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The Biosecurity Approach

A review and evaluation of its application by FAO, internationally and in various countries

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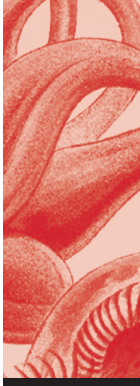

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The Biosecurity Approach

A review and evaluation of its application by FAO, internationally and in various countries

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This paper reviews and evaluates current biosecurity approaches, specifically approaches being applied in various international bodies and individual countries. This paper was drafted by M. Megan Quinlan, James Alden, Ferdinand Habbel and Rebecca Murphy, through Imperial College Consultants Ltd., and reviewed by the IPPC Implementation Facilitation Unit.

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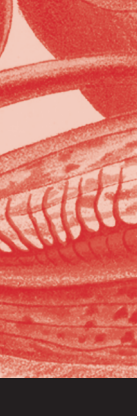


Acronyms

AGP	Plant Production and Protection Division (of FAO)
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BAHA	Belize Agricultural Health Authority
BCA	Biocontrol agent
BTWC	Biological and Toxin Weapons Convention
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CPM	Commission on Phytosanitary Measures (of the IPPC)
CSIRO	Commonwealth Scientific and Industrial Research Organisation (of Australia)
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMPRES	Emergency Prevention System
EMPRES AH	Emergency Prevention System for Animal Health
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GHSA	Global Health Security Agenda, a partnership launched by WHO, FAO and OIE
HACCP	Hazard analysis and critical control point
IAEA	International Atomic Energy Agency
IAS	Invasive alien species
ICPM	Interim Commission on Phytosanitary Measures (predecessor of the CPM)
IHR	International Health Regulations (WHO)
IICA	Inter-American Institute for Cooperation on Agriculture
INFOSAN	International Food Safety Authorities Network (under the WHO)
IPPC	International Plant Protection Convention
IRSS	Implementation Review and Support System (of the IPPC)
ISPM	International Standards for Phytosanitary Measures
MOAF	Ministry of Agriculture and Forests (of Bhutan)
MERCOSUR	Grupo Mercado Común Del Sur
NBSAP	National Biodiversity Strategy and Action Plan
NGO	Non-governmental organization
NPPO	National plant protection organization
OHCEA	One Health Central and Eastern Africa
OIE	World Organisation for Animal Health
PHEIC	Public Health Emergency of International Concern (of WHO)
PVS	Performance, vision and strategy tool prepared by IICA (various versions referenced)
QCQD	Quality Control and Quarantine Division (predecessor of BAFRA)
QCRS	Quality Control and Regulatory Services (now BAFRA)
RPPO	Regional plant protection organization
SARS	Severe acute respiratory syndrome
SENASA	Servicio Nacional de Sanidad y Calidad Agroalimentaria (of Argentina)

SPS	Sanitary and phytosanitary, such as the system or theme related to the SPS Agreement
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures (of WTO)
SPS Commission	Intersectoral Commission of Sanitary and Phytosanitary Measures
STDF	Standards and Trade Development Facility
TCP	Technical Cooperation Programme (of FAO)
UN	United Nations
UNEP	United Nations Environment Programme
USAID	United States Agency for International Development
VKM	Norwegian Scientific Committee for Food Safety
WCS	Wildlife Conservation Society
WHO	World Health Organization
WTO	World Trade Organization

Notes on style:

The usage of the term biosecurity varies widely across countries and often is difficult to translate. The 2002 FAO Expert Consultation on Biosecurity in Food and Agriculture agreed that, when written, *Biosecurity* should be italicized and capitalized for use in all language, in order to avoid confusion, delimit its scope and avoid translation difficulties. However, for the purposes of this report and in line with International Plant Protection Convention (IPPC) general style, we have used simply: biosecurity.

Similarly, to simply the report, each country mentioned is by short country name (aligned with FAO's use, http://www.fao.org/countryprofiles/iso3list/en/) rather than the official name. Citations for various legal and regulatory texts are also by the short country name and number and/or year of the act or regulation. Other details, e.g. Parliament or Council of, are included only if the cited document is clear on this point. Because these are not full legal citations, they appear by date under an alphabetical country list at the end of references, rather than with the others. Documents prepared by governments that are cited, but which are not laws or regulations, appear in the references section alphabetically by author (this may be a public unit, department, ministry or national government)

Preface

For more than a decade, the Food and Agriculture Organization of the United Nations (FAO) has been a leader in developing the biosecurity approach. This study of current practice has found biosecurity to encompass a range of previously distinct fields of expertise – in plant, animal and human health; trade and economic development; biodiversity conservation and environment; security considerations covering terrorism; food security; and national patrimony among other elements – in an interlinking and interdisciplinary approach that remains vague albeit of increasing importance.

Trends in international development and government initiatives often follow trigger events, and biosecurity is no different. In the 1980s food security was an important organizing principle for development initiatives following some major food crises in the 1970s. Over time, this concept became more complex and nuanced, to encompass livelihood protection, rural development, nutrition, household-level access and so forth. In the 1990s, the progression of the negotiations on tariff and nontariff barriers (under the General Agreement on Tariffs and Trade (GATT)) culminated in the World Trade Organization (WTO) being founded and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) development and enactment. The "Earth Summit", or United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, and international attention to deforestation and habitat destruction along with other environmental concerns led to the Convention on Biological Diversity (CBD) entering into force in 1993. The subsequent adoption of its Cartagena Protocol on Biosafety (in 2000) showed that issues relating to genetically modified organisms came to be clustered as distinct rather than integrated into existing risk assessment and regulatory frameworks. Also in 2000, the declaration of the United Nations Millennium Development Goals expressed a combined commitment for addressing global challenges remaining in the twenty-first century. This is now progressing as a post-2015 dialogue facilitated by the United Nations Development Group, including FAO. These global objectives were further stated in the Sustainable Development Goals agreed at the "Rio+20" United Nations Conference on Sustainable Development in 2012. For the past two decades, a resurgence of foodborne illness and emerging disease discovery, local impacts and even pandemics linked with zoonosis, such as the severe acute respiratory syndrome (SARS), have emphasized the need for coordinated and efficient surveillance and response systems in animal and human health.

Biosecurity as a concept has also been affected by all of these world events and perceptions of the same. Furthermore, the concept has evolved with its application. In this instance, however, the use of the term seems to have diverged into parallel concepts rather than more nuanced versions of the original one. Owing to these developments, it was time to reconsider FAO's position and guidance on biosecurity.

This desk study was commissioned to support an internal discussion and make external interested parties aware of the changes in the concept over the past decade. It shows the main drivers of uptake and change in the application of biosecurity. Some representative case studies contribute insights on what has gone well and what remains challenging in the application of the concept at a national level. A series of questions to consider and recommendations are offered as a platform for FAO to determine the best approach to biosecurity, and its terminology, for the coming decade.

1 Biosecurity Definitions and Principles

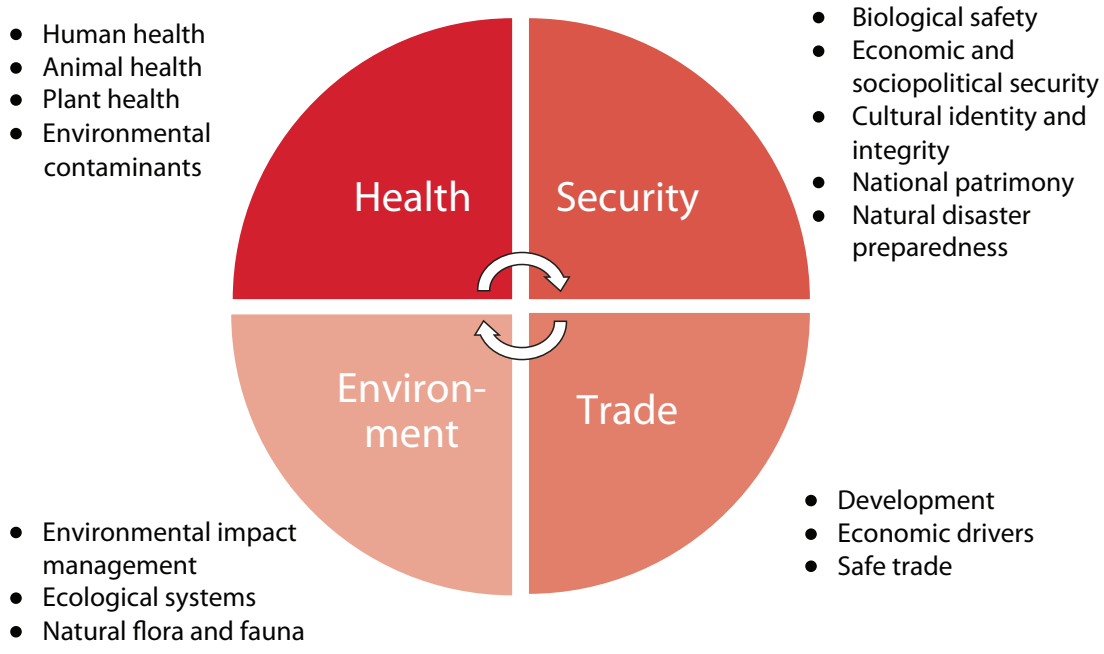
This study begins with a consideration of definitions and principles because of the great variability in meaning when the word biosecurity is chosen. Examples of how the term biosecurity is used in various national instruments, primarily laws, appear in this section and in the Annex 1 summary.

Some of these variations among the approaches and the use of the term – and the well-known difficulty in its translation – have been discussed in reviews such as WHO and CBD (2015), Quinlan et al. (2015), Secretariat of the Biological Weapons Convention (2011), Koblentz (2010), Normann (2010), Rappert (2009), Waage and Mumford (2008), Zmorzynska and Hunger (2008), Defra (2005), Cock (2003), O'Toole and Inglesby (2003), Meyerson and Reaser (2002) and numerous others. Therefore, this is not an exhaustive review, but an attempt to represent the primary principles included in the biosecurity approach.

1.1 The FAO vision of biosecurity

The innovation in approach arose in the context of the Food and Agriculture Organization of the United Nations (FAO) experience in various factors that might be grouped under biosecurity such as: codes of conduct and guidance on intentional release of beneficial organisms (ISPM 3. *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) and pollinators; appropriate use, storage and disposal of pesticides; disease notification through the EMPRES (Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases – shifting to Emergency Prevention System for Animal Health (EMPRES AH); FAO, 2013a); early and ongoing initiatives in agricultural biotechnology (FAO, 2009a); forestry and ecosystem services support; and, more recently, collaboration in initiatives to prevent and

Figure 1.1. Schematic of interlinking components of biosecurity from the various perspectives of health, environment, trade and security, with various subcomponents.



reduce the likelihood of zoonoses at the level of a national production sector or of a farm and aquaculture production unit. One of the key publications from FAO on biosecurity is the toolkit (FAO, 2007a), which supports capacity development and describes the continuum from completely separate sectoral approaches to a fully integrated one. The FAO biosecurity toolkit considers biosecurity as the sanitary and phytosanitary (SPS) type system. This was followed by an analytical tool aimed specifically at gap analysis in biosecurity legislation (FAO, 2007b).

This innovative perspective aiming for a more integrated approach must have also been encouraged by the fact that two of these standard setting bodies are hosted at FAO in Rome: the International Plant Protection Convention (IPPC) and the Codex Alimentarius Commission (CAC). This integration in line with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) development and enactment (WTO, 1994) became one of the drivers for integrated policy and, in cases, institutions as well as some regulatory changes, as documented below. The holistic approach is illustrated in Figure 1.1 as maintaining sectoral capacity, legislation and identify, while coordinating across themes.

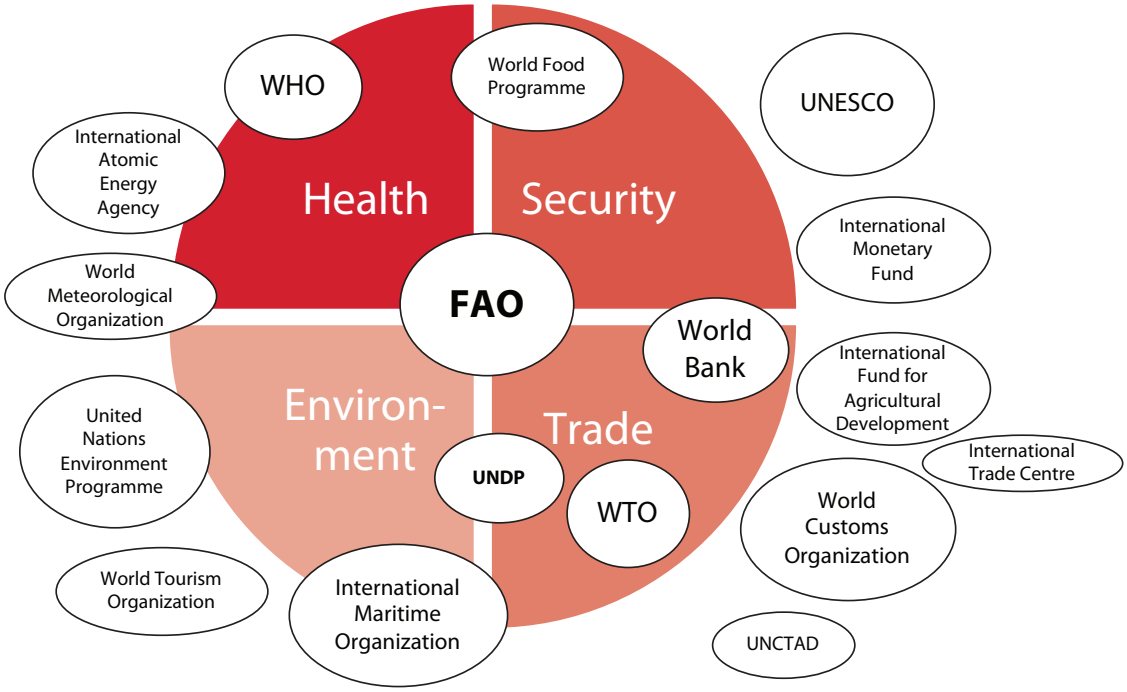
With this context, FAO was confident to lead a new trend in institutional and policy integration towards greater efficiencies.

Other initiatives were evolving even at the time that FAO began developing a biosecurity approach, however; these initiatives used similar terminology but different foundational concepts. In fact, many of the United Nations (UN) agencies have some role to play in ensuring biosecurity, in its broadest scope (see Figure 1.2). Over time, these other initiatives also influenced the concept of biosecurity within FAO, probably because of FAO's strong role in collaboration with and facilitation of multiple stakeholders.

The original biosecurity concept at FAO is captured well in the definition used in numerous publications of 2000–2014 (one example from the Fisheries and Aquaculture Department is FAO, 2014a; phrase in square brackets below added from FAO, 2005):

> Biosecurity is a strategic and integrated approach that encompasses the policy and regu-

Figure 1.2. Schematic of international organizations and programmes working on biosecurity-related issues.
FAO, Food and Agriculture Organization of the United Nations; UNCTAD, United Nations Conference on Trade and Development; UNDP, United Nations Development Programme; UNEP, United Nations Environment Programme; UNESCO, United Nations Educational, Scientific and Cultural Organization; WHO, World Health Organization; WTO, World Trade Organization.



> latory frameworks [including instruments and activities] that analyse and manage risks in the sectors of: food safety; animal life and health; plant life and health, including associated environmental risks.

The scope of biosecurity was also defined in FAO publications (e.g. FAO, 2007b), carrying on with the definition statement:

> These sectors include: food production in relation to food safety; the introduction of plant pests, animal pests and diseases and zoonoses; the introduction and release of genetically modified organisms and their products; and the introduction and safe management of invasive alien species and genotypes.
>
> The objective of Biosecurity is to identify, assess and respond appropriately to all pests and diseases posing a significant threat to agriculture, forestry, horticulture, fisheries, native biodiversity and human health. Appropriate responses include eradication, containment and ongoing control.

Other FAO publications included the statement that: "Biosecurity is defined as a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity" (e.g. FAO, 2005). These statements of definition include principles important to FAO and its hosted treaties, codes and initiatives. Aspects of the concept are reflected in Table 1.1.

The underlying principles (italicized for emphasis) expressed in Table 1.1 are *safety and health* for a biological system or specific human population; *integration* and synergy across disciplines that are

Table 1.1. Aspects of FAO statements of definition and scope of biosecurity

Principles and scope	Technical or sectoral themes	Management measures
Holistic	Sustainable agriculture	Policies, regulations and other instruments
Strategic	Food safety and effects on humans	Hazard identification (*implied*)
Integrated	Plant life and health	Risk assessment (*implied*)
Risk-based	Animal life and health	Risk analysis and management
Approach to policy and regulatory frameworks (instruments and activities)	Environmental risks associated with the above themes; environmental protection	Steps for safe introductions (of genetically modified organisms, exotic agents, potentially invasive species, etc.) – not elaborated on but could include disease-free stock, analysis of non-target effects, or review of novel traits and potential invasiveness, period of quarantine, etc.
Covering both managed and semi- or unmanaged flora and fauna	Food production including food processing	
Covering both land and aquatic systems	Genetically modified organisms	
Covering both human and other life forms	Zoonoses	Monitoring for detection and delimitation of incursion (*implied*)
Concept of significant threats (distinguishing levels of threat)	Genetics (including identification of distinct genotypes)	Containment and ongoing control (e.g. suppression)
Management proportional to risks (as assessed)	Possibly pesticides and other agricultural inputs sectors	Eradication
Not explicit whether it covers chemical, physical or other changes as threats (i.e. associated environmental risks)	Biodiversity: habitat disruption, ecosystem services, conservation and pollution themes	No explicit reference to reduction of consequences through adaptation to changes in biosecurity (e.g. insurance)

still supported by in-depth expertise; strategic *prioritization* based on significance of threat, availability of measures, and opportunities for success; and *sustainability* of systems, measures and resources. The principle of prioritization for efficient use of resources, noted above, shows the influence of the adoption of the SPS Agreement and of increasing global use of environmental impact assessments over the same time period.

FAO added ideas into the biosecurity concept owing to its unique perspective. FAO works through its Plant Production and Protection Division (AGP) to provide guidance, technical assistance and projects on pest control options, including pesticides and integrated pest management (IPM). FAO AGP supports the implementation of the FAO–WHO *International Code of Conduct on Pesticide Management* (FAO and WHO, 2014) and management of obsolete pesticides. An interdepartmental working group has been supporting development of supporting programmes and materials for organic agriculture. This includes policy and legal documents as well as field experiences. FAO publications on organic agriculture, numbering well over 200, include work on livestock modelling (FAO, 2013b) and certification of fisheries for sustainability (FAO, 2001) as well as numerous publications by the CAC. Beyond these initiatives in sustainable agriculture is the work in plant health undertaken through the IPPC, recognized by the SPS Agreement along with guidance on the legal context (FAO, 2012a).

It is clear that much thought and discussion went into the original, corporate (entire institution) FAO statements of definition, which show the wide range of topics covered by the concept of biosecurity.

While these principles remain the same, the use of the concept has evolved considerably over the past years. The changes will be discussed further in section 2, Drivers and trends.

1.2 Integration of sanitary and phytosanitary measures

The concept of an integrated system across human health aspects of food safety, animal health and plant health is generally known as an SPS system. The SPS Agreement named three rule-making treaties as the reference bodies for implementing the agreement: the IPPC, the World Organisation for Animal Health (OIE) and the CAC. Descriptions of this system, for example by Day (2013), sometimes use the term biosecurity to convey a more integrated and coordinated approach across those sectors than was achieved before the SPS Agreement was conceived and adopted.

The Standards and Trade Development Facility (STDF) related the FAO toolkit (FAO, 2007a) to other capacity evaluation tools for these topic areas (STDF, 2011). The Inter-American Institute for Cooperation on Agriculture (IICA) created a tool called "Performance, vision and strategy" (PVS) (IICA, 2008a) on SPS overall, designed to cover key institutional aspects of delivery of an SPS system. This included stakeholder interactions (both within the government and with the private sector), market access and resources (human and financial) (IICA, 2010; OECD, 2010). IICA adapted its tool in the context of animal health (IICA, 2008b; both terrestrial and aquatic versions now updated as OIE, 2013a and 2013b), but later created versions for plant health (IICA, 2009) and food safety (IICA and PAHO, 2008). The initial attempt to translate the plant health PVS directly from an animal health focus to plant health, for example, proved challenging. Crossing sectors required practically starting again, because direct translation between these fields results in awkward frameworks not entirely matching the underlying concepts in either sector (lead author's personal observation). Attempts to combine evaluation of all sectors can lead to compromised concepts, to achieve a "one size fits all". The PVS tools and other tools for capacity evaluation, especially of the overarching SPS system (e.g. IICA, 2008a; NRI, 2011) help to define what integration of these previously separate SPS sectors would look like and where synergies might lie. The overview of SPS, or from a biosecurity perspective, can provide an important complement to the sectoral evaluation process, but cannot replace the more in-depth evaluation by sector.

Other SPS decision-support tools (e.g. from the STDF *Beyond Compliance* project, Quinlan et al.,

2016a) are risk-based with an acknowledgement that, pragmatically, risks will exist and should be analysed and managed to a specified threshold or acceptable level, with the most resources going to the more significant threats. That choice of what should be managed, or managed first, reflects the holistic approach of considering what resources and approaches are available, what is at stake and so forth. Indeed, the need for greater efficiencies, institutional autonomy and availability of resources for biosecurity emergencies and priorities was one the drivers for the SPS-based biosecurity approach.

There was a period of transition to a trade-based vision of food availability linked with economic development, and a clear agenda of ensuring safe trade in the decade following the signing of the SPS Agreement. The early efforts of FAO to create and follow a biosecurity approach were therefore framed in that World Trade Organization (WTO) SPS rubric of food safety, animal health and plant health. Despite this linkage, the IPPC, one of the three rule-making organizations cited in the SPS Agreement, does not define the term biosecurity in its glossary (ISPM 5) and normally the term biosecurity is not used in IPPC text. Exceptions were found in IPPC statements when interacting with other treaties or organizations or when referring to regional or national initiatives or laws already using that term. The IPPC website page that explains the importance of the IPPC[1] also refers to biosecurity in relation to the FAO Strategic Objectives. (For further consideration of how the concept relates to the FAO Strategic Objectives, see Table 1.2.)

