vaccines, the International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases. OIE standards are recognized by the WTO as reference international sanitary rules. More information is available on the OIE web site (www.oie.int/eng/en_index.htm).

World Trade Organization (WTO)
The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business. More information is available on the WTO web site (www.wto.org).

4. EXPERIENCES OF BELIZE IN MOVING TOWARDS AN INTEGRATED BIOSECURITY APPROACH

Reasons for adoption of an integrated approach

- Limited resources to perform key functions in agricultural health and food safety
- Funds out of a consolidated government revenue – competition among public ministries / agencies
- Duplication of roles across ministries / agencies
- Outdated legislative support
- International trade requirements (SPS Agreement)
- Scattered focus, poor coordination of agricultural health and food safety

Agencies responsible for components of biosecurity before change

- Ministry of Agriculture and Fisheries (plant and animal health including fish health)
- Ministry of Health (meat and food inspection, public health functions, zoonoses (rabies programme)
- Ministry of Trade (permits and licences for imported goods including agricultural goods and commodities)
- Bureau of Standards (consumer protection, food standards)
- Ministry of Natural Resources (forestry, environmental functions including biosafety)
- Customs department (ports inspection)

Agencies responsible for biosecurity after change

- Belize Agricultural Health Authority (BAHA) – agricultural health and food safety including aquatic animal health and biosafety
- Ministry of Health – human health and food safety at retail level (through memorandum of understanding)
- Bureau of Standards (food standards, consumer protection)
- Ministry of Natural Resources, Dept. of Environment (environmental impact assessments, environmental monitoring)
- Fisheries Department (aquaculture production)

Responsibilities of agencies involved in biosecurity after change

- Belize Agricultural Health Authority (BAHA) responsible for agricultural health and food safety (animal health, plant health, food safety, quarantine, sanitary and phytosanitary measures, regulation of imports sand exports) based on a risk analysis approach
  - Hosts the focal point for OIE, IPPC, SPS enquiry point and the Biosafety Focal Point (including the Biosafety Clearing House)
  - Codex Contact Point located in the Bureau of Standards under the Government appointed Standards Advisory Council (chaired by BAHA)
- Ministry of Health responsible for human health including food safety at the retail level (restaurants, retail outlets, meat shops, hotels, etc.)
- Ministry of Natural Resources (Dept. of Environment) responsible for environmental programmes and serves as the CBD contact point
- Pesticide Control Board responsible for regulation of pesticides (BAHA on Board of Directors)

Challenges

- Status of staff (including conditions of employment) in BAHA: new staff employed on contract basis while original staff retained their status as civil servants
- Maintaining competency with shrinking resources (human and financial)
- Legal support for BAHA's wide (and expanding) mandate
- Cost recovery for public good programmes (a government function)
- Wide, porous borders – difficult to provide full coverage
- Position under and relationship to parent ministry and weak inputs from other ministries and agencies
- Private sector involvement (raises questions of influence)
- Local recognition as a money generator (raises questions related to sustainability and need for government funds)
- Seen as mainly providing support for the export market and less for local production
- International certification capabilities (recognition of BAHA certification in HACCP, GAP, etc.)

Start-up and other costs associated

- Inter-American Development Bank project (US$3.6 million) covered start-up costs of infrastructure (buildings), equipment, training, etc. and Government of Belize provided US$1.2 million for operational costs
- Resources required to finance vehicles, laboratory buildings, recurrent costs (e.g. reagents and laboratory supplies), insurance, pension funds, etc.

Benefits

- Agricultural health and food safety under one authority provide synergies for effective administration of agricultural health and food safety in Belize
- Increase in agricultural health standards
- One stop shop for processors exporting food and agricultural products and importers (permits)
- Shared resources between the various departments (e.g. quarantine, inspection, internal quarantine for medfly outbreaks, farm quarantine, food safety assessments, surveillance programmes, etc.) – food safety inspectors in slaughter plants perform dual role of food safety and animal health surveillance
- Cost recovery increases sustainability of services provided

Examples of biosecurity capacity building provided to other countries

- Quarantine manual shared with Dominica
- Some parasitoids (biological control) produced in Pink Hisbiscus Mealybug laboratory in BAHA shipped to Mexico and Central America
- Technical cooperation activities with Costa Rica to share experiences in agricultural health and food safety frameworks
- Attachment with BAHA quarantine services (Suriname)
- Consultancies of BAHA technical officers with Caribbean Poultry Association (animal health and food safety programmes and codes of practices) to be shared with CARICOM countries

5. IMPLEMENTING A BIOSECURITY CONCEPT: REFORMING THE FOOD SAFETY, ANIMAL AND PLANT HEALTH ADMINISTRATION IN NORWAY[72]

Background

Until 2004, Norway had separate national control bodies for feed and plant health, animal health and animal welfare and food control, respectively. The central food control authority was a state body, while local food control was performed by municipal authorities. Control of seafood for export was performed by the Directorate of Fisheries. Control of animal health and welfare was performed by district veterinary officers reporting to regional units and the central unit of the Animal Health Authority and control of plant health and feed was performed by plant health inspectors in four regional units and one central unit of the Agricultural Inspection Services.

During the 1990s there was a growing political consensus that the organization of public food administration was not appropriate. Both the structure of the legislation (13 different laws) and the tasks and responsibilities of the different control bodies were fragmented. The industries were also not satisfied with the organization of the control bodies or the control they performed, emphasizing the need to make sure that controls were following a common policy, both between geographical regions and between different sectors along the farm to fork axis.

A process, which went through several phases, encompassed a rather long phase from the political agreement for the need for simplified legislation (a White Paper in 1994) to a preliminary preparation of a reorganized control authority and simplification of legislation in 2002 within the involved ministries. In 2003 an interim authority was established alongside the existing authorities to prepare the practicalities for a physical reorganization of the national and municipal responsibilities and culminated in 2004 in a new control authority and revised and simplified legislation.

The process represented a realization of several overlapping and complementary political signals, both nationally and internationally. These may briefly be summarized as a need to have a clear chain of command and clear constitutional responsibilities along the entire food chain, a need to have a clear separation of tasks between the scientists performing risk assessment and the managers considering risk management, a need to bring regulators closer to the public and operators, and a requirement to simplify regulations in general.

This process overlapped in time with some key issues for Norway on the international scene, namely an European Economic Area (EEA) Agreement between the European Free Trade Association (EFTA) States and the EU encompassing much of the veterinary and food legislation in 1994 and later also encompassing a common veterinary border control in 1998, the WTO agreement in 1995 removing custom barriers to international trade and the fact that the EFTA States Sweden, Finland and Austria chose to join the EU in 1995, while Norway chose to retain the EEA agreement and thereby become one of the only remaining EEA States. These international agreements all had, and continue to have, a major impact on the structure and material content of Norwegian veterinary and food legislation.

Elements and aims of the reorganization

The reorganization of public food, animal and plant health control in Norway consisted of four main elements:

- modernization of the legislation;
- restructuring of responsibility between ministries;
- establishment of a new, national authority for all food and feed production including animal and plant health; and
- reorganization of the scientific support for the new authority.

The aims of the process were:

- to ensure that food (including drinking water) that is produced or sold is safe for consumers;
- to avoid fraudulent practices;
- to ensure that the quality of food complies with national and international standards;

---

[72] Case study prepared by Keren Bar-Yaacov, Chief Veterinary Officer, Norwegian Food Safety Authority and Gunnar Hagen, Senior Adviser, Ministry of Agriculture and Food. For further information, contact kebay@mattilsynet.no.

- to ensure good animal health, plant health and animal welfare in Norway; and
- to ensure a more cost-efficient administration.

Modernization of the legislation

Before 2004, Norwegian legislation for feed and food production was fragmented and consisted of 13 different laws. A new food law replacing these 13 laws was enforced from 1 January 2004. The law aims at ensuring food safety, animal and plant health and improving quality and other consumer interests, commercial and environmental aspects. The new law has contributed to simplification of the legislation and also enforces a new system of control fees and taxes. Animal welfare is still regulated in a separate law.

A new law represented the first step in a major restructuring of the regulations in the field of food safety, plant health and animal health. Regulations under all the old laws were updated to take into account the new organizational structure and competence, but two years on there is still much left to be done with regard to realizing the political signal pertaining to a simplified regulatory framework.

The new food law strengthened the official legal powers, giving the authority power to demand action by an operator, act on the operators' behalf and at their expense should they themselves not comply with the authorities demands, impose fines, close business until action is taken, impose a quarantine on businesses for up to six months, and actively inform the public. In addition, the courts may impose penalties.

A major challenge for the new authority is to harmonize actions, so that operators throughout the country can expect both proportionate and consistent reactions to similar situations and conditions. A new organization is only part of the solution, and this is a theme that the authority will have to focus on during the early years.

