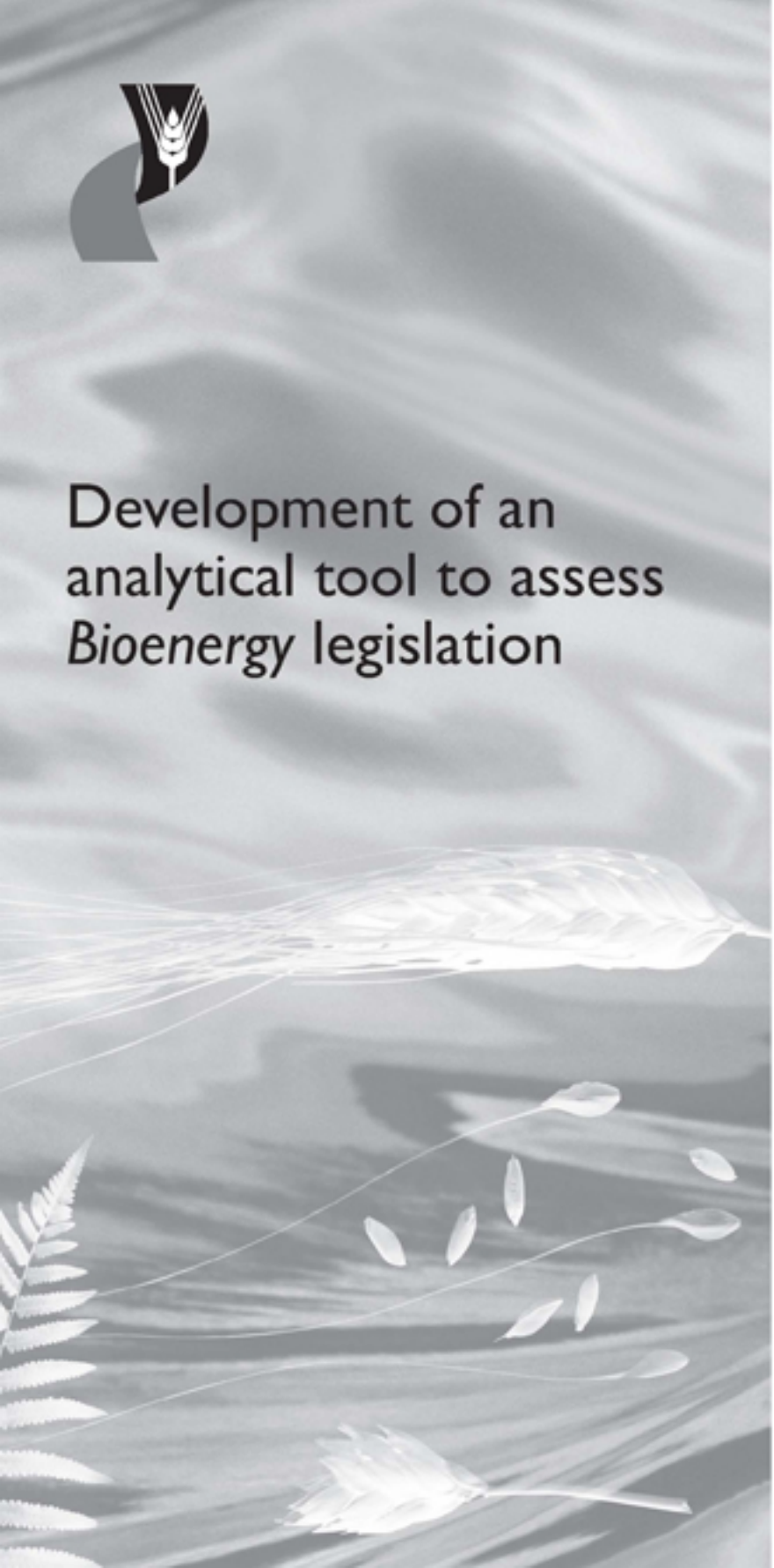
ISSN 1014-6679

FAO
LEGISLATIVE
STUDY

96

Development of an analytical tool to assess *Bioenergy* legislation



FAO
LEGISLATIVE
STUDY

96

Development of an analytical tool to assess *Biosecurity* legislation

by
Daniele Manzella
Jessica Vapnek

for the
Development Law Service
FAO Legal Office

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2007

ISBN 978-92-5-105871-8

TABLE OF CONTENTS

PREFACE

Globalization of trade in agricultural products brings opportunities and risks. On the one hand, it generates wealth in countries exporting their produce to foreign markets and brings that produce to the tables of consumers in far-away lands. On the other hand, it opens new pathways for pests and diseases that can damage natural resources with accompanying economic and environmental consequences. In order to capture those opportunities and manage those risks, there is an increasing recognition of the need to integrate and improve coordination of regulatory activities designed to protect human, animal and plant life and health and the environment.

Interest in *Biosecurity* comes in response to these needs. It attempts to draw together the policy and regulatory frameworks for risk assessment and risk management across the sectors of food safety, animal life and health (including fisheries) and plant life and health. *Biosecurity* aims to manage biological risks in these three sectors while protecting the environment and contributing to its sustainable use. In essence, *Biosecurity* balances enthusiasm for international trade with the need to protect against risks. Transparent and efficient controls in these sectors need not create unnecessary barriers to international trade; rather they facilitate it.

Biosecurity is an interdisciplinary activity that covers a wide range of subjects and approaches. As *Biosecurity* works towards the integration of animal health, plant health and food safety in order to streamline risk assessment and risk management practices, the division of responsibilities among national agricultural regulatory authorities comes under scrutiny. Controls and authorities for *Biosecurity* matters tend to be scattered over a variety of ministries, including the ministries of agriculture, health, environment and trade and industry. The objective of *Biosecurity* is to draw together relevant regulatory authorities or to create coordinating mechanisms to streamline approaches to managing biological risks. To implement the necessary coordination, countries must look closely at their national legal frameworks. This will aid in implementing the most efficient institutional set-up while also protecting rights and establishing responsibilities in a way that is conducive to the active participation of public authorities, the private sector and consumers.

To implement a *Biosecurity* approach, governments should first identify and analyse the existing constellation of legal provisions covering the subject areas of *Biosecurity*. At times this may not be easy as *Biosecurity* is often regulated in a plethora of parliamentary-level and subsidiary pieces of legislation of different natures, scopes and objects. The present study elaborates an orderly methodology to facilitate the review and assessment of national legal frameworks for *Biosecurity*. The methodology arises from work carried out in six pilot countries – Ethiopia, Ghana, India, Kenya, Uganda and Viet Nam – by national legal experts actively testing and refining the analytical tool.

The methodology set out in this study should enable a comprehensive evaluation of national laws and regulations covering the main subject areas of *Biosecurity*, comparing national rules with international requirements and providing an overall evaluation of the national regulatory framework *vis-à-vis* the objectives of *Biosecurity*. It is hoped that the methodology will be a useful tool for countries wishing to assess and develop updated legislation to achieve a *Biosecurity* approach.

A number of people have participated in the development of this legal analytical tool. Daniele Manzella and Jessica Vapnek were the principal authors. International legal consultants Emmanuelle Bourgois and Charlotta Jull provided discrete inputs, while Ariella D'Andrea, Jennifer Hilton, Abdul Rahman Lediju, Victor Mosoti, Valerio Poscia and George Sarpong provided excellent research assistance or comments on the overall methodology. Wondwossen Sintayehu Wondemagegnehu (Ethiopia), George Sarpong (Ghana), Roopa Madhav and Adil Hasan Khan (India), Patricia Kameri-Mbote (Kenya), Judy Obitre-Gama (Uganda) and Duong Thanh An (Viet Nam) carried out the national legal studies which formed the basis of the methodology and which are set out in Chapters 5–10. Niek Van der Graaff and Mike Robson provided key support for the concept and enabled the effective execution of the project. Essential funding was provided by the Government of Norway under the Programme Cooperation Agreement for *Biosecurity*.

Stefano Burchi
Chief, Development
Law Service,
Legal Office

Ezzeddine Boutrif
Director, Nutrition and Consumer
Protection Division and
Chair, Interdepartmental
Working Group on *Biosecurity*

1

INTRODUCTION

Contents

I. OVERVIEW

In 2006, the Government of Norway and the Food and Agriculture Organization of the United Nations (FAO) entered into a Programme Cooperation Agreement (PCA) to work on food security and poverty reduction, policy assistance and capacity building in low-income developing countries.