The CAC refers to biosecurity in its work overlapping with World Health Organization (WHO) in relation to food safety. A recent definition from this sector is (INFOSAN, 2010):

> Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks for the environment. It is based on recognition of the critical linkages between sectors and the potential for hazards to move within and between sectors, with system-wide consequences.

This aligns closely with the FAO original definition, with an added comment on the relationship between the SPS topics of human, animal and plant health. Codex Alimentarius is more closely linked, however, with the OIE in its joint work, rather than with the topics considered under the IPPC. OIE is the SPS body that has most embraced the use of the term biosecurity, as discussed further in animal health below. (It is interesting to note that OIE has taken the earlier PVS (IICA, 2008b) and developed it as a far more in-depth sectoral capacity tool for veterinary services and aquatic animal health (OIE, 2013a, 2013b). These various tools play different purposes and the desired outcome of any evaluation should be clear before selecting the best tool.)

Overall, the FAO definition of biosecurity was firmly planted in the SPS rubric. While acknowledging the environmental aspects of human, animal and plant health, the primary focus was clearly in the thematic areas covered by the SPS Agreement, with an implied inclusion of biotechnology. More recently, the scope of these SPS rule-making bodies themselves has expanded or been clarified. This corresponds with other aspects of the biosecurity approach coming up in FAO publications and what seems to be an expanded use of the term

1.3 Plant health and biosecurity

The IPPC is nearing its sixty-fifth year since enactment. It originated in the context of protecting agricultural resources from the transboundary introduction and spread of serious pests. As shown in Table 1.2, the IPPC's mandate and strategic objectives match closely with the FAO Strategic Objectives, in particular number 4. *Enable more inclusive and efficient agricultural and food systems at local, national and international levels*. Although in neither case are the strategic objectives stated in terms of the FAO biosecurity approach, increasing efficiency is one of the main drivers for taking a biosecurity approach, as discussed in section 2: Drivers and trends. If FAO remains committed to supporting a biosecurity approach, it may be beneficial to show

1/ This reference to biosecurity by the IPPC is located at https://www.ippc.int/en/biosecurity-in-food-and-agriculture/

Table 1.2. FAO Strategic Objectives, their challenges and the possible relationship with the IPPC Strategic Objectives

FAO Strategic Objectives	Identified global challenges (many overlap the objectives)	IPPC Strategic Objectives relating to FAO Strategic Objectives and challenges
1. Contribute to the eradication of hunger, food insecurity and malnutrition	• Food demand increasing • Type of food wanted is changing (meat, vegetable oil, sugar)	A. Protect sustainable agriculture and enhance global food security through the prevention of pest spread
2. Increase and improve provision of goods and services from agriculture, forestry and fisheries in a sustainable manner	• Competition for land use • Diminishing quality and quantity of natural resources • Loss of ecosystem services • Biofuels may be needed for energy security	A. and B. Protect the environment, forests and biodiversity from plant pests
3. Reduce rural poverty	• Higher costs for food • More food price volatility • Migration of work force to urban areas • Less robust employment opportunities and skewed gender roles	A. and C. Facilitate economic and trade development through the promotion of harmonized scientifically based phytosanitary measures
4. Enable more inclusive and efficient agricultural and food systems at local, national and international levels	• Increased industrialization of the agriculture sector • More options and technology in hands of private, commercial sector • Globalization of food production • Changes in trade patterns • Need for stronger central governance to achieve development	C. and D. Develop phytosanitary capacity for members to accomplish A., B. and C.
5. Increase the resilience of livelihoods to threats and crises	• Climate change affecting production • Increased vulnerability to man-made and natural disasters • Trade policies based on other objectives	A. and B.

that link more explicitly in the language of the Strategic Objectives.

Plant health is delivered through a national plant protection organization (NPPO), each national government's designated authority, with regional coordination and support from the nine regional plant protection organizations (RPPOs) recognized by the IPPC. This international coordination is the key mechanism for reducing additional damage to crops and the use of pesticides and other pest control measures. There are several International Standards for Phytosanitary Measures (ISPMs) that consider aspects of pest surveillance and border activities, which many national governments refer to as biosecurity measures. (Such measures would be within the definition of *phytosanitary measures* for that Convention.)

The primary role of the IPPC for biosecurity is to reduce the introduction and spread of pests of agriculture. The principles underlying the IPPC (among those laid out in the 2007 revision of ISPM 2 (*Framework for pest risk analysis*)) include those principles of FAO's biosecurity approach (elucidated in section 1.1), in terms of safety and health with the principle of *sovereignty* and *technical justification* and in terms of sustainability in the form of *harmoniza-*

tion, *cooperation*, use of *equivalence of phytosanitary measures* and *minimal impact* in approaches, techniques and standards so as to achieve greater efficiency in resource use and avoid hidden trade barriers. The idea of prioritization emerges through the principles of *transparency*, *necessity* and *managed risk*. The concept of integration is promoted by the IPPC more as an approach to other sectors, working from within plant health, than as the primary mandate of the Convention.

For example, the role of the IPPC in preventing introduction and spread of plants that are pests (weeds) – an issue crossing over different disciplines – has increased over the years. While this was always within the Convention's mandate, the stand was strengthened with additional conferences, papers and guidance to NPPOs and RPPOs after consultations with the Convention on Biological Diversity (CBD) (e.g. IPPC Secretariat, 2005). The Recommendation ICPM[2] -7/2005 (IPPC, 2005) clarified the role of the IPPC and its national counterparts. In 2004, supplemental guidance to ISPM 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*), subsequently in the 2013 version incorporated into the text and as an annex to ISPM 11 (*Pest risk analysis for quarantine pests*) explained how the pest risk analysis (PRA) standards of the time applied to weeds. Since then, another significant enhancement in terms of environmental objectives occurred with ISPM 36 (*Integrated measures for plants for planting*), which recognizes the higher risk of international trade of plants destined for planting in the importing country – both from possible cryptic infestation or latent disease and from the possibility of the invasiveness of the plant itself.

Examples of environmental objectives of the IPPC include management of pest risks affecting forestry and from aquatic plants that are invasive, and coordination to stop entry of invasive species that are plants through parallel trade channels. The *Aquatic plants: their uses and risks – a review of the global status of aquatic plants* study under the Implementation Review and Support System (IRSS) (IPPC, 2013) recognizes a significant role for the NPPO of an affected country in delimiting and managing invasions from aquatic weeds. They also state that:

> National plant protection organizations should regulate those species that are not already in their area of responsibility, if possible to prevent their introduction, based on an appropriate risk analysis.

While the mandate for regulating plants that can be pests (weeds) has been clearly established on land, the aquatic weeds are often not covered by NPPOs, although within their authority. This is due to lack of resources and expertise in most instances. The Commission on Phytosanitary Measures (CPM) encouraged NPPOs to establish mechanisms for identifying e-commerce traders and their products that are of concern in terms of pest risk, so as to improve compliance (IPPC, 2014).

Therefore, while the NPPOs operate primarily within national agriculture institutional frameworks, implementation of the IPPC relies on coordination across ministries to bring in environmental concerns, criteria and management. The guide on establishing an NPPO (IPPC, 2015) discusses all of the national government authorities that are potential stakeholders for fulfilling the IPPC mission. Specific approaches to this coordination are considered in the case studies in section 4.

1.4 Animal health, zoonotic diseases and biosecurity

For about the same period that FAO has used the term for animal health and more broadly, biosecurity has also been used in animal health more specifically to mean activities taken to prevent or manage diseases. This has been employed for international, multilateral and bilateral initiatives (e.g. FAO, 2010a; Royal Norwegian Embassy in Hanoi, 2014) or standards through OIE and regional (FAO, 2008a) or national programmes (Håstein et al., 2008; FAO, 2014b). In some instances, it has been employed for all of these levels in the same publication (FAO, 2011a).

2/ The Interim Commission on Phytosanitary Measures (ICPM) was the membership body preceding adoption of the latest revision of the Convention (IPPC, 1997), which then became the Commission on Phytosanitary Measures (CPM).

There are numerous legislative or regulatory instruments aimed at control of specific, named animal diseases (e.g. FAO, 2010b) related to this use of the concept of biosecurity, as discussed further in section 3, Legal frameworks. Other resources are organized by sector (e.g. poultry, beef cattle, dairy farms (CFIA, 2012, 2013), pigs, goats, aquaculture (Håstein et al., 2008), shrimp production) or situation (e.g. open markets, slaughter houses, animal transport) owing to the specificity of appropriate biosecurity actions. The shift towards choosing and talking about a biosecurity approach seems rooted in the recognition of the need for greater coordination, efficiency and effectiveness in addressing the spread of disease. For management of specific animal diseases, it has been seen as the measures required to prevent spread of an infection. As one manual puts it:

> This [after introduction of an agent] is the period of undetected presence and potentially 'silent' spread. … Surveillance is the tool used to minimize this period, and biosecurity is the method of limiting spread. (FAO, 2011a)

The social and economic consequences of such introductions (e.g. foot-and-mouth disease) have been devastating to developing and developed nations alike, often leading to trade restrictions, costly vaccination programmes or other indirect costs in addition to the direct impacts on food security and poverty (Knight-Jones and Rushton, 2013; UNCTAD, 2013).

Whereas biosecurity is used interchangeably in this sector with what others might call simply animal health or sanitary measures, at times it has represented this larger overview of providing a sense of biological security through all of the other activities (OIE, 2003):

> The main points to be addressed in order to reassure the biosecurity of the international community are compliance by Member Countries with OIE standards and guidelines, training where necessary for those involved, and the availability of appropriate material and human resources, notably for developing countries.

This raises capacity and human resources as an important component of biosecurity, a thread that runs throughout current thinking on biosecurity.

An important permutation of this concept has been using the same terms at very different spatial scales. Other FAO publications refer to measures applied at the level of a production unit (FAO, 2011b):

> … all the cumulative measures that can or should be taken to keep disease (viruses, bacteria, fungi, protozoa, parasites) from a farm and to prevent the transmission of disease (by humans, insects, rodents and wild birds/animals) within an infected farm to neighbouring farms.

This has also been the primary message from FAO in regard to aquaculture and fisheries biosecurity (FAO, 2013c). Because activities directly affecting risk are often on the production-unit level, it is a natural progression of thought, but it has caused a divergence in word usage across sectors.

In the past decade, a practically revolutionizing global initiative fostered by OIE (2013c), FAO, WHO and other influential bodies has evolved in response to concerns over emerging disease and zoonosis. This initiative has come to be called One Health. Bresalier et al. (2015) and CDC (2013) give a history of this movement, which is still evolving. Concern over emerging disease as well as ongoing challenges to environmental health, such as pesticide contamination, underpins One Health, as discussed further in section 2, Drivers and trends. Among the various definitions of this concept, using a term originated by the Wildlife Conservation Society (WCS) (WCS, 2004) but which is not restricted in use (holding no trade mark or copyright), one definition may focus on the range of scale and objectives:

> One Health is the integrative effort of multiple disciplines working locally, nationally, and globally to attain optimal health for people, animals, and the environment. (AVMA, 2008)

Other definitions emphasize the range of disciplines required for the approach:

> … a broad and holistic paradigm that addresses and frames the complex interactions between human health, livestock, pet and wildlife health, environmental health, ecosystems services, climate, water, sanitation, food systems, energy, human development, equity and justice. (Global Risk Forum Davos, 2015)

Much of what is included in the One Health concept is biosecurity as defined by FAO, but what

has traditionally been known as plant health is not generally covered by this initiative other than as part of ecosystems and environment (http://www.onehealthinitiative.com/about.php). The social factors included in this definition mirror the increasing recognition of human cultural and sociopolitical aspects in biosecurity, particularly in the context of biodiversity. If FAO continues with a biosecurity approach, that approach's relationship to One Health should be clarified.

1.5 Food safety and biosecurity

As already noted, the primary rule-setting body for food safety is hosted by FAO. The CAC (CAC, 1992) was established as a joint programme in food standards by FAO and WHO. More recently, OIE has added food safety as a mandate in regard to handling of animal products and potential zoonosis (OIE, 2015). The new perspective of a biosecurity approach in relation to food safety includes a focus on monitoring and management of risks along the entire food supply chain and more integrated surveillance. This embodies the holistic and comprehensive perspectives of a biosecurity approach. The increasing vigilance for mycotoxins (CIRAD, 2011), including a Global Harmonization Initiative Working Group on Mycotoxins, shows another aspect of broadening monitoring, which is fairly recent. Other non-living contaminants could be classed under biosecurity, if the definition is revised to go beyond living biological hazards, but this should be done intentionally. At this time, it is not clear if the FAO approach to biosecurity includes all environmental threats to health or is primarily aimed at biological threats.

There are similar developments in seafood and aquaculture safety and quality (FAO, 2004a, 2014a). Emerging diseases and the impacts of climate change add to the pressures on this sector to maintain production and profit while meeting consumer demands of safety, quality and sustainability. The synergy of a biosecurity approach is found in using concepts and tools at various spatial and economic levels, such as the application of hazard analysis critical control point (HACCP) at a sectoral level following an entire production–processing–transport chain, as it has been applied in an individual processing plant or at the farm level (FAO, 2014a).

1.6 Biodiversity and biosecurity

Biosecurity has been used to describe the process of protecting the natural resources and maintaining the pest status (absence of or containment of regulated pests), which then contributes to greater opportunity for domestic production and exports but also reduces the need for pesticides and other management measures (Day, 2013). Flood and Day (2016) elaborate this idea further in a discussion of global commodity networks and the need for global biosecurity plans for the commodity crops that are shipped as raw materials in huge volumes, versus plans at a national level only. The potential devastation from cross-continental introductions of commodity pests or diseases for perennial crops such as rubber, cocoa or nuts illustrates a linkage between both natural and agricultural biodiversity (Quinlan et al., 2006). A successful approach to accessing local-level discovery of plant pests with international state of the art diagnosis and identification has been demonstrated through a global plant health network[3] (Bentley et al., 2003; Boa, 2009). Bresalier et al. (2015) tie this network model and capacity back to One Health and other integrative approaches.

Another area of biosecurity linked with biodiversity is the prevention of entry of poisonous spiders, slugs and snails, snakes or other organisms, which may not be invasive but can cause human discomfort or harm. The gaps in existing mandates and frameworks were identified early on in the scientific discussions around invasive species (CBD Secretariat, 2001).

As noted in the Preface, world events – sometimes literally events such as conferences or meetings – can trigger changes in governance or initia-

3/ The programme is now called Plantwise, described at https://www.plantwise.org/

Box 1.1 How biosecurity and biological control collide

Classical biological control of non-native pests, through introduction of natural enemies as biocontrol agents (BCAs), usually collected from the pest's area of origin, can sustainably reduce target pest populations and so reduce their impacts on agriculture and indigenous biodiversity. Yet BCAs are naturally disseminating non-native species themselves. When the target species are weeds, BCAs cause damage to plants (as intended), and this may clash with the wording of plant protection legislation. Biosecurity frameworks have struggled to accommodate this perceived paradox. Nevertheless, classical biological control can be a robust, environmentally benign approach to introduced pest problems that have evaded early detection and eradication, and an important tool for comprehensive management to underpin biosecurity.

Consideration of potential impact on indigenous biodiversity is a key factor (Hajek et al., 2016). The CBD's precautionary approach was implicated in a steep fall in new BCA introductions as governments became increasingly risk-averse* and regulatory requirements more onerous; see Sheppard et al. (2003) and Cock et al. (2016). Introducing BCAs into complex natural ecosystems on top of increased environmental awareness fuels demand and research for improved risk analysis** (e.g. Sheppard et al., 2003; Simberloff, 2012; Hajek et al., 2016). Detailed studies have shown that risks are more academic than actual (Lynch and Thomas, 2000; Kenis et al., 2009; Suckling and Sforza, 2014). Post-introduction impact assessment is becoming more common, not least because funders are increasingly accountable for results.

Setbacks and delays in using BCAs continue to be experienced, but there are indications that give some cause for optimism. Some regulatory deadlocks are being lifted: in South Africa interinstitutional collaboration reinvigorated a peer-review process for assessing applications for new weed BCAs (Moran et al., 2013). Additional countries are navigating the relevant regulatory frameworks: introduction of a BCA for Japanese knotweed in the United Kingdom was the first such introduction for a weed in Europe (Shaw et al., 2011); Ethiopia has also introduced its first weed BCA (Mersie and Muniappan, 2014). Regional or global programmes can facilitate a rapid response to minimize impacts of major invasive alien species, most recently papaya mealybug (e.g. Myrick et al., 2014). International cooperation is allowing technology developed for cassava mealybug in Africa to be transferred to Southeast Asia (Wyckhuys et al., 2014). Several countries in Asia and the Pacific have introduced a pathogen against mikania, with impact already reported from Papua New Guinea (Day et al., 2013), while an introduced pathogen that attacks miconia is helping to restore threatened indigenous forest in French Polynesia (Meyer et al., 2012).

The recent history of "pathophobia" is being overcome using systematic frameworks: the United Kingdom introduced the first plant pathogen BCA (for Himalayan balsam) in Europe (Tanner et al., 2015). Vast experience with the introduction of biological control in agriculture worldwide can be built on and the risks have been shown to be minimal (Lynch and Thomas, 2000; Kenis et al., 2009; Hajek et al., 2016). In 2016 the CBD will assess use of introduction biological control in natural areas. This will determine whether the only effective, sustainable and economic approach for pest control over large natural areas will arguably continue to collide with biosecurity or will become aligned.

* Uncertainties about the CBD's access and benefit sharing also hindered the approach (CBD, 2010a; Cock et al., 2010).

** Although the rate of introductions globally has fallen (Winston et al., 2014; Cock et al., 2016), for insect BCAs at least establishment and success rates have risen, suggesting that improved risk assessment and the information it provides is allowing countries to make BCA introductions that are more effective as well as safe, therefore increasing confidence (Cock et al., 2016).

tives such as has occurred with biodiversity. The advent of the CBD (UNEP, 1992) triggered the creation of national frameworks and, in some cases, legislative instruments to capture the emerging concepts related to conservation, habitat preservation, prevention and management of invasive species, equitable sharing of benefits of resources, and respect for cultural heritage. These objectives came

to be seen as the ingredients for resilience and reduction in vulnerability, which are now known to link with decreased incidence of plant, animal and human disease (WHO and CBD, 2015). The broadest sense of this theme includes a concept of national patrimony, comprising flora and fauna of cultural significance, but also cultural or heritage icons, areas of public access to nature and so forth. This is a concept that has tended to fall into disuse over the decades, but remains in Philippines legislation (Fernandez, 2007) among others. The European Commission (2011) and the European Parliament (2012) class the need for biodiversity protection as the key to maintaining natural capital. They also link the biodiversity issue straight back to the fundamentals of plant health, animal health, and sustainable practices in agriculture, forestry and fisheries.

Conservation and wildlife protection (FAO, 2008b) was traditionally part of many national agendas for economic development when wildlife provided an attraction for increased tourism. Policies related to, for example, land ownership, timber extraction, habitat preservation, ecosystem services, wildlife conservation and restoration and water quality could be linked back to biosecurity under the environmental component, as shown in Figure 1.1.

The use of biological control is consistent with objectives to reduce pesticides, and also to restore the natural health and resilience of agro- and natural ecosystems. This approach has encountered regulatory hurdles within the context of biosecurity, however, as explained in Box 1.1.

Some of the complexities of achieving biodiversity objectives within a national framework, even with the highest of political will, are described for New Zealand by Schneider and Samkin (2012). Further discussion of national implementation appears in section 3.

1.7 Biotechnology, biosafety frameworks and biosecurity

The term biosecurity has been used for laboratory-based research to mean maintaining control and integrity of the research organisms, to prevent loss, theft or escape of potentially dangerous life forms, such as pathogens, which might be used to cause public health harm in addition to the original intention of the research, referred to as dual use (WHO, 2004). In this context, the term laboratory biosafety dates back further to indicate proper procedures in a laboratory to reduce risks to workers there, whereas biosecurity implies (Gaudioso et al., 2009 discussing CDC and NIH, 2007): "... more than simply physical security; it also includes personnel management, material control and accountability, information security, transport security, and program management."

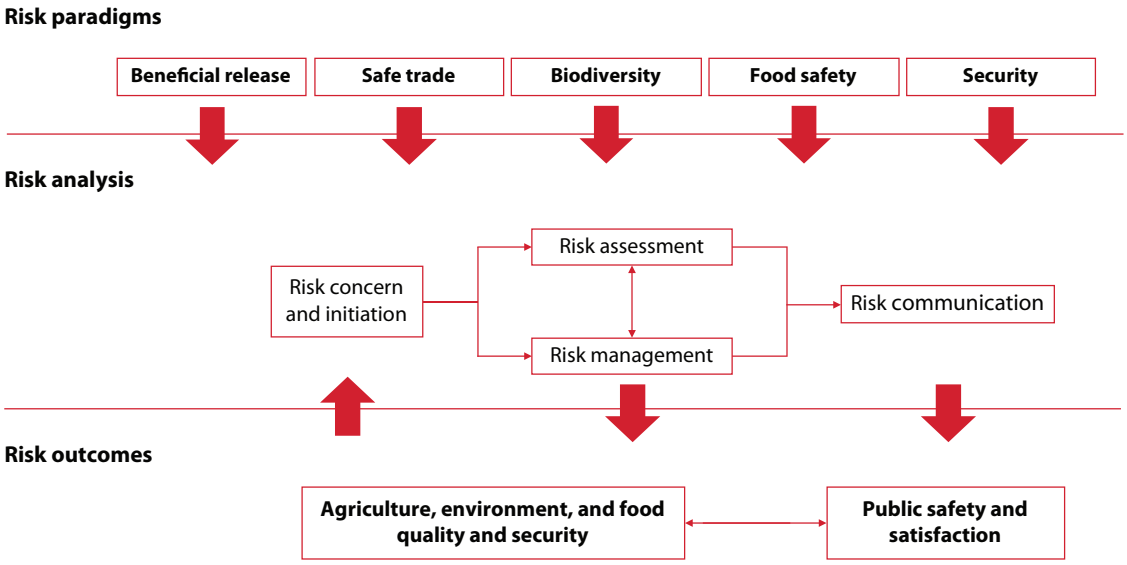
The use of this concept of laboratory biosecurity appears to link closely to the application of the term to animal health and zoonoses: diseases which can be transmitted between animals and humans. News articles relating to the Grupo Mercado Común del Sur (MERCOSUR) refer to biosecurity laboratories (MercoPress, 2004, 2012), which are laboratories recognized in diagnostics for animal (or less frequently plant) health or zoonoses. This therefore makes a bridge to the idea of taking measures to ensure biological security outside the laboratory setting. These measures include surveillance, vigilance and coordination for protection against the introduction of disease and pathogens, often presented at a national level.

