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:

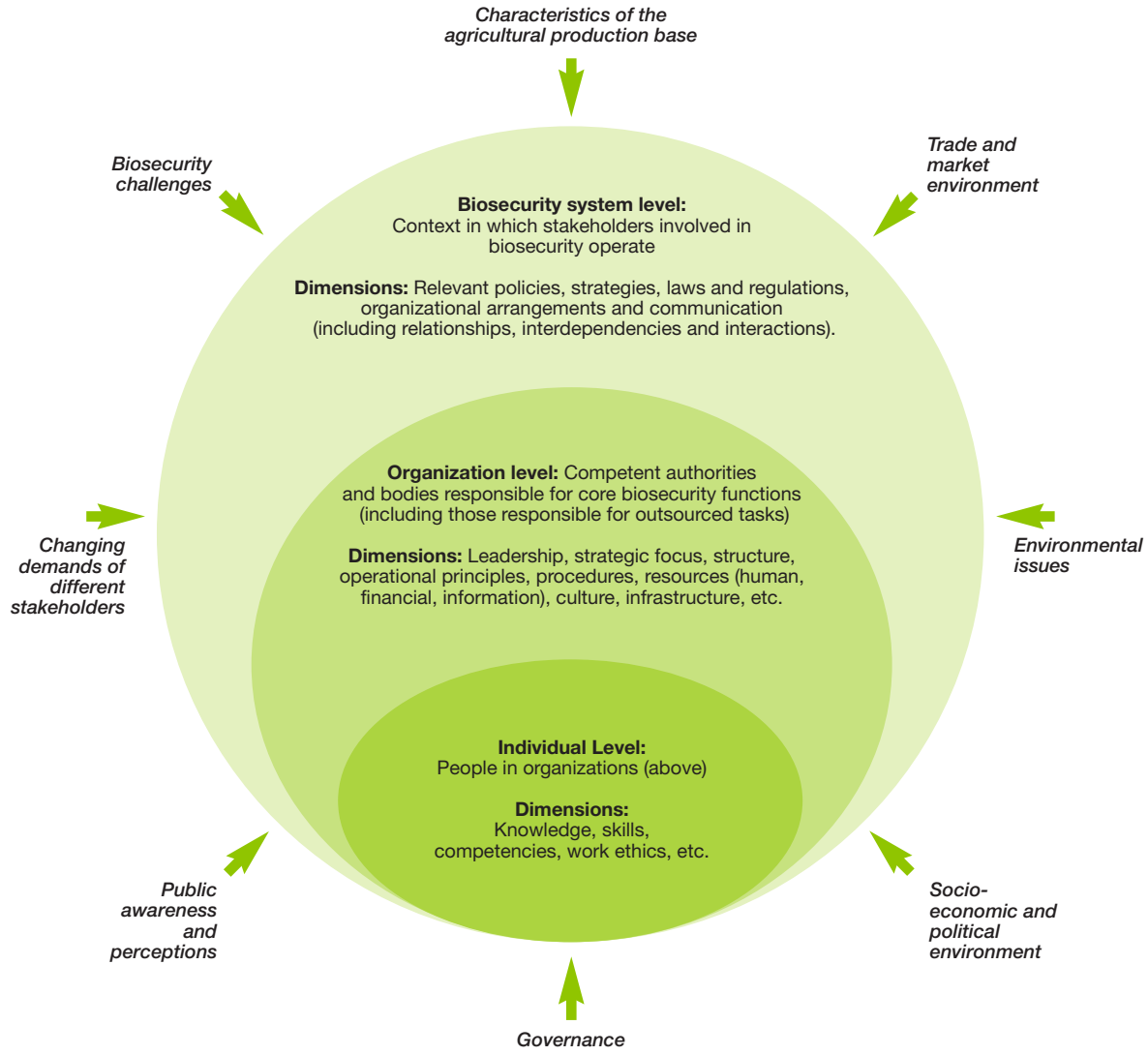
- determine how to improve the safety of food and agricultural products for human consumption;
- identify ways to better protect animal and plant life and health, and the environment;
- clarify the biosecurity roles and responsibilities of different government agencies so as to avoid duplication of effort 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.