The fundamental goal of the FAO-Norway programme of cooperation is to alleviate hunger. In pursuance of this goal, the PCA seeks to help developing countries improve national capacities to meet domestic and international marketing requirements, decrease biological risks and improve preparedness for food crises that increase the risk of market collapse. The PCA activities address several of the UN Millennium Development Goals, aiming to eradicate hunger and poverty, ensure environmental sustainability and develop an open trading system that is rule-based, predictable and non-discriminatory.

Biosecurity[1] draws together the policy and regulatory frameworks for risk management across the sectors of food safety, animal life and health (including fisheries) and plant life and health. The approach aims to manage biological risks in these three sectors while protecting the environment and contributing to its sustainable use.

Within the area of *Biosecurity*, the PCA programme has activities in:

- animal health;
- food safety;
- plant health;
- fish product safety;
- socio-economic analysis;
- policy development; and
- development law.

[1] Because translation of the word "biosecurity" into French and Spanish can lead to confusion, FAO capitalizes and italicizes it when referring to this regulatory approach in these three official FAO languages. See Biosecurity *in Food and Agriculture*, FAO Committee on Agriculture, 17th Session, 31 March–4 April 2003, Rome.

An important result of improving *Biosecurity* is that it enables countries to participate in an increasingly standards-driven international food and agricultural trading market, which is one of the key means of alleviating poverty in developing countries.

Biosecurity is an interdisciplinary subject, and thus the projects and studies under the umbrella of the PCA cover a wide range of disciplines and approaches. Along with this legal study, other projects undertaken through the PCA include testing of the *Biosecurity* Capacity Assessment Tool;[2] defining data items for animal health/*Biosecurity* country profiles; improving support for FAO's crisis management; carrying out studies in East Africa on district-level *Biosecurity* problems; and preparing studies on market collapse, fish product safety, aquatic animal health and the socio-economic aspects of *Biosecurity*. All activities take into account social, economic and gender issues; focus on poverty alleviation; and are undertaken in strategic cooperation with relevant regional groups, international organizations and other partners.

Under the PCA, the Legal Office proposed to develop an analytical tool to assess national *Biosecurity* legal frameworks. The tool consists of a methodological examination of the national laws and regulations covering the main subject areas of *Biosecurity*, comparing national rules with international requirements and providing an overall evaluation of national regulatory and institutional frameworks *vis-à-vis* the objectives of *Biosecurity*. The analytical tool is designed either for stand-alone use or for use with the *Biosecurity* Capacity Assessment Tool.

The programme of work for the development of this analytical tool consisted of the following activities:

(1) identifying six low-income countries in different regions as the pilot countries for the activity;
(2) recruiting one national legal consultant for each country to analyse the existing legislation on *Biosecurity* and the institutional structures for its implementation;

[2] The *Biosecurity* Capacity Assessment Tool (currently in draft form) assists in assessing *Biosecurity* capacity needs across all sectors and all sector organizations at national level. It is a part of a larger *Biosecurity* tool kit and focuses on policy, legal and institutional frameworks, infrastructure and operations, risk analysis, technical capability and information exchange.

(3) drawing together the six analyses and developing the methodology for use in subsequent country assessments;
(4) editing and preparing the results for publication.

The first two countries selected as pilot case studies to develop the methodology were Ghana and Kenya, and additional case studies in Ethiopia, India, Uganda and Viet Nam followed. The lead author carried out national consultations in Ghana, Kenya and Uganda, with the support of the respective national legal consultants. The purpose of the consultations was to discuss the findings of the national legal consultants' reports and the feasibility of legislative change.[3]

II. DEFINITION OF *BIOSECURITY*

As noted above, *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; and
- 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,

[3] The national consultations took place in Ghana from 22 to 26 January 2007, in Kenya from 30 April to 4 May 2007 and in Uganda from 5 to 11 May 2007.

horticulture, fisheries, native biodiversity and human health. Appropriate responses include eradication, containment and on-going control.

III. INTERNATIONAL CONTEXT

Biosecurity is of growing interest as a result of developments at the international level, including globalization of the world economy, technological progress and the rapid increase in communications, transport and trade. Against this background, there is concern that the appropriate level of protection of human, animal and plant life and health is not being maintained as risks increase.

The term *Biosecurity* does not appear in any instrument of international law. But as will be described in greater detail in the next chapter, the main international regulatory instruments and organizations that led FAO to adopt the concept and promote a specific work programme in relation to the *Biosecurity* approach are:[4]

- the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
- the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (Cartagena Protocol);
- the Codex Alimentarius Commission (Codex);
- the *Office international des épizooties* (OIE, or World Organization for Animal Health); and
- the International Plant Protection Convention (IPPC).

The SPS Agreement identifies the rights of states concerning sanitary and phytosanitary measures in relation to international trade and also provides common obligations that govern those rights. Sanitary measures are those designed to protect animal and human life and health, while phytosanitary measures refer to the life and health of plants. The SPS Agreement provides for a unified approach to the different sectors of *Biosecurity*. The approach is

[4] For an analysis of the major international instruments relevant to *Biosecurity*, see A. Ingrassia, *International and Regional Regulatory Frameworks Relevant to* Biosecurity *for Food and Agriculture*, paper presented at the FAO Technical Consultation on Biological Risk Management in Food and Agriculture (unpublished).

centred on harmonization through international standards, science-based risk assessment and minimization of interference with international trade.

While traditional sanitary and phytosanitary controls were designed to ensure efficient production through the protection of natural resources, modern controls tend to integrate these concerns into a wider spectrum of issues, such as preservation of the environment and protection against the loss of biodiversity. Increasing awareness of these threats has expanded the scope of *Biosecurity* from its traditional focus on protection of primary production and trade. Under the SPS Agreement, three organizations – Codex, the IPPC and the OIE – are recognized as the sources of international standards for food safety, plant life and health and animal life and health, respectively.

The SPS Agreement recognizes the right of countries to take emergency measures based on incomplete information. In that respect, the agreement is complemented by the Cartagena Protocol,[5] which is based on the precautionary principle. In this context the principle provides that, where an activity increases the threat of harm to human health or the environment, precautionary measures should be taken even if some causal relationships are not fully established scientifically.

Other international instruments can be said to form part of the *Biosecurity*-related regulatory framework. For instance, the OIE Terrestrial Animal Health Code, the Aquatic Animal Health Code and their respective Manuals for Diagnostic Tests outline import and export procedures to avoid disease spread and structures for the communication of epidemiological information. Several Codex documents are also relevant, including the Principles for Food Import and Export Certification and Inspection; Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems; and Guidelines for the Exchange of Information between Countries on Rejections of Imported Food.

In addition, some IPPC standards (more precisely, some International Standards on Phytosanitary Measures – ISPMs) elaborate on environmental

[5] The objective of the Cartagena Protocol is to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms possessing a novel combination of genetic material obtained through the use of modern biotechnology (art. 1).

considerations and are relevant to the management of invasive alien species under the Convention on Biological Diversity (CBD). Article 8(h) of the CBD requires contracting parties to prevent the introduction of, and control or eradicate, those alien species which threaten ecosystems, habitats or species.[6]

The multiple impacts of invasive alien species (IAS) call for coordinated international action to minimize their environmental as well as economic effects. Toward this end, the CBD and IPPC have been working cooperatively in several ways. The CBD Conference of the Parties and the IPPC have collaborated on the preparation of a supplement to ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*) in order to incorporate risks to biodiversity posed by IAS that are considered plant pests. Further collaboration has taken place in the revision of ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) in order to manage risks to biodiversity that beneficial organisms may generate.

ISPM No. 11 includes the analysis of risks that living modified organisms (LMOs) present. In this regard, the IPPC standard is relevant to the regime regulating LMOs under the Cartagena Protocol. The protocol establishes an informed agreement procedure for ensuring that countries are provided with information in advance, including an assessment of risks to biological diversity, necessary to make informed decisions before agreeing to the import of such organisms into their territory. In the assessment of risks to biological diversity, ISPM No. 11 can be applied for LMOs that are categorized as plant pests.

Risk analysis is the basis for the establishment of sanitary and phytosanitary measures for the import of plants, animals and foods, and the concepts are the same across these sectors. Thus, risk analysis is one common thread among the many international instruments relevant to *Biosecurity*. But although international standard-setting and cooperation are important, the establishment, implementation and monitoring of *Biosecurity* in agriculture is a matter for national governments. How to implement a *Biosecurity* approach at national level is the subject of the next section.