There is extensive literature about the laboratory practices aspect of biosecurity (CDC and NIH, 2007; OECD, 2007). FAO uses the term in this manner in recent news (e.g. FAO, 2015a) and in publica-

Table 1.3. Translations of the term biosecurity

English	Biosecurity	Biosafety
French	Biosécurité	Biosécurité, Sécurité biologique
Spanish	Bioseguridad	Bioseguridad, Seguridad biológica
Chinese	生物安全 (shēngwù ānquán)	生物安全 (shēngwù ānquán)
Russian	Биозащищенность (biozashchishchennost')	Биобезопасность (biobezopasnost')

Figure 1.3. Risk paradigms for global biosecurity (Mumford et al., 2013).



tions (e.g. FAO, 2012b). However, it is currently used at FAO in conjunction with biosafety in these examples – either biosafety/biosecurity or biosafety and biosecurity – rather than as a stand-alone term.

There also has been much confusion between the terms biosecurity and biosafety when used in relation to evaluation and safe introduction of products of modern biotechnology. This is in part due to the issue of translation (Table 1.3).

FAO has been a leader in supporting appropriate use of genetically modified crops for sustainable intensification of agriculture. Biotechnology was classified by many national frameworks developed in response to the Cartagena Protocol on Biosafety in a fairly restrictive manner, specifically relating to genetic modification. As new technologies emerge for field trials and eventually wider use, FAO might step back into leadership for novel biotechnology assessment and management. This would appear to be in line with the FAO position (FAO, 2009a):

> Biosafety within the biosecurity framework refers to safe use of new biotechnologies within the framework of managing, in a holistic manner, biological risks associated with food and agriculture (which is understood to include fisheries and forestry).

Biosafety within a biosecurity framework generally refers to the safe use of new biotechnologies within the framework of managing biological risks associated with food and agriculture (FAO, 2010a, 2016). Although the terms for this desk study excluded in-depth discussion of biosafety of biotechnology, it has been a significant component of the biosecurity conversation and will need to be considered in any refinement of terminology of a biosecurity approach.

1.8 Security and biosecurity

Security concerns have been articulated in international agreements, principally the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BTWC, 1976). There could be considerable value in linking this existing framework and its networks and methodologies (Walker, 2003; FBI, 2015; Foreign and Commonwealth Office, 2015) with the plant and animal health and food safety networks (Stack et al., 2010; Mumford et al., 2016), just as with invasive species management (IPPC Secretariat, 2005). This may occur in surveillance, diagnostics, risk analysis, risk communication and other areas of expertise, as outlined in Figure 1.3.

The concerns around biosecurity in the food sector also circle back to issues of laboratory biosafety and biosecurity and international terrorism (NRC, 2009, 2010). The security concern has been explored further in recent European projects, includ-

ing CropBioterror and PlantFoodSec[4] (Mumford et al., 2016) as well as a Green Paper of the European Commission (Commission of the European Communities, 2007). The review of biosecurity in terms of national security draws on studies considering commonalities among the originally separate sectors and organizations, such as those shown in Figure 1.1 and Figure 1.2, to organize around shared concerns and the risk-based approaches shown in Figure 1.3.

While security *per se* has not been a mandate of FAO in the past, the FAO toolkit on biosecurity (FAO, 2007a) raised two important aspects of the concept (*emphasis added*):

> … 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*.

The reference to consumers reiterates the importance of recognizing various stakeholders, which was already noted. Food supply and food chain security are intricately linked with the FAO mandate of food safety.

1.9 Overview of the principles and interconnectedness of biosecurity

The FAO approach to biosecurity began at a time of seeking greater integration across the SPS system, as reflected in the definition and initial publications from FAO. The approach was unified and carefully constructed to include associated environmental aspects of food safety and animal and plant health. This extended to sustainable agriculture and consideration of agricultural biotechnology as well. The FAO biosecurity approach reflected aspects of the FAO Strategic Objectives (shown in Table 1.1.) and their underlying principles, but also specific management measures. For example, principles included safety and health, integration, prioritization and sustainability of the approach. While specific management methods were the development of policy, regulations, a legislative framework, risk analysis, risk management, monitoring, containment and eradication. From the beginning applying this approach implied maintaining technical expertise in each sector, specifically in food safety, animal and plant health and related sciences.

Also as noted above, an aspect that has entered the conversation around biosecurity relates to consumer awareness and consumer confidence, as acknowledged in the FAO biosecurity toolkit (FAO, 2007a). Although about biotechnology, the statement from one FAO publication (FAO, 2009a) more clearly brings in stakeholders to the concept (*emphasis added*):

> Biosecurity covers three main sectors: food safety; plant life and health; animal life and health. The biosafety within biosecurity approach, encompassing all policy and regulatory frameworks to manage biological risks associated with food and agriculture (including relevant environmental risks), is necessary to protect: 1) agricultural production systems, agricultural producers and their associated interests; 2) human health *and consumer confidence in agricultural products*; and 3) the environment.

This also reflects the perceived relationship between biosafety and biosecurity. Furthermore, it is presented "within its [FAO's] wider mandate to eradicate hunger and reduce poverty in developing countries and economies in transition" (FAO, 2009a). The addition of biodiversity, beyond simply direct environmental impacts, seems to have emerged over time. The reference to laboratory biosafety within a biosecurity approach is fairly recent.

Outside FAO, it should not be forgotten that the initial call for One World-One Health™ (now largely taken over by the broader One Health initiative) came from a wildlife conservation organization (WCS, 2004). The importance of biodiversity to poverty alleviation, sustainable agriculture and protection of natural resources is recognized in

4/ Further details may be found, at the time of this study, at: https://ec.europa.eu/research/fp6/ssp/crop_bioterror_en.htm and https://www.plantfoodsec.eu/

FAO initiatives and publications (e.g. FAO, 2004b, 2009b). In addition, FAO, among numerous others, has acknowledged that the progression of climate change and desertification will only increase vulnerability of the poor (FAO, 2009c, 2011c). The interconnectedness of food security with resilience in the face of climate change, natural disasters and food price volatility has been at the heart of recent FAO initiatives, as seen, for example, through the collaboration with the European Union (EU) in supporting better national capacities via the FIRST and INFORMED projects. (FAO, 2015b, 2015c).

One of the key challenges of the biosecurity approach at this time is its expansion to cover so much. The initial focus on SPS is being lost to a more generic use of the term as maintaining health. The rest of this report addresses both the SPS-based biosecurity approach and the broadened approach, as used in FAO.

2. Drivers and Trends

Trade and its associated economic development has been a driver for much of the investment in biosafety, biosecurity and legal support from FAO (FAO, 2007c). More environmentally motivated factors are of increasing importance, however, and the link between these and sustainable agriculture, safe trade, ecosystem services and One Health is becoming more apparent. The study revealed various drivers in both interpretation and application of the biosecurity approach. Table 2.1 lists a few of the drivers identified by a food safety network in this regard.

As mentioned above, the original FAO biosecurity approach was probably driven by the influences 1–5 in Table 2.1, relating at the start in particular to the legal obligations of the SPS Agreement. Over time, the other issues have influenced FAO's interpretation and application of the concept.

Increasing trade and travel have been cited as drivers of increased concern over food safety, and the need to integrate across entities involved in that single sector. Emerging food safety and zoonotic disease situations that require cross-collaboration between food safety authorities and those in animal health have been a major driver of the biosecurity approach that focuses on maintaining health status of a farm, sector or nation.

A trend in Latin America over the past decade and among the smaller nations, e.g. of the Pacific islands, has been to seek greater autonomy and cross-sector coordination in order to achieve efficiency and most effective use of resources, relating to point 9 on scarcity of resources. Situations arose during economic crises in which the SPS sector lost credibility owing to a lack of funds to even conduct inspections by the end of the fiscal year. Smaller nations tend also to rely on food imports (point 10), although not always.

Climate change and other pressures on biodiversity similarly drive an increase in vulnerability to pests and disease. The failure of existing systems to have prevented introductions of exotic pests and disease is a leading driver currently to the call for heightened protection. Some of the other drivers for taking a biosecurity approach include increased concern about terrorism, and the possible intentional misuse of pathogenic agents or insect pests as a weapon by individuals (versus by states, as addressed by the Biological and Toxin Weapons Convention (BTWC)). Mumford et al. (2013) (Figure 1.3, this study) illustrate the common risk paradigms and methodologies that motivate cross-sector col-

Table 2.1. Some factors influencing biosecurity (from INFOSAN, 2010)

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

laboration and further integration for prevention of agroterrorism.

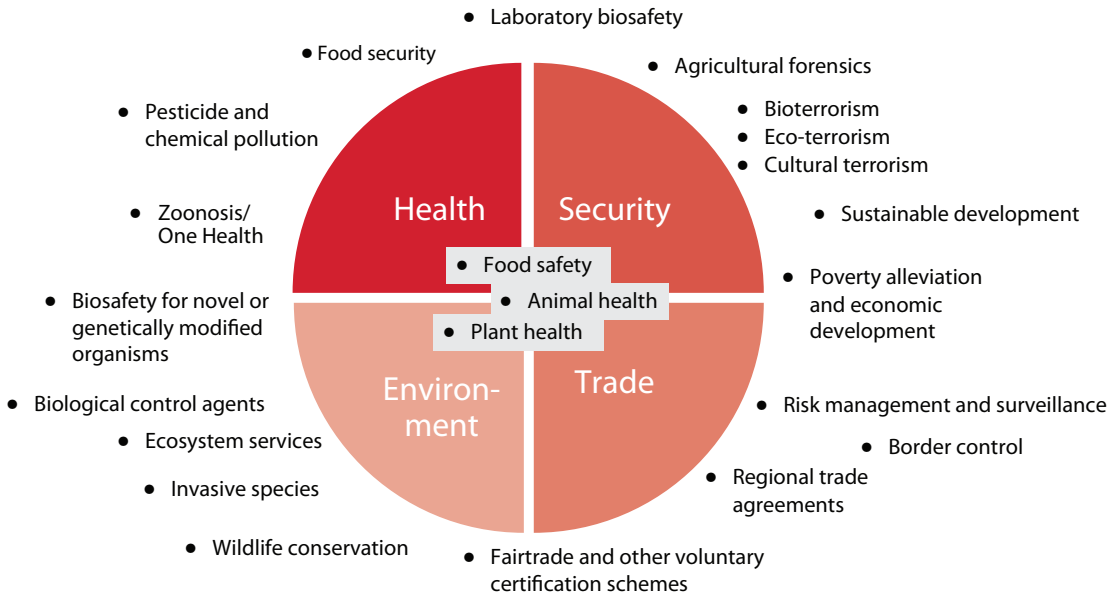
A trend in biosecurity has been increasing reliance on stakeholders as partners rather than less active constituents in the biosecurity approach (e.g. Department of Agriculture, Fisheries and Forestry, 2012). The public have proven useful and reliable in watching for invasive species of high concern or other citizen science activities. An intensive consultation process has begun in New Zealand to reach national consensus on a new strategy for biosecurity strategy to run to 2025 (Ministry of Primary Industries, 2016). This strategy poposes that the biosecurity team become a new partnership "every New Zealander becomes a biosecurity risk manager and every business manages their own biosecurity risk" (Ministry of Primary Industries, 2016). This involvement of stakeholders works well when there is a high level of understanding of and alignment with the principles and objectives relating to biosecurity.

Increased public awareness can have opposing impacts (Kruger, 2012a, 2012b; Kruger et al., 2012), however. First, consumer demands and public participation can make a significant difference in the public sector agenda and allocation of resources, as can corporate or interest group participation. Second, an engaged, but not necessarily informed, public can end up placing undue burdens on a biosecurity system and provoking possibly uneven delivery of benefits because of their own individual priority issues (for example, in biotechnology decision-making; see Quinlan et al. (2016b) on public engagement). Stakeholder engagement does not automatically promote the values of evidence-based decision making or equitable distribution of benefits.

In short, there are multiple drivers to shift towards a more coordinated and integrated biosecurity approach, even while the concept of what that entails is evolving. Figure 2.1 shows some of the various independent initiatives in trade, health, environment and security that relate back to the overarching biosecurity concept.

In addition to some sectoral trends identified in section 1, Biosecurity definitions and principles, these multiple and increasing drivers have set a trend for the definition of biosecurity to expand. For example, the inclusion of issues surrounding pesticides is not clearly included or excluded from the biosecurity approach although it is firmly planted in the FAO work plan (FAO and WHO, 2014). Expansion of its meaning is a natural and not uncommon trend, but one that has already caused confusion around the term. The reaction to this expansion of scope appears to be either to take the term, biosecurity, as one's own – linking it to what in the past might have been considered an individual sector,

Figure 2.1. Schematic of some of current topics and concerns related to biosecurity.



theme or area of expertise; or to abandon the term altogether. The former loses the critical factor of integration and synergy across disciplines and leads to multiple definitions, while the latter loses the years of development of the concept and the sustainability that the term itself promotes.

Meeting legal obligations for signatories of relevant international agreements is a driver for all four components of biosecurity, as represented in the figures. The next section discusses the international framework and how these are translated into implementation on a national level.

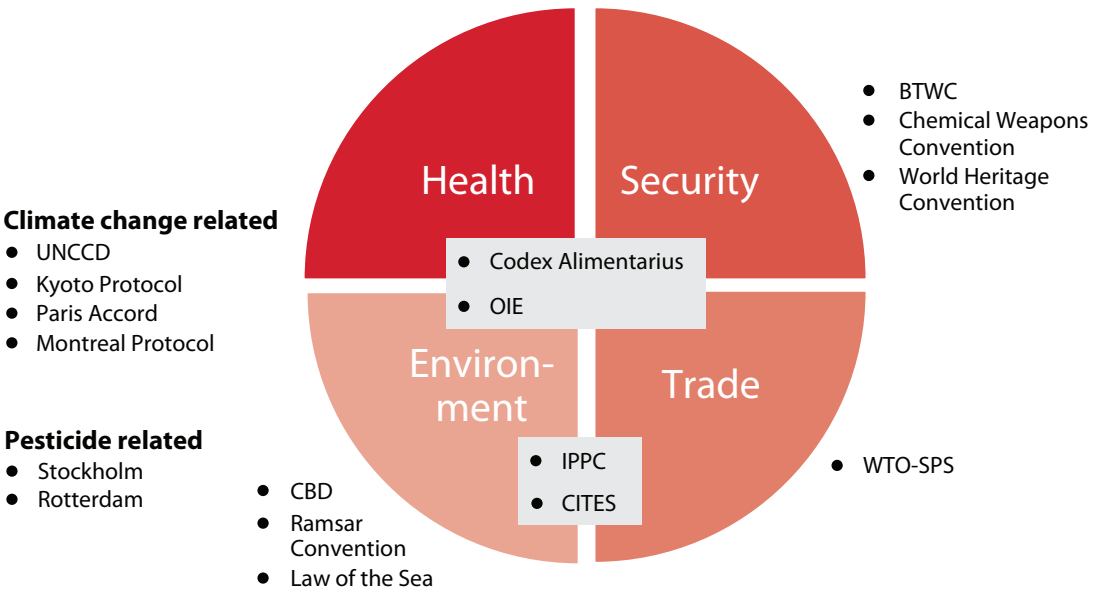
3. Frameworks for Mandates and Authority

3.1 International frameworks

Each of the identified realms or themes of expertise associated with biosecurity, as shown in Figure 1.1, have their own, previously and/or separately existing framework for policy, legislation, regulations and decision-making. Frameworks for national authorities often reflect the guidance from international treaties, codes of conduct, funder or international implementing body policies or public sector institutional initiatives. Figure 3.1 shows a few of the international agreements and bodies relating to and affecting the implementation of a biosecurity approach, as one could interpret it from the more recent, expanded FAO use of the term. Both the FAO biosecurity toolkit and the legal analysis guidance (FAO, 2007a, 2007b) discuss the role of international legal obligations in regard to biosecurity when considering implementation on the national level.

The landscape of international frameworks, from both official and unofficial bodies, also has a significant influence on any national context. Some of the issues for the SPS topics are noted above. The CBD and its precedents have had a large influence on the concept of biosecurity. (See also discussion on the precedents to the Cartagena Protocol on Biosafety in Quinlan, 2014). These precedents and the process for its implementation on the national level are described in the text box below. Yet, the CBD is relatively recent and other, earlier agreements also influence current national implementation on biodiversity. For example, Stoett (2009) assembled information on all of the international agreements on "bioinvasion" and invasive alien species (IAS), and created a country profile database on Bioinvasion and Global Environmental Governance (Stoett, 2010). He cautioned against considering bioinvasion only through the perspective of scope and guidance from the CBD, given the multitude of international frameworks and obligations (Stoett, 2010).

Figure 3.1. Schematic of some of the international-level intergovernmental treaties related to biosecurity.
BTWC, Biological and Toxin Weapons Convention; CBD, Convention on Biological Diversity; CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora; IPPC, International Plant Protection Convention; OIE, World Organisation for Animal Health; WTO-SPS, Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization; UNCCD, United Nations Convention to Combat Desertification.



Box 3.1 The implementation of the CBD on a national level

In May 1989, the United Nations Environment Programme (UNEP) established the Ad Hoc Working Group of Technical and Legal Experts to prepare an international legal instrument for the conservation and sustainable use of biological diversity. The group were to consider "the need to share costs and benefits between developed and developing countries" as well as "ways and means to support innovation by local people" (CBD, 2016a). The convention entered into force on 29 December 1993.

Under Article 6 of the convention ("General measures for conservation and sustainable use"), each signed member shall develop and report a national strategy, and subsequent action plan or programme, to ensure that the goals of the convention are met. Specifically, each member should (CBD Secretariat, 2005, 2011):

> Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned. (CBD, 1992)

> Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies. (CBD, 1992)

Similar to Article 6, Article 26 relates to the feedback of information and the implementation procedure of the convention, by member parties. Article 26 requires each nation to prepare national reports at defined time periods, within which it must be clearly stated what actions or plans have been put in place to ensure implementation of the convention, and to state the efficacy of these actions and plans in achieving their objectives (CBD, 2010b).

The terms of Article 6 are achieved through the development of a National Biodiversity Strategy and Action Plan (NBSAP) report by each member party. This report obliges each member party to consider biodiversity objectives during national planning. The NBSAP takes into consideration the specific national circumstances, which affect the efficacy or scale of national biodiversity planning, as part of the convention's plan to share the costs and benefits of biodiversity among the developing and developed nations (CBD, 2011).

The biggest challenge set to member parties by the CBD is to ensure that conservation and the sustainable use of biological resources are considered and implemented during all national decision-making processes (Balmford et al., 2005).

According to recent reports to the CBD, 185 of 196 parties (94 percent) have developed NBSAPs in line with Article 6. Many of these parties have begun the implementation process of achieving these targets, by amending or generating legislation (CBD, 2016b). Regional reviews, however, have shown that progress by specific members has been varied. In a review of the NBSAP progress from South Pacific nations (Carter, 2007), some nations had already begun to implement changes within national policy, other nations had made very little progress. Carter identified funding restraints to be a key factor that can limit progress (Carter, 2007; European Commission 2015a, 2015b, 2015c).

Biodiversity strategies can be developed in place of NBSAPs, if they meet the required CBD objectives. For example the EU agreed on a regional biodiversity strategy: *Our life insurance, our natural capital: an EU biodiversity strategy to 2020* (European Commission, 2011). This report refers directly to the tenth Conference of the Parties to the CDB as a driver for creating it, while also acknowledging the need to meet the EU's own biodiversity goals and other international commitments. For example, in Europe there were already two Directives (Europe, Council Directive 79/409/EEC and Council Directive 92/43/EEC): one on birds and their habitats (79/409/EEC) and, later, one on habitats protection for nature conservation (92/43/EEC). This was an early example of extending nature conservation of specific species to all species within protected habitat areas (Zdanowicz et al., 2005). The Council of Europe's Con-

Box 3.1 The implementation of the CBD on a national level *(continued)*

vention on the Conservation of European Wildlife and Natural Habitats (1979), commonly referred to as the Bern Convention, was the first unifying agreement across Europe. Although the United Kingdom has had a framework for protecting wild birds and preventing cruelty to animals since the nineteenth century, many European countries did not have specific legislation until signing the Bern Convention and then working to implement it.

This background would imply that countries did not need to enact new legislation to carry out their CBD responsibilities, but in fact many did. A good example has been Japan, which also took early steps towards implementing the CBD with its 1995 National Biodiversity Strategy. The experiences from formulating and implementing this strategy and subsequent updates led to a more informed biodiversity framework (Japan [Government of], 2008) which appeared to be fairly successful in providing the framework required.

3.2 National implementation

The biosecurity approach faces a complicated pathway to implementation, particularly if one is considering this approach to cover SPS systems (often associated with trade), biodiversity, security and other authorities and objectives. The international framework for biosecurity, comprising all multiple agreements, is carried out on national levels in various ways. Diverse domestic policies are also likely to overlap in regard to biosecurity objectives.

Figure 3.2 shows a continuum of approaches that the authors consider to fall within a biosecurity approach. The creation of a legislative framework to implement all biosecurity objectives remains a fairly rare approach. Australia's Biosecurity Act (2015), discussed in the case studies, covers biosecurity risks, human disease and even names ballast water. In this way, it addresses the concepts of trade, environment and health. It seems motivated to some degree by the failure to prevent incursions and invasions under the previous sectoral approaches. Bhutan, another case study, has implemented a full biosecurity approach with emphasis on protection of resources and its people. This is certainly a national biosecurity approach given the legislative, institutional and administrative integrated approach. A biosecurity approach of creating new framework legislation may be used to better integrate the SPS system and achieve synergies and resource efficiency, as is described for Belize below, or in implementation of biodiversity objectives (discussed elsewhere). Despite these significant examples of national implementation of biosecurity approaches, there are no examples of a single legislative framework that clearly covers all of the objectives and sectors shown in Figure 1.1.