Restructuring of constitutional responsibility between ministries

Three different ministries are responsible for regulations under the new Food Law. These are the Ministry of Agriculture and Food, Ministry of Fisheries and Costal Affairs and Ministry of Health and Care Services. The constitutional responsibility between the ministries has been reorganized. The ministries have been through a process of clarifying their responsibilities, defined both between primary production and end product and between animal, fish, plant and human health.

All responsibility related to primary production and plant and animal health is placed in the Ministry of Agriculture and Food for terrestrial production and Ministry of Fisheries and Costal Affairs for aquatic production. The Ministry of Health and Care Services is responsible for measures related to human health and also for a majority of rules intended to avoid fraudulent practices.

The Ministry of Agriculture and Food is administratively responsible for the new control authority, while the Ministry of Health and Care Services is administratively responsible for the new risk assessment body.

Establishment of a new, national food control authority for all food production, animal and plant health

In April 2002, the Government proposed an organization with two different control bodies, one for terrestrial production and one for aquatic production. When this matter was discussed in Parliament (Stortinget), the majority of representatives agreed that it would be better to establish one food control authority with responsibility for both terrestrial and aquatic production. The main argument for establishing one control body was to ensure that the needs of industry would be met by an efficient and coordinated body. Many business operators would otherwise be subject to inspection from different control authorities. This conclusion was also in line with the outcome of a broad hearing of the proposed reorganization.

A revised proposal of one food control authority for all food production from farm to fork got broad support from Parliament after being presented in November 2002. In essence this meant that the authorities responsible for seafood controls were given a much shorter time to prepare for the proposed reorganization than the other authorities.

It was decided that the new authority should be operative from 1 January 2004. The authority should have three organizational levels (central, regional and local) and inspections and decisions concerning the food businesses and primary production should be performed primarily by the local level. As responsibility for the tasks performed by the food control authority is divided between three different ministries, a special coordinating group has been set up headed by the administrative leaders in the three ministries.

Much of the practical preparation was performed by working groups with profound knowledge of the matters to be handled. To ensure involvement of different stakeholders (industry, consumers and other NGOs), a reference group was also set up.

An interim organization was set up one year before the new control authority was to be operative. This organization was headed by the already appointed Director General of the new authority who had the necessary power to direct work during an interim period. Employees from all of the former authorities that were to merge into the new authority were involved in the interim organization. Employee organizations were quickly contacted to form a representative reference group (see addendum with comments on the process from this reference group).

For the ministries it was important that the reform also resulted in a more efficient control body (i.e. reduced cost). An objective of at least 10 percent cost reduction was established. This objective should be met by 2008 and, so far, a cost reduction of seven percent has been imposed in the yearly budgets of the new control authority.

The new authority represents a merger of four government authorities and 89 municipal authorities, which in total covered the responsibility for controls along the entire food chain, from the farm to the fork, but in a fragmented organizational and constitutional system. The reorganization involved approximately 1,600 employees, both at central level and throughout the country.

The merging authorities were:

- The Norwegian Food Control Authority
- The Norwegian Animal Health Authority
- The Norwegian Agriculture Inspection Service
- The Directorate of Fisheries, Seafood inspectorate
- The Municipal Food Control Authorities

The new authority is a governmental body responsible for controls along the entire food chain, from primary production to product delivery. The new authority also covers animal welfare and health not related to the food chain, plant health also not related to the food chain, drinking and production water and cosmetics.

The role of the new authority is to:

- prepare draft legislation;
- inform and guide on legislation;
- perform risk-based inspections;
- monitor food safety, plant and animal health; and
- plan for contingencies.

The new authority does not have its own diagnostic services; such services are procured by the authority either on the basis of tenders or through separate agreements with government reference laboratories. This solution was adopted due to political signals to make a clear distinction between government controls and service delivery (see next section).

As required during the political process, a three-level organization has been set up. There is a head office, with approximately 130 employees, eight regional offices with approximately 240 employees and 63 district offices with approximately 950 employees. Most first instance decisions have been delegated to the district level.

Among the eight regional offices, three offices have been designated as national centres for specific productions (terrestrial animal production, aquatic animal production and plant production) and two have been designated specific administrative support functions (data support and archive, book keeping and payments). These are intended to support the entire organization within their specified competence areas so as to boost a small head office. The reasoning behind this organizational choice is partly based on historical factors such as where some of the authorities were based before the reorganization and the desire to maintain competence. However, is was also a major compensation for the political decision to limit the size of the head office in Oslo due to a general political aim to reduce government offices in the capital and decentralize them to rural areas.

During the one year preceding the actual reorganization, the preparations were project based. Some of these projects focused on preparing a set of administrative tools, such as one central electronic archive, electronic document handling and electronic budget planning and control. Other projects focused on preparing major thematic issues such as export certification and seafood controls and finally there were also projects aimed at building a common “brand” including a name for the new authority, a logo and agreed aims and responsibilities. The meetings where such issues were discussed around the whole country were also used as an introduction to cultural fusion between the old authorities.

The most difficult aspect of the reorganization was the process of assigning personnel to new offices. All top management positions (director general and regional directors) were advertised and were open for external candidates. All other management positions

were only open for candidates from the former authorities (including the municipal food control authorities). Once these positions were filled, personnel were given the opportunity to state where they believed they belonged in the new organizational chart and the new managers made a round of interviews to clarify who was to work where.

In this complicated process there was a further complication due to two very difficult issues. One was the decision to sever the contact between the local authority and existing local laboratories. This meant there had to be a clarification concerning which personnel primarily belonged to the new authority and which personnel had to stay behind with the laboratory units. The other was a decision to limit the possibility for local official veterinarians to take part in private practice. In many rural areas of Norway this mix of official work and private practice was historically the only possibility to recruit practitioners to these areas. These employees were, in the process of the reorganization, given the choice to join the new authority as full-time officials or leave and become full-time practitioners. This was a very difficult decision for many, and their choice could also leave the authority very vulnerable in some regions, since very experienced employees often preferred private practice to full-time official work. The consequences of these two very difficult issues are still felt two years on.

The process of identifying which office one was to work from was rather simpler at local and regional level than head office. The background for this was the decision to limit the size of the head office. This limit meant that many employees working at central level in the old authorities would not be given a slot at this level in the new authority. These employees were then offered positions at the national centres at regional level. For many this meant a geographical move. Employees were given leeway to prepare their move over 18 months (i.e. no one was forced to physically move before July 2005 and compensation was provided to cover moving expenses as well as to those who decided to resign). Still, this was a very traumatic experience for many employees who had worked for many years in the same position.

Reorganization of scientific support for the new authority

An important element in the reorganization was to ensure that the risk management performed by the authority was scientifically based. Many international food and animal health crisis during recent years have focused on the need to have a clear separation of tasks between risk assessors and risk managers. In order to ensure independent scientific risk analyses for the authority and ministries, a new scientific committee with an independent budget was created.

The scientific committee shall provide a scientifically based risk assessment covering the remit of the new authority. In addition to serving the new authority, the committee may also themselves initiate and perform risk assessments. The structure of the scientific committee mirrors the structure chosen by the European Union in the establishment of the European Food Safety Agency (EFSA), a small secretariat serving eight independent scientific panels. The participants on the panels are chosen based on their scientific merits in the appropriate field covered by the panel.

A challenge in relation to utilizing this asset is to have clear routines and understanding on communication between the authority and the committee secretariat. During the two first years a document describing the interaction between authority and scientific committee has been developed and refined.

Another central element in the reorganized scientific support was the question of laboratory support. In order to have a clear separation between service providers and public administration, laboratory services were not included in the new authority. Before the reorganization, the municipal food control units had integrated laboratory services as part of their remit. This in effect meant that the local food control units had to be split into elements that joined the new authority and elements that were not included in the authority, and therefore had to find other solutions for personnel and equipment. This was a very traumatic and difficult process for all involved.

The new authority was also given the task of solving their laboratory needs through official tenders. There was in this matter in many ways a steep learning curve both for the buyers and for the sellers. A political requirement to be both cost efficient and to support rural development was also a very difficult balance to keep.

Conclusions and lessons learned

The reform of the food safety administration in Norway represents one of the larger administrative reforms in Norway in recent years. The reform included many

elements, which all are interdependent in achieving a successful conclusion to such a radical process. The reform required clarification of the constitutional responsibilities, strengthening and simplification of legal powers, a clear division of risk assessment and risk management, and a coherent and effective operational body in close contact with operators and the public.