---

[6] Under the CBD, an alien species is defined as "a species, subspecies or lower taxon, introduced outside its natural past or present distribution" and an invasive species is "an alien species whose introduction and/or spread threaten biological diversity" (art. 8(g)).

IV. IMPLEMENTATION OF *BIOSECURITY* AT NATIONAL LEVEL

The ultimate objectives of *Biosecurity* at the national level are to protect domestic agricultural production and natural resources from biological hazards and to safeguard the health of consumers in the food chain. To comply with the SPS Agreement, risk assessment in accordance with applicable international standards or scientific justification shall underlie domestic decision-making regarding the import and use of plants, animals and foods.

Countries require strong global and regional relationships to identify and manage emerging risks and this international network in turn supports appropriate national actions such as:

- comprehensive, competent surveillance programmes and diagnostic services to detect and identify the arrival and spread of pests and diseases;
- sufficient capability to conduct timely assessments of threats from new species;
- rapid response capability to eradicate new pests and diseases before they establish and spread; and
- standardization of science-based identification of all risk pathways and high-risk organisms, and implementation of pre-border and border measures to prevent pests and diseases from entering the country.

In order to enforce effective controls and to comply with international standards, countries need to build capacity in their administrations. There are several components of national capacity building which may assist countries in reducing unjustified obstacles to trade while protecting food safety, animal and plant life and health. These include developing national infrastructure, enhancing specific expertise and strengthening personnel and training.

In some countries (e.g. Belize and New Zealand), capacity building has concentrated on institutional aspects with a view to achieving the integration of the animal health, plant health and food safety sectors. The objective is to draw together relevant authorities and ministries in charge of these three sectors, or at least to create coordinating mechanisms. This tendency derives from the fact that responsibility for *Biosecurity* matters tends to be scattered over a variety of ministries, including the ministries of agriculture, health, environment and trade.

Coordination among the relevant authorities and ministries will improve outcomes with respect to activities such as:

- participation in the meetings of international standard-setting bodies for the definition of common international standards;
- exchange of relevant official information;
- allocation of national resources and capacities;
- input of scientific advice into all levels of policy, planning and decision-making;
- technical support of stakeholders across the spectrum of *Biosecurity* interests;
- elaboration of effective education and awareness programmes to encourage compliance with legislation; and
- enforcement of legislation.

Before coordination can take place, however, there is a need to assess existing policies and legislation and the allocation of responsibilities among the different institutions involved with agricultural trade. Government policies determine the desired levels of *Biosecurity* protection while laws and regulations outline how that protection will be achieved. Good policies and laws can create an environment conducive to the application of *Biosecurity* by the government and the private sector, including farmers and other small-scale producers and the commercial agro-food supply chain.[7]

V. LEGISLATIVE REVIEW AND ASSESSMENT

The general objectives of legislation are to protect rights and establish responsibilities as well as to enable the meaningful participation of all stakeholders, from central institutions to local communities. Good legislation establishes predictable rules for the exercise of public powers, which can encourage investment and facilitate the operation of markets while protecting public interests such as the conservation of natural resources.

Before a government can develop new legislation or amend the legislation in place, however, it must identify and analyse the existing constellation of legal

[7] M. Robson, E. Boutrif, P. Kenmore and A. Randell, *Aid for Safer Trade: Policies to Support Biosecurity in the Agro-Food Supply Chain as Part of the Aid for Trade Initiative*, discussion paper from the FAO Interdepartmental Working Group on *Biosecurity*, draft 11 September 2007, p. 10.

provisions covering the relevant subject areas. In other words, it is essential to know what the legislation says and to understand how the system operates under that legislation before making recommendations for change. An assessment of national legislation on *Biosecurity* should evaluate both compliance with international obligations and the allocation of roles and responsibilities of sectoral bodies in the management of biological risks for food and agriculture.

In some cases, where there are no laws or regulations on some or all of the elements of *Biosecurity*, entirely new legislation must be drafted. In other cases, there may be an existing legal framework but it may be outdated or insufficient, or rife with overlaps and gaps, and thus call out for a complete overhaul. In still other cases, only minor changes may be necessary, for example to add a few specific obligations or to enhance coordination among government bodies.

Effective institutional coordination avoids duplication, inconsistency and disputes among the relevant agencies and also helps improve efficiency in the application of sanitary and phytosanitary measures. The ultimate goal of upgrading national legal frameworks to regulate, manage and control *Biosecurity* for food and agriculture is to implement effective controls, increase cost effectiveness and improve consistency across sectors. Of course, if the analysis of the existing framework leads to the determination that the current legislation is good enough, time is better spent on other matters such as improving implementation and enforcement of existing laws.[8]

The next chapter provides an overview of the international framework for *Biosecurity*, while Chapter 3 presents the results of the gap analysis of the legislative frameworks for *Biosecurity* in the countries reviewed under the auspices of this project. Chapter 4 proffers a suggested analytical methodology to assess national *Biosecurity* legal frameworks and design an appropriate legal strategy for their improvement. Chapters 5 to 10 contain the national case studies while Chapter 11 offers some concluding observations.

---

[8] J. Vapnek and M. Spreij, *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, FAO Legislative Study No. 87, 2005, p. 153.

REFERENCES

FAO. Biosecurity *Capacity Assessment Tool* (forthcoming).

FAO. Biosecurity *for Agriculture and Food Production* available at www.fao.org/biosecurity.

FAO. 2005. *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, by Vapnek, J. & Spreij, M. FAO Legislative Study No. 87, Rome.

FAO. 2003a. Biosecurity *in Food and Agriculture*, Committee on Agriculture, 17th Session, 31 March–4 April, Rome (COAG/2003/9).

FAO. 2003b. *Report of the Technical Consultation on Biological Risk Management in Food and Agriculture*, 13–17 January, Bangkok (TC/BRM/Rep.).

FAO. 2002a. *Law and Sustainable Development Since Rio: Legal Trends in Agriculture and Natural Resource Management*, FAO Legislative Study No. 73, Rome.

FAO. 2002b. *Report of the Expert Consultation on* Biosecurity *in Food and Agriculture*, 10–13 September, Rome (TC/BRM 03/3).

FAO. 2001. Biosecurity *in Food and Agriculture*, Committee on Agriculture, 16th Sess., 26–30 March, Rome (COAG/2001/8).

FAO. 2001. "Economic Impacts of Transboundary Plant Pests and Animal Diseases", in *The State of Food and Agriculture*, *Part III,* FAO, Rome.

FAO/WHO. 2003. *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Systems*, FAO Food and Nutrition Paper No. 76, Rome.

FAO/WHO. 1997a. *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL No. 26).

FAO/WHO. 1997b. *Codex Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* (CAC/GL No. 25).

FAO/WHO. 1995. *Codex Principles for Food Import and Export Certification and Inspection* (CAC/GL No. 20).

Global Fora and Regional Conferences on Food Safety (www.foodsafetyforum.org).

Ingrassia, A. 2003. *International and Regional Regulatory Frameworks Relevant to* Biosecurity *for Food and Agriculture*, paper presented at the FAO Technical Consultation on Biological Risk Management in Food and Agriculture (unpublished).

International Portal on Food Safety, Animal & Plant Health (www.ipfsaph.org).

IPPC Secretariat. 2005. *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms* (ISPM No. 3).

IPPC Secretariat. 2004. *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms* (ISPM No. 11).

OIE. 2007a. *Aquatic Animal Health Code.*

OIE. 2007b. *Terrestrial Animal Health Code.*

OIE. 2006. *Manual of Diagnostic Tests for Aquatic Animals.*

OIE. 2004. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.*

Robson, M., Boutrif, E., Kenmore, P. & Randell, A. *Aid for Safer Trade: Policies to Support Biosecurity in the Agro-Food Supply Chain as Part of the Aid for Trade Initiative*, discussion paper from the FAO Interdepartmental Working Group on Biosecurity, draft 11 September 2007

2

INTERNATIONAL REGULATORY FRAMEWORK FOR *BIOSECURITY*

Contents

I. INTRODUCTION

As described in Chapter 1, *Biosecurity*, according to the FAO official definition, comprises three sectors: food safety, plant life and health and animal life and health. These sectors include the introduction and release of genetically modified organisms (GMOs) and the introduction and safe management of invasive alien species (IAS). The international legal framework for *Biosecurity* encompasses all international instruments governing these sectors, as well as instruments relevant more generally to management of risks associated with food and agriculture. The embrace of a *Biosecurity* approach at national level calls for the harmonization of national legislation with these international instruments.