New Zealand was one of the first countries to create an integrated biosecurity approach through legislative authority, an integrated institutional arrangement and budget. It was also one of the first to employ that term, biosecurity, in its Biosecurity Act 1993 (New Zealand (1993); "An Act to restate and reform the law relating to the exclusion, eradication

Figure 3.2. Mechanisms to implement a biosecurity approach on the national level.
IAS, invasive alien species.

Fully integrated biosecurity framework	Separate sectors working through integrated institutions or add on frameworks	Separate sectors with integrated functions for biosecurity	Separate sectors collaborating on biosecurity with ad hoc or informal mechanisms
New biosecurity legislation providing mandate and authorities, institutional arrangements, budget etc.	• Legislation or regulations to create institutions • Add on frameworks, such as for IAS	Specific functions, possibly already defined in other frameworks, are applied to biosecurity objectives	• Information sharing • Ad hoc cross ministerial committees • Response on specific incidents or outbreaks

and effective management of pests and unwanted organisms"). While this definition may appear to be in the rubric of more historical approaches to SPS, New Zealand's approach took a more environmental perspective in terms of protection of "valued biological systems". This reflects a cultural motivation for taking this approach as much as a resource efficiency one. This cultural motivation may be related to the situation for Norway as discussed further below, although the biosecurity integrated approach covers the SPS system while the biodiversity objectives are fulfilled under other mechanisms.

A number of orders and regulations have subsequently been administered under New Zealand's Biosecurity Act 1993, in order to implement the biosecurity approach. An example of this can be seen in the Biosecurity (National American Foulbrood Pest Management Strategy) Order 1998, which regards the identification and management of American foulbrood disease (New Zealand, 1998). The order was administered with regard to section 68 of the Biosecurity Act 1993 "Regional pest management plans" (New Zealand, 1993). American foulbrood is bacterial disease that affects the larvae of bees and that, if left untreated, can threaten the status of the entire hive (Animal & Plant Health Agency, n.d.). Because of the potential threat of American foulbrood, the Biosecurity (National American Foulbrood Pest Management Strategy) Order 1998 was administered as a pest management strategy with the aim to reduce the reported incidence of the disease, and eventually eliminate the disease in beehives entirely (New Zealand, 1998). Regulation of pollinator health is an example of an area that does not fit precisely in traditional SPS legislation, and may be better handled through a biosecurity framework.

Regulations created in pursuance of the Biosecurity Act 1993 have also included the implementation of functions derived from the act. An example of this type of regulation includes the Biosecurity (Costs) Regulations 2010, which defines and sets out the costing structure of activities undertaken for the purpose of implementing the Act (New Zealand, 2010). Activities are defined within the regulation as "the performance or exercise, by a general inspector, a veterinary inspector, or a biosecurity adviser, of any function, power, or duty prescribed in the second column of the Schedule" (New Zealand, 2010).

A more frequent mechanism has been a unifying institutional arrangement, while maintaining different legal frameworks providing authority in each sector. The integration through either a coordinated or a single institutional approach has arisen for the SPS systems in Latin America, for example. Argentina is a case in point where a combined institution was created to cover what is primarily SPS objectives, but sectoral legislation remains in place. Furthermore, important issues such as IAS, which many would place under biosecurity, are not clearly included in the same institutional operations. Not everyone would consider these national examples to be classed as a biosecurity approach, but the authors consider it one mechanism to achieve the objectives of this concept.

Another way that separate sectors have worked to collaborate towards biosecurity is using regulations or decrees to establish new initiatives based on existing legal authorities to better address evolving biosecurity objectives and concerns. For example, Vanuatu amended its Animal Importation and Quarantine Act (Consolidated Act of 2006) with Act No. 37 of 2014 to alter penalties associated with biosecurity objectives.

This manner of national implementation has also been achieved by updating legislation with new approaches. Amendments to existing sectoral laws that established the original authority have been used in biosecurity. For example, South Africa amended six existing pieces of environmental legislation to take into account new commitments and concepts in biosecurity (South Africa, National Environmental Laws Amendment Act. No. 14 of 2009). Specifically for biosecurity, this new act adjusted penalties, changed definitions, extended the rights for inspection to vehicles, and addressed general surveillance monitoring. The act did not state it was to achieve biosecurity, however; it was simply a mechanism to update details of existing laws. South Africa has also emphasized public consultation prior to taking actions in the biodiversity sector (GLOBE et al., 2014).

Alternatively, these functions can be carried out

cross-sectorally even though related authorities often will reside in different ministries. If legal and institutional integration is not appropriate for the national context, operational integration or devolved or delegated functions for biosecurity may still be achieved. This would occur for activities related to the biosecurity approach such as border control, inspection of cargo, general surveillance for pests and disease, monitoring of priority species or landscapes (e.g. protected areas), stakeholder forums and engagement, regulatory impact review, risk assessment, data management and other support activities such as cost-recovery mechanisms, training and certification.

Less comprehensive approaches to achieve some of the synergy and coordination include establishing interministerial committees, consultations or communication mechanisms. Colombia, in its Decree No 4.003, laid out an integrated approach to its SPS system in terms of the principles, such as notification and emergency measures, as contained in the SPS Agreement. This decree was signed by and related to authorities of the Ministry of Agriculture and Rural Development, the Ministry of Social Protection (Welfare), and the Ministry of Commerce, Industry and Tourism and also cites obligations from membership in the Andean Community (Comunidad Andina de Naciones), specifying Decision 515 and 562. Subsequently, along with many other Latin American countries in that era, Colombia set up an method for coordinating across the SPS system covering food safety, plant health and animal health through Decree 2833 (Colombia, Decree No 2.833). The creation of an Intersectoral Commission of Sanitary and Phytosanitary Measures (SPS Commission) was done by the Department of National Planning and the president of the nation. This included membership of the above ministries plus the Ministry of Environment and National Planning. The objectives were to coordinate policies and plans, review projects and strengthen links across the themes at regional and local levels as well as nationally. In this example, the emphasis is on coordination and none of the authorities given through legislation were changed, as they remained in force on a sectoral basis.

In the examples reviewed, institutional integration also took place within sectors, such as food safety, by coordinating different technical entities and ensuring compliance to the SPS Agreement principles for that topic (Costa Rica, Decree No 35.960/S/MAG/MEIC/COMEX); or the Chilean animal health sector (Resolution 8309, 4 January 2012). This is largely what was done in Kenya, with the animal health and human health/zoonoses objectives combined to a unit to highlight a priority area and support a more agile response. This is not a full biosecurity approach, in that it is limited to a more narrow interpretation of biosecurity. However, with the shift in use of the term biosecurity it could be interpreted as a mechanism to achieve biosecurity, albeit for only specific objectives (e.g. animal health, food safety, IAS or so forth).

A legislative review of national-level instruments, described in more detail in Annex 2, led to the conclusion that there are various ways for national implementation of a biosecurity approach, even though the full integration of these functions under a single legislative framework is the most clearly identifiable. If there is a legal mandate or authority to carry out the activities comprising a biosecurity approach, the integration may occur through regulations, codes of conduct or other approaches that may fit in with an already existing legal foundation. This is likely to gain authorities from existing sectoral legislation such as a food safety and hygiene law. In other cases, a new mechanism for coordination could result in an administrative entity whose responsibilities will be complemented by more specific norms or regulations as needed and when new information emerges, for example with the entry of new diseases. The review suggests that non-legislative instruments such as national strategies, coordinating committees, multisectoral review boards (e.g. the biotechnology biosafety committees[5] that pull in expertise from various ministries) or other methods should also be considered by countries seeking to implement a more holistic approach. This is the mechanism used most for implementing overarching responsibilities

5/ Many of the national biosafety committees have been created through legislation and regulations, however, rather than as an implementation mechanism for existing legislation.

under the CBD, through preparation of a National Biodiversity Strategy and Action Plan (NBSAP), such as reported by Ethiopia and Timor-Leste in Annex 2 of this study.

The mechanisms employed for national implementation of biosecurity objectives are examined further with case studies in the next section.

This section has focused on how countries address gaps in national biosecurity approaches. The challenge of overlapping mandates has been problematic. Pesticide regulation is always challenged by the division of mandates for registration (environmental), establishing and monitoring maximum residue levels (human health and food safety), efficacy (agriculture) and safety (labour). Analysis and rationalization in this sector is supported by FAO through its Legal Office (e.g. FAO, 2007d) and by the secretariats of relevant treaties. As with biosecurity, this requires a situation analysis and policy based on the priorities of the country, rather than a "one size fits all" approach. It also must take into account what international instruments are already signed by the national government.

Multiple and overlapping mandates administered by different government ministries or regional organizations often leads to duplication of effort and impasse (Sheppard et al., 2003), or to gaps in coverage. For example, the release of non-native biocontrol agents (BCAs) is generally managed under four frameworks for plant health alone:

- ISPM 3, which was noted as "timely and appropriate" for environmental, economic and food security issues, although a need for additional support was noted. It, or similar national legislation, was supporting BCA introductions in most countries implementing introduction biological control (Kairo et al., 2003). ISPM 2 and ISPM 11 are also relevant.
- CBD Article 8(h) and Aichi Biodiversity Target 9 (Decision X/2 of the Tenth Conference of the Parties) require parties to manage IAS to protect biodiversity (CBD, 1992; CBD, 2010c). Guiding Principle 15 of the Rio Declaration on Environment and Development (UNEP, 1992) advises a precautionary approach to protect the environment. Decision VI/23 of the Sixth Conference of the Parties includes biological control for integrated management of IAS, while endorsing precaution "in particular with reference to risk analysis" (CBD, 2002).
- Relevant national and regional legislation: usually at least two pieces of legislation usually administered by different agencies are involved in this instance (see Sheppard et al., 2003). These are often used pragmatically, whereas ideally regional and national legislation should be complementary and not have duplications or overlapping. Regional and national competences should equally be coordinated and not create a duplication or overlapping, if they are prepared with such a case in mind.
- An internationally recognized framework for assessing potential BCAs for weeds (Wapshere, 1974) has been adapted for other groups (e.g. Bigler et al., 2006; Hunt et al., 2008) as an unofficial standard of evaluation.

For this single measure that may play a role in biosecurity, therefore, a combination of instruments of very different legal nature (from a convention to soft law) would require national implementing legislation, if not regional legislation. This challenge is at the heart of an interdisciplinary and synergistic approach and warrants more consideration.

Beyond the legislative mandate, the European Commission (2014) laid out elements for implementation of the regional biodiversity objectives, which overlap somewhat with the biosecurity ones: (1) creation of an EU-level governance framework; (2) encouragement of ownership of the strategy across all relevant policy areas; (3) involvement of all interested stakeholders; and (4) support for information sharing and syngeries across public and private efforts.

As already noted, legal authority for biosecurity is derived either from existing sectoral mandates and guidance, usually by creating unifying institutional, financial or operational policies or regulations, or by a unifying legal instrument covering the entire biosecurity approach, although this is less common. A strategy, regulation or even law may be used to ad-

dress details for implementing what had been a gap for biosecurity objectives in the existing framework, for example to implement IAS policy.

A frequent mechanism for what is termed biosecurity within animal health has been the issuance of new norms or regulations by specific notifiable disease, so that specific biosecurity actions or programmes can be implemented under the overall animal health authority. Examples of this include regulations about avian influenza issues in Turkey and several members of the EU; or about foot-and-mouth disease issued in Brazil and by the EU (see Annex 2). The new normative actions introduce greater coordination, sometimes funding, more precise required actions and so forth to achieve the holistic approach so urgently needed for fast-spreading infectious disease. Annex 2 catalogues these approaches with its list of countries and each instrument identified, using the FAOLEX database, and by noting the general approach of each.

There has been a demand for guidance on developing integrated legislation or regulatory frameworks for biosecurity as a single cross-cutting theme, as had been given historically by FAO for other, albeit more defined, thematic areas (FAO, 2006a, 2006b, 2007c, 2007e, 2008b, 2012c, 2013c, 2015d). The FAO Legal Unit is moving away from prescriptive guidelines and model laws, and simultaneously the meaning of biosecurity for FAO is being questioned. The requests for guidance on integrated biosecurity legislation was part of the impetus for conducting this desk study.

4 Case Studies of Approaches

Experiences in applying the institutional approaches outlined above were considered using case studies for SPS-type systems in Argentina and Belize, where existing institutions were merged to work across the SPS spectrum and provide services for public good and private industry. Kenya has taken on a one-health approach to zoonoses, complementing an already operational SPS system. In Bhutan, the new framework began from a biosecurity perspective. Australia shows a situation where biosecurity has become a key policy nationally and among a range of stakeholders, overshadowing somewhat the individual sectoral approaches. Finally, the case of Norway lays out further how an integrated SPS system for biosecurity may be interfacing with environmental protection and biodiversity authorities. The relatively short timeframe, and lack of published literature for most cases, limits full analysis. Belize and Norway are the longest running of the cases considered.

The government of each case study country is a member of OIE and WTO (and thereby a signatory to the SPS Agreement), except for Bhutan which is in the process of accession to WTO. Each also is a signatory to the IPPC, the CAC and the CBD. Observations drawn from the cases appear in section 5, Conclusions and recommendations. (Citations for legal instruments are at the end of the References section, while other types of government documents are in the References alphabetically by author.)

4.1 Argentina

Although it is not defined in the legislation as such, Argentina's biosecurity approach rests primarily with the Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA), which is an autonomous body attached to the Ministerio de Agricultura, Ganadería y Pesca. SENASA has technical, administrative and financial autonomy and works in a geographically decentralized fashion (operating on a regional basis). The agency was created by combining the animal health, and the plant health and food quality institutes in 1996 (Argentina, 1996).

This was in the epoch of consolidation under the SPS Agreement, when a number of Latin American countries combined services. One of the main objectives was to strengthen the authorities of the implementing agencies by creating a more autonomous financial and administrative body, which would then be more agile and capable of responding to SPS threats. Although the mandate was initially for imported and exported plant and animal products, in 2003 the agency was funded to create 15 regional centres that addressed the existing mandate but also added further responsibilities related to food safety and consumer protection for both domestic and international markets. SENASA also covers animal feed, and agricultural inputs such as fertilizers and pesticides in its scope.

The term biosecurity (*bioseguridad*) is used by SENASA for animal health to mean almost exclusively measures taken at the farm or national level that protect the sanitary status in terms of freedom from particular diseases (diseases usually listed individually with specific measures to prevent, monitor for, diagnose and control). General approaches to biosecurity by sector (e.g. by type of animal or farm) are identified, such as appropriate design of facilities, worker hygiene, disposal of animal carcasses, and so forth. The aspect of worker safety (protection of those working with the animals from contracting disease from the animals) is also noted. It may also be used for plant health in terms of the systems in place to prevent, detect and react to a new outbreak (SENASA, 2015).

The federal constitution was amended in 1994 and provides general principles for the protection of the environment, and empowers the federal government to determine the minimum standards for protection. The Secretary of Environment and

Sustainable Development (supported through the Secretariat of Environment and Sustainable Development and Environmental Policy) sits within the executive branch of the federal government and meets with the provincial environment authorities in a coordinating committee: the Environmental Federal Council (Consejo Federal de Medio Ambiente (COFEMA)).

Although the authority of SENASA includes protection of the country's phytosanitary and sanitary patrimony, IAS are covered more directly, albeit through a fragmented legal base, by two laws:

- Law on national environmental policy (Argentina, National Law 25.675)
- Law on environmental protection of native forests (Argentina, Law 26.331).

The strong combined authority with some autonomy can present advantages and disadvantages to implementing a biosecurity approach. This allows effective responses to biosecurity threats, because of the level of autonomy, but also means that resources may be diverted more easily to one sector over another (e.g. animal health over plant health).

4.2 Australia

In current world literature, the geographical centre of the term biosecurity in publications is overwhelmingly Australia and New Zealand. Their approaches developed separately, but are embedded for national institutional implementation of SPS in both cases. The term is used in Australia by government, the private sector, researchers and academics. It is used in popular press and apparently understood as a national priority and guiding principle for related policies.

In the Biosecurity Act 2015 (Australia, Biosecurity Act 2015), biosecurity is defined as "managing diseases and pests that may cause harm to human, animal or plant health or the environment". The Department of Agriculture and Water Resources website (Department of Agriculture and Water Resources, 2016) further defines biosecurity as:

> ... a critical part of the government's efforts to prevent, respond to and recover from pests and diseases that threaten the economy and environment. The department works to ensure continued market access for our products and to maintain our high standards for emergency response.

In an interview (Department of Agriculture and Water Resources, 2011) with Lois Ransom (Chief Plant Protection Officer, Department of Agriculture, Forestry and Fisheries), Ransom identified the key focus of plant biosecurity in Australia as "preventing the entry of exotic pests and diseases and about minimizing the impact of pests and diseases on primary production, on the environment, on social amenity." Ransom also identified the importance of implementing a suitable and up-to-date biosecurity strategy, using the example of a previous incursion of the papaya fruit fly into an area of Queensland. She stated that the incursion of this pest resulted in significant economic losses, not only through the cost of eradicating the pest from the infested area, but also from the negative impact on the industry.

Despite being named the Biosecurity Act 2015, the act did not actually come into force until June 2016. The 12-month delay was to ensure that staff, stakeholders and clients understood their rights and responsibilities under the Biosecurity Act and that there was a smooth transition to the new regulatory arrangements.

Even before the draft of the Biosecurity Act 2015, Australia has been progressive regarding the subject. The Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia's national science agency, published a report in 2014 titled *Australia's biosecurity future*, which identified five biosecurity mega-trends set to impact on the country's economy, health and environment (Simpson and Srinivasan, 2014). The report used previous global biosecurity disasters to highlight the need to address the issue; the examples included: the arrival in Australia of the varroa mite which could severely hit European honey bee populations, potentially costing the industry AU$90 million per year but also an additional AU$4–6 billion in lost pollination services (Plant Health Australia, 2014); and the 2001 foot-and-mouth outbreak in the United Kingdom (Newcomb, 2004; Simpson and Srinivasan, 2014).

Among other national influences to improve

biosecurity strategy as a whole, one example that motivated a biosecurity response in Australia was the 2007 equine influenza outbreak. Previously vaccination and certification was only required for imported horses, but this procedure was superseded by a more lateral biosecurity strategy following the outbreak. The new strategy included monitoring and evaluation to predict and prevent future outbreaks from occurring. This multifaceted approach is how the Biosecurity Act 2015 was developed, rather through than focusing on one aspect of prevention.

Australia's biosecurity legislation, the Biosecurity Act 2015, came into force on 16 June 2016, replacing the Quarantine Act 1908 (Australia, Quarantine Act 1908). Under the same structure as before, the new act will be co-administered by the Department of Agriculture and Water Resources and the Department of Health. The act, once enforced, will then replace the Quarantine Act 1908 as the primary biosecurity legislation in Australia.

The objects of the Biosecurity Act 2015 are:

1. To provide for managing the following:
   - **a)** Biosecurity risks
   - **b)** The risk of contagion of a listed human disease
   - **c)** The risk of listed human diseases entering Australian territory or a part of Australian territory, or emerging, establishing themselves or spreading in Australian territory or a part of Australian territory
   - **d)** Risks related to ballast water
   - **e)** Biosecurity emergencies and human biosecurity emergencies.
2. To give effect to Australia's international rights and obligations, including under the International Health Regulations, the SPS Agreement and the CBD.

Australia ratified the CBD (CBD, 2016c) in 1993, and has published an NBSAP in compliance with the membership of the convention (NRMMC, 2010). Within Australia's NBSAP, a 20-year conservation strategy was established. Australia was already a contracting party to the IPPC and also became a member of WTO, and its SPS Agreement, in 1995. Therefore, it may be inferred that complying with Australia's pre-agreed international obligations was also a factor in the writing of the Biosecurity Act 2015.

The act provides a strong regulatory framework, which includes principles for managing biosecurity risks, requirements, powers and tools for assessment and management of biosecurity risk, and enforcement tools. The act also provides for powers to be exercised to monitor, respond to and control biosecurity risks posed by diseases or pests that may be in or on goods or premises in Australian territory not previously covered specifically in the Quarantine Act 1908.

Chapter 9 of the act gives officers powers to ensure people are complying with this act, to investigate non-compliance, and to enforce the act by means such as civil penalties, infringement notices, enforceable undertakings and injunctions. In many cases this is done by applying the Regulatory Powers Act 2014. The chapter also makes provision for warrants for officers to enter premises and exercise powers for some other purposes relating to biosecurity, as well as powers for officers to enter premises and exercise powers without a warrant or consent.

Subsequent chapters deal with matters relating to governance and officials. This includes provisions relating to the functions and powers of the Director of Biosecurity, the Director of Human Biosecurity, biosecurity officers, biosecurity enforcement officers, chief human biosecurity officers and human biosecurity officers.

The act allows for charging fees in relation to activities carried out under it, and provides for the recovery of those fees and other charges imposed to recover costs. The act provides the regulations to: prescribe fees that may be charged and other rules about fee-bearing activities; sets out rules about payment of cost-recovery charges; sets out how unpaid cost-recovery charges may be dealt with; provides for the Director of Biosecurity to sell certain goods and conveyances, including in order to recover unpaid cost-recovery charges; and contains miscellaneous provisions, including the power to remit or refund a cost-recovery charge.

A number of other acts aid the transition from the Quarantine Act 1908 to the Biosecurity Act 2015:

- Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015
- Quarantine Charges (Imposition-General) Amendment Act 2014
- Quarantine Charges (Imposition-Customs) Amendment Act 2014
- Quarantine Charges (Imposition-Excise) Amendment Act 2014.

According to the Department of Agriculture and Water Resources website, the act:

- provides a modern regulatory framework
- reduces duplication and regulatory impacts
- allows for current and future trading environments
- allows for collaboration across government and industry.

To aid implementation of the act, an interactive tool has been created (Department of Agriculture and Water Resources, 2016). The aim of the tool is to provide stakeholders with an easy-to-understand introduction into how the biosecurity changes will affect businesses and individuals. As well as introducing new terminology and outlining the key implementing bodies. The tool provides case study examples of how the act may have an effect in real-life situations.

It seems apparent that Australian motivation in developing the Biosecurity Act 2015 was not simply to comply with international treaties or current trends, but rather a demonstrated commitment by the government to develop a preventative structure to protect environmental and agricultural interests within Australia before outbreaks occur, as has been seen previously in Australia and elsewhere.