Some immediate lessons learned are:

- Make sure the political signals are clarified early on.
- Ensure that operational capacity is maintained in the existing authorities while preparing for the new one.
- Ensure that legislation gives the new authority sufficient legal powers.
- Political and organizational decisions concerning changes to personnel requires time. It is wise to try and limit the number of different processes to be handled at once. Consider if some decisions may be better delayed. Avoid "brain drain".
- Do not overestimate the readiness to learn and understand new administrative solutions in a very turbulent, and for many, personally difficult situation. New and technically advanced solutions require time if they are to become efficient. Non-essential revolutions are probably best planned for a stage where things have begun to settle down.
- Do not expect success from day one. Do not underestimate the cost-effectiveness of local solutions, and how much new solutions really cost, both in relation to budget and in relation to human resources to change a system.
- Cultural differences in the merging organizations need special focus. In the aftermath of the first wave of inspiration, there is often a sense of personal loss.
- Estimate that there will often be a gap between expected time and actual time spent on solving different tasks. Organizational theory implies that it might take two to four years to finally settle down. In the meantime, efforts need to be taken to minimize energy loss.

ADDENDUM: PARTICIPATION OF EMPLOYEES' ORGANIZATIONS IN THE FOUNDING OF THE NORWEGIAN FOOD SAFETY AUTHORITY[73]

The employees' organizations were included in the work involved in establishing one single food safety authority in the autumn of 2001. Two working groups, which were functional throughout 2002, were set up:

- One was supposed to assess the new Norwegian Food Safety Authority's professional areas of focus, which names and terms should be used within the organization and whether there should be two or three administrative levels
- The second was supposed to appraise the ramifications of moving the local food control authorities' functions to the State, look at personnel matters related to founding the Norwegian Food Safety Authority and the transferral of personnel from municipal to state activities

Part of the reason the process involved in establishing the Norwegian Food Safety Authority has been deemed a success, as opposed to many other attempts at reorganization of government authorities, was that the employees' organizations were included in the process very early on.

The Norwegian Food Safety Authority was solely responsible for building up an organization to prepare for the founding of the new Norwegian Food Safety Authority. The director soon brought in the employees' organizations. The principles guiding the organizations' participation in the founding of the Norwegian Food Safety Authority were regulated by a special agreement between the Ministry of Modernization and the main employer organizations.

Political decisions

Parliament made important political decisions on the establishment of the Norwegian Food Safety Authority. These political decisions had wide-ranging repercussions on employees. The decision to have a "slimmed down" head office entailed reducing the number of employees in relation to the total labour force at two of the three original authorities (the Agricultural Inspection Service had its main office in Ås) which had their main office in Oslo. A great many employees' jobs were transferred to other parts of the

[73] Written by Ingunn Bråthen, Senior Adviser, Confederation of Vocational Unions (YS) and Odd Jenvin, Senior Adviser, Federation of Norwegian Professional Associations.

country. However, many people could not imagine moving with their jobs. Some were offered other jobs, but there is reason to believe that the decision to have a "slimmed down" head office led to the Norwegian Food Safety Authority losing employees and thus important skills during the reorganization process.

Parliament decided that laboratory services would not be a part of the new Food Safety Authority. The laboratories in the remit of the municipal food safety authorities were expected to become independent units. Not all these units could survive; some were closed down and some employees lost their jobs.

Excluding laboratory services made it difficult to match municipal workers to jobs in the Norwegian Food Safety Authority. Some employees' jobs were connected to laboratory services only in part. Some employees worked at the laboratory and for the municipal administration, or for the municipal food safety authority. This made gaining an overview difficult, i.e. whether the person concerned should stay in the municipality, be placed in a new job in the Norwegian Food Safety Authority or carry on working at a newly independent laboratory.

Parliament's decision in November 2002 that the Norwegian Food Safety Authority should be operative from 1 January 2004 meant that reorganization would have to take place over an extremely short period of time. A lack of time was a real obstacle to cooperation between the Norwegian Food Safety Authority's management and the employees' organizations. On a number of matters, it was impossible to have thorough and inclusive discussion. Many employees have thus been left with the impression that decisions were made without their involvement. This posed a dilemma for the organizations: either to participate in a process with very short deadlines and thus only have limited chances to scrutinize matters thoroughly and inclusively or to be mere onlookers.

Transferral of employees from municipalities

It was most problematic that there was a great deal of insecurity among the employees of the 89 municipal food control authorities, who were supposed to be integrated into the new, state-administrated Norwegian Food Safety Authority, as it was not known how many employees would be transferred in total.

Negotiations were conducted between the Ministry of Agriculture and the municipalities on transferring approximately 800 people. These negotiations were only completed in August 2003. Only jobs in which more than 50 percent of the tasks came under the remit of the Norwegian Food Safety Authority were transferred. The organizations were not involved in these negotiations.

Municipal employees were thus placed in new jobs, but a uniform system for salaries and job structure had not yet been fully worked out. One important challenge for the Norwegian Food Safety Authority in the time ahead will thus be how to respond to the differences in salaries which have arisen within the same job code. The same applies to variations in and between the regions concerning use of job codes within the same skills field.

Employees' skills went unused

Establishing the Norwegian Food Safety Authority did not just entail merging five existing authorities, but also extensive restructuring of the way these authorities operate. The farm-to-fork principle entailed a new and more uniform inspection philosophy. This meant that employees had to develop new methods of working. When assigning tasks between head office and the regional centres was decided, this process did not sufficiently involve the employees who had the relevant skills. Skilled employees were not consulted when the management was deciding to move tasks and transfer methods of working.

Summary

From the point of view of the employees' organizations, some aspects of the process facilitated the extensive reorganization during a short period of time. First, a completely new authority was to be established. There is broad agreement that merging will be beneficial from the point of view of efficiency in a number of areas. In addition, the Norwegian Food Safety Authority is not regarded as being just an organizational continuation of one of the earlier authorities. It is a brand new organization with a new inspection philosophy. Second, a director was employed at the Norwegian Food Safety Authority whose background was not from one of the merged authorities. The director appeared to be independent, unbiased towards any one authority and could thus think in new ways. Third, it is important to emphasize that the Norwegian Food Safety Authority's management had an open and inclusive attitude towards the employees' organizations in most areas. The Norwegian Food Safety Authority's

management was interested in finding solutions. Solutions to problems which appeared along the way were found mainly thanks to cooperation and dialogue with the employees' organizations. The form of cooperation which was established between the management of the Norwegian Food Safety Authority's interim organization and the employees' organizations is still in place today, even after the formal founding of the Norwegian Food Safety Authority has been completed.

6. BROAD QUESTIONS TO TAKE STOCK OF EXISTING CAPACITY AND PERFORMANCE OF CORE BIOSECURITY FUNCTIONS

Scientific research and advice

- Are there established policies, procedures and regulations governing the provision of scientific advice?
- What is the scope of scientific research and advice (outputs) provided?
- Which stakeholders are responsible for the provision of scientific advice? What are their respective roles and responsibilities? How do they work together?
- What operational principles (scientific integrity, honesty, impartiality, etc.) and procedures (e.g. risk analysis) guide the provision of scientific advice?
- What is the capacity for risk assessment?
- What human, financial and other resources are available for the provision of scientific advice? How are they allocated?
- What linkages exist between those responsible for the provision of scientific advice and other stakeholders (e.g. public health and academic institutions, inspection services, national / international laboratories, etc.)?

Risk profiling and priority setting

- Is there an established policy governing risk profiling and priority setting?
- What is the scope and nature of risk profiling activities carried out? How are priorities set?
- Which government agencies and other stakeholders are involved in risk profiling and priority setting? What are their respective roles?
- What operational principles and procedures guide risk profiling and priority setting activities?
- What resources (e.g. human, financial, information) are available for risk profiling and priority setting? How are they allocated?
- What linkages exist between those responsible for risk profiling (a scientific activity) and those responsible for priority setting (a risk management activity)?
- Are there linkages between biosecurity sectors that facilitate cross-sectoral priority setting where appropriate?

Setting and implementing biosecurity regulatory activities

- Are there established policies, procedures and regulations governing biosecurity regulatory activities?
- What is the scope of biosecurity regulatory activities including standard setting and implementation?
- What operational principles and procedures guide biosecurity regulatory activities and their implementation?
- Which stakeholders are involved in standard setting and other biosecurity regulatory activities? What are their respective roles?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for implementation of biosecurity regulatory activities? How are they allocated?
- What linkages exist between those responsible for biosecurity regulatory activities and other concerned groups (e.g. industry)?

Diagnostic services

- Are there established policies, procedures and regulations governing diagnostic services?
- What is the scope and type of diagnostic services (outputs) provided?
- Which stakeholders are responsible for diagnostic services? What are their respective roles and responsibilities? How do they work together?
- What operational principles (e.g. independent, unbiased, etc.) and procedures (e.g. sampling protocols, analytical procedures, quality assurance, reporting and documentation, etc.) guide the provision of diagnostic services?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for the provision of diagnostic services? How are they allocated?
- What linkages exist between those responsible for the provision of diagnostic services and other stakeholders (e.g. public health and academic institutions, inspection services, national/international laboratories, etc.)?