This chapter examines the relevant international instruments to understand their content and the main obligations they generate in the main *Biosecurity* sectors. Considering that these sectors intersect with and, to some extent, are shaped by the international trade regime of the World Trade Organization (WTO), the chapter starts by presenting that overarching regime. The analysis of the international regulatory framework for food safety, animal health, plant protection, GMOs and IAS follows. The chapter concludes with a brief overview of other international instruments that are also relevant to *Biosecurity*, in that they address the management of risks associated with food and agriculture.

II. WTO AGREEMENTS

2.1. SPS Agreement

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[1] aims to prevent the use of sanitary and phytosanitary measures (SPMs) as disguised barriers to international trade and is binding upon all WTO member states. According to Annex A of the agreement, SPMs are defined as any measures applied to:

[1] Agreement on the Application of Sanitary and Phytosanitary Measures (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 59 (1999), 1867 U.N.T.S. 493.

- protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases or disease-carrying organisms;
- protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- protect from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- prevent or limit other damage from the entry, establishment or spread of pests.

The SPS Agreement is the cornerstone of *Biosecurity*, attempting to strike a balance between the protection of human, animal and plant life and health on the one hand and the removal of barriers to international trade on the other. It establishes that SPMs may be applied only to the extent necessary to protect human, animal and plant life or health and must be based on scientific principles and sufficient scientific evidence (art. 2.2). Countries are obligated to ensure that their SPMs do not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail, and more fundamentally, SPMs shall not be applied in a manner which would constitute a disguised restriction on international trade (art. 2.3).

The SPS Agreement allows countries to set their own level of protection based on the assessment of risks to human, animal and plant life and health, and to establish SPMs in accordance with that level of protection (art. 5.1). However, the agreement encourages countries to apply international standards where they exist, and in Annex A identifies the official international standard-setting bodies. As long as a WTO member state employs international standards in the formulation of its national SPMs, these are presumed to be consistent with the provisions of the SPS Agreement (arts. 3.1 and 3.2).

Nonetheless, countries may adopt measures which result in a higher level of protection than that offered by an international standard, guideline or recommendation. In such cases, a WTO member state may be asked to provide scientific justification or to demonstrate that it had to depart from the relevant international standard because applying it would not have resulted in the level of protection the country considered appropriate (art. 3.3).

The SPS Agreement is designed to improve the transparency of SPMs, by requiring WTO member states to notify other countries of any new or changed sanitary and phytosanitary requirements which affect trade. The SPS Agreement requires each member state to establish an office (a so-called SPS Enquiry Point) to provide advance notice of any new or changed SPMs, thus giving other member states an opportunity to comment on them and facilitating information-sharing.[2]

In the event that available scientific evidence to justify a measure is insufficient, the SPS Agreement provides some flexibility for member states to adopt SPMs provisionally. Provisional SPMs can be adopted on the basis of "available pertinent information" derived from a variety of sources. However, member states must subsequently seek additional information to objectively assess the risk further and to review the SPM within a reasonable period of time (art. 5.7).

For the first phase of implementation (until the year 2000), developing and least developed countries, which make up about two-thirds of the WTO membership, were accorded special and differential treatment under the SPS Agreement (art. 10).[3]

2.2. TBT Agreement

The WTO Agreement on Technical Barriers to Trade (TBT)[4] is an instrument that is peripheral to the SPS Agreement, which seeks to ensure that technical regulations and standards do not create unnecessary obstacles to international trade. Such technical regulations and standards include packaging, marking and labelling requirements.

The TBT Agreement does not apply to sanitary and phytosanitary measures as defined in Annex A of the SPS Agreement (art. 1.5). Rather, it applies to unsafe products which may have an effect on human, plant or animal life and health based on their packaging, marking and labelling. In that regard, it is relevant to *Biosecurity*.

---

[2] See article 7 and Annex B.

[3] See J. Vapnek and D. Manzella, *Guidelines for the Revision of Phytosanitary Legislation*, FAO Legal Paper Online No. 63, January 2007, p. 2, www.fao.org/legal.

[4] Agreement on Technical Barriers to Trade (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 121 (1999), 1868 U.N.T.S. 120.

Under the TBT Agreement, WTO member states are required to use international standards whenever they impose technical regulations on products that are covered by the agreement (art. 2.4). Whenever a technical regulation is based on an international standard and is prepared, adopted or applied with respect to one of the legitimate objectives listed in article 2.2,[5] it is "rebuttably presumed not to create an unnecessary barrier to trade" (art. 2.5). Nonetheless, member states can deviate from these international standards so long as they still fulfil one or more of the enumerated legitimate objectives under article 2.2. Technical regulations cannot be more trade-restrictive than necessary to fulfil the legitimate objectives (art. 2.2).

In the event that an international standard does not exist, or the technical content of a proposed technical regulation is not in accordance with the technical content of an existing international standard, and the technical regulation may have a significant effect on trade, the TBT Agreement requires the member state to engage in consultations with other member states (art. 2.9). The required steps are set out in the TBT Agreement (e.g. written justification; notice; notification through the secretariat; making copies available; reasonable time for comments) (arts. 2.5 and 2.9). However, some of these steps may be omitted in emergency situations (art. 2.10).

Annexed to the TBT Agreement is a *Code of Good Practice for the Preparation, Adoption and Application of Standards* to guide the development of standards in WTO member states. Standardizing bodies must not act contrary to or inconsistently with the code (art. 4.1). The application of standards by member states is premised on the same principles of international trade as technical regulations: national treatment (i.e. treatment of products originating in the territory of any other WTO member in a manner no less favourable than that accorded to like products of national origin); non-discrimination (i.e. equal treatment to products originating in the territory of any other WTO member no less favourable than that accorded to like products originating in any other member country); proportionality (i.e. measures should be no more strict than necessary) and avoiding unnecessary obstacles to trade (art. 5.1.2). Likewise, there is a preference for deriving national standards from international standards, guidelines and recommendations (art. 5.4).

---

[5] "Legitimate objectives" include national security requirements, the prevention of deceptive practices and the protection of human health or safety, animal or plant life or health or the environment.

III. PLANT HEALTH

The main international instrument regulating plant health is the International Plant Protection Convention (IPPC).[6] The IPPC was adopted in 1951 and revised twice, in 1979 and in 1997. The 1997 New Revised Text came into force in October 2005 and is binding upon all contracting parties. The IPPC is a multilateral treaty whose main purpose is to secure "common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (art. I.1). "Pest" is broadly defined in the convention as "any species, strain or biotype, animal life or any pathogenic agent injurious or potentially injurious to plants or plant products" (art. II.1). The IPPC's scope is broad enough to include the potential impacts of plant pests on the environment and the importation of living modified organisms that may directly or indirectly affect plants or other organisms. There is therefore potential for overlap with the Convention on Biological Diversity (CBD) and its Cartagena Protocol,[7] which has led to growing cooperation between the two agreements.

The IPPC identifies modern phytosanitary concepts, such as pest risk analysis and the designation of pest free areas, and embraces a number of principles that align its provisions with the SPS Agreement. The first of these principles is state sovereignty, which recognizes that countries have the right to use phytosanitary measures, including measures taken in emergency situations, to protect their territories and their citizens from phytosanitary threats from other states. The effect of this right is, however, tempered by other principles, such as the principle of necessity, which requires states to adopt restrictive measures only where they are necessary for phytosanitary protection; and the principle of minimal impact (also contained in the SPS Agreement), which requires restrictive measures to have the least possible impact on the international movement of people and goods (IPPC, art. VII.2). Another important principle is cooperation, which requires states to cooperate to prevent the spread and introduction of quarantine pests and to promote measures for their official control (art. VIII).

The principle of non-discrimination requires that phytosanitary measures be applied without discrimination between countries with the same

---

[6] International Plant Protection Convention (New Revised Text Approved by the FAO Conference at its 29th Session – November 1997).
[7] See Part VII.

phytosanitary status. In the case of regulated pests within a country, measures are to be applied without discrimination between domestic and imported consignments. The principle of transparency requires countries to publish and disseminate phytosanitary prohibitions, restrictions and requirements and, on request, to make available the rationales for them (art. VII.2). The principle of emergency action permits countries in the face of a new or unexpected phytosanitary situation to take immediate emergency measures on the basis of a preliminary pest risk analysis. Such measures are to be temporary and the validity of their application in the long term is subject to a detailed pest risk analysis as soon as possible (art. VII.6).

The SPS Agreement identifies the IPPC as the organization responsible for international phytosanitary standard setting. The IPPC secretariat established its standard-setting programme in 1992. The first International Standards for Phytosanitary Measures (ISPMs) were approved by the FAO Conference in 1995. From 1998 to 2005 they were approved by the Interim Commission on Phytosanitary Measures, now the Commission on Phytosanitary Measures. Twenty-seven ISPMs have been approved to date.[8]

Like the SPS Agreement, the New Revised Text of the IPPC makes provision for contracting parties to provide technical assistance to other contracting parties, especially developing countries, with the objective of facilitating implementation of the IPPC and its standards (art. XX).

IV. ANIMAL HEALTH

The *Office international des épizooties* (OIE), or World Organization for Animal Health, is designated under the SPS Agreement as the standard-setting body for animal health. The OIE has three main objectives: (1) to inform governments of the occurrence and course of animal diseases and of ways to control disease outbreaks; (2) to coordinate international scientific research on the surveillance and control of animal diseases; and (3) to facilitate the harmonization of regulations pertaining to trade in animals and animal products.

OIE member countries, usually through their official veterinary services, are obligated to collect information on animal diseases extant in their territories, which the OIE then analyses and distributes in order to facilitate prevention

[8] See J. Vapnek and D. Manzella, *supra* note 3, p. 4.

and control elsewhere. The OIE also provides expertise and technical support to member countries requesting assistance with animal disease control and eradication operations, including for diseases transmissible to humans (zoonoses). In addition, the OIE develops standards for international trade in animals and animal products, again with the intention of preventing the transmission of animal diseases.

OIE member countries must immediately report outbreaks of certain diseases and also periodically report on the presence and distribution of those diseases. WTO member states are allowed to take zoosanitary measures, including import controls, based on that information. They are also expected to submit their national regulations, particularly those that apply to imports, to the OIE. States may apply different standards only where the importing country demonstrates scientifically that national animal health conditions require standards over and above those established by the OIE.

The OIE develops and updates normative documents, such as the *Terrestrial Animal Health Code*, the *Manual of Standards for Diagnostic Test and Vaccines*, the *Aquatic Animal Health Code* and the *Diagnostic Manual for Aquatic Animal Diseases*, all of which contain a list of definitions, disease notification criteria, procedures for international reporting of diseases, principles for import risk analysis and import and export procedures. The standards, guidelines and recommendations contained within these health codes apply to trade in animals, animal genetic material and animal products. WTO member countries can use the information in these documents to devise measures to protect against animal diseases without setting up unjustified trade barriers.[9]

V. FOOD SAFETY[10]

The Codex Alimentarius (Latin for "food code") and its organization, the Codex Alimentarius Commission (Codex), serve as a global reference point for consumers, producers and national food regulatory agencies on internationally adopted food standards, codes of practice and residue limits of pesticides and veterinary drugs. Codex is recognized by the SPS Agreement as the source of

---

[9] A. Ingrassia, *International and Regional Regulatory Frameworks Relevant to* Biosecurity *for Food and Agriculture*, paper presented at the FAO Technical Consultation on Biological Risk Management in Food and Agriculture, 2003, unpublished.

[10] This section draws from J. Vapnek and M. Spreij, *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, FAO Legislative Study No. 87, 2005, pp. 29–37.

international food safety standards. The Codex Alimentarius contains more than 200 standards for individual foods or groups of foods.

The preparation of draft food standards and related texts, whether intended for worldwide use, for a given region or for a select group of countries, takes place in Codex committees. Membership in these committees is open to all Codex member states, and international organizations may attend (as observers) committee sessions that are of interest to them. Generally, committees are financially maintained and hosted by member states. The two types of Codex committees are Commodity Committees and General Subject Committees.

Codex Commodity Committees are often referred to as vertical committees because they develop standards that apply to aspects of specific foods or classes of food. Such standards generally concern quality factors such as the composition or presentation of certain products. The subject matters of the Codex Commodity Committees range from fresh fruits and vegetables to processed meat and poultry products. Currently, eleven such committees are active or in recess. Some of these committees have completed their work and have ceased operation for an unspecified period of time until there is the need to call them back into service, while still others have remained active for the purpose of reviewing standards in order to bring them in line with current practice.

In recent years, there has been a shift in focus away from quality concerns towards food safety and the protection of human health. Thus, within Codex attention has turned to "horizontal" subjects – food hygiene, labelling, additives and contaminants – which, unlike vertical standards, cut across different types and classes of foods. As a result, the Codex General Subject Committees have grown in responsibility and prominence. These committees develop concepts and principles applicable to foods in general or applicable to specific foods or groups of foods, reviewing provisions in Codex commodity standards and developing recommendations pertaining to consumer health and safety. Currently, there are nine such committees, including the Committee on Food Additives and Contaminants, the Committee on Food Hygiene and the Committee on Food Labelling.

In addition to the established committees, from time to time Codex, following its rules of procedure, establishes *ad hoc* task forces to deal with specific new problems and issues. At present, one *ad hoc* task force is in the

process of developing standards, guidelines and recommendations for foods derived from biotechnology. The *ad hoc* task forces function in the same manner as the Codex General Subject and Commodity Committees except that they are dissolved after the specified work is completed or when the time limit allocated for the work has expired.

In addition to its many food standards, the Codex Alimentarius contains advisory instruments such as guidelines, principles, recommendations and codes of practice, with the goal of improving compliance with Codex standards. The codes of hygienic practice provide guidance on the production of food that is safe and suitable for consumption, while the codes of technological practice aim to ensure that the processing, transport and storage of food are carried out such that consumers receive end products that are wholesome and of the requisite quality. Many of these Codex instruments have been revised and updated over the years. For example, the Recommended International Code of Practice on General Principles of Food Hygiene, which is one of the most widely used Codex texts applying to all foods, has been revised four times since its adoption. During its recent revisions, the concept of risk analysis, as well as management tools such as the Hazard Analysis and Critical Control Point (HACCP) system, were included to emphasize the food chain approach, from primary production through to final consumption, highlighting the key hygiene controls required at each stage.

New instruments have been prepared over the last decade as well. For example, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods were developed in 1999 in light of the growing production of and international trade in organically produced food, with a view to facilitating trade and preventing misleading claims. There are also several noteworthy initiatives in the area of biosafety. For example, the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology developed Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Microorganisms, which were adopted as official Guidelines at the 26th Session of Codex in July 2003.

More than forty years after its creation, the Codex Alimentarius has become the authoritative collection of internationally adopted food standards

covering all the principal foods traded internationally, whether processed, semi-processed or raw. The Codex Alimentarius is also supplemented by the many maximum residue limits established for pesticides in foods and animal feeds, residue levels for veterinary drugs in foods of animal origin and acceptable levels of food additives and contaminants.

VI. INVASIVE ALIEN SPECIES AND BIODIVERSITY

Invasive alien species (IAS) are species introduced deliberately or unintentionally outside their natural habitats into habitats where they have the ability to establish themselves, invade, out-compete natives and take over their new environment. IAS are relevant to *Biosecurity* because they have the ability to affect the human, animal and plant life and health of their new habitats. Moreover, they are of interest since the modern vision of *Biosecurity* includes a concern for the preservation of the environment and prevention of loss of biological diversity.

The most important international instrument in this sector is the Convention on Biological Diversity (CBD),[11] which has three main objectives: (1) conserving biological diversity, (2) promoting the sustainable use of its components and (3) encouraging equitable sharing of the benefits arising out of the utilization of genetic resources (art. 1). Biological diversity is defined in the CBD as "the variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and ecosystems" (art. 2).

Article 8 of the CBD deals directly with IAS, providing that member states must prevent the introduction of, control or eradicate any IAS which threaten ecosystems, habitats or species. IAS have also been addressed by the CBD's Conference of the Parties, which approved Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threatens Ecosystems, Habitats or Species.[12] These guidelines endorse a systematic approach to the control of IAS along the following lines:

- priority attention should be given to preventing the entry of potential IAS, both between and within states;

[11] Convention on Biological Diversity (1992).
[12] CBD, *Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species*, 2003.

- if entry has already taken place, actions should be undertaken to prevent the establishment and spread of alien species;
- the preferred response is eradication at the earliest possible stage; and
- if eradication is not feasible or cost-effective, containment and long-term control measures should be considered.

Other CBD provisions are pertinent to the conservation of the environment and biological diversity and are therefore also relevant to *Biosecurity*. Member states are required to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or areas beyond the limits of national jurisdiction (art. 3). If there is imminent danger or damage to biodiversity either originating under a member state's jurisdiction or within its control outside its jurisdiction, that state must immediately notify potentially affected states of such danger or damage, as well as initiate action to prevent or minimize such danger or damage (art. 14).

Biotechnology is defined under the CBD as any technological application that uses, *inter alia*, living organisms to make or modify products or processes for a specific use (art. 2). Member countries are required to "take all practicable measures" that would give priority access to the results or benefits that come from biotechnologies based on genetic resources (art. 19(2)). Parties were mandated to consider the need for, and the modalities of, a protocol setting out appropriate procedures for the safe transfer, handling and use of any living modified organism that may have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity (art. 19(3)). This obligation was fulfilled by the adoption of the Cartagena Protocol on Biosafety (Cartagena Protocol).

VII. LIVING MODIFIED ORGANISMS

The Cartagena Protocol was adopted by the Conference of the Parties (COP) of the CBD on 29 January 2000 and came into force on 11 September 2003. The objective of the protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified

organisms[13] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements" (art. 1).

Although the protocol is basically an environmental instrument, it does include within its objectives protection against the possible impacts of living modified organisms (LMOs) on human health. The protocol recognizes that there are intrinsic risks associated with LMOs – both to the environment and human health – and promotes *Biosecurity* by setting the rules for the safe transfer, handling and use of LMOs, focusing on the transboundary movement of LMOs intended for the release into the environment. Among other things, the protocol requires that shipments of LMOs intended for intentional introduction into the environment be accompanied by documentation clearly stating that the shipment contains LMOs (art. 18).

The Cartagena Protocol provides for an "advance informed agreement" (AIA) between the exporting state and the importing state. The AIA involves a notification in writing by the exporting state before it exports a consignment of LMOs to the importing state. Crucially, upon receipt of this notification, the importing state must indicate whether its own regulations or those provided in the protocol will have to be followed with regard to the importation (art. 9.2(c)). The importing state shall make a decision on the importation within a prescribed time frame (art. 10.3) and has a right to refuse entry of the consignment of LMOs based on risk assessment (art. 10.1); the parameters of these risk assessment procedures are contained in Annex III to the protocol. Failure to acknowledge receipt of notification does not imply that the movement of the LMOs is permitted (art. 9.4). Similarly, failure to communicate the decision within the prescribed time frame does not imply any consent to the movement of LMOs (art. 10.5).

The protocol provides that in case of scientific uncertainty regarding the potential adverse effects of the LMOs in question, the importing state can

---

[13] "Living modified organism" is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" (art. 3(g)). The term is wider than genetically modified organism (GMO) as it does not require the insertion of genetic material. However, in many countries the term GMO is used to cover LMOs. See R. Mackenzie, F. Burhenne-Guilmin, A. La Viña and J. Werksman, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN, 2003, p. 46.

still decide against the import in order to prevent the possible adverse effects (art. 10.6). Thus the protocol embraces the precautionary principle.

It is important to note that the AIA procedure only applies to those LMOs intended for intentional introduction into the environment, and not to: (1) LMOs identified in a decision of the COP as not likely to have adverse effects on biodiversity conservation and sustainable use, (2) LMOs in transit, (3) LMOs for contained use, (4) pharmaceuticals that are intended for human use or (5) LMOs intended for direct use as food or feed or for processing (art. 5). With regard the last category, governments that approve LMOs for domestic use or for import shall communicate this decision and related information to the Biosafety Clearing-House (BCH) Mechanism.

The BCH is an information exchange platform established in the protocol and designed to facilitate the exchange of scientific, technical, environmental and legal information and experience on LMOs. Member states of the protocol are required to make available to the BCH any information regarding their national biosafety situation, including existing laws, regulations and guidelines for implementation of the protocol, information required for the AIA, any bilateral, regional and multilateral agreements and arrangements as well as summaries of risk assessments and final decisions (art. 20).

VIII. OTHER INSTRUMENTS

Biosecurity covers a wide range of sectors, including the food safety aspects of food production and fisheries. Hence, sectoral international instruments in those areas, binding and non-binding, are relevant to *Biosecurity* for the purposes of food and agriculture and can be said to form part of the international *Biosecurity* framework.[14] An illustrative (but not exhaustive) list would include the following instruments:

- Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade;
- Convention on Persistent Organic Pollutants;
- FAO International Code of Conduct on the Use and Distribution of Pesticides;
- Biological and Toxin Weapons Convention;

[14] See Biosecurity *in Food and Agriculture*, FAO Committee on Agriculture, 17th Session, 31 March–4 April 2003, Rome.

- FAO International Code of Conduct on Responsible Fisheries;
- Ramsar Convention on Wetlands;
- Protocol to the Antarctic Treaty on Environmental Protection;
- Bonn Convention on the Conservation of Migratory Species of Wild Animals;
- Global Programme of Action for the Protection of the Marine Environment from Land-based Activities;
- United Nations Framework Convention on Climate Change;
- United Nations Convention on the Law of the Sea.

In the discussion that follows, these international instruments are grouped according to those aspects of *Biosecurity* to which they are most relevant, using the same general *Biosecurity* categories as above: (1) food safety and plant and animal life and health and (2) IAS and LMOs.

Food Safety, and Plant and Animal Life and Health

(a) Rotterdam Convention

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade[15] seeks to protect human health and the environment from the possible risks resulting from trade in highly dangerous pesticides and chemicals by creating legally binding obligations for the implementation of a prior informed consent procedure by importing countries. As pesticides and chemicals pose risks to both the environment and food safety, the convention is relevant to *Biosecurity*.

(b) POPs Convention

The Stockholm Convention on Persistent Organic Pollutants[16] (POPs) is intended to eliminate or restrict the production, use or release of a dozen POPs including pesticides, industrial chemicals and hazardous by-products of combustion. Like the Rotterdam Convention, the POPs Convention aims to protect human health and the environment from substances that are toxic to humans and wildlife, and thus has *Biosecurity* implications.

---

[15] 1998 Rotterdam Convention on the Prior Informed Consent Procedure in Certain. Hazardous Chemicals and Pesticides in International Trade, 38 I.L.M. 1 (1999).
[16] Stockholm Convention on Persistent Organic Pollutants, *opened for signature*, 23 May 2001, 40 I.L.M. 532 (2001).

(c) FAO International Code of Conduct on Pesticides

The FAO International Code of Conduct on the Distribution and Use of Pesticides[17] sets forth voluntary standards for governments and the private sector on pesticides management. The code embodies principles such as risk reduction and support for sustainable agricultural development. As the code aims to protect human and environmental health, it is relevant to *Biosecurity*.

(d) Biological and Toxin Weapons Convention

The so-called Biological and Toxin Weapons Convention[18] prohibits the development, production and stockpiling of biological and toxin weapons. The convention is relevant to *Biosecurity* from the unique perspective of biological warfare, which may specifically target plants or crops.

(e) Code of Conduct for Responsible Fisheries

The FAO Code of Conduct for Responsible Fisheries[19] is widely recognized by governments and non-governmental organizations as the global standard for sustainable fisheries and aquaculture. It sets out principles and international standards of behaviour for responsible practices with a view to ensuring the effective conservation, management and development of living aquatic resources, with due respect for ecosystems and biodiversity. It is the basis for reviewing and revising national fisheries legislation, which may include provisions on the prevention of fish diseases.[20]

As *Biosecurity* includes fisheries, the aquatic animal health and food safety provisions of the code are important elements of the international framework for *Biosecurity*. For instance, the code mandates states to promote effective farm and fish health management practices favouring hygienic measures and vaccines (art. 9.4.4). States should also regulate the use of chemical inputs in aquaculture which are hazardous to human health and the environment (art. 9.4.5).

---

[17] International Code of Conduct on the Distribution and Use of Pesticides (2002).
[18] Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, *opened for signature*, 10 April 1972, 26 U.S.T. 583, T.I.A.S. No. 8062, entered into force on 26 March 1975.
[19] FAO Code of Conduct for Responsible Fisheries (1995).
[20] See FAO, *Law and Sustainable Development Since Rio, Legal Trends in Agriculture and Natural Resources Management*, FAO Legislative Study No. 73, 2002, p. 194.

Invasive Alien Species and Living Modified Organisms

(a) Ramsar Convention

The Ramsar Convention on Wetlands[21] (Ramsar Convention) is an international treaty that provides the framework for national action and international cooperation for the conservation and wise use of wetlands and their resources. Although the convention's text itself does not mention invasive alien species (IAS), contracting parties addressed the topic of "Invasive Species and Wetlands" in Resolution VII/14.[22] The resolution calls upon member states to address the impact of IAS on wetlands within their jurisdictions and to identify methods of control and solutions for combating IAS.

(b) Protocol on Environmental Protection to the Antarctic Treaty

Annex II to the Protocol on Environmental Protection to the Antarctic Treaty[23] has provisions connected to the international *Biosecurity* framework. For example, article 4 imposes upon member states the requirement that no non-native species can be introduced into Antarctica, except with a permit (art. 4.1).

(c) Bonn Convention

The Convention on the Conservation of Migratory Species of Wild Animals[24] (Bonn Convention) requires its member states to endeavour "to the extent feasible and appropriate to prevent, reduce or control factors that are endangering or are likely to further endanger certain species, including strictly controlling the introduction of, or controlling or eliminating, already introduced exotic species" (art. III(4)(c)). Any action taken to implement those provisions may be part of an overall IAS risk management programme.

---

[21] Convention on Wetlands of International Importance especially as Waterfowl Habitat, 996 U.N.T.S. 245; 11 I.L.M. 963 (1972).
[22] Resolutions of the San Jose Conference, Resolution VII.14 on Invasive Alien Species and Wetlands.
[23] Protocol on Environmental Protection to the Antarctic Treaty (1991).
[24] Convention on the Conservation of Migratory Species of Wild Animals (23 June 1979) 1459 U.N.T.S. 362 (1979).

(d) Global Programme of Action for the Protection of the Marine Environment from Land-based Activities

The Global Programme of Action for the Protection of the Marine Environment from Land-based Activities[25] was convened by the Executive Director of the United Nations Environment Programme (UNEP). One of its goals is to prevent the introduction of alien species known to have serious effects upon marine ecosystem integrity. Its overall aim is to help facilitate the preservation of the marine environment through international legal obligations such as the United Nations Convention on the Law of the Sea (UNCLOS) and Agenda 21.

(e) UNFCCC

The United Nations Framework Convention on Climate Change[26] (UNFCCC) has the aim of stabilizing (and eventually reducing) greenhouse gas concentrations in the atmosphere so as to prevent dangerous anthropogenic interference with the climate system. The convention and its Kyoto Protocol are of relevance to *Biosecurity* in that they attempt to prevent climate effects which will have an effect on biodiversity and on the movement of IAS.

(f) UNCLOS

Pursuant to UNCLOS,[27] member states must take all measures necessary to prevent, reduce and control "the intentional or accidental introduction of species, alien or new, to a particular part of the marine environment, which may cause significant and harmful changes thereto" (art. 196). These provisions can be interpreted to support, for example, risk assessment for genetically modified organisms prior to their release into the marine environment.

---

[25] Global Programme of Action for the Protection of the Marine Environment from Land-based Activities (1991).

[26] United Nations Framework Convention on Climate Change (9 May 1992), 1771 U.N.T.S. 107, 31 I.L.M. 849, entered into force on 21 March 1994.

[27] United Nations Convention on the Law of the Sea (10 December 1982), 1833 U.N.T.S. 3, 21 I.L.M. 1261 (1982), entered into force on 16 Nov. 1994.

IX. CONCLUSION

Biosecurity covers a number of subjects, each with its own intricacies. The international regulatory instruments introduced here also deal with the components of *Biosecurity* from sectoral perspectives. The task for national governments will be to identify conventions and international agreements which it is bound to or desires to follow, and assess its national legislation for conformity with those agreements. The main international instruments relevant to *Biosecurity* described in Parts III to VII of this chapter should be the starting point for the analysis.

Identifying other international agreements relevant to the adoption of a *Biosecurity* approach, such as those set out in Part VIII, may be a more challenging task. The key for national lawmakers will be to examine the constellation of potentially relevant international instruments from the perspective of whether they have an impact on the management of risks to food and agriculture. In this era of burgeoning international trade, national governments must carry out a delicate balance: implementing their international obligations and aligning their national laws with these international obligations, while structuring their national legal and institutional frameworks in a manner most conducive to the protection of their natural resources for food and agriculture.

REFERENCES

CBD. 2003. *Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species.*

FAO. 2007 *Guidelines for the Revision of Phytosanitary Legislation* by Vapnek, J. & Manzella, D., FAO Legal Paper Online No. 63, January 2007, available at www.fao.org/legal.

FAO. 2005. *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, by Vapnek, J. & Spreij, M., FAO Legislative Study No. 87, FAO, Rome.

FAO. 2003. Biosecurity *in Food and Agriculture*, Committee on Agriculture, 17th Sess., 31 March–4 April, Rome (COAG/2003/9).

FAO. 2002. *Law and Sustainable Development Since Rio: Legal Trends in Agriculture and Natural Resource Management,* FAO Legislative Study No. 73, Rome.

Ingrassia, A. 2003. *International and Regional Regulatory Frameworks Relevant to* Biosecurity *for Food and Agriculture*, paper presented at the FAO Technical Consultation on Biological Risk Management in Food and Agriculture (unpublished).

IUCN. 2003. *An Explanatory Guide to the Cartagena Protocol on Biosafety*, by Mackenzie, R. Burhenne-Guilmin, F. La Viña, A. & Werksman, J., Bonn.

IUCN. 2001. *Invasive Alien Species: A Tool Kit of Best Prevention and Management Practices*, by Wittenberg, R. & Cock, M.J.W. (eds.), Bonn.

IUCN. 2000. *A guide to designing legal and institutional frameworks on alien invasive species* by . Shine, C. Williams, N. & Gündling, L., IUCN Environmental Policy and Law Paper No. 40, Bonn.

3

REVIEW OF PILOT CASE STUDIES

Contents

I. LEGISLATION OVERVIEW

National legal consultants in Ethiopia, Ghana, India, Kenya, Uganda, and Viet Nam examined a range of national legislative instruments in the various sectors of *Biosecurity*. The instruments included parliamentary-level and subsidiary legislation (such as regulations and ministerial orders), and consisted of legislation in force as well as draft instruments under consideration.

This section sets out a list of the legislation reviewed in each country[1] while the subsequent sections contain a gap analysis of each of the five sectors of the legislative framework for *Biosecurity*: food safety, plant health, animal health, invasive alien species and biosafety. The chapter concludes with a review of the institutional set-up for *Biosecurity* controls in each of the six countries.

The Ethiopia study was based on the following pieces of legislation:

SECTOR	LEGISLATION
Food Safety	Quality and Standards Authority of Ethiopia Proclamation No. 413/2004; Re-establishment and Modernization of Customs Authority (Amendment) Proclamation, No. 368/2003; Public Health Proclamation, No. 200/2002; Drug Administration and Control Authority Proclamation No. 176/1999; Ethiopian Health and Nutrition Research Institute Establishment, Council of Ministers Regulations No. 4/1996; Ministry of Health Proclamation No. 4/1995.
Animal Health	Animal Diseases Prevention and Control Proclamation No. 267/2002; Draft Regulation for Animal Diseases Prevention and Control, 2000; Draft Regulation for Controlling Movement of Animals and Transportation of Animal Products and By–products, 2000; Draft Regulations to Provide for the Registration and Licensing of Animal Health Professionals, 2000;

[1] A detailed description of the content of the various legislative instruments in the six countries can be found in Chapters 5–10.

SECTOR	LEGISLATION
	Meat Inspection Amendment Proclamation No. 81/1976; Meat Inspection Proclamation, No. 274/1970; Meat Inspection Regulations No. 428/1970.
Plant Health	Seed Variety and Release Law No. 206/2002; Plant Quarantine Regulation, Schedules I and II, Proclamation No. 4/1992; Regulations on Pesticide Registration, Council of Ministers Special Decree No. 20/ 1990; Plant Protection Decree No. 56/1971.
Invasive Alien Species	Institute of Biodiversity Conservation Re-establishment Proclamation, No. 381/2004; Environmental Impact Assessment Proclamation No. 299/2002.
Biosafety	Draft National Biosafety Framework, 2000.[2]

In Ghana, the following instruments were analysed:

SECTOR	LEGISLATION
Food Safety	Draft Standards Bill, 2000 and 2006; Draft Meat Inspection Bill, 1999 and 2004; Draft Food and Drugs Regulations, 2000; Food and Drugs (Amendment) Act, 1996; Pesticides Management and Control Act, 1996; Environmental Protection Agency Act, 1994; Food and Drugs Law, 1992; Ghana Standards Board (Food, Drugs and Other Goods) General Labeling Rules, 1992; Ghana Standards Board (Amendment) Decree, 1979; Standards Decree, 1973; Ghana Standards (Certification Marks) Rules, 1970; Ghana Standards (Certification Marks) (Amendment Rules), 1970; Animals (Control of Importation) Ordinance, Diseases of Animals Act, 1961.

[2] The National Biosafety Framework is a policy document containing an outline of the biosafety legislation to be drafted.

SECTOR	LEGISLATION
Animal Health	Local Government (Accra Metropolitan Assembly) (Establishment) Instrument, 1995; Environmental Protection Agency Act, 1994; Local Government Act, 1992; Sale of Goods Act, 1962; Animals (Control of Importation) Ordinance, Diseases of Animals Act, 1961.
Plant Health	Local Government (Accra Metropolitan Assembly) (Establishment) Instrument, 1995; Environmental Protection Agency Act, 1994; Local Government Act, 1992; Seed Inspection and Certification Decree, 1972; Prevention and Control of Pests and Diseases of Plants Act, 1965.
Invasive Alien Species	Wetland Management (Ramsar Sites) Regulations, 1999 (LI 1659).
Biosafety	Draft Biosafety Bill, 2004.

In India, the country study is based on the following legislation:

SECTOR	LEGISLATION
Food Safety	Atomic Energy (Control of Irradiation of Food) Rules, 1996; Bureau of Indian Standards Act, 1986; Export (Quality Control and Inspection) Act, 1963; Fruit and Vegetables Product (Control) Order, 1955; Prevention of Food Adulteration Act, 1954; Agricultural Produce (Grading and Marking) Act, 1937.
Animal Health	Livestock Importation Act, 1989; Wild Life Protection Act, 1972
Plant Health	Plant Quarantine Order, 2003; Insecticides Act, 1968; Seeds Act, 1966; Destructive Insects and Pests Act, 1914.

SECTOR	LEGISLATION
Biosafety	Guidelines on Biosafety, 1990, 1994 and 1998; Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells under the Environment Protection Act, 1989.

In Kenya, the following legislation was analysed:

SECTOR	LEGISLATION
Food Safety	Standards Act, Chapter 496, 1974, as amended in 1981, 1982 and 1995; Meat Control Act, Chapter 356, 1973, with regulations in 1973, 1976 and 1980; Food, Drugs and Chemical Substances Act, Chapter 254, 1970; Public Health Act, Chapter 242, 1921, as revised in 1986.
Animal Health	Animal Diseases Act, Chapter 364, 1972, as revised in 1989; Cattle Cleansing Act, Chapter 359, 1937; Crop Production and Livestock Act, Chapter 321, 1926, as last amended in 1968.
Plant Health	Suppression of Noxious Weeds Act, Chapter 325, 1986; Pest Control Products Act, Chapter 345, 1983, with regulations issued in 1984 and 2006; Seeds and Plant Varieties Act, Chapter 326, 1972, as amended in 2002; Plant Protection Act, Chapter 324, 1962, as amended in 1979.
Invasive Alien Species	Environmental Management and Coordination Act, No. 8 of 1999.
Biosafety	Draft National Biosafety Bill, 2003; Draft Regulations and Guidelines for Biosafety in Biotechnology for Kenya, 1998; Science and Technology Act, Chapter 250, 1977.

The national legal consultant reviewed the following legislation in Uganda:

SECTOR	LEGISLATION
Food Safety	Uganda National Bureau of Standards Act, Chapter 327, No. 1, 1983; Public Health Act, Chapter 281, 1964; Food and Drugs Act, Chapter 278, 1964.
Animal Health	Animal Breeding Act, 2001; Uganda Wildlife Act, Chapter 200, 2000; Veterinary Surgeons Act, Chapter 277, 1966; Cattle Traders Act, Chapter 43, 1964; Animal Diseases Act, Chapter 38, 1964.
Plant Health	Draft Plant Protection Bill, 2006; Draft Seed and Plant Bill, 2005; Draft Plant Protection Bill, 2003; National Forestry and Tree Planting Act, 2003; Cotton Development Act, Chapter 30, 1994; Agricultural Seeds and Plant Act, Chapter 28, 1994; Plant Protection Act, Chapter 31, 1976.
Invasive Alien Species	National Environment Act, Chapter 153, 1995.
Biosafety	Draft National Biotechnology and Biosafety Policy, 2006; Uganda National Council for Science and Technology Act, Chapter 209, 1990.

The Viet Nam study reviewed the following legislation:

SECTOR	LEGISLATION
Food Safety	Decision No. 21/2007/QD-BYT of the Ministry of Health on Health Measures in Food Manufacturing Sites; Decree No. 21/2006/ND-CP of the Vietnamese Government on the trade in and use of nutrition products for children; Decision No. 43/2006/QD-TTg of the Prime Minister on the National Action Plan on Hygiene and Food Safety to 2010; Aquaculture Law, 2003; Law on the Protection of People's Health, 2000;

SECTOR	LEGISLATION
	Ordinance on Consumer Protection, 1999; Ordinance on Food Hygiene and Safety, 2003.
Animal Health	Decree No. 33/2005/ND-CP; Ordinance on Livestock Breeds, No. 16/2004/UNTVQH11; Ordinance on Veterinary Controls, No. 18/2004/PL/UBTVQH11; Fisheries Law No. 17/2003/QH11.
Plant Health	Decision No. 34/2007/QD-BNN promulgating a List of Articles Subject to Plant Quarantine and Pest Risk Analysis Before Import into Viet Nam; Decree No. 02/2007/ND-CP on Plant Quarantine; Decision No. 16/2004/BNN-BVTV on Procedures for Plant Quarantine Inspection; Decree No. 26/2003/ND-CP on Penalties for Administrative Offences in Plant Protection and Quarantine Matters; Ordinance No. 03/2004/L-CTN on the Management of Plant Seeds; Circular No. 110/2003/QD-BTC on Charges and Fees for Plant Protection and Quarantine Services; Circular No. 73/2003/TT-BNN on Domestic Plant Quarantine; Circular No. 17/2003/TTLT/BTC-BNN & PTNT-BTS on Inspection and Supervision of Commodities Subject to Plant Quarantine, Animal Quarantine and Fishery Quarantine; Decision No. 88/2003/QD-BNN on Duties, Powers and Structure of the Plant Protection Department; Decision No. 89/2002/QD-BNN-KHCN regulating the Import of Plant Seeds and Beneficial Organisms; Decision No. 84/2002/QD/BNN regulating Fumigation Activities; Ordinance on Plant Protection and Quarantine, 2001; Decision No. 56/2001/QD-BNN-BVTV on the List of Regulated Articles for Import, Export, Re-import, Re-Export and in Transit; Vietnamese Standard 6908: 2001 – Phytosanitary Measure – Imported Regulation-Guidance on Pest Risk Analysis (PRA); Vietnamese Standard 6907: 2001 – Phytosanitary Measure – Principles of Plant Quarantine Relating to International Trade;

SECTOR	LEGISLATION
	Vietnamese Standard 3937: 2000 – KDTV – Glossary of Phytosanitary Term and Definitions; Decision No. 117/2000/QD- BNN-BVTV on the Quarantine Pest List; Decision No. 128/1998/QD/BNN-KHCN establishing Phytosanitary Standards; Decision No. 70/1998/ QD-BNN-KHCN on Procedures for Fumigation; Vietnamese Standard TCVN 4731-89 – Plant Quarantine Sampling Method.
Invasive Alien Species	Law on Forest Protection and Development, 2004; Decree No. 109/2003/ND/CP on the Preservation and Sustainable Development of Wetlands.
Biosafety	Draft Law on Biodiversity, 2006; Law on Environment Protection, 2005; Decision No. 212/2005/QD-TTg on Regulations for the Management of Biosafety; Decision No. 178/1999/QD-TTg on the Labelling of Domestic and Import-Export Goods.

II. FOOD SAFETY

2.1. Ethiopia

The Government of Ethiopia issued Public Health Proclamation No. 200 in 2002. In the proclamation, the Ministry of Health is given general powers on public health matters, which include food safety. The proclamation broadly defines food as "any substance whether processed, semi-processed or raw which is intended for human consumption and includes drinks, chewing gum, and/or treatment of food, not including tobacco, cosmetics or substances used only as drugs".[3]

The proclamation establishes an advisory board at the federal level and regional health bureaux for the purpose of advising the appropriate health

[3] The definition mainly tracks the Codex definition of food.

authority (the Ministry of Health) on the implementation of the proclamation. The proclamation sets forth general prohibitions of manufacture, import or sale of food not in compliance with national quality standards. Draft Food Safety Regulations detailