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

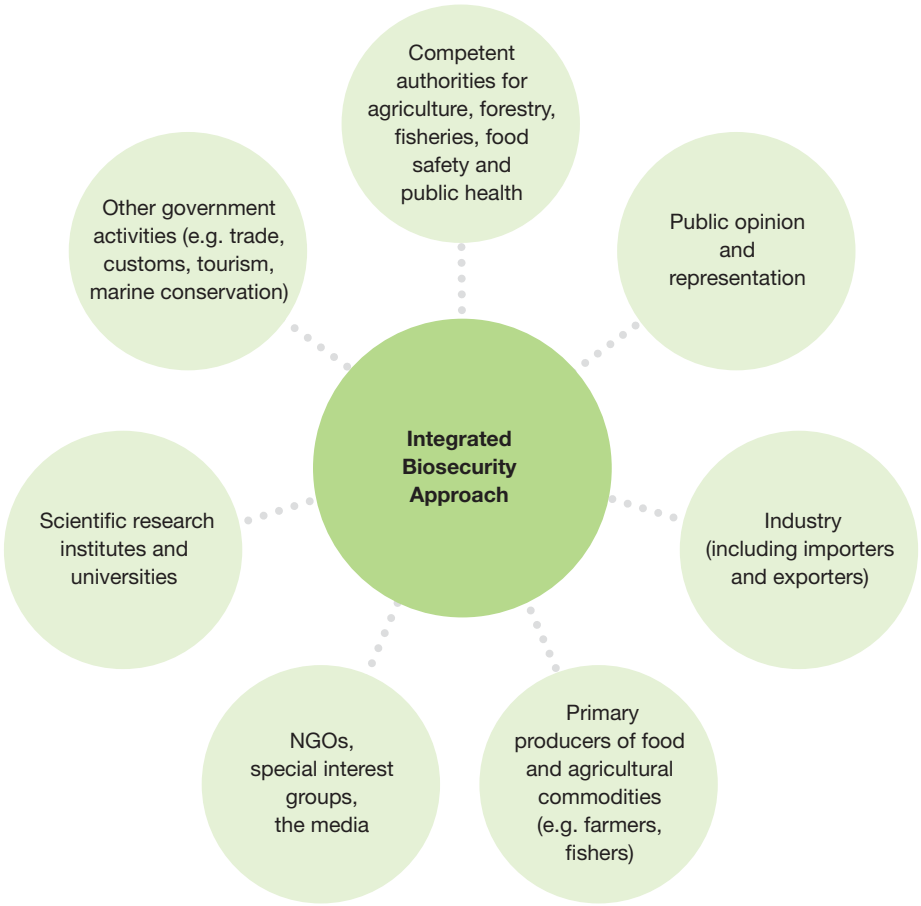
Biosecurity involves many different kinds of stakeholders at the national level. Government agencies have a primary interest but industry, scientific research institutes, specialist interest groups, non-governmental organizations (NGOs) and the general public all have a vital role to play.

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.

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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).

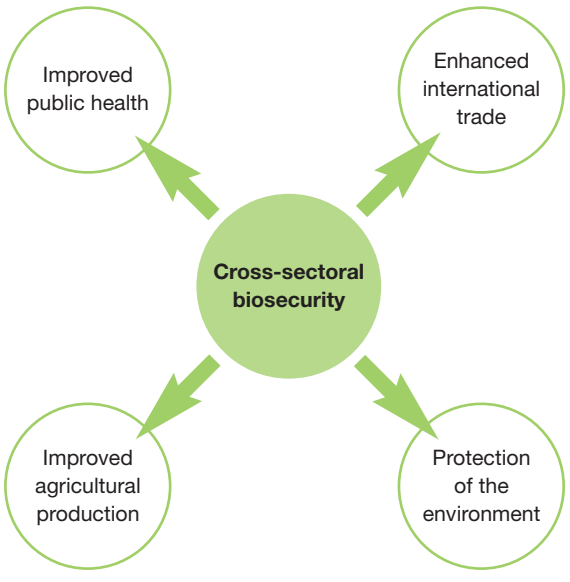
Rationale for a harmonized and integrated approach to biosecurity

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).