The challenges encountered over the years include:

- balancing federal government and state and territory government responsibilities
- managing state and territory, client, industry and other stakeholder needs and expectations while continuing to deliver biosecurity outcomes
- building a common understanding of biosecurity and risk management across governments and the public
- building a culture of shared responsibility – governments, industry and the general public.

Implementing the act will benefit Australia's:

- agricultural industry by helping to protect it from exotic pests and disease – this will save on pest and disease management and mitigation costs as well as retaining domestic and international market access
- community by targeting areas of high risks and focusing on the things that matter most, including improved tools to better manage human health and environmental risks
- environment by helping to protect Australia's unique flora and fauna from the threat of exotic pests and diseases
- businesses and the economy through protecting access to international markets and the ongoing sustainability of Australia's tourism industry.

4.3 Belize

As a net exporter of agricultural products, biosecurity is of high importance to Belize. Approximately three-quarters of Belizean exports come from agricultural products, and the agricultural sector accounts for over a quarter of the labour force (New Agriculturist, 2005).

Belizean understanding of biosecurity is based upon the FAO definition (FAO, 2007a). The main issues that arose for stakeholders during the development of a biosecurity framework in Belize included the cost-recovery procedure, interactions between the regulatory agency and other stakeholders, and legislative authority and the role of regulatory third parties (Outhwaite, 2010). A significant step to being able to develop and implement a successful integrated biosecurity approach was the establishment of the Belize Agricultural Health Authority (BAHA). This was a notable internal change in the public sector of Belize. BAHA operates under the Ministry of Agriculture and Fisheries, and provides a single framework through which agricultural health issues are regulated. In particular, it provides services in plant and animal health,

quarantine and more recently food safety.

BAHA was created under the Belize Agricultural Health Authority Act, Chapter 211 in 2000, and is governed by a board of directors, the core policy-makers, with members coming from both the government and the private sector. The creation of BAHA as an authority gives it a significant level of autonomy in decision-making. Furthermore, as part of the overarching financial and human resource administration system of all technical departments, BAHA's resource management, especially in a case of sanitary or phytosanitary emergency, is less bureaucratic, simpler and expedited. This has been aided by BAHA creating revenue by increased efficiency and charging for services.

BAHA has obtained regional and international recognition for its work in agricultural health, although the legislation guiding and enforcing the Belizean biosecurity approach has had a number of key gaps. This initially was because BAHA was originally intended to address animal and plant health and quarantine only. It has subsequently expanded its activities to incorporate food safety and aquatic animal health (Belize Legal Framework Upgrade).

BAHA recognized that its international requirements were not entirely met by existing legislation, but it needed external guidance on how to strengthen its overall approach to biosecurity. The Government of Belize obtained relevant guidance from the FAO Technical Cooperation Programme (TCP) under a small project TCP/BZE/3003, "Strengthening the biosecurity framework" (FAO, 2008c), which helped to fully develop the legislation underpinning BAHA's biosecurity framework during the course of a year (2005). The guidance also ensured that the framework met current and future international obligations.

As a result of these activities, five draft laws were prepared:

- a new BAHA bill envisioning a more defined mandate but still including the previous administrative provisions necessary for its functioning
- a plant protection bill, prepared in first draft under a previous FAO TCP project
- an animal health bill, covering both terrestrial animal health and aquatic animal health
- a food safety bill, setting out BAHA's mandate in detail in this area
- a biosafety bill, incorporating the philosophy and concepts of the Cartagena Protocol on Biosafety.

Cost recovery for biosecurity services is set out in the Belize Agricultural Health Authority (Service Fees) Regulations, 2004. The legislation states that: "Every exporter of a commercial commodity or product, or his authorised agent, shall pay to the Authority ... [set] fees for the issuance of a Phytosanitary Certificate for such commodity". All fees under this regulation are borne by the exporter and paid to the designated officer upon completion of the inspection, or to BAHA at any of their offices throughout the country. Example fees include:

- "commercial commodities or products amounting to less than a truck load or 20 feet container load": BZ$20.00
- commercial commodities or products amounting to more than a truck load or 20 feet "container load": BZ$100.00 (per shipment).

Other guidance or regulations introduced practices that reach the level of international standards, as listed below.

Belize HACCP guidelines for food safety (Belize Agricultural Health Authority (Food Safety) Regulations, 2001 (S.I. No. 25 of 2001)):

Introducing controls at critical points. Plans at a minimum must:

1. List the food-safety hazards that are reasonably likely to occur
2. List the critical control points
3. List the critical limits
4. List the monitoring procedures
5. List pre-determined corrective action plans
6. List the verification measures including:
   - **a)** timely reassessment of HACCP plan
   - **b)** scheduled calibration of equipment
   - **c)** provide for a system of monitoring records.

Procedures on import risk analysis:

1. If:
   a) a commodity has never been previously imported into Belize, or
   b) a commodity or product originates from a country or region not previously approved, or
   c) a commodity or product originates, comes from or passes through a country or region whose health status changes or is not known by the authority, or
   d) there is new information on a particular pest or disease

   it is required that a country or region provides evidence that an export commodity does not present threat or risk to Belize, then an import risk analysis shall be conducted.
2. Every import risk analysis conducted under sub-regulation (1) shall incur a fee of one thousand dollars (BZ$1000.00) of which two hundred dollars (BZ$200.00) shall be paid to the Authority immediately upon application and the remaining balance shall be paid to the Authority upon completion of the import risk analysis.

Based on the experiences in Belize, it seems that the BAHA model has advantages and disadvantages. Belize has continued to operate as one of the original implementers of a biosecurity-based integrated system, and has achieved resource efficiency but also critical autonomy to face biosecurity threats through this process. Since BAHA charges for services, which generates a greater part of its financial resources, procurement procedures are simpler and expedited compared with other parts of the government system.

The other advantage is resource management. There is one overarching financial and human resource administrative system for all BAHA technical departments, hence there is no duplication. If the need arises, such as in case of a sanitary or phytosanitary emergency, resources can be moved temporarily from one unit to another with minimal bureaucracy.

While being one step away from the Ministry of Agriculture can be an advantage, it can also be a disadvantage if budgets are reduced. BAHA's allocation from the government may be at risk in this circumstance, since the government's priority becomes the formal units under its mandate and not the statutory bodies.

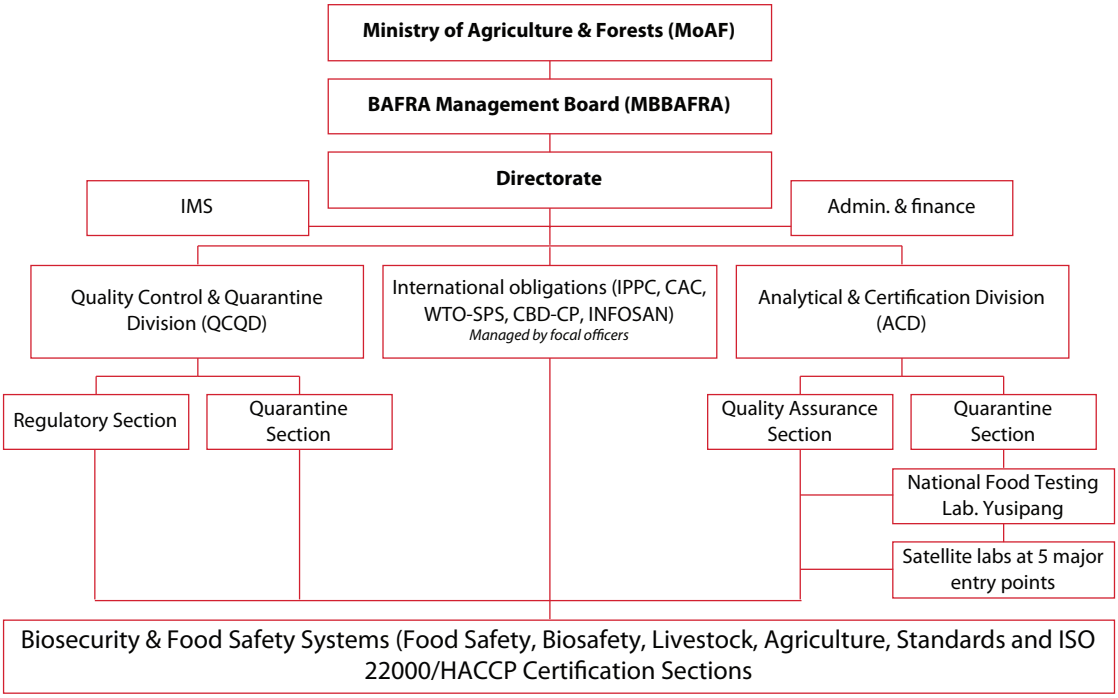
With the involvement of the "client", one concern has been the possibility of a conflict of interest arising for members of the board of directors from the private sector. In practice, however, there is positive peer pressure not to abuse the system. Another area of concern is that if the private sector pays for everything (through cost recovery), they could then want to exert some level of influence that may compromise the official mission. However, in Belize there are still many services that are not operating on cost recovery because they are more for public good, such as surveillance systems. To date, the experience in BAHA is reportedly one of achieving a healthy balance between cost-recovered services and public-good services, with the latter being clearly linked to the country's desirable SPS status.

Overall the system is considered to function well. The public expects a high-quality service, given involvement of the private sector and understanding of the benefits of a good SPS system. The legislative mandate that established BAHA and the additional laws related to the sector have given a level of influence among agricultural policies. This biosecurity structure has reportedly encouraged the country to be more dedicated to the SPS mandate and has elevated the level of professionalism within the implementing organization. This high-quality delivery of service arises from the level of ownership and the pride from outcomes of the work being clearly identifiable.

4.4 Bhutan

The Kingdom of Bhutan is located within the Himalayan region between China and India and is host to a range of biomes, from subtropical plains to glacial mountains. Bhutan still retains 65 percent forest cover. The vast majority of Bhutan's population are subsistence farmers, usually including dairy farming and poultry rearing. Bhutan applies the concept of

Figure 4.1. Biosecurity organizational structure in Bhutan (BAFRA, 2015).
CAC, Codex Alimentarius Commission; CBD-CP, Convention on Biological Diversity – Cartagena Protocol; HACCP, hazard analysis and critical control point, IMS, Information Management Section; INFOSAN, International Food Safety Authorities Network (under WHO); IPPC, International Plant Protection Convention; WTO-SPS, Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.



"gross national happiness" as a holistic and sustainable approach to development. This is reflected in their biosecurity vision (Frampton, 2010):

Biosecurity shall contribute to achieving Gross National Happiness by ensuring Bhutanese people, the biological resources, plants and animals are protected from the harmful effects of pests and diseases, invasive alien species, genetically modified organisms, toxic chemicals and food additives.

This is an example of a policy based on public satisfaction rather than predominantly by economic or health benefits, although these outcomes are all linked. Reduced risk to trade from tackling biosecurity issues effectively will unquestionably have indirect benefits to the economy and to public, animal and plant health, but it should be noted that to achieve this the Government of Bhutan has opted to implement a unified approach led by a single body.

The Bhutan Agriculture and Food Regulatory Authority (BAFRA), under the Ministry of Agriculture and Forests (MOAF), is Bhutan's legislative authority for biosecurity and food safety. BAFRA intends to promote the quality and safety of food and agricultural products, and was initially created as the Quality Control and Regulatory Services (QCRS) in August 2000. BAFRA contains two major divisions that lead implementation of biosecurity: Quality Control and Quarantine Division (QCQD) and Analytical and Certification Division.

As with BAHA in Belize, BAFRA is governed by a management board (Management Board of the Bhutan Agriculture and Food Regulatory Authority), which is intended to reflect the interests of stakeholders and key groups. Representatives of the key department and agencies with MOAF are represented on the management board, alongside external representatives from other key departments and ministries (Department of Trade, Ministry of Economic Affairs, Department of Public Health, Ministry of Health, Department of Revenue and Customs, Ministry of Finance) and the Bhutan Chamber of Commerce and Industry (representing the private sector).

Implementation of Bhutan's biosecurity approach includes carrying out inspections and certification of food and agricultural goods and products. Import and export of food and agricultural goods and products require SPS permits, which are grant-

ed by BAFRA. Import and export cannot occur prior to receiving the SPS permits.

Bhutan's biosecurity approach is implemented through the following legislation:

Plants and plant products

- The Bio Diversity Act of Bhutan (2003)
- Forest & Nature Conservation Act of Bhutan (1995)
- The Pesticides Act of Bhutan (2000)
- The Plant Quarantine Act of Bhutan (1993)
- The Plant Quarantine Rules and Regulation (2003)
- The Seed Act of Bhutan (2000)
- The Seed Rules and Regulations of Bhutan (2006).

Food safety

- Food Act of Bhutan (2005)
- Food Rules and Regulations of Bhutan (2007).

Livestock

- Livestock Rules and Regulations of Bhutan (2008)
- Livestock Act of Bhutan (2001).

Implementation by users is guided by a plethora of guidelines and standards.

The overall organizational structure for biosecurity, including a link to its international obligations, is shown in Figure 4.1.

As indicated above, Bhutan's policy aims to ensure happiness for its citizens. The country's approach to implementation has been to accept external guidance to ensure a high efficacy of its legislation, in addition to seeking compliance with international treaties. FAO provided support for the development of this approach. A former surveillance programme manager for Animal Health Australia also has been working with Bhutan as a biosecurity advisor for BAFRA. The country is working on translating biosecurity policy and legislation into action, by reviewing biosecurity procedures and practices at different levels, from national and district, through to households and small commercial farms.

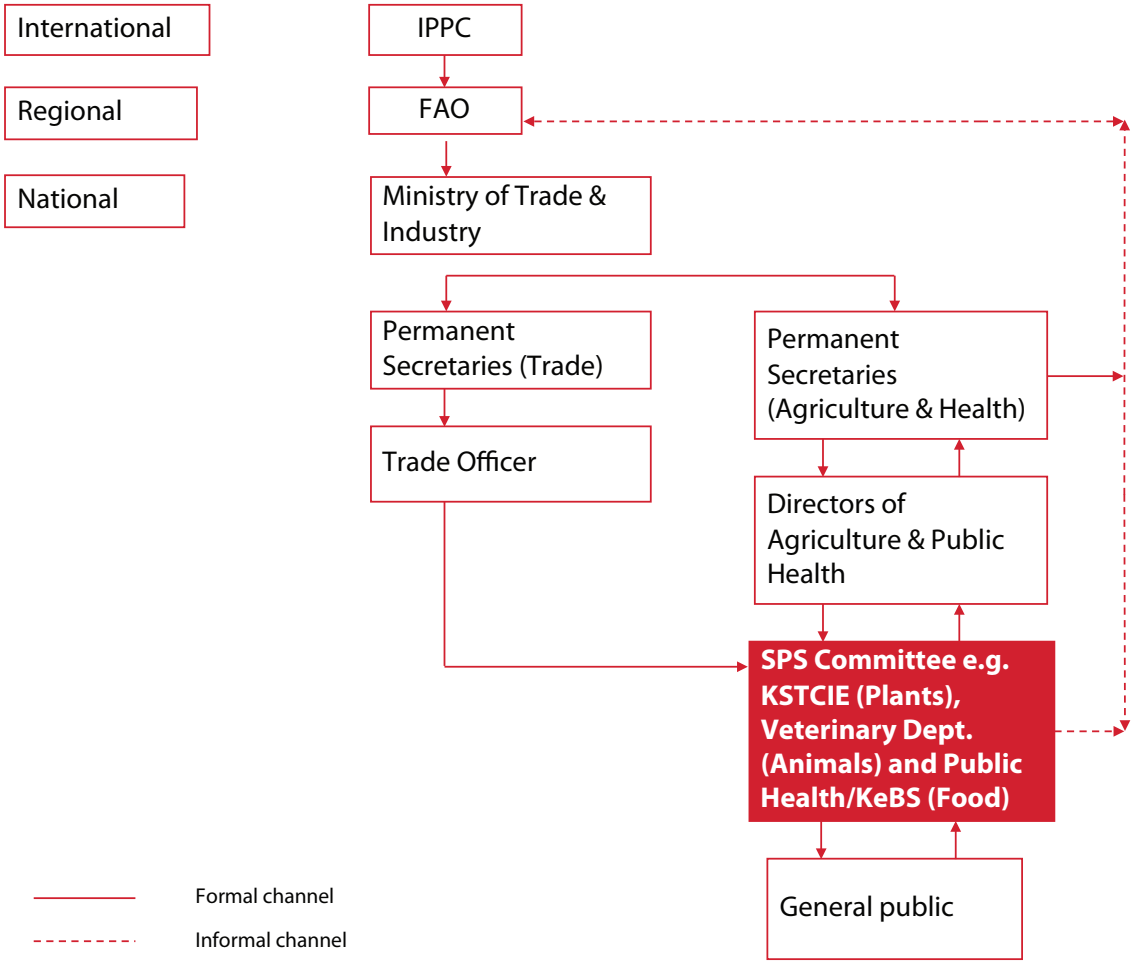
Because the majority of national experts have been educated in Australia or New Zealand, the approach in Bhutan is likely to be based upon the Oceania style and experiences. The current biosecurity approach in Bhutan is still relatively new, however. It remains to be seen if this structure is achieving the efficiencies. Available information is promising, however. For example, in 2016 a database for managing plant and animal health information has been updated and covers online import and export applications, permits, and approvals; in-country movement of livestock; inspection records; and legal cases (BAFRA, 2016). The coordination and efficiency from data management alone suggests that the integration has been successful.

4.5 Kenya

Kenya has approached biosecurity in different ways over time. Kenya's horticultural sector is important to the national economy and for employment. Challenges to the SPS system have tested its capacity and response, for example during a cholera outbreak that stopped fisheries exports to Europe, and with the introduction of a new fruit fly species of significance (Day et al., 2012). The country is recognized as a leader in African SPS systems, however, and the use of sustainable agricultural strategies and measures such as biological control. A 2005 study of interactions and the knowledge network for taking decisions about release of BCAs described the structure at that time (Figure 4.2; Kairo et al., 2005). Environmental agencies have since played an increasing role, associated with the implementation of the CBD.

A separate framework was established for genetically modified organisms – Biosafety Act 2009, section 2 Interpretation ("for the avoidance of risk to human health and safety, and the conservation of the environment, as a result of the use of genetically modified organisms"). The plant health framework was recently revised as the Crops Act 2013; Part VI, Article 31 includes provisions for infected areas and how the governmental authority (Cabinet Secretary) deals with plant diseases. There is also an Agriculture, Fisheries and Food Authority Act 2013 to establish this authority, with provisions for noxious and invasive weeds (Part V).

Figure 4.2. Knowledge network for sanitary and phytosanitary (SPS) decisions in Kenya (Kairo et al., 2005).



Rising concern over zoonotic disease outbreaks and two related international initiatives have acted as drivers to reorganize Kenya's animal health sector:

- International Health Regulations (IHR): a 2005 mandate by WHO, that all states develop core capacities needed to detect, assess, report and respond to events that could constitute a public health emergency of international concern (PHEIC) (WHO, 2005)
- Global Health Security Agenda (GHSA): a partnership, launched by WHO, FAO and OIE, with the goal of "a world safe and secure from infectious disease threats".

This has led Kenya to follow a one-health approach, supported by foreign assistance at this stage (Standley et al., 2015). This implies a high level of institutional coordination across animal health, food safety and public health in the face of emerging zoonotic diseases. This is a largely institutional arrangement for achieving international, regional and domestic coordination. Specifically, Kenya is a member of One Health Central and Eastern Africa (OHCEA), a network of seven public health and seven veterinary higher education institutions in eastern Africa founded in 2010, which is supported by the United States Agency for International Development (USAID). The Kenya Zoonotic Disease Unit was created in 2012 and is a collaborative effort between the Ministry of Agriculture, Livestock and Fisheries and the Ministry of Health. Table 4.1 gives details about the unit. Figure 4.3 shows its structure.

The one-health approach aligns with the FAO definition of a biosecurity approach, although with a different emphasis. As noted above, the Kenyan

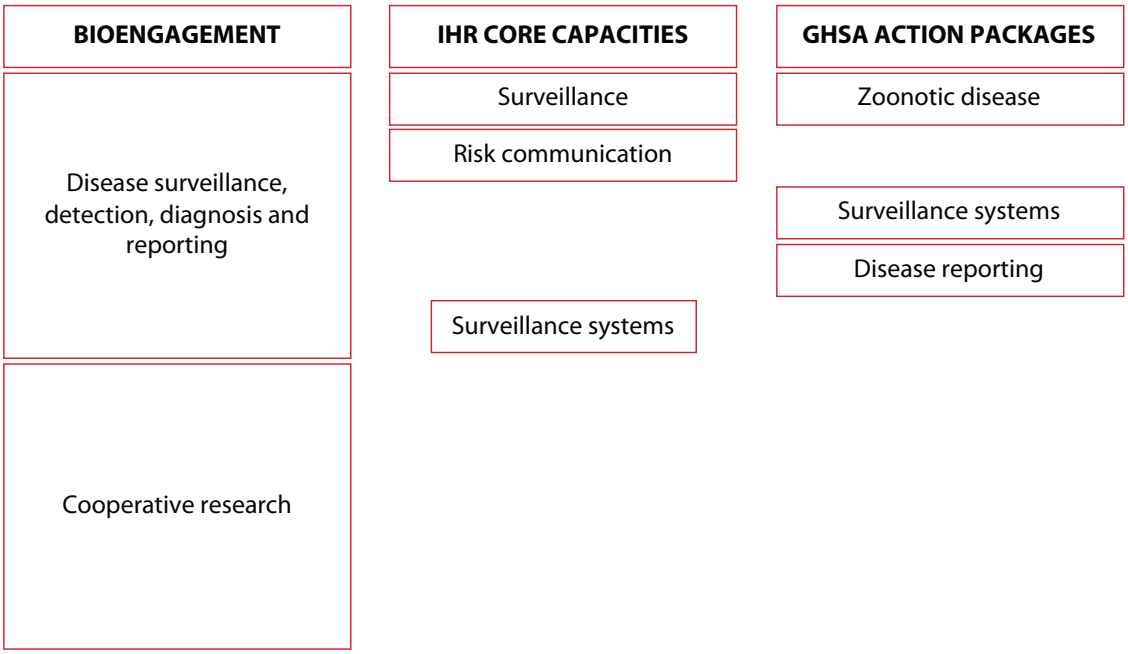
Table 4.1. One example of an institutional arrangement working towards Kenyan biosecurity approach (adapted from Standley et al., 2015)

Kenya Zoonotic Disease Unit goals (2012–2017)	"Bioengagement pillar" Mechanisms for delivery
To strengthen surveillance, prevention and control of zoonoses in both humans and animals	Disease surveillance, detection, diagnosis and control
To establish structures and partnerships that promote one-health approaches	Disease surveillance, detection, diagnosis and control
To conduct applied research at the human–animal–ecosystem interfaces in order to better understand the mechanism of maintenance and transmission of zoonotic pathogens	Cooperative biological research

approach to what could be considered biosecurity focuses on human and animal health in most cases, although some practitioners are considering plant health and land use in terms of drivers for vulnerability and change in disease vector populations.