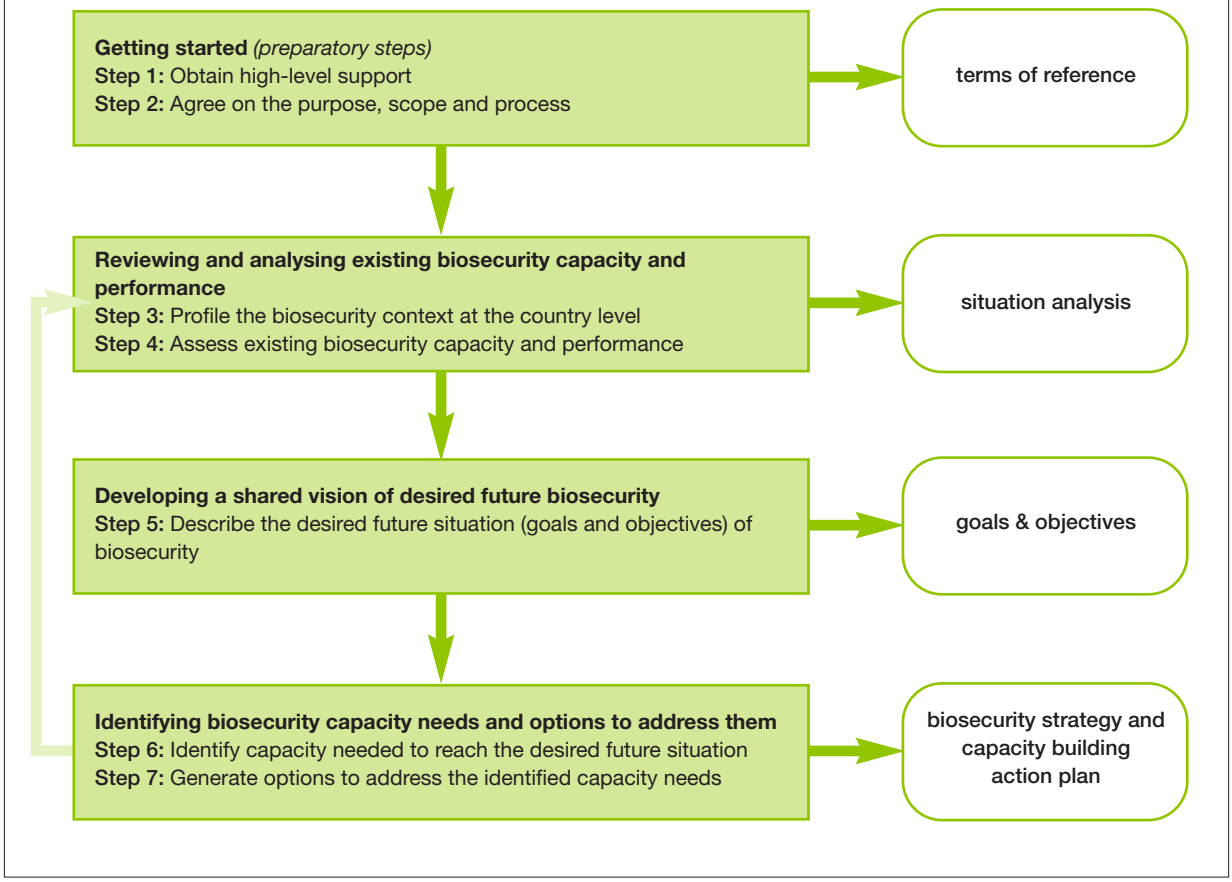
The analytical framework in Table 2.1 provides guidance to assess capacity needs across the entire biosecurity arena. The focus is on dimensions of capacity that cut across the sectors of biosecurity and their respective organizations. This encompasses dimensions of capacity in:

- 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.

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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.

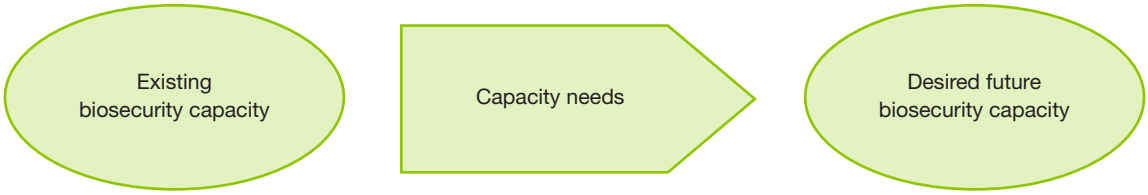
Step 6 is critical to be able to effectively identify the requirements to develop and implement a harmonized and integrated biosecurity approach. It focuses on the identification of capacity needs at the various interfaces between human, animal and plant life and health, and associated environmental 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.