Inspection, verification and enforcement

- Are there established policies, procedures and regulations governing inspection and enforcement?
- What is the scope and type of inspection, verification and enforcement?
- Is inspection and verification risk-based?
- Which stakeholders (government and others) are involved? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide inspection, verification and enforcement?
- What human, financial and other (infrastructure, equipment, etc.) resources are available? How are they allocated?
- How are competencies for personnel other than government established and maintained (e.g. accredited training programmes)?
- What linkages exist between those responsible for inspection, verification and enforcement and other stakeholders (e.g. laboratories, industry, general public)?

Quarantine and certification

- Are there established policies, procedures and regulations governing quarantine and certification?
- What is the scope and type of quarantine services (e.g. border control, animal quarantine, plant quarantine, human quarantine, government and/or third party certification)?
- Which stakeholders are responsible for quarantine and certification? What are their respective roles and responsibilities? How do they work together?
- What operational principles (e.g. independent, unbiased, etc.) and procedures (e.g. sampling protocols, analytical procedures, quality assurance, reporting and documentation, etc.) guide quarantine and certification?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for the provision of quarantine services? How are they allocated?
- What linkages exist between those responsible for the provision of quarantine services and certification and other stakeholders (e.g. inspection services, laboratories, etc.)?

Emergency preparedness and response (including contingency planning)

- Are there established policies, procedures and regulations for biosecurity emergency preparedness and response?
- What type of work is carried out under emergency preparedness and response?
- Which stakeholders are responsible for biosecurity emergency preparedness and response? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide biosecurity emergency preparedness and response?
- Are risk analysis principles applied with ranking of risks as appropriate?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for emergency preparedness and response? How are they allocated?
- What linkages exist between the organizations responsible for biosecurity emergency preparedness and response, organizations responsible for preparing for and responding to other types of emergencies, and other concerned stakeholders (e.g. consumers, industry, general public)?

Risk communication

- Are there established policies, procedures and regulations governing risk communication?
- What is the scope of work carried out as part of risk communication? Does it cover both “outgoing” communication to inform stakeholders about biosecurity risk(s) and measures to manage it (them), and “incoming” communication to obtain information, data, opinions and feedback from them?
- Which agencies are responsible for biosecurity risk communication? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide biosecurity risk communication?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for biosecurity risk communication? How are they allocated?
- What linkages exist between the organizations responsible for biosecurity risk communication and other stakeholders?

Monitoring and surveillance

- Are there established policies, procedures and regulations governing monitoring and surveillance?
- What is the scope of monitoring and surveillance activities?
- Which stakeholders are responsible for monitoring and surveillance? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide monitoring and surveillance?
- What human, financial and other resources are available for monitoring and surveillance? How are they allocated?
- What linkages or communication procedures exist between those responsible for monitoring and surveillance and emergency response? What linkages exist with other stakeholders (e.g. inspection services, general public, industry, etc.)?
- Are biosecurity outcomes subject to regular evaluation with review of risk management options if appropriate?

7. STAKEHOLDER ANALYSIS FOR BIOSECURITY

The following template can be used to identify the stakeholders responsible for different aspects of biosecurity.

Task	Ministry / department / group responsible
Formulation and implementation of policies addressing: • public health • food safety • animal health • plant health / forestry • biosafety / biotechnology • environment • fisheries • invasive alien species	
Formulation, implementation and enforcement of legislation addressing: • public health • food safety • animal health • plant health / forestry • biosafety / biotechnology • environment • fisheries • invasive alien species	
Regulatory activities including: • provision of scientific advice • risk profiling and ranking • setting of hazard-based and risk-based regulatory standards • inspection, verification and enforcement • quarantine • certification • diagnostic services • emergency preparedness and response • information exchange and risk communication • monitoring and surveillance	
Competent body / third party activities including: • inspection • verification • certification and /or trade permits • diagnostic services • emergency preparedness and response • monitoring	

(continued)

Task	Ministry / department / group responsible
Coordination and participation in the work of international and/or regional organizations and bodies related to biosecurity: • CAC • FAO • WHO • OIE • WTO • CPM/IPPC • UNEP • Regional bodies	
Implementation and oversight of relevant international agreements, conventions and codes of practice: • GATT • SPS Agreement • TBT Agreement • CBD • IPPC, ISPMs and other international standards • Code of Conduct for Responsible Fisheries	
• Major finance and budgetary decisions related to food and agriculture	
• Formulation of national development plans, strategies, etc.	
• Export promotion and development	

8. SWOT ANALYSIS SCENARIO FOR BIOSECURITY

SWOT analysis is a strategic planning tool that can be used to identify and assess strengths and weaknesses of biosecurity, as well as the opportunities and threats. The process of conducting a SWOT helps to facilitate a common understanding of "reality" among a group of people. This makes it easier to understand and identify key capacity goals and needs, as well as possible solutions. An example SWOT analysis scenario for biosecurity is presented below.

	Positive	***Negative***
Internal	**Strengths:** internal assets that enable those concerned to perform their mandate effectively. • Good animal health status inside the country – effective control and eradication programmes in place for endemic animal and zoonotic diseases and import controls to exclude exotic diseases • Central food analysis laboratory accredited by an international agency • Plant protection border control inspectors in place • Increased interest in biosecurity among government agencies • Adequate risk analysis capacity	**Weaknesses:** internal deficits that constrain those concerned from effectively carrying out their mandate. • Limited understanding and knowledge about biosecurity in some competent authorities • Inconsistent approaches and systems • Fragmented accountabilities • Lack of overall leadership for biosecurity • Inefficient use of human resources available • Poor inter-agency coordination • Resources not allocated on the basis of major risks faced • Weaknesses in monitoring and evaluation • Overall lack of preparedness to cope in the event of a major biosecurity emergency – no strategy or plan for control or containment • Budgetary constraints within government • Competition for government funds among ministries involved in different aspects of biosecurity
External	**Opportunities:** any external circumstance or trend that could positively affect operations. • Recent membership of the WTO and increasing opportunities for international trade • Recent membership of the OIE • Increased attention to biosecurity risks at the regional level following animal disease outbreak in a neighbouring country • Increased availability of international standards • Scientific and technological advances • Availability of risk assessments carried out by international bodies or other national governments • Increased availability of donor financing for biosecurity	**Threats:** any external circumstance or trend that could negatively affects operations. • Other issues competing for high level national attention and resources • Weak capacity of some neighbouring countries to identify and adequately respond to biosecurity risks • Migratory birds • Transboundary animal and plant disease • Pressure to permit entry of certain commodities (imports) • Dumping of inferior quality food products • Civil unrest

9. KEY QUESTIONS TO SUPPORT THE IDENTIFICATION OF BIOSECURITY CAPACITY NEEDS

Existing capacity and performance ***(Step 4)***	**Desired future** ***(Step 5)***	**Capacity needs and options to address them** ***(Steps 6 and 7)***
• How is biosecurity handled at present? • What is the nature and effectiveness of the existing: - policy framework? - legal and regulatory framework? - organizational arrangements (including coordination)? - mechanisms for communication? • What is the scope of biosecurity functions (scientific research and advice, diagnostic services, risk profiling and priority setting, standard setting and implementation, quarantine and certification, inspection, verification and enforcement, emergency preparedness and response, monitoring and surveillance, etc.)? • Which competent authorities and competent bodies are responsible for these functions? What are their respective roles and responsibilities? Is there any duplication or gaps? • What operational principles and procedures guide the delivery of core biosecurity functions? • What resources are available for the delivery of core biosecurity functions? How are they allocated? • What linkages exist between competent authorities and competent bodies responsible for core biosecurity functions and other stakeholders? • What are the main strengths and weaknesses of the existing arrangements for biosecurity?	Describe the desired future of biosecurity in terms of the outcomes and results achieved • What outcomes should be expected of the biosecurity system? • How should biosecurity outcomes be enhanced in the future? • What would the biosecurity system achieve as a whole if it worked effectively and maximized potential cross-sector gains?	• What is required to move from the existing situation to the desired future situation? • What minimum level of capacity is necessary to perform core biosecurity functions, ensure cross-cutting aspects of biosecurity are addressed effectively, and achieve the goals identified? • What maximum level of capacity could be properly utilized? • What are the critical capacity needs (i.e. those that should be addressed first)? • What options are available to address the identified needs? • What are the expected biosecurity impact, costs and benefits, feasibility, affordability, legitimacy and timeliness of these options? • What are the obstacles to achieving the goals identified and what is required to overcome them? • Which actions and activities would be most effective?

10. OPTIONS TO ADDRESS BIOSECURITY CAPACITY NEEDS

This annex presents a variety of options to address biosecurity capacity needs. These options are offered as guidance and are not definitive. As discussed under Step 7 in the Guide to Assess Biosecurity Capacity (Part 2), several options exist and different courses of action will suit different countries, based on their national needs and priorities as well as their access to external support (for instance through technical advice, financial support, mentoring or twinning). Some of the options presented below can be pursued simultaneously and they are not therefore mutually exclusive. There is no inherent "best" set of options. Consequently, the specific type, combination and sequence of options pursued by countries may differ widely.

I. OPTIONS TO STRENGTHEN THE BIOSECURITY POLICY FRAMEWORK

A biosecurity policy framework sets out a broad course of action to address biological risks in food and agriculture based on appropriate public goals and a set of beliefs about the best way of achieving those goals. It provides a common framework for assessing biosecurity risks and priorities, and gives direction and guidance to all the parties concerned.

The options available to strengthen the biosecurity policy framework in a particular country will depend on the nature of relevant existing policies and the policy process. Some countries may already have formulated a policy or policies related to biosecurity or particular sectors of biosecurity. In other countries, the policy framework for biosecurity may be incomplete or outdated. Depending on the needs identified and the future goals of biosecurity, changes may focus on the scope and substance of biosecurity policy and/or the policy process (formulation, implementation to monitoring and evaluation, etc.).

Option 1: Align and harmonize existing sectoral policies related to biosecurity

Advantages

- Policy integration: provides an opportunity to simultaneously a) revisit existing but outdated policies and associated strategies and programmes in light of new and anticipated realities, and b) create a forward-looking system of policies geared towards current biosecurity goals and requirements.
- Continuity: builds on what already exists, providing an opportunity to maintain institutional memory and use local capacities.

Challenges

- Complexity: the traditional definition of roles and responsibilities on a sectoral basis tends to create barriers and conflicts. As a result, harmonization of existing policies, strategies and programmes may be overly ambitious.
- Resources required: reviewing and updating existing sectoral policies may require significant time and resources.

Option 2: Formulate a new national biosecurity policy

Advantages

- Raise awareness: provides a means to increase awareness about biosecurity.
- Clean start: incorporates the latest scientific knowledge and may provide a more effective way to overcome organizational resistance.

Challenges

- High-level support: will require high-level government endorsement.
- Adequately representing all interests: need to avoid domination by particular sector interests.

Option 3: Involve stakeholders in the policy process to reflect the multi-sectoral nature of biosecurity

Advantages

- Legitimacy: reflects the multidimensional nature of biosecurity and diversity of the stakeholders involved in managing biosecurity.
- Feasibility and acceptability: involving concerned stakeholders from the outset can help to build awareness of biosecurity, increase acceptance of the need for coordinated action, and enhance the ownership and sustainability of future biosecurity related programmes and activities.

Challenges

- Resource intensive: consulting stakeholders on policy formulation in a meaningful way often requires significant inputs in terms of time and financial and human resources.
- Diverging views: different types of stakeholders have different views, increasing the possibility of conflict if the process is not well managed.

Option 4: Develop / adopt a regional approach to policy formulation

Advantages

- Holistic: recognizes the knock-on effects of issues (e.g. species distribution, ecological boundaries, communicable diseases, etc.) that are not confined by national borders.
- Sharing experiences: provides a wider database from which to share knowledge and experiences.
- Improved outcomes: regional collaboration to implement international agreements related to biosecurity can generate concrete benefits such as improved protection, increased competitiveness, economic growth, regional consensus at international forums, etc.

Challenges

- Country diversity: different national characteristics (e.g. population, income, agricultural production, trade patterns, etc.) mean that needs are not uniform, increasing the difficulties of developing a common policy.
- Balancing costs and benefits: costs and benefits will not be shared equally among countries and sub-regions.
- Absence of supranational institutions: regional action works only if the national and regional agendas are aligned, and may be easier to achieve in regions where there are supranational institutions with the power to mandate regional-based action.

Other options, or a combination of the above, are possible. Regardless of the course of action selected, biosecurity policy should be based on sound, independent science and clearly defined goals and objectives for biosecurity to provide a clear rationale for decisions related to investment and resource allocation.

II. OPTIONS TO STRENGTHEN BIOSECURITY LEGISLATION

Sound biosecurity legislation (encompassing laws, regulations and standards) is necessary to create an enabling environment of predictability and certainty through good governance and respect for the rule of law. Legislation clarifies the roles, responsibilities and rights of stakeholders, including those parts of government with policy and delivery roles for biosecurity outcomes and programmes. However, most countries have a variety of laws and regulations in place related to different aspects of biosecurity. These normally cover public health, food safety, animal and plant health, and associated aspects of the environment. In many cases, other legislation that focuses on newer aspects of biosecurity such as products of modern biotechnology, invasive alien species, protection of fish and aquatic environments, etc. may be in force or under development, and is also relevant for biosecurity. Often, these laws and regulations may have developed over time in response to specific needs and requirements and different facets of biosecurity may be directly or indirectly regulated by many, often inconsistent and/or incompatible, Acts.

Countries can address capacity needs in biosecurity legislation in different ways. One option is to review and improve existing biosecurity legislation by removing inconsistencies, addressing gaps and better meeting international obligations. A second option is to create a new biosecurity law and supporting regulations to cover all the relevant subject areas. However, regardless of which option is selected, it is important to ensure that legislation, *inter alia*:

- states overarching biosecurity goals and objectives;
- includes a clear definition of biosecurity to ensure consistency and legal security;
- clearly identifies the mandates and responsibilities of government agencies and other stakeholders responsible for different aspects of biosecurity;
- includes provisions to ensure transparency and access to accurate information
- ensures that standards will be set based on scientific advice and risk analysis; and
- captures the country's regional and international obligations related to biosecurity.

Option 1: Review and improve existing laws and regulations related to biosecurity

Review and amend relevant parts of existing sectoral legislation as a means to remove inconsistencies, address gaps and meet current national and international needs and requirements related to biosecurity.

Advantages

- Enhances existing legislation: provides a way to address overlaps, gaps and inconsistencies in existing legislation.
- Less controversial: modifying existing legislation is often less controversial than developing new legislation.

Challenges

- Challenging, meticulous work: requires substantial technical and legal expertise and needs to draw on operational experience.
- Group effort: requires significant inter-agency coordination and collaboration.
- Potential delays: whenever existing legislation is reexamined, government and other stakeholders can raise other unrelated issues and stall the process.

Option 2: Create a new biosecurity law and supporting regulations

Draft a new biosecurity Act encompassing all aspects of biosecurity and prepare supporting regulations to clarify the relationship of this law to existing sectoral legislation and creation of cross-sectoral linkages.

Advantages

- Clean start: easier to capture the new concepts and structures.
- Time required: in some cases, it may be faster to create a new law than to harmonize existing legislation.

Challenges

- Complexity: many existing laws may be directly and indirectly related to biosecurity so it will be necessary to carefully determine whether and to what extent to consolidate relevant provisions of these laws by enfolding them into a new act.
- Delay: it can often take several years to get a new law passed.

Norway's approach to strengthen the legislative framework for biosecurity

As part of the efforts to reform the Food Safety Administration in Norway and move towards an integrated approach to biosecurity, the Norwegian authorities decided on the need for a major restructuring of legislation related to food safety, plant health and animal health. The following actions were taken:

- 13 acts related to food safety, plant health and animal health were merged into a new Food Law, which was given royal assent in December 2003.
- Other acts focused on animal welfare, animal breeding, cosmetics, plant breeders rights and animal health personnel are also being modernized.
- Regulations under all the old laws were updated to reflect the new institutional arrangements and competencies ■

III. OPTIONS TO STREAMLINE ORGANIZATIONAL ARRANGEMENTS FOR BIOSECURITY

Experiences from countries that have moved towards an integrated approach to biosecurity illustrate that the shape and scope of the organizational arrangements can vary. Different models and options will suit different countries depending on various factors such as: i) the political, socio-economic and physical environment; ii) the number and nature of government organizations responsible for biosecurity; iii) readiness to streamline existing government organizations responsible for different functions of biosecurity; and iv) available resources.

Three main options to streamline organizational arrangements for biosecurity are presented below. These options differ in the extent to which the resulting structure is organizationally independent and able to make independent decisions regarding biosecurity planning, implementation, resource allocation, etc. No one option is inherently better than another. Ultimately, the organizational arrangement selected should: i) reflect the goals of biosecurity; ii) ensure focus, accountability and efficiency in the planning and delivery of core biosecurity functions; and iii) facilitate an appropriate level of coordination and consistency of approach across the sectors of biosecurity. As such, they will promote a risk-based approach that enables those involved to plan and implement biosecurity decisions and allocate resources based on the risks faced.

Option 1: Coordinated multi-agency system

A coordinated multi-agency system relies on the infrastructure and capacity of its member agencies. Its power to make biosecurity decisions and allocate resources depends on the ability and willingness of sector competent authorities (normally involved on an equal basis) to work together. Under this model, concerned agencies would regularly share information and seek to harmonize their respective processes and systems for priority setting, programming, monitoring and review. However, each competent authority would retain responsibility for its core sectoral functions.

A coordinated multi-agency system requires the establishment of some sort of mechanism - such as a biosecurity coordinating committee or task force - to discuss biosecurity strategies, priorities and other relevant issues, and make recommendations for consideration by the competent authorities concerned. This mechanism could be established outside the authority of the main agencies involved (for instance under the prime minister's office) or implemented through an existing structure (such as a national SPS committee). It may include the participation of national Codex and OIE contact points and possibly committees if they exist, and National Plant Protection Organizations (NPPOs). A coordinated multi-agency system is likely to be selected where few resources are available, and it works best when the competent authorities concerned have both the desire and the determination to work together effectively.

Advantages

- Straightforward approach: often the fastest and most straightforward way to institutionalize an integrated approach to biosecurity as it does not require substantial reorganization or rationalization of roles and responsibilities.
- Acceptability: likely to be more acceptable bureaucratically and to encounter less resistance from competent authorities and staff involved in various aspects of biosecurity as it does not require large-scale organizational restructuring.
- Enhanced use of existing resources: can contribute to more effective use of existing resources and technical expertise if there is genuine commitment and collaboration.
- Potential for stakeholder involvement: provides a mechanism to bring together diverse stakeholders including representatives of competent authorities, government regulators, academics, scientists, NGO representatives, etc.
- Flexibility: often has the power to appoint sub-groups and co-opt individuals with technical expertise to provide specific inputs as needed.

Challenges

- Agreeing on operational rules and procedures: requires the establishment of effective mechanisms for administration, coordination and decision-making in areas of common concern.
- Inter-agency collaboration: effectiveness depends to a large extent on the readiness of those involved (leaders and staff) to think beyond the traditional boundaries of their organization, share information and engage in genuine collaboration. Overlaps, inconsistencies and incompatibilities in the roles, responsibilities, procedures and culture of the competent authorities involved may give rise to difficulties and conflicts, and permit only small changes in existing policies or procedures as opposed to major innovations that may be required.
- Temporary nature of national committees: national committees are often seen as temporary structures – to be seen as a legitimate part of the government, they may need to be institutionalized as a permanent office within government. The work of a national biosecurity committee can be held back when members are appointees or volunteers with limited time to devote to biosecurity activities.

Option 2: Lead Agency Approach

Another option to institutionalize an integrated approach to biosecurity is to place overall responsibility for biosecurity with one ministry or government department, which will take the lead while working with other concerned parts of government. This approach builds on the existing roles of government ministries and departments, and seeks to establish clear lines of accountability. The designated

Organizational arrangements for an integrated biosecurity approach in New Zealand

Biosecurity New Zealand is the new lead agency in New Zealand's biosecurity system. Established in November 2004, it is tasked with a "whole of system" leadership role, encompassing economic, environmental, social and cultural outcomes. It also has international trade and animal welfare responsibilities. In particular, Biosecurity New Zealand is responsible for biosecurity protection encompassing economic interests, health, natural environment, native flora and fauna, biodiversity, marine areas and a range of resources uniquely important to Maori.

Biosecurity New Zealand replaces the former Biosecurity Authority in MAF. It was created as a new division of the Ministry of Agriculture and Forestry (MAF) and reports to the MAF Assistant Director-General.

Biosecurity New Zealand's structure is based on a "points of intervention" model. It consists of six structural units - Pre-clearance, Post-clearance, Policy & Business Development, Animal Welfare, Compliance & Enforcement, and Incursion Investigation & Reference Laboratories.

Source: Extracted from Biosecurity New Zealand web site (available at: http://www.biosecurity.govt.nz/about/overview.htm)

lead competent authority normally already plays a major role in one or more components of biosecurity. It may be charged with developing biosecurity policies and overseeing the process of planning and implementing activities in collaboration with other concerned organizations. These activities would be additional to its regular work as a line ministry.

Advantages

- Builds on existing resources: can build on existing infrastructure for staffing, budgeting, coordination, etc.
- Requires fewer resources: may be faster and less resource intensive to implement than the establishment of a new biosecurity agency.

Challenges

- Willingness and ability of partners: effectiveness depends to a large extent on the capacity of the lead competent authority, as well as the commitment and readiness of other concerned organizations to work with it.
- Strain on lead competent authority: unless additional resources are available to help meet the new responsibilities, there is a risk of overburdening the staff and budget of the lead agency.
- Reaching agreement on lead competent authority: there may be competition among government ministries and departments to be designated as lead agency.
- Lack of influence: lead competent authority may have limited ability to influence the functions carried out by other competent authorities responsible for biosecurity functions.
- Open mind: Lead competent authority must be ready and willing to appropriately accommodate, prioritize and coordinate responses to risks previously dealt with by another competent authority.

Option 3: Independent Biosecurity Agency

Some countries may decide to create a biosecurity agency as an autonomous entity with its own budget (see following example of Belize). This competent authority may have responsibility for all aspects of biosecurity policy and regulatory functions, planning, programming and implementation. Alternatively, it may be responsible for normative functions (such as policy formulation, regulatory development, risk analysis, coordination, monitoring and evaluation, etc.) leaving responsibility for technical functions and operations (such as inspection and enforcement activities, diagnosis) to existing competent authorities and competent bodies.

Advantages

- Demonstrates importance: establishing an independent biosecurity competent authority provides a clear sign of the importance and high priority that the government gives to biosecurity.
- Innovation: presents an opportunity to overcome some of the institutional obstacles associated with a coordinated multi-agency system or lead competent authority approach (see above).

Challenges

- Agreeing on roles and responsibilities: may be difficult to determine the responsibilities to be transferred to the new competent authority and those to remain in sector competent authorities.
- Institutional rivalry: disinclination of some competent authorities to see their influence or mandate reduced and some of their roles or responsibilities transferred to a new biosecurity competent authority.
- Institutional constraints: the existing institutional context may not be conducive to enable a new competent authority to be effective.
- Start-up costs: significant leadership, facilitation, time and resources may be required to address start-up costs associated with organizational reorganization or establishment of a new competent authority.
- Financial sustainability: if the new competent authority is autonomous, gets support from external funders and charges fees for its services, the government may seek to reduce its contribution over time, which may affect long-term financial sustainability.
- Start-up difficulties: during the start-up period there may be a temporary reduction in the performance of activities due to disruptions to processes related to the reorganization and establishment of the new competent authority, confusion with respect to roles, responsibilities and accountability, assimilation of employees into a organizational culture, etc.

IV. OPTIONS TO FACILITATE BIOSECURITY COMMUNICATION

The complexity inherent in identifying, managing and preventing biosecurity risks in food and agriculture requires communication among a wide range of

Establishment of a semi-autonomous biosecurity agency in Belize

During the 1990s, the reduced availability of resources in the public sector in Belize, competition between and within ministries for available resources, and the new challenges posed by international trade pointed to the need to reorganize agricultural health services then provided by the Ministry of Agriculture, Fisheries and Cooperatives (MAFC). The Belize Agricultural Health Authority (BAHA) was established in response to these organizational problems and challenges. It was intended to provide a new and economically viable organizational model to meet the challenges of ensuring safe agricultural products for domestic use and fulfilling the requirements of international trade.

In 1999 the Government of Belize adopted legislation (BAHA Act No.47) to establish the Belize Agricultural Health Authority (BAHA) as a semi-autonomous, statutory body under the MAFC. Initially, the Authority included three departments with responsibilities for animal health, plant health and quarantine. However, in response to the impact of a number of animal health activities on human health and the need to demonstrate the compliance of shrimp exports with international food safety standards, a food safety department was subsequently created.

In establishing the Belize Agricultural Health Authority, Belize was the first country in the Caribbean and Central America to adopt an integrated approach to biosecurity. In practice, this means that animal health, plant health, quarantine and food safety are all managed by one institution. Therefore staff, supplies and equipment can be used across departments as necessary. For instance, food safety inspectors combine the inspection of slaughter and processing establishments with animal health surveillance activities. Technicians in the Mediterranean fruit fly surveillance programme visit livestock farms along their surveillance routes to assist with vesicular disease surveillance.

Other innovative aspects and achievements of the model adopted in Belize include:

i) **a private sector approach** which permits the collection of fees on a cost-recovery basis and faster decision-making in response to market demands;
ii) **the establishment of user groups** (including representatives of farming and processing industries, and related government departments) to discuss issues affecting services provided by BAHA;
iii) **high-level political support** from relevant ministers to ensure an effective environment for the enactment of laws and regulations, cost-recovery of services and cooperation with relevant agencies such as the Ministries of Health and Natural Resources.
iv) **collaboration and partnerships** with relevant government and non-governmental organizations, national associations and client representatives;
v) **public awareness programmes** and consultation to build support for BAHA among the general public who are seen as the primary users and beneficiaries of BAHA's activities and services
vi) **human resource development** to create a highly-trained, dedicated and motivated group of employees who are recognized as leaders in the application of disease control and phytosanitary measures in Central America and the Caribbean.

Source: Góngora, V. 2003. Veterinary Services in Belize: adapting organizational models to the needs of small economies. *Rev. sci. tech. Off. Int. Epiz.*, 22 (2), 463-471 (available at: http://www.oie.int/eng/publicat/RT/2202/10_GONGORAang.pdf)

stakeholders including government agencies, the private sector (agricultural producers, processors, enterprises, importers/exporters, etc.), the scientific and research community and the general public. Communication helps to provide timely, relevant and accurate information to, and obtain information from, concerned stakeholders. Effective communication is an essential part of biosecurity capacity.

The nature of the organizational arrangements for biosecurity, the extent to which roles and responsibilities are defined in legislation and the existence of a policy framework that sets out an overall course of action for biosecurity will all have an important effect on the feasibility and potential success of communication options. Such options may include the following.

Option 1: Regulate risk communication through legislation

Regulating risk communication through legislation provides a clear basis for systematic consultation and dialogue with interested parties on matters related to biosecurity.

Advantages

- Enhances legitimacy and trust: stakeholder interests and responsibilities may be significantly affected by the regulatory decisions taken as a result of risk analysis. Transparent and systematic communication on these decisions therefore promotes public confidence in the decision-making process, enhances the legitimacy of resulting government policies and action and fosters trust in the regulatory system in general.
- Improved outcomes: the information and knowledge obtained through systematic communication on biosecurity-related matters will inform the decision-making process, clarify the feasibility of different courses of action and improve overall results.

Challenges

- Resources required: effective communication will require significant human resources and financial resources.

- Number and diversity of interested stakeholders: the existence of many different consumer groups, interest groups, industry associations, etc. and absence of national federations or networks may make it more difficult to identify the main players and will make two-way communication more complex.
- Political tradition: the general political ideology in some countries may discourage real dialogue, or make it more difficult to achieve.

Option 2: The creation of memoranda of understanding defining roles and mechanisms for multi-stakeholder communication

Another option to facilitate biosecurity communication is to create memoranda of understanding (MOU) defining the specific roles, responsibilities and accountabilities of the competent authorities and other organizations involved in core biosecurity tasks, and specifying the mechanism for communication and information exchange between them and with other concerned groups.

Advantages

- Flexibility: MOUs can be generated on the basis of inter-agency agreement rather than imposed from above or through lengthier legislative or legal procedures; hence they can be more easily updated to reflect changing needs.
- Cost-effectiveness: Due to this flexibility and their ability to be targeted at particular activities, MOUs are normally cost-effective to develop and implement.

Challenges

- Complexity: bilateral MOUs between two agencies can quickly proliferate in light of the cross-cutting nature of biosecurity, resulting in overlaps, inconsistencies or conflicts. On the other hand, multilateral MOUs are more difficult to negotiate in the absence of crises or high-level demands, especially when the organizations involved have very different institutional histories and cultures as well as diverging perceptions of biosecurity.
- Informality: without commitment from the leadership of the competent authorities involved or strong incentives for implementation, the responsibilities enshrined in MOUs, as well as the requisite accountabilities, are difficult to guarantee.

Option 3: Establish stakeholder advisory groups

The establishment of stakeholder advisory groups provides a mechanism for regular and systematic dialogue between particular stakeholder groups (e.g. scientific institutions, industry, environment, consumers, etc.) with a role to play in the identification, management and/or prevention of biosecurity risks, or to provide independent advice to the government on the performance of biosecurity. Such groups could possibly be implemented through or in coordination with an existing structure (such as a national SPS, CAC and/ or OIE committee or NPPO).

Advantages

- Knowledge generation: opinions and knowledge from different stakeholders can inform biosecurity policy and decision making and management.
- Legitimacy: provides a forum for concerned public, private and non-governmental sectors to interact and communicate with the government on issues related to biosecurity, thereby enhancing legitimacy.

Challenges

- Conflict: given the divergent perspectives of stakeholders, conflict may be inevitable and skilled moderation will be imperative to channel the constructive dimensions of such conflict.
- Incentives: some stakeholders may not want to engage in dialogue with government and may seek more confrontational ways of influencing biosecurity outcomes.

Option 4: Develop biosecurity information systems

The development of biosecurity information systems facilitates the collection, analysis and reporting of relevant data and information to support a more integrated decision-making process. These systems could use existing biosecurity-related information systems, such as the International Portal on Food Safety, Animal and Plant Health (www.ipfsaph.org).

Advantages

- Comprehensive: facilitates risk-based decision making across the entire biosecurity arena.
- Efficiency: enables competent authorities responsible for biosecurity management to identify and respond to gaps and overlaps in the availability of required data and information.
- Transparency: strengthens ability of national notification authorities and SPS enquiry points to provide required information to the WTO and other member countries.

Challenges

- Compatibility: existing data sets or information systems developed and used by competent

authorities responsible for different aspects of biosecurity may be incompatible with each other, requiring new biosecurity information systems to be developed from scratch.
- Content and maintenance: adequate resources (human, financial, information) and sound procedures are essential for content development and maintenance.
- Analysis and reporting: regardless of the contents, human resources are required to ensure that any information systems can effectively generate the necessary outputs.
- Quality versus quantity: the quality and/or quantity of the data and information necessary to develop such systems may be problematic.

V. OPTIONS TO IMPROVE BIOSECURITY FUNCTIONS

Some options to improve the delivery and performance of biosecurity functions are presented below. These options are not mutually exclusive and one or more may be pursued at the same time. The range of possible options will be linked to the organizational arrangements for biosecurity (see section III above on options to streamline organizational arrangements for biosecurity) including the way in which roles and responsibilities are allocated.

Option 1: Involve competent bodies and/or other third parties in the provision of some biosecurity functions

Involving competent bodies and/or other third parties in the provision of some biosecurity functions, such as inspection or diagnostic services, can provide a way to enhance delivery and results. This can be achieved in different ways from sub-contracting some services to the private sector or academic or research institutes (while maintaining overall responsibility) to complete privatization. The best mechanism will depend on the function(s) in question and the particular country situation.

Advantages
- Improved efficiency and performance: involving competent bodies and/or other third parties can increase efficiency and improve the quality of services.
- Access to new resources: the private sector often has new sources of capital and resources, knowledge of new technologies, etc.
- Likelihood for success: may be simpler and more effective to involve competent bodies and/or other third parties in the delivery of specific services than to overcome vested interests and patronage networks to render public services more competitive.

Challenges
- Prerequisites necessary: involving competent bodies and/or other third parties requires the government to have clear specifications/standards for this purpose in place, and also requires the existence of capable service providers.
- Inadequate capacity: private sector involvement does not provide an automatic solution when the private sector itself has inadequate technical capacity, resources, etc.

Option 2: Apply a cost-recovery model for services provided

The application of a cost-recovery model can generate additional revenues, which can help to improve the quality, quantity and sustainability of services. Introducing a fee for services provided is often associated with the involvement of the private sector, however, under certain circumstances and in some legal systems, government agencies can also charge for particular services.

Advantages
- Access to additional resources: resources generated through fees charged for services can be used to improve the quality of services delivered (e.g. by upgrading technology or skills).
- Cost effective: increased cost-effectiveness and efficiency due to scrutiny of costs by industry.
- Sustainability: applying a cost recovery model can enhance the sustainability of service delivery particularly during times of budgetary constraints.

Challenges
- Unexpected outcomes: when cost-recovery models are seen as being successful, this may lead to a reduction in the availability of funding from central government.
- Stakeholders' ability to pay: not all users may have the capacity to pay, which may bias the delivery of such services towards certain groups (e.g. export-oriented firms) but fees can be designed differently for different groups (based on the size or value of consignment, for example).
- Need for new rules and regulations: in some cases, government agencies may be unable to charge fees

for services without legal action to amend the rules and regulations governing their work

Option 3: Use shared infrastructure and technical expertise

Sharing infrastructure (such as laboratories or import inspection facilities) and technical expertise across competent authorities can generate efficiencies and improve service delivery. For instance, competent authorities in some countries have decided to share laboratory facilities (especially for microbiological analysis).

Advantages

- Increased efficiency: more effective and faster service for users including streamlined procedure and reduced time to obtain necessary import permits and permissions, which will be especially valuable for importers of fresh and perishable products.
- Cost savings: saving may result from a reduction in duplication of services rendered by different competent authorities.

Challenges

- Obtaining agreement from the agencies involved: it may be difficult for competent authorities to agree on operational rules and procedures and financing including respective contributions to the budget and technical expertise, the allocation of technical and financial resources, the rights of contributing agencies to use the shared infrastructure and the amount to be contributed for use of services. There may also be competition from competent authorities to head the "shared" unit.
- Uneven use of facilities: difficulties may arise if one competent authority uses the shared infrastructure much more than the other agencies participating unless there is clear agreement on rules, rights and obligations for different types of access and use.
- Inter-agency collaboration: effectiveness depends to a large degree on the ability of individuals from different competent authorities and technical areas to work together effectively as a team.

Option 4: Develop shared information systems for specific technical areas

Shared information systems may be developed and operated for particular technical areas such as diagnostic services, inspection, verification and enforcement, and/or monitoring and surveillance.

Advantages

- Function-based: presents an opportunity to pursue collaboration in specific areas (e.g. inspection, verification and enforcement, monitoring and surveillance), which may be more likely to be successful than efforts to integrate all information systems related to biosecurity.
- Enhanced resource allocation: will support the delivery of services based on risk so that resources can be allocated to areas for which there is greatest need.

Challenges

- Incompatible data: may be more difficult or require additional resources if existing data sets developed and used by competent authorities are not compatible.
- Inter-agency collaboration: requires agreement from the competent authorities involved on what information will be shared, what resources will be contributed, operational rules and procedures, user rights, etc.

Option 5: Utilize risk analysis to prioritise risks and guide biosecurity decision-making

Risk analysis (comprising risk management, risk assessment and risk communication) provides a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to biosecurity problems. It can be used to support and improve the identification and prioritization of risks, to develop biosecurity standards and inform other regulatory activities, as well as to address biosecurity issues that result from emerging hazards or breakdowns in the application of controls.

Advantages

- Improved decision-making and outcomes: the process of conducting a risk analysis enables competent authorities to identify the various points of control at which measures could be applied, to weigh up the costs and benefits of these different options, and to determine the most effective one(s)
- Focuses resources on hazards of greatest risk: using risk analysis to prioritize risks helps to ensure that attention and resources are focused on the issues and areas of greatest importance to life and health.
- Enhanced trade access: the use of risk analysis enables governments to meet their obligations under the SPS Agreement and to strengthen their basis for trading foods internationally.

- Take advantage of resources available internationally: risk assessments carried out by international bodies can be partially or fully applied at the national level (depending on particular circumstances), which can reduce the technical resources required in the country.
- Ensuring transparency: Full documentation of risk assessment and risk management inputs allows all interested stakeholders to understand risk-based decisions.

Challenges

- Prerequisites necessary: the successful use of risk analysis for biosecurity requires countries to have certain essential conditions in place including sound legislation, efficient institutions, effective inspection and laboratory services, infrastructure and equipment, and officials who understand risk analysis and the value it adds to biosecurity sectors.
- Scientific capability required: the use of risk analysis in biosecurity requires specialized scientific knowledge and skills, which may be unavailable or in short supply in some countries.
- Availability of scientific inputs for risk assessment: scientific data gaps are often a significant limitation.
- Stakeholder support and participation: the effective use of risk analysis is dependent on transparent and open processes and the support and participation of key interested stakeholders such as consumers, academic and industry.

Option 6: Develop shared training materials and programmes

Common biosecurity concerns and methodologies (including risk analysis) are often shared between sectors and this means that there is much to be gained from the alignment of training materials and programmes focused on core functions of biosecurity.

Advantages

- Cross-fertilization: taking advantage of common biosecurity concerns and methodologies to develop joint shared training resources can enrich the content of training materials and learning outcomes achieved.
- Food chain biosecurity: developing shared training materials and programmes enables a consideration of complete hazard exposure pathways, which supports the implementation of controls at those points where they will be most effective.
- Cost sharing and efficiencies: the development and delivery of shared training materials and programmes can contribute to savings and efficiencies in the use of available resources.

Challenges

- Inter-agency collaboration: developing joint training materials and programmes requires competent authorities to work together effectively and success depends on the willingness and ability of those involved to effectively collaborate and liaise on work programmes and roles.

SUGGESTIONS FOR FURTHER READING

Anderson, M., Adams, H., Hope, B. and Powell, M. 2004. Risk Assessment for Invasive Species. *Risk Analysis* 24(4): 787-793.

Apostolakis, G. 2004. How useful is quantitative risk assessment? *Risk Analysis* 24 (3): 515-520.

Carey, J., Beilin, R., Boxshall, A., Burgman, M. and Flander, L. 2007. Risk-based approaches to deal with uncertainty in a data-poor system: Stakeholder involvement in hazard identification for marine national parks and marine sanctuaries in Victoria, Australia. *Risk Analysis* 27 (1): 271-281.

Claxton, K., Cohen, J. and Neumann, P. 2005. When is Evidence Sufficient? *Health Affairs* 24(1): 93-101.

CBD/UNEP. 2003. *Biosafety and the Environment: An Introduction to the Cartagena Protocol on Biosafety*. Secretariat of the Convention on Biological Diversity, United Nations Environmental Programme. Geneva (available at: http://www.cbd.int/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf).

Covello, V., McCalluum, D. and Pavlova, M. eds. 1989. *Effective Risk communication: The Role and Responsibility of Government and Non-Government Organizations*. Plenum Press, New York.

FAO. 1999. Prospects for the future: Nutrition, the environment and sustainable food production. Paper by M.L. Wahlqvist for the Conference on International Food Trade Beyond 2000: Science-based decisions, harmonization, equivalence and mutual recognition, 11-15 October, Melbourne. ALI/COM 99/18 (available at: http://www.fao.org/docrep/meeting/X2638E.htm).

FAO. 2002. *Report of the Expert Consultation on Biosecurity in Food and Agriculture*. Rome, 10-13 September, 2002. FAO, Rome TC/BRM 03/3 (available at: ftp://ftp.fao.org/es/esn/food/tc_bangkok/tc_brm_03_3en.doc).

FAO. 2003. *Report of the Technical Consultation on Biological Risk Management in Food and Agriculture*. Bangkok, 13-17 January 2003. TC/BRM 03/4. FAO, Rome (available at: ftp://ftp.fao.org/es/esn/food/tc_bangkok/tc_brm_report_en.pdf).

FAO. 2005. *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Risks and Living Modified Organisms*. ISPM Publication No. 11. FAO Rome (available at: ftp://ftp.fao.org/docrep/fao/008/y5874e/y5874e00.pdf).

FAO/WHO. 2004. Emerging risks related to the environment and new technologies. Paper prepared by the FAO/WHO Secretariat for the Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, 12-14 October 2004. GF 02/12 (available at: ftp://ftp.fao.org/docrep/fao/meeting/008/j3255e/j3255e00.pdf).

FAO/WHO. 2006. *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*. FAO Food and Nutrition Paper No. 87. FAO Rome (available at: ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf).

FAO/WHO. 2007. Working Principles for Risk Analysis for Food Safety for Application by Governments. ALINORM 07/30/REP, Appendix IV. Codex Alimentarius Commission (available at: http://www.codexalimentarius.net/web/archives.jsp?lang=en).

FAO/WHO. 2007. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. In *Codex Alimentarius Commission. Procedural Manual*. 16th Edition. Joint FAO/WHO Food Standards Programme (available at: http://www.codexalimentarius.net/web/procedural_manual.jsp).

Hawkes, C. & Ruel, M. 2006. The links between agriculture and health: an intersectoral opportunity to improve the health and livelihoods of the poor. *Bulletin of the World Health Organization*, 84 (12), 2006 (available at: http://www.who.int/bulletin/volumes/84/12/05-025650.pdf).

Jebara, K.B. 2004. Surveillance, detection and response: managing emerging diseases at national and international levels. *Scientific and Technical Review of the World Association for Animal Health*. 23(2): 709-715.

King, L., Marano, N. and Hughes, J. 2004. New partnerships between animal health services and public health agencies. *Scientific and Technical Review of the World Association for Animal Health*. 23(2): 717-726.

Morse, S. 2004. Factors and Determinants of Disease Emergence. *Scientific and Technical Review of the World Association for Animal Health*. 23(2): 443-451

OIE. 2004. *Import Risk Analysis - Guidelines for Risk Analysis. Terrestrial Animal Health Code*. 13th Edition. OIE Paris (available at: http://www.oie.int/eng/normes/Mcode/en_sommaire.htm).

OIE. 2004. *Handbook on Import Risk Analysis for Animals and Animal Products. Introduction and Qualitative Risk Analysis*. Volume 1. OIE Paris (available at: http://www.oie.int/eng/publicat/ouvrages/A_IRAvol1.htm).

Post, D. L. 2006. The precautionary principle and risk assessment in international food safety: How the World Trade Organization influences standards. *Risk Analysis* 26 (5): 1259-1273.