This new initiative has not replaced the existing SPS framework nor the implementation of the biodiversity objectives of the CBD. Rather, it is an additional mechanism for implementing what may be described as a biosecurity approach, in this case through closer coordination between animal health, human health, food safety and ecological drivers of disease. It will be interesting to see if the expanding concept of One Health as a global initiative will grow to cover other, more traditional areas of biosecurity based more on the SPS Agreement, for example. In the meantime, taking this approach in Kenya has increased capacity in the area of zoonosis but not necessarily in other aspects of biosecurity.

Figure 4.3. Republic of Kenya Zoonotic Disease Unit case study (adapted from Standley et al., 2015).
IHR, International Health Regulations; GHSA, Global Health Security Agenda.



4.6 Norway

Norway was one of the earliest countries to adopt a biosecurity approach[6] towards food safety and plant and animal health. The biosecurity approach rests firmly on Norway's cultural heritage and the importance given to environmental concerns (values reflected similarly in the national approach to biodiversity, as described in GLOBE et al., 2014).

Norway has reformed its food safety administration over time, most recently in 2004 with the creation of the Norwegian Food Safety Authority (Mattilsynet). The new authority was formed by merging the:

- Norwegian Food Control Authority
- Norwegian Animal Health Authority
- Norwegian Agriculture Inspection Service
- Directorate of Fisheries' Seafood Inspectorate
- Municipal food control authorities.

The formation of a single authority was done to give better oversight of the entire food chain (from production to delivery to consumer) and to separate more clearly the scientific assessment process from risk management decisions. In addition the food law merged what had been 13 separate acts. The current Act No. 124 of 2003 relative to Food Production and Food Safety, etc. (Food Act) is designed to guarantee healthy, safe food and safe drinking water for consumers, promote health, regulate environmentally friendly production and prevent the spread of animal and plant diseases.

The reform also provided stronger authority and powers for imposing fines, quarantines and other remedial actions. Under these provisions the constitutional authority remained in three ministries, for health, agriculture and fisheries (Norwegian Food Safety Authority, 2005).

Technical decisions are made using expert committees that are generally parallel to those operated by the European Food Safety Authority (EFSA). These are convened by the Norwegian Scientific Committee for Food Safety (VKM), which also conducts risk assessments for genetically modified organisms, exotic or alien organisms and micro-organisms as well as for species covered by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) for the Norwegian Environment Agency (Miljødirektoratet) (Norwegian Scientific Committee for Food Safety, n.d.). This supporting technical body is one way in which the SPS topical areas find synergy and coordination with more traditionally environmental topics. EFSA recognized VKM as the Norway Focal Point in a focal point agreement made in 2014 (EFSA uses focal points to interface with national food safety authorities, research institutes, consumers and other EFSA-related stakeholders (EFSA, 2010)). Membership of VKM is through selection by the Ministry of Health and Care Services.

Norway was also one of the first countries to have a cabinet-level ministry for environmental matters (established in 1972). The institutional structure for environment now comprises the Ministry of Climate and Environment, and four subordinated directorates including the Norwegian Environment Agency and the Directorate for Cultural Heritage[7]. Norway is a member of the European Economic Area Agreement, which brings together EU and European Free Trade Association (EFTA) states[8]. Norway follows many EU policies but has its own national legislation, as described on the Government web portal, www.Government.no

> The Government maintains its ambition to be a driving force in international climate efforts. Focus will be placed on conservation of forests, access to clean energy, and financing of climate mitigation and adaptation, with particular emphasis on programmes for food security, the prevention of natural disasters and conservation of biodiversity. (Norwegian Government, 2014)

The contents of the Nature Diversity Act (2009) are discussed in relation to other case study countries in

6/ This refers to the combination of human, animal and plant health in terms of the issues under the SPS Agreement, although English translations of Norwegian policy are now also using the term for security-related issues, see Report No. 27 to the Storting [Norwegian Parliament] (2007–2008) on disarmament and non-proliferation where it discussed biosafety and biosecurity (Norwegian Ministry of Foreign Affairs, 2008).

7/ Other bodies interacting with VKM include the Norwegian Directorate for Nature Management (www.dirnat.no), which is an advisory body for conservation and environmental protection and part of the Norwegian framework for evaluation of products of modern biotechnology.

8/ EFTA is an intergovernmental trade organization and area consisting of four European states: Iceland, Liechtenstein, Norway and Switzerland (http://www.efta.int/eea/eea-agreement).

a 2014 study (GLOBE et al., 2014). This explains, for example, how the Ministry of Climate and Environment delegates responsibilities to the Ministry of Fisheries for marine resources. Neither in the law nor in this discussion, however, is there explanation of coordination between the plant health and animal health sectors for overlapping issues beyond stating that if permits are required through other regulation the law does not pre-empt that requirement.

Two pieces of legislation are relevant for managing alien species: Law No. 100 on the Management of Biodiversity (Relating to the Management of Biological, Geological and Landscape Diversity (Nature Diversity Act) of 19 June 2009 and the Wildlife Act (No. 38 of 1981). Regulation No. 716 on Alien Organisms[9] was enacted in 2016 to provide a framework for management of these species. Regulation 716 is aimed at preventing entry of IAS and managing IAS that have already entered Norway's land territory and inland waterways. It applies to the plants, invertebrates, micro-organisms and other organisms that are listed in the regulation, together with information on obtaining a permit for import. The regulation also specifies which organisms require a permit for release into the environment.

The application of this new regulation will require some coordination between the Ministry of Climate and Environment, where it is issued from, and the traditional sectoral units covering animal health, plant health and food safety. Since 2004 these are incorporated as the Norwegian Food Safety Authority (Mattilsynet), which includes the agencies traditionally charged with plant and animal health. The method of coordination to implement this new regulation was not yet documented at the time of this study.

The most recent NBSAP, which updates the previous one made 14 years ago, was going before Parliament in early 2016 and was not yet available in English at the time of this study (Royal Norwegian Ministry of Climate and Environment, 2016).

Norway has a history of incorporating its environmental values into international development assistance. It provides approximately 1 percent of gross national income for external aid. National policy includes delivery through non-governmental organizations (NGOs) and partnering with UN agencies and other multilateral agencies. This is relevant because of initiatives specifically aimed at biosecurity.

The opportunities encountered by Norway in taking the biosecurity approach in the context of SPS have included:

- efficiency and synergy of specialized groups for functions such as risk assessment, data management and public engagement
- combined approaches for import, export or border issues; and monitoring and surveillance.

The challenges noted from that transition were:

- combining staff from different technical and work-style cultures, including different administrative contexts (Norwegian Food Safety Authority, 2005)
- trying to implement changes all at once, rather than in a phased progression
- maintaining in-depth expertise for each topic
- defining and eliminating overlaps or filling remaining gaps
- defining more clearly the constitutional authorities at the time of reform (Norwegian Food Safety Authority, 2005).

A short-term solution was to have each member of staff cover their previous responsibilities until they were clearly assigned to new ones and their former ones were covered. Transitions of this scale may take 2–4 years to implement fully (Norwegian Food Safety Authority, 2005).

These same issues could arise in attempting to coordinate across the combined SPS topics and emerging environmental ones, specifically for IAS. However, with the experience of the earlier integration and the national emphasis on environmental and climate issues, Norway has a better chance of this coordination succeeding than many countries that are only now trying to integrate to a biosecurity approach. Clear authority for each mandate, whether the mandate includes responsibility for implementation or is only advisory, will also improve the chance for success.

9/ A copy of Regulation 716 in Norwegian is available from http://faolex.fao.org/docs/pdf/nor149019.pdf

5 Conclusions and Recommendations [10]

At the turn of this century, FAO was among the first to declare an important initiative aimed at identifying synergies, integration, effective use of resources, improved methodologies and more successful outcomes for SPS-related biosecurity. The concepts were well thought out, interdisciplinary and supported broadly within the organization. Since that time, however, the scope of the biosecurity approach has been stretched well beyond SPS, associated primarily with trade, to include other environmental, health and security issues associated with biological risks. At the same time, the concept has been reduced by particular sectors to a meaning based on their own interpretations, sometimes leaving out even the original three SPS sectors.

In this study, the SPS-based biosecurity approach has been considered alongside more recent initiatives in biodiversity, environmental impact, public health, biosafety, economic development and security, cultural integrity and national patrimony, and even way of life and happiness. The realms shown in Figures 1.1–1.3 (environment, trade and health, security) and the associated initiatives and treaties shown in Figures 2.1 and 3.1 remain valid. The relevance and value of following a biosecurity approach are not in question, but the appropriate use of the term biosecurity and the best mechanisms for implementation of the approach are.

The initial drivers for taking up a biosecurity approach are also still valid, if not actually increasing in intensity. For SPS, primary among these is the need to be better able to defend national agricultural and natural resources against greater threats each year with limited resources. As one NPPO staff member interviewed stated:

Not a single agricultural health system will ever have all the resources needed to execute its full mandate. The challenge lies in maximizing what we have and being creative in finding ways and opportunities to continuously improve.

The three recognized SPS foundational agreements have proven that collaboration can increase effectiveness; collaborations such as the IPPC and FAO, OIE and the CAC, OIE and WHO, or the CAC and WHO. Other UN agencies can also contribute significant expertise and sometimes funding. The Joint Division of FAO and the International Atomic Energy Agency (IAEA) champions many pest control and eradication projects. The interactions between the IPPC and the CBD have created synergies and efficiency at the international level and provided opportunities for improved regional and national approaches to IAS. Despite the importance of these international collaborations, successful delivery of the biosecurity approach rests largely with the public sector at the national level and depends entirely on having qualified and resourced topic-specific expertise ready to join in with collaborations.

Invasions and introductions of pests and diseases are likely to occur at increasing rates owing to climate change and habitat disruption. These have been identified as likely drivers for emerging zoonoses as well. Mechanisms for institutional coordination are needed, but should not become the objective in themselves. Biosecurity committees that bring together SPS and biodiversity and environment public sector authorities should not become an additional layer of bureaucracy, but rather must operate flexibly as a means to producing a greater outcome than would be achieved in isolation. Efforts to improve methodologies such as surveillance (see IPPC, 2012a for reports on regional reviews of national implementation of ISPM 6 *Guidelines for surveillance*) or risk analysis can lead to improvements for the overall biosecurity of a country.

For some time, the use of purpose-designed sectoral capacity evaluation tools has proven very successful for capacity enhancement, preparation

10/ Conclusions by the authors do not imply any endorsement by FAO, its departments or other entities that have shared information for or reviewed this study. A separate document lists further recommendations for FAO to consider internally.

of national strategies, refinement of project plans, engaging stakeholders and highlighting priorities for investment (FAO, 2006c; IICA, 2010; STDF, 2011; IPPC, 2012b). These should not be replaced by overarching biosecurity tools that miss the detail required for technical and complex topics. A biosecurity perspective is an important complement to the sectoral process, however, just as consideration of SPS or biodiversity frameworks and experiences is very important to provide larger context for sectoral affairs. Therefore, facilitated and concurrent capacity evaluation of each SPS sector could lead to discussions for a national SPS system strategy, with environmental sector representatives contributing that perspective to ensure coordination, to avoid overlaps and gaps. This is a first step, but an essential one, for increasing capacity and introducing monitoring, evaluation and indicators of a biosecurity strategy.

Another possible approach is to tackle a specific cross-cutting problem, such as aquatic weeds. In this instance, it would be appropriate to begin with a broad range of stakeholders but to focus on solutions for the specific issue, for clarity of purpose and deeper discussion. Johnson et al. (2015) describe a process in Australia of engaging stakeholders with a wide range of expertise in order to address an ongoing issue of algal blooms in waterways and coastal waters near Brisbane. By using an integrated Bayesian model as a discussion tool, the various experts were able to agree on a work plan and priority research. Noticeable success with one issue could motivate the policy and science community to work together cross-sectorally on future problems.

The ability of many countries to implement their biodiversity strategy, or other policies set out to achieve the goals of the CBD, has been enhanced by external funding resources. In many cases, less economically developed countries must subsidize self-funded measures with multilateral support or bilateral cooperation agreements to ensure full implementation. For example, the Guyanese Environmental Protection Act (1996) (implemented through the Protected Areas Commission), which has achieved a protection or conservation status for 9 percent of Guyanese territory (Environmental Protection Agency, 2014) was, in part, aided by a bilateral agreement with Germany for €2.56 million transferred through the Protected Areas Trust Fund, with a further €5.15 million agreed for phase 2 (Caribbean Trakker, 2014; Environmental Protection Agency, 2015). Similarly international collaboration and joint funding will be needed to implement a biosecurity approach for many smaller or less economically developed countries. This necessity makes the role of FAO as a neutral party even more critical.

Countries facing any of the drivers or constraints discussed should be able to seek technical advice and support on SPS issues through coordinating bodies such as FAO or STDF, which in turn would turn to the sectoral units, departments, collaborating agencies or consultants for providing necessary in-depth expertise. The mechanisms for progressing biosecurity objectives may follow suit. There have been project grants under STDF aimed at developing a national biosecurity strategy. The Liberia grant (STDF, 2010) utilized the FAO biosecurity toolkit to carry out a full overview of the country's SPS-related status. This was done by an external consultant, although local stakeholders were involved. In other cases, such as for Cambodia (STDF, 2013), there was insufficient local buy-in to continue with the process after an initial phase, most probably because a larger development project with some overlap that diverted attention away from initial accomplishments. These types of effort will always face challenges, but lessons learned can benefit the outcome. IICA has successfully identified common features across the SPS system as well as unique features of each sector when working on capacity evaluation and strategic planning. IICA has also understood the role of the private sector as an informed constituency to keep the public sector process and policies on track.

This study indicates that a considered balance between sector-specific and overarching biosecurity efforts is needed. Considering the original motivation for this study, it is recommended that new guidance covering the key elements of a successful biosecurity policy and legislative framework be prepared. This does not imply, however, that biosecurity legislation is always needed. Rather, priority setting and gap analysis should be conducted by country or region, with the localized context and objectives

in mind. Individual projects through the FAO TCP or with the Legal Unit of FAO will allow more "fit-for-purpose" guidance than a model law could ever provide. Gap analysis for biosecurity may extend to policies, institutions and capacities without diverging too greatly from existing sectoral-based analysis, planning and capacity development activities.

FAO can play a unique role in the biosecurity approach. Although there is an urgent need to again consolidate the Organization's corporate definition and concepts, the demand for this makes the effort worthwhile.

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7 Annexes

Annex 1. Example definitions from international and national laws and other documents

Table of the concept of biosecurity as used by FAO in official publications (or cited by FAO in publications)

Definition	Document name/Source
Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks to analyse and manage risks in the sectors of: food safety; animal life and health; plant life and health, including associated environmental risks. These sectors include: food production in relation to food safety; the introduction of plant pests, animal pests and diseases and zoonoses; the introduction and release of genetically modified organisms and their products; and the introduction and safe management of invasive alien species and genotypes. The objective of Biosecurity is to identify, assess and respond appropriately to all pests and diseases posing a significant threat to agriculture, forestry, horticulture, fisheries, native biodiversity and human health. Appropriate responses include eradication, containment and on-going control.	FAO biosecurity legal doc.
Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. Biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes. Biosecurity is defined as a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.	FAO, 2005
A strategic and integrated approach that encompasses both policy and regulatory frameworks aimed at analysing and managing the risks of the sectors dealing with food safety, animal life and health, plant life and health and the environment.	Fisheries and Aquaculture Department, FAO. FAO, 2014b
Management of all biological and environmental risks associated with food and agriculture, including forestry and fisheries.	Agriculture Department, FAO website. FAO, 2001
…'harm' is the damage done by something that might have been prevented through biosecurity, whereas 'risk' is the chance of that harm occurring.	Cock, 2003
Biosecurity plans require the adoption of a set of attitudes and behaviours that reduce risk in activities involving … production and marketing. A comprehensive, detailed, practical and easily understood plan is most effective.	FAO, 2011b
All the cumulative measures that can or should be taken to keep disease (viruses, bacteria, fungi, protozoa, parasites) from a farm and to prevent the transmission of disease (by humans, insects, rodents and wild birds/animals) within an infected farm to neighbouring farms.	Terminology (Ar), CPAM, FAO, 2013; Terminology Project, FAO-ESCWA, 2012

Aquatic biosecurity is a system of procedures for dealing with the risks of diseases, pests and other hazards (such as genetic pollution) in aquatic environments. In the Pacific region, the main aims of aquatic biosecurity are to safeguard human health, the environment, and national economies.	Australian Government, n.d.
Biosafety within a biosecurity framework – generally refers to the safe use of new biotechnologies within the framework of managing biological risks associated with food and agriculture.	ATG, CSCM, FAO, 2010
Biosecurity Australia provides science based quarantine assessments and policy advice that protects Australia's favourable pest and disease status and enhances Australia's access to international animal and plant related markets. NOTE Update Australia info here: http://www.agriculture.gov.au/biosecurity Under Dep Agric and Water Resources, DAWR.	Australian Government, Department of Agriculture, Fisheries and Forestry, 2006 (http://www.daff.gov.au/biosecurityaustralia)
Management of all biological and environmental risks associated with food and agriculture, including forestry and fisheries.	Agriculture Department, FAO website. FAO, 2001
Appropriate level of protection; biosecurity risk analysis frameworks; biosecurity toolkit; FAO biosecurity toolkit	FAO Language Resources Project, 2010 - Dr M. H. Kassem, Agricultural Research Centre, Cairo, Egypt
The FAO biosecurity 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.	FAO, 2007a

Table of definitions of biosecurity or scope and introductory description of biosecurity legislation from national, subnational or regional sources

Organization/ Country	Keyword (Biosecurity/ Biological security/etc.)	Definition, scope or legislation chapeau	Source (sources are legislation listed in Annex 2 if not noted)
Australia – also see Queensland, Tasmania, Victoria, Western Australia	Environmental biosecurity	Protection of the environment and social amenity from the negative effects associated with invasive species; including weeds, pests and diseases. It occurs across the entire biosecurity continuum: pre-border preparedness, border protection and post-border management and control	Australian Government, 2013
Bhutan	Biosecurity	It shall contribute to achieving Gross National Happiness by ensuring Bhutanese people, the biological resources, plants and animals are protected from the harmful effects of pests and diseases, invasive alien species, genetically modified organisms, toxic chemicals and food additives.	Frampton, 2010
Botswana	Biosecurity	An act to prevent the introduction, spread and establishment of plant pests; to facilitate trade in plants; to enable Botswana to comply with its international obligations; and to provide for matters incidental thereto.	
	Biosecurity	Plant Protection: subsidiary legislation index to subsidiary legislation.	
Canada	Farm-level biosecurity	(For dairy cattle) Farm-level biosecurity is a series of management practices designed to minimize or prevent and control: the introduction of infectious disease agents onto a farm; spread within a farm production operation; and export of these disease agents beyond the farm that may have an adverse effect on the economy, environment and human health	CFIA, 2013
	Another sector biosecurity	(For beef cattle) Those practices that prevent or mitigate disease from entering, spreading within or being released from operations that may contain livestock	CFIA, 2012
Cook Islands	Biosecurity	Control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects from such pests and diseases on the economy and health of the Cook Islands.	

Cook Islands *(continued)*	Biosecurity Act 2008 Long Title	An act to prevent the entry of animal and plant pests and diseases into the Cook Islands, to control their establishment and spread in to the Cook Islands, to regulate the movement of animal and plant pests and diseases and of animals and plants and their products; to facilitate international cooperation in respect of animal and plant diseases; and to make ancillary and related provisions.
Ethiopia	Biological Security	Growth of the agriculture sector in Ethiopia was hampered by a series of policy and structural constraints which resulted in a low input/low output trap, due in part to low levels of investment, low technology application, and low capacity. The solution needs to involve a structural change, for which major capacity development is needed, including a quantum change in human capacity, input supply, technology adoption, and provision of infrastructure.
Fiji	biosecurity	Control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects from such pests and diseases on the economy and health of the Fiji Islands.
	Biosecurity Promulgation 2008 Title	To prevent the entry of animal and plant pests and diseases into the Fiji Islands; to control their establishment and spread in the Fiji Islands; to regulate the movement of animal and plant pests and diseases and of animals and plants and their products; to facilitate international cooperation in respect of animal and plant diseases; and for related matters.
Ghana	Biological Security	The implementation of this policy will be through the formulation and implementation of a comprehensive 20-year Forestry Development Master Plan to fit into the national poverty reduction strategy. The following strategic directions and policy actions would be pursed to guide the implementation this policy
Indonesia	Biosecurity	that in an effort to improve consumer protection, preserve the natural resources, provide business certainty, transparency, and simplification of licensing process, orderly import administration, as well as following up on the economic rescue policy package created and approved in the Limited Ministerial Meeting on 23 August 2013, necessitate the rearrangement of the import and export provision of animal and animal product.

Kenya	Biosecurity	(1) No person shall import or export a pest control product for commercial purposes unless that person is in possession of a licence issued under these Regulations. (2) No licence shall be issued for the importation of a pest control product unless the pest control product is registered in accordance with the Pest Control Products (Registration) Regulations, 1984. (3) No licence shall be issued under these Regulations unless the Board is satisfied that the provisions of the Pest Control Products Act, 1982 have been complied with.
	Biosecurity	A person shall not import a plant, plant product or regulated article except in the manner provided for under these Rules.
	Biosecurity	The importation is prohibited of any live rabbits from any country, port or territory whatsoever, except such rabbits as may be imported with the sanction in writing of the Director and subject to such conditions as he may in any case impose.
Kiribati	biosecurity	Control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects from such pests and diseases on the economy and health of Kiribati.
	Biosecurity Act 2011 Title	An act to prevent the entry of animal and plant, pests and diseases into Kiribati; to control their establishment and spread in regulate the movement of animal and plant pests and diseases and of animals and plants and their products; to facilitate international cooperation in respect of animal and plant diseases; and to make ancillary and related provisions
New Caledonia	Biosécurité	L'ensemble des activités visant à ne pas introduire, à éradiquer ou à contenir tout agent biologique d'origine animale ou végétale nuisible à la santé humaine, à l'économie ou à l'environnement.
	Google Translate of above	All activities not to introduce, to eradicate or contain any harmful biological agent of animal or vegetable origin for human health, the economy or the environment.
	Délibération du congrès n° 238 du 15 décembre 2006 Title	La présente délibération décrit les dispositions générales relatives à la biosécurité devant être appliquées aux frontières internationales de la Nouvelle-Calédonie. Tous les termes y figurant en italiques renvoient aux définitions mentionnées à l'article 2.

New Caledonia *(continued)*	Google Translate of above	This decision describes the general provisions relating to biosecurity to be applied to international borders of New Caledonia. All terms are in italics refer to terms defined in Article 2.	
New Zealand	Biosecurity Act 1993 Title	An act to restate and reform the law relating to the exclusion, eradication, and effective management of pests and unwanted organisms.	
	biosecurity	Exclusion, eradication or effect management of risks posed by pests and diseases to the economy, environment and human health	New Zealand Government, n.d.
Queensland	Biosecurity Act 2014 Title	An act to provide for a comprehensive biosecurity framework to manage the impacts of animal and plant diseases and pests in a timely and effective way and ensure the safety and quality of animal feed, fertilizers and other agricultural inputs.	
Samoa	biosecurity risk	Risk of the likelihood of: (a) a disease or pest being introduced, established or spread in Samoa; and (b) the disease or pest causing damage to human beings, animals, plants, other aspects of the environment or economic activities as a result of the introduction, establishment or spread of the disease or pest.	
	Scope of biosecurity	In this act, biosecurity includes, but is not limited to, measures: (1) For, or in relation to, the examination, exclusion, detention, observation, segregation, isolation, protection, testing, treatment and regulation of conveyances, installations, people, regulated articles or other goods or things; and (2) Having as their object the prevention or control of the introduction, establishment or spread of pests and diseases that could cause significant damage to human beings, animals, plants, other aspects of the environment or economic activities.	
Seychelles	biosecurity	A strategic and integrated approach that encompasses the policy and regulatory framework for analysing and managing relevant risks to animal and plant life and the associated risks to the environment, economy and public health.	
	Animal and Plant Biosecurity Act 2014 Title	An act to prevent the entry of animal and plant pests and diseases into, and their establishment and spread in, Seychelles, to regulate and control the movement of animal and plant pests and diseases and of animals and plants and their products within Seychelles, to facilitate international trade and cooperation in respect of animal and plant pests and diseases and for matters connected therewith and incidental thereto.	

Solomon Islands	biosecurity	Control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects from such pests and diseases on the economy and health of Solomon Islands.	
	Biosecurity Act 2013 Title	An act to prevent the entry of animal and plant pests and diseases into the Solomon Islands; to control their establishment and spread in the Solomon Islands; to regulate the movement of animal and plant pests and diseases and of animals and plants and their products; to facilitate international co-operation in respect of animal and plant diseases and related matters.	
South Africa	National Environmental Laws Amendment Act 2009	An Act to amend the National Environmental Management: Biodiversity Act, 2004, so as to provide for general surveillance monitoring; to provide further considerations for a biodiversity management plan; to provide that an environment impact assessment must be obtained when genetically modified organisms are involved; to introduce notification requirements in the discovery phase of a bioprospecting project; to take into consideration knowledge of specific individuals when issuing specific bioprospecting permits; to allow the Director-General or a trustee to manage the Bioprospecting Fund; to allow for the renewal or amendment of a permit; to amend the regulations to allow for hunting; and to effect certain textual alterations.	
Tanzania	National Agriculture Policy	Biotechnology has been used for a long time in areas such as tissue culture applications, characterization of germplasm using molecular marker techniques and in disease diagnosis. In view of the fact that people are averse by use of biotechnology since it may also come with risks, this technology needs bio-safety measures to minimize perceived risks. Biotechnology development in the country is hindered by limited public awareness on this modern technology and bio-safety issues; bio-safety regulations that do not facilitate genetic engineering; limited physical infrastructure; and inadequate trained human resources and facilities for management of biotechnology.	
Tasmania	biosecurity	Protection of industries, the environment and public well-being, health, amenity and safety from the negative impacts of pests, diseases and weeds.	Government of Tasmania, 2007

Tokelau	biosecurity risk	The likelihood that any introduction, establishment, and spread of a disease or pest will result in harm being caused to human beings, animals, plants, other aspects of the environment, or economic activities as a result of the introduction, establishment, and spread of the disease or pest, and includes the likely extent of such harm.	
Trinidad and Tobago	Biosecurity	An act to make better provision for the control of diseases and pests injurious to plants.	
Turks and Caicos	Biosecurity	An ordinance to prevent the introduction and spread of plant pests, to protect and promote plant health, to control the movement of regulated articles into, from and within the Turks and Caicos islands; and for connected purposes.	
UK GB Non-Native Species Secretariat	Biosecurity	Taking steps to make sure that good hygiene practices are in place to reduce and minimize the risk of spreading invasive non-native species.	GB NNSS, 2011
Vanuatu	biosecurity	Control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects from such pests and diseases on the economy and health of Vanuatu.	
Victoria	biosecurity	Protection of the economy, the environment, social amenity or human health from negative impacts associated with the entry, establishment or spread of animal or plant pests and disease, or invasive plant and animal species' (State Government of Victoria, Department of Primary Industries, 2010)	State Government of Victoria, 2010
Western Australia	biosecurity	Protection from the adverse effect an organism has or may have on — (a) another organism; or (b) a human being; or (c) the environment, or part of the environment; or (d) agricultural activities, fishing or pearling activities, or related commercial activities carried on, or intended to be carried on, in the State or part of the State.	
Windhoek Declaration 2009	biosecurity	Safeguards animal health, protects biodiversity, promotes environmental sustainability and enhances food safety. The livelihoods of many people depend on fisheries and aquaculture, including some of the most vulnerable in the region	

Inclusion in this table does not imply that the sources are of the same nature in terms of the role in terms of regional or national mandate or implementation.

Annex 2. Legislative search for biosecurity

The desk study began with a review of legislation, regulations and national strategies to determine how countries are using the term biosecurity and what it means to them. This broad-ranging review also included literature from FAO, over approximately 15 years.

This Annex summarizes the findings of the legislative and FAO reviews in more detail and explains the method, for those who may wish to repeat it at a future time. The FAOLEX unit has indicated that there is a revision of the database structure, however. Therefore a search after those enhancements could give different results. The conclusions of this part of the review appear in the body of the report, along with observations from a more general literature review.

Methodology

As agreed in the study contract, the FAO legal database was used as the sole source of legislation, regulation and strategies for this phase of review. The database can be accessed through the following link: http://faolex.fao.org/faolex/ .

The initial search used the keyword 'biosecurity' and 'biological security'. Later it was clarified that full-document text searching requires entry of English, French and Spanish terms to pick up cases where the relevant document was not tagged with the corresponding keyword in other languages. Therefore, this was not a comprehensive search of that database but was representative.

The database allowed a fairly rapid review of numerous countries, in English, Spanish, French, German and Portuguese (the languages understood by the team). There were only a few texts that required either an attempt at translation (ie. Using Google Translate to get the general gist of the document), or assistance from others (e.g. for Arabic, Finnish and Croatian).

Compared to even a decade ago, a high number of countries are putting their legislation on websites, making documents available by searching the internet. Twenty years ago, it would have required individual contacts in each country to obtain this material. Attempting to identify and locate legislation from this range of countries would have been impossible, however, without the database because of the time allocated for the study. Also, even when checking individual country sites it is possible to miss important documents. The Seychelles and Burkina Faso, for example, have relatively new laws. Some sites are not easy to search or decipher in terms of organization.

Challenges or gaps in the database

We were told by the Arabic legal consultant that the database is not fully populated or updated for the available Arabic texts.

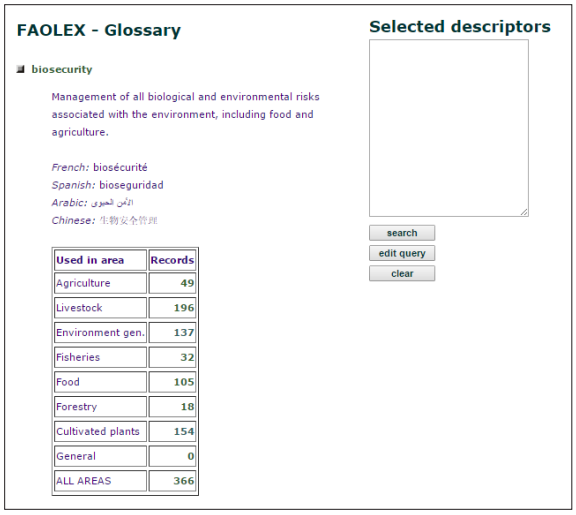
The issue of assigning a keyword such as 'biosecurity' was discussed with the FAO legal database office. Because as many as a dozen legal specialists, most not FAO employees, are entering the laws, etc., and assigning keywords, there are differences in choices of keywords. This may be addressed by plans already in play to edit the keyword system.

The use of this term follows styles or trends that are not consistent with the FAO concept. For example, Croatia has a lot of legislation containing 'biosecurity' as a term, or concept, but not all of it relates to the topic at hand. The choice of the word may be a matter of language or the organizational culture.

FAOLEX advanced search

After learning more about the options in using the FAO database, an advanced search was performed by choosing "all" topical categories and using the glossary term Biosecurity (versus simply searching by this term from the top page of the database).

The result can be seen from the screenshot on the following page: 366 results were found in total, com-



FAOLEX - Glossary

biosecurity

Management of all biological and environmental risks associated with the environment, including food and agriculture.

French: biosécurité
Spanish: bioseguridad
Arabic: الأمن الحيوي
Chinese: 生物安全管理

Used in area	Records
Agriculture	49
Livestock	196
Environment gen.	137
Fisheries	32
Food	105
Forestry	18
Cultivated plants	154
General	0
ALL AREAS	366

Selected descriptors

search
edit query
clear

pared to 384 results found by simply searching for the keyword 'biosecurity'.

To assess the difference between the two methods of searching, a comparison was made between the results from the 'biosecurity' keyword search, and the results from the advanced search. Owing to time restrictions, an exhaustive comparison was not possible, so for the advanced search, only the Environment General category was analysed.

The comparison looked to show which legislation arose from the keyword search alone, which arose from the advanced search alone, and which results were common to both search methodologies. If keywords were consistently used throughout the database, you would in general expect that the same results would be generated for both methodologies.

The results from this comparison showed that out of the 137 results from the Environment General category (from the advanced search), only 52 were also found using the standard 'biosecurity' keyword search. This meant that 85 search results were unique to using the glossary term 'biosecurity' through an advanced search.

Because of limits on time for this activity, the team did not pursue these options further. They will report to the FAO database office, however, to exchange experiences and ideas on best approaches to address these discrepancies.

The challenge of identifying documents in the database that may relate to biosecurity is not based solely on the keyword coding, however. As noted in the table of usage of the term in FAO publications (Annex 1), and citations in publications, there is a wide and even inconsistent use of the term over time even within FAO. This reflects the development of concepts and sometimes parallel but diverging evolution of the meaning of the term outside FAO and is considered in depth in the report.

Biosecurity definitions

Using the results of the database search using the keywords 'biosecurity' and 'biological security', all definitions from national legislation were compiled in an Excel spreadsheet.

From the initial combined search results of 493 documents, 33 definitions of 'biosecurity' were established. Some of these definitions came from the scope, introduction or goals and aims of the legislation, by the inference that this defines the concept. Legislation that did not contain a definition for biosecurity was not included in this spreadsheet (shown below as a table, but maintained as an Excel summary).

For each definition the following information was noted (though some columns are hidden in the tables below, as not relevant to the general reader):

- Organization/nation
- Keyword searched
- Definition
- Document name
- Location of document

FAOTERM Portal or FAO Glossary

Just after the team had gone through various FAO documents, they discovered the FAO Glossary or FAOTERM Portal. This site was also used to search for the term 'biosecurity', to provide current definitions provided by the FAO. The same information was recorded as above.

Terms from the database that were not relevant to our project, but emerged via keyword search, were listed but noted as 'Irrelevant search results'.

Further FAO publications review

The nature of this review emphasizes the importance of the FAO Legal Office as a source of information and guidance. From the website, http://www.fao.org/legal/home/legal-office/en/, the team located various documents. Additional ones have been added since from the Legal Office (not all yet incorporated below).

Relevant documents were found primarily as Legal Papers or Legal Studies, while further search led to partner publications and FAO publications not arising from the Legal Unit. It was not easy to look up a general study on biosecurity, however, since the Legal Office responds to individual country or regional requests. Therefore, several location-specific publications or studies were found to be representative of the FAO legal view of principles of biosecurity and elements required for appropriate legislation. That said, the evolution of the concept and use of the term was not lost on the legal advisors and more recent papers may avoid the word altogether.

More on principles and findings appears in the body of the report.

Table of documents found through the FAOLEX search

Country/Region	Legislation Name
Angola	Executive Decree No. 62/11 approving the Regulation on Biosecurity
	Presidential Decree No. 104/15 approving the Regulation of Livestock Farms.
	Resolution No. 1/10 approving the National Policy on Forests, Wildlife and Conservation areas.
	Executive Decree No. 62/11 approving the Regulation on Biosecurity.
Australia (Western Australia)	Biosecurity and Agricultural Management (Repeal and Consequential Provisions) Act, 2007 (Act No. 24 of 2007).
	Biosecurity and Agriculture Management (Agriculture Standards) Regulations 2013.
	Biosecurity and Agriculture Management (Identification and Movement of Stock and Apiaries) Regulations 2013.
	Biosecurity and Agriculture Management Regulations 2013
	Biosecurity and Agriculture Management Act, 2007 (Act No. 23)
	Biosecurity and Agriculture Management (Quality Assurance and Accreditation) Regulations 2013.
	Biosecurity and Agriculture Management (Agriculture Standards) Regulations 2013.
	Biosecurity and Agriculture Management Industry Funding Scheme (Cattle) Regulations 2010.
	Biosecurity and Agriculture Management Industry Funding Scheme (Grains) Regulations 2010.
	Biosecurity and Agriculture Management Industry Funding Scheme (Sheep and Goats) Regulations 2010
Australia (Queensland)	Biosecurity Act, 2014.

Australia (Victoria)	Plant Biosecurity Act 2010 (No. 60).
	Plant Biosecurity Regulations, 2012.
Australia (Northern Territory)	Livestock Act, 2008 (Act No. 36).
Armenia	Nothing Found
Argentina	Resolución Nº 241/2012 - Establécese el régimen aplicable para la autorización de las actividades que se lleven a cabo en invernáculos de bioseguridad con organismos vegetales genéticamente modificados.
Bangladesh	Sixth Five Year Plan 2011-2015: Accelerating Growth and Reducing Poverty.
	National Environment Management Action Plan (NEMAP).
Belize	Décret nº 2004-293 portant création, attributions, composition et fonctionnement du Comité national de bio-sécurité (CNBS).
Bhutan	Nothing Found
Bolivia	Nothing Found
Bosnia and Herzegovina	Law on freshwater fisheries.
Botswana	Plant Protection Regulations (S.I. 58 of 2009).
	Plant Protection Act (Chapter 35:02)
Brazil	Norm No. 5 establishing the Technical Regulation of biosecurity for manipulating the virus of Foot and Mouth Disease.
	Norm No. 7 of 8 May 2012 creating the National Programme for Hygiene and Sanitary Control of Bivalve Molluscs (PNCMB).
	Law No. 14.486 creating the State Policy on Organic Production and Agroecology.
	Normative Instruction No. 58 instituting the monitoring system for agro-chemical waste on fruit exported to the EU..
Burkina Faso	Décret n° 2015-444/PRES-TRANS/PM/MRSI/MEF du 30 avril 2015 portant attributions, composition, organisation et fonctionnement de l'Observatoire national de biosécurité.
	Décret N°2015-874/PRES/PM/MRSI/MEF/MARHASA/MERH/MS/MRA du 14 juillet 2015 portant approbation des statuts particuliers de l'Agence Nationale de Biosécurité (ANB).
	Décret N°2015-834/PRES-TRANS/PM/MEF/MRSI du 13 juillet 2015 portant érection de l'Agence Nationale de Biosécurité (ANB) en établissement public de l'Etat à caractère scientifique, culturel et technique.
	Décret 2015-213 PRES-TRANS/PM/MRSI/MESS/MERH du 05 mars 2015 portant évaluation des risques biotechnologiques.
	Décret n° 2015-253/PRES-TRANS/PM/MRSI/MEF du 17 mars 2015 portant attributions, composition, organisation et fonctionnement du Comité Scientifique National de Biosécurité (CSNB).
Cabo Verde	Decree No. 7/2002 establishing conservation and protection measures for fauna and flora species.

Cameroon	Décret n° 037/2003/ du 4 février 2003 portant ratification des statuts de l'Agence Africaine de Biotechnologie.
Canada	Nothing Found
Chad	Stratégie Nationale et Plan d'Actions pour la Mise en Oeuvre de l'Initiative Grande Muraille Verte au Tchad.
Chile	Decreto Nº 887 - Establece área de manejo y explotación de recursos bentónicos para la X Región de Los Lagos
	Resolución Nº 8.309 - Establece la compartimentación como instrumento para la gestión sanitaria.
Colombia	Resolución Nº 3.651 - Requisitos para la certificación de granjas avícolas bioseguras de postura y/o levante.
	Resolución Nº 3.652 - Requisitos para la certificación de granjas avícolas bioseguras de engorde.
	Resolución Nº 957 - Medidas de bioseguridad en las granjas avícolas comerciales y granjas avícolas de autoconsumo.
	Resolución Nº 3.283 - Medidas básicas de bioseguridad para las granjas avícolas comerciales.
	Resolución Nº 3.570 - Modifica la Resolución Nº 3.283, sobre medidas básicas de bioseguridad para las granjas avícolas comerciales.
	Resolución Nº 5.236 - Modifica la Resolución Nº 3.283, sobre medidas básicas de bioseguridad para las granjas avícolas comerciales.
	Resolución Nº 1.183 - Condiciones de bioseguridad que deben cumplir las granjas avícolas comerciales para su certificación.
	Decreto Nº 2.833 - Crea la Comisión Intersectorial de Medidas Sanitarias y Fitosanitarias.
	Decreto Nº 4.003 - Procedimiento administrativo para la elaboración, adopción y aplicación de reglamentos técnicos, medidas sanitarias y fitosanitarias en el ámbito agroalimentario.
	Resolución Nº 47 - Guía General de Carácter Voluntario, referente a la Adopción y Certificación de Buenas Prácticas Avícolas (BPA).
Cook Islands	Biosecurity Act, 2008 (No. 14 of 2008).
Costa Rica	Decreto Nº 37.588/MAG/MS/MICIT/MINAET - Modifica el Decreto Nº 26.921/MAG, Reglamento a la Ley de protección fitosanitaria.
	Decreto Nº 35.960/S/MAG/MEIC/COMEX - Política Nacional de Inocuidad de los Alimentos.
Croatia	Law amending the Law on sanitary inspection.
	Regulation on the Content and Manner of Filing Applications for Deliberate Release of Genetically Modified Organisms into the Environment.
	Regulation on the list of existing active substances permitted in biocidal products.
	Regulation of Food Enriched with Nutrients.

Croatia *(continued)*	Regulation on the Monitoring of Certain Substances and Residues Thereof in Live Animals and Animal Products.
	Regulation on Maximum Level for Certain Contaminants in Foodstuff.
	Regulation on Conditions for the Introduction of Products of Animal Origin in the Traveler's Personal Luggage.
	Regulation on Pharmacologically Active Substances and their Classification in Relation to the Maximum Levels of Residues in Foods of Animal Origin.
	Regulation amending the Regulation on maximum level for certain contaminants in foodstuff.
	Regulation amending the Regulation on the implementation of obligatory measures in approved facilities to minimize microbiological and other contamination of meat, meat products and other products of animal origin intended for human consumption.
	Regulation on the Content and Scope of Risk Assessment for the Marketing of Genetically Modified Organisms or Products Containing and/or Consisting or Deriving from Genetically Modified Organisms.
	Regulation on the list of active substances in biocidal products.
	Regulation on the Level of Genetically Modified Organisms in Products which are Marketed and Not Labelled as Products Containing Genetically Modified Organisms.
	Law amending the Law on genetically modified organisms.
	Regulation on Measures for the Prevention of Occurrence and Spread of Classic Swine Fever.
	Regulation on Health Suitability of Materials and Articles Intended to Come into Direct Contact with Food.
	Regulation on Special Conditions for Objects in the Food Business of Animal Origin and Activities that are Granted under Special Conditions.
	Ordinance on the Methods of Sampling and Analysis Standards for Performance of Analysis and Super-Analysis on Foods and General Use Items.
	Regulation on Procedures for Reducing the Prevalence of Salmonella Enteritidis and Salmonella Typhimurium in Broiler Chickens.
	Regulation Amending the Regulation on the Implementation of Obligatory Measures in Approved Facilities to Minimize Microbiological and other Contamination of Meat, Meat Products and other Products of Animal Origin Intended for Human Consumption.
	Regulation on the protection of agricultural land from pollution.
	Regulation on Requirements for Dealing with Feed.
	Law on the Protection of the Population from Infectious Diseases.
	Regulation on Transitional Measures for Certain Animal By-Products Not Intended for Human Consumption (Category 1 and Category 2).
	Regulation on the Control of Imported Agricultural Propagating Material and the Application Form for the Import of Agricultural Propagating Material
	Regulation on special conditions for the import of food and feed originating in or shipped from Japan after the incident at the Fukushima nuclear plant.

Croatia *(continued)*	Regulation on special conditions for the import of food and feed originating in or shipped from Japan after the incident at the Fukushima nuclear plant.
	Regulation on the Rapid Alert System for Food and Feed.
	Regulation on the Scope and Frequency of Sampling in Order to Monitor Certain Substances and Residues Thereof in Certain Animal Products.
	Law on Sanitary Inspection
	Regulation on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin.
	Law Amending the Law on the Protection of the Population from Infectious Diseases.
	Regulation on Microbiological Classification and Procedure in Case of Contamination of Live Bivalve.
	Regulation on animal health requirements applicable to aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.
	Regulation on the quality of bathing water.
	Environmental Protection Act.
Denmark	Act on the use of certain European Union legislations on economic relations with third countries (No. 635 of 2011).
	Statutory Order on the approval of experimental release and of marketing of genetically modified organisms (No. 1098 of 1992).
	Guidelines for the approval of aquaculture water supply in connection to IPN and BKD health status as Category I or II.
	Order No. 893 on subsidy for conservation projects of Danish animal species, breeds and plant genetic resources.
Ecuador	Resolución Nº 72 - Autorización de la ampliación de uso para el control de plagas en ciertos cultivos específicos de los plaguicidas químicos, bioinsumos y extractos vegetales.
Egypt	Ministerial Decree No. 188 of 2010 concerning the Veterinary National Laboratory for poultry production control.
Ethiopia	National Biodiversity Strategy and Action Plan.
	Ethiopia's Agricultural Sector Policy and Investment Framework (PIF).
	Agricultural Policies, Programs and Targets for a Plan for Accelerated and Sustainable Development to End Poverty (PASDEP).
European Union	Commission Regulation (EC) No. 616/2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments.
	Commission Decision 2005/745/EC amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk.

European Union *(continued)*	Commission Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk.
	Commission Decision 2005/855/EC amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk.
	Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC.
Fiji	Biosecurity Emergency (Termites) Regulations 2010 (L.N. No. 41 of 2010).
	Biosecurity Promulgation 2008 (No. 28 of 2008).
Finland	Decree of the Ministry of Agriculture and Forestry relative to control on salmonella in establishments in the meat industry (No. 134 of 2012).
	Decree of the Ministry of Agriculture and Forestry Agriculture on general principles of integrated pest control (No. 7 of 2012).
	Ministry of the Environment Decree on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (No. 20 of 2008).
	Ministry of the Environment Decree amending the Decree on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (No. 115 of 2010).
	Ministry of the Environment Decree amending the Decree on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (No. 153 of 2012).
	Ministry of the Environment Decree amending the Decree on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (No. 347 of 2011).
	Act to amend section 7a of the Forest Insect and Fungi Damage Prevention Act.
	Decision of the Food and Veterinary Department of the Ministry of Agriculture and Forestry to amend the Decision relative to control on salmonella affecting bovines and swine (No. 15 of 1996).
	Decree No. 630 of 2012 of the Ministry of Agriculture and Forestry amending the Decree on animal health requirements for certain live animals, animal by-products and certain goods on the EU internal market.
	Decree of the Ministry of Agriculture and Forestry on basic and additional measures related to environmental support and environmental special support to agriculture (No. 503 of 2007).
	Decree of the Ministry of Agriculture and Forestry amending the Decree on basic and additional measures related to environmental support and environmental special support to agriculture (No. 1370 of 2009)

Finland *(continued)*	Decree of the Ministry of Agriculture and Forestry relative to a programme for the control on salmonella in hens (No. 1172 of 2009).
	Decree of the Ministry of Agriculture and Forestry to amend the Decree relative to a programme for the control on salmonella in hens (No. 75 of 2012).
	Decree No. 1002 of 2010 of the Ministry of Agriculture and Forestry on animal health requirements for certain live animals, animal by-products and certain goods on the EU internal market.
Ghana	Ghana Forest and Wildlife Policy.
Greece	Ministerial Decree No. 258493 amending Ministerial Decree No. 309873/2005 with regard to the establishment of additional biosecurity meters concerning the avian flu.
	Ministerial Decree No. 276863 amending Ministerial Decree No. 309873/2005 with regard to the establishment of additional bio security meters concerning the avian flu.
	Presidential Order No. 33 laying down measures for the control of avian influenza, in compliance with Council Directive 2005/94/EC.
Guinea	Politique Nationale de l'Environnement (PNE) en République de Guinée, 2011.
Honduras	Acuerdo Nº 917/13 - Medidas de regulación sanitarias para el funcionamiento de las granjas avícolas de engorde.
	Acuerdo Nº 916/13 - Medidas de regulación sanitarias para el funcionamiento de las granjas avícolas de postura.
	Acuerdo Nº 918/13 - Mitigación del riesgo sanitario en el sector avícola.
	Acuerdo Nº 903/15 - Operatividad de unidades de producción avícola con fines educativos respecto a la mitigación del riesgo sanitario en el sector avícola.
Indonesia	Regulation of the Minister of Trade of RI No. 46/M-DAG/PER/8/2013 concerning Animal and Animal Product Import and Export Provision.
	Regulation of the Minister of Agriculture of RI No. 04/Permentan/PP.340/2/2015 on the Food safety inspection on plant origin fresh food import and export.
	Law of Republic of Indonesia No. 33 Year 2014 concerning Halal Product Assurance.
Ireland	European Communities (Avian Influenza) (Precautionary Measures) (Amendment) Regulations 2011 (S.I. No. 11 of 2011).
	European Communities (Avian Influenza) (Precautionary Measures) (Amendment) Regulations 2012 (S.I. No. 306 of 2012).
	Diseases of Animals Act 1966 (Registration of Poultry Premises) (Amendment) Order 2011 (S.I. No. 57 of 2011).
	European Communities (Agriculture, Fisheries and Food) (Compliance) Regulations 2009 (S.I. No. 424 of 2009).
	Diseases of Animals Act 1966 (Prohibition on the Use of Swill) (Amendment) Order 2009 (S.I. No. 12 of 2009).
	European Communities (Direct support schemes) Regulations 2010 (S.I. No. 309 of 2010).
	Animal Health and Welfare Act 2013 (No. 15 of 2013).

Ireland *(continued)*	European Communities (Protection measures in relation to avian influenza in poultry and other captive birds) Regulations 2006 (S.I. No. 478 of 2006).
	European Communities (Control of Avian Influenza) Regulations 2006 (S.I. No. 701 of 2006).
Japan	Basic Act on Biodiversity.
Kazakhstan	Ministerial Decree No. 278 of 1993 regarding arrangements for the protection of sturgeon fish stocks and other valuable biological resources of Ural and Caspian basins.
Kenya	Pest Control Products (Importation and Exportation) Regulations, 1984 (Cap. 346).
	Plant Protection (Importation of Plants, Plant Products and Regulated Articles) Rules, 2009 (Cap. 324).
	Prohibition and Regulation of Importation Under Section 8 (Cap. 364).
	Management Plan For Fisheries Targeting Small And Medium Sized Pelagic Fish
Kiribati	Biosecurity Act, 2011 (No. 2 of 2011).
Liberia	Executive Order No. 1 - GoL Forest Sector Reform.
Madagascar	Programme Environnement III.
Malaysia	Nothing Found
Mali	Décret N°10-683 P-RM du 30 décembre 2010 fixant les attributions, la composition et les modalités de fonctionnement du comité national de biosécurité.
Mauritania	Cadre Stratégique de Lutte contre la Pauvreté 2011-2015 (CSLP III)
Mexico	Acuerdo por el que se delegan en el titular del Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria y en sus directores generales de Salud Animal, Sanidad Vegetal e Inocuidad Agroalimentaria, Acuícola y Pesquera, las facultades y funciones que se indican.
	Programa Estratégico Forestal para México 2025.
Montenegro	Law on food security.
	Environmental Law.
Mozambique	Decree No. 64/2011 creating the National Centre of Biotechnology and Biological Science (CNBB).
	Resolution No. 7/2014 approving the Statute of the National Centre of Biotechnology and Biological Science (CNBB).
	Environmental Strategy for the Sustainable Development of Mozambique.
Nepal	An Approach Paper to the Thirteenth Plan (FY 2013/2014-2015/2016).
New Caledonia	Délibération du congrès n° 238 du 15 décembre 2006 relative à la biosécurité aux frontières internationales de la Nouvelle-Calédonie.
New Zealand	Biosecurity Amendment Act, 2004.
	Biosecurity (Forms) Amendment Regulations, 2010.
	Biosecurity Amendment Act, 2005.
	Biosecurity Amendment Act, 2008.
	Biosecurity (Infringement Offences) Regulations, 2010.

New Zealand *(continued)*	Biosecurity Amendment Act, 2007.
	Biosecurity (Costs) Regulations, 2010.
	Biosecurity (Forms) Regulations, 1995.
	Biosecurity (Bovine Tuberculosis - Cattle Levy) Amendment Order, 2001.
	Biosecurity (Status of Specified Ports) Amendment Act, 2005
	Biosecurity (Animal Identification Systems) Amendment Regulations, 2000
	Biosecurity (Animal Identification Systems) Amendment Regulations, 2001.
	Biosecurity (Notifiable Organisms) Order, 2010.
	Biosecurity (Ruminant Protein) Amendment Regulations, 2004
	Biosecurity (National American Foulbrood Pest Management Strategy) Order, 1998.
	Biosecurity (Notifiable Organisms) Order 2006.
	Biosecurity (Form of Search Warrant) Regulations, 2012.
	Biosecurity (Ruminant Protein) Regulations, 1999.
	Biosecurity (Ruminant Protein) Regulations, 1999.
	Biosecurity (Ruminant Protein) Amendment Regulations, 2010.
	Biosecurity (Animal Identification Systems) Regulations, 1999
	Biosecurity (Bovine Tuberculosis – Cattle Levy) Order, 1998.
	Biosecurity (Animal Identification Systems) Regulations, 1999.
	Biosecurity (Rabbit Calicivirus) Amendment Act 1998 (No. 12 of 1998)
	Biosecurity (Imported Animals, Embryos, and Semen Information) Regulations, 1999.
	Biosecurity (System Entry Levy) Order, 2010.
	Biosecurity (National Bovine Tuberculosis Pest Management Strategy) Order, 1998.
	Biosecurity (National Bovine Tuberculosis Pest Management Strategy) Amendment Order, 2004.
	Biosecurity (American Foulbrood—Apiary and Beekeeper Levy) Order, 2003.
	Biosecurity (National Bovine Tuberculosis Pest Management Strategy) Order, 1998.
	Biosecurity (Meat and Food Waste for Pigs) Regulations 2005.
	Biosecurity (Deer and Other Testing Costs) Regulations 1998.
	Biosecurity Act, 1993 (Act No. 95 of 1993).
	Biosecurity Act 1993 (Act No. 95 of 1993).
	Animal Welfare (Glueboard Traps) Order, 2009.
	National Animal Identification and Tracing Act, 2012 (Act No. 2).
	Animals Act 1967
	Agricultural Compounds and Veterinary Medicines Act 1997.
Nicaragua	Ley N° 862 - Crea el Instituto de Protección y Sanidad Agropecuaria.
	Estrategia Nacional Ambiental y del Cambio Climático. Plan de Acción 2010-2015.

Norway	Regulation No. 93 on declaration and labeling of microbiologic resulting in damages to the environment.
	Decree No. 93 regulating the marking and declaration of microbiological products which may affect the environment.
	Regulation No. 675 on or special protection against classic swine fever in certain countries in the EU.
	Regulation No. 716 on alien organisms.
Palestinia	Ministerial Cabinet decree No. 380 of 2005 regarding Poultry Hatcheries.
	Ministerial Council Resolution No. 8 of 2010 on animal health monitoring system.
	Council of Ministers Resolution No. 380 of 2005 on the system of poultry hatcheries.
	Council of Ministers Resolution No. 12 of 2006 on poultry farms system.
Panama	Nothing Found
Peru	Resolución N° 367/11/AG/SENASA - Relación de virus adventicios que deben ser objeto de control en la vacuna contra peste porcina clásica.
	Decreto Supremo N° 009/13/MINAGRI - Política Nacional Forestal y de Fauna Silvestre.
Russia	Regional Law No. 16-ZKO "On environmental security".
	Order No. 569 of the Federal Security Service validating the Regulation on the protection of marine biological resources.
	Ministerial Decree No. 367 implementing Article 54 of the Federal Law No. 166-FZ on fisheries and conservation of aquatic biological resources.
	Order No. 675 of the Federal Security Service validating the Regulation on state control in the sphere of protection of marine resources.
	Joint Order No. 319 of the Federal Coastguard Service, No. 827 of the Ministry of Interior, No. 30613/gs of the Ministry of Foreign Affairs, No. BG-3-11/325 of the Ministry of Taxes and Dues, No. 172 of the Ministry of Natural Resources, No. 97n of the Ministry of Finance, No. 1 of the Ministry of Economic Development and Trade, No. 223 of the Federal Fisheries Committee, No. 785 of the State Customs Committee, No. 465 of the Federal Security Service, No. 278 of the Federal Taxation Police and No. OD-212 of the Central Bank validating the Regulation on interaction and coordination of activity of the Federal executive bodies in the sphere of protection of aquatic biological resources and supervision over external trade of fish products.
	Regional Law No. 44 "On environmental protection".
	Joint Order No. 56/91 of the Federal Security Service and of the Federal Fisheries Agency validating the Regulation on passage by the Russian and foreign fishing vessels of control points.
	Regional Law No. 578 "On protection of the population and territory against natural and technological disasters".
	Regional Law No. 25-Z "On protection of the population against natural disasters of classified as inter-municipal and regional type".
	Regional Law No. 3-ZS "On environmental protection".
	Ministerial Decree no. 428 on arrangements for carrying out fisheries in the EEZ of the Russian Federation.

Rwanda	Rwanda Vision 2020
Saint Lucia	National Agricultural Policy 2009-2015.
Senegal	Loin° 2009-27 portant sur la biosécurité.
	Décret n° 2009-1408 portant missions, organisation et fonctionnement du Comité National de Biosécurité (CNB).
	Décret n° 2009-1409 portant missions, organisation et fonctionnement de l'Autorité Nationale de Biosécurité (ANB).
Serbia	Law amending the Nature Protection Law.
	Nature Protection Law.
Seychelles	Animal and Plant Biosecurity (Designation of Agency Responsible for Biosecurity) Order, 2014 (No. 65 of 2014).
	Animal and Plant Biosecurity (Fees and Charges) Regulations, 2014 (No. 82 of 2014).
	Animal and Plant Biosecurity (Biosecurity Import Permit) Regulations, 2014 (S.I.No. 80 of 2014).
	Animal and Plant Biosecurity (Animal and Plant) Regulations, 2014 (No. 78 of 2014).
	Animal and Plant Biosecurity (Designation of Biosecurity Points of Entry and Departure) Regulations, 2014 (S.I. No. 81 of 2014).
	Animal and Plant Biosecurity Act 2014 (No. 10 of 2014).
	Animal and Plant Biosecurity (Animal) Declaration of Notifiable Diseases Regulations, 2014 (S.I.No. 79 of 2014).
	Animal and Plant Biosecurity (Regulated) Quarantine Plant Pests Regulations, 2014 (S.I. No. 84 of 2014).
Slovenia	Regulation on preserving biodiversity in livestock breeding.
Solomon Islands	Biosecurity Act, 2013 (No. 3 of 2013).
Somoa	Quarantine (Biosecurity) Act.
South Africa	Identification under section 21 of activities which may have a substantial detrimental effect on the environment.
	National Environmental Laws Amendment Act, 2009 (No. 14 of 2009).
	Strategic Plan for the Department of Agriculture, Forestry and Fisheries 2012/13-2016/17.
	A National Climate Change Response Strategy for South Africa.
	Plant Health Policy for South Africa
	Forestry 2030 Roadmap (Forest Strategy 2009-2030).
Sweden	Decree containing instructions for the Chemical Inspection Agency (SFS 2007:1064).
Switzerland	Ordinance on proceeding coordination and environmental impact assessment.
Tanzania	National Agriculture Policy.

Timor-Leste	Decree-Law No. 21/2003 regulating sanitary control on goods imported and exported.
	Strategic Development Plan 2011-2030.
	National Biodiversity Strategy and Action Plan of Timor-Leste (2011-2020).
Tokelau (NZ)	Biosecurity Rules 2003.
Trinidad and Tobago	Plant Protection Act (Cap. 63:56).
	Plant Protection Regulations (Cap. 63:56).
Tunisia	Arrêté du ministre de l'agriculture du 4 janvier 2013, modifiant et complétant le cahier des charges type de la production végétale selon le mode biologique approuvé par l'arrêté du 28 février 2001.
Turkey	Regulation on establishment and functions of risk assessment committees and commissions.
	Agriculture Law No.5488.
	Regulation on avian influenza.
	Ninth Development Plan 2007-2013.
Turkmenistan	Law "On environmental protection".
Turks and Caicos	Plant Health Ordinance 2012 (No. 39 of 2012).
Tuvalu	Tuvalu's National Adaptation Programme of Action.
UK	Biocidal Products (Fees and Charges) Regulations 2013 (S.I. No. 1507 of 2013).
	Plant Protection Products (Sustainable Use) Regulations 2012 (S.I. No. 1657 of 2012)
	Avian Influenza and Newcastle Disease (Biosecurity Guidance and Disease Control (Slaughter) Protocol) (England and Wales) Order 2003 (S.I. No. 2035 of 2003).
	Animal Health Act, 2002
UK (Scotland)	Poultry Compartments (Scotland) Order 2010 (S.S.I. No. 150 of 2010).
	Animal Health and Welfare (Scotland) Act 2006 (2006 asp 11).
UK (England)	Poultry Compartments (England) Order 2010 (S.I. No. 108 of 2010).
	Avian Influenza (Preventive Measures) Regulations 2005 (S.I. No. 2989 of 2005).
UK (Northern Ireland)	Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2013 (S.R. No. 207 of 2013).
	Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015 (S.R. No. 254 of 2015).
	Diseases of Animals Act (Northern Ireland) 2010 (2010 Chapter 1).
UK (Wales)	Avian Influenza (Preventive Measures) (Wales) Regulations 2005 (W.S.I. No. 2985 (W.219) of 2005).
UK (Great Britain)	Plant Protection Products Regulations 2011 (S.I. No. 2131 of 2011).
Ukraine	Law No. 3677-VI "On fishery, industrial fisheries and protection of fishing resources".
USA	Food, Conservation, and Energy Act of 2008 (7 U.S.C. 8701).
	Federal Water Pollution Control Act (Clean Water Act).

Vanuatu	Plant Protection (Amendment) Act 2013 (No. 26 of 2013)
	Animal Importation and Quarantine (Amendment) Act 2014 (No. 37 of 2014).
	Penalty Notice Regulation Order 2014 (No. 138 of 2014).
Venezuela	Resolución N° 129 - Crea la Comisión Nacional de Atención y Gestión de Riesgos de Emergencias y Desastres del Ministerio para la Salud.
	Resolución N° 92 - Crea los Comités para Emergencias y Desastres en todas las dependencias del Ministerio para la Salud.
	Decreto N° 1.557 - Ley de la organización nacional de protección civil y adminstración de desastres.
	Resolución N° 112 - Suspende temporalmente la exigencia del Registro para el transporte de plaguicidas químicos, agentes de control biológico de uso agrícola, doméstico, salud pública e industrial.
	Decreto N° 18 - Modifica la Resolución N° 112, que suspende temporalmente la exigencia del Registro para el transporte de plaguicidas químicos, agentes de control biológico de uso agrícola, doméstico, salud pública e industrial.
Yemen	Republican Resolution No.218 of 2004 on the organizational by-law of the Ministry of Water and Environment.

Annex 3. Case study questions

The following questions will help us identify the what, how and why, surrounding Biosecurity legislation and implementation for each case study that we look at.

The objective of having case studies is to find out the challenges and opportunities encountered by those countries that have implemented a biosecurity approach.

I. The following questions will help identify what Biosecurity means for the group in question:

If available (via literature, legislation or personal communication), how does this group define Biosecurity?

If a definition for Biosecurity is not available, does this group use (/refer to) any other terminology in reference to this topic? (For example, Biological Security or Biosafety)

Has this group reported any issues regarding the subject of Biosecurity which has/will affect themselves, currently or in the past? If so, please provide a brief description of the Biosecurity issue identified, and how this issue would potentially affect the group in question.

II. The following questions will help identify why action is being taken by the group in question:

What can be identified as the purpose of this group's Biosecurity strategy?

What explicit drivers can be identified that have influenced the legislative procedure, regarding Biosecurity, for the group in question? (For example, CBD ratification, WTO agreements, etc.)

What implicit drivers can be identified that have influenced the legislative procedure, regarding Biosecurity, for the group in question? (For example, previous legislation, country size, cost, etc.)

What other factors, that can be identified, may have influenced this group's Biosecurity strategy?

III. The following questions will help identify how action is being taken by the group in question:

Has this group released a Biosecurity strategy, regarding how the issue will be addressed? If so, what are the key points of this document?

What institutional arrangements are in place to ensure that Biosecurity strategy or legislation is implemented as intended?

What tools has this group implemented regarding the issue of Biosecurity? (For example, certification, surveillance, quarantine, etc.)

Has this group taken a sectoral or top down legislative approach?

What budget has this group set for this task, and are there any cost recovery plans in place to offset part or all of this budget?

Does the implementation methodology use a risk-based approach or another approach?

IV. Scope

Have the following areas of Biosecurity been addressed within the country's legislation?

- The issuance of phytosanitary certificates
- Surveillance with the object of reporting the occurrence outbreak and spread of pests, and controlling those pests
- Inspection of consignments of plants and plant products and regulated articles with the object of preventing the introduction and/or spread of pests

- Disinfection or disinfestation of consignments to meet phytosanitary requirements
- Protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence
- The conduct of pest risk analysis to ensure phytosanitary security of consignments after certification, prior to export
- Training and development of staff

IPPC

The International Plant Protection Convention (IPPC) is an international plant health agreement that aims to protect cultivated and wild plants by preventing the introduction and spread of pests. International travel and trade are greater than ever before. As people and commodities move around the world, organisms that present risks to plants travel with them.

Organization

- The number of contracting party signatories to the Convention exceeds 181.
- Each contracting party has a National Plant Protection Organization (NPPO) and an Official IPPC contact point.
- 10 Regional Plant Protection Organizations (RPPOs) have been established to coordinate NPPOs in various regions of the world.
- IPPC liaises with relevant international organizations to help build regional and national capacities.
- The Secretariat is provided by the Food and Agriculture Organization of the United Nations (FAO-UN).

International Plant Protection Convention (IPPC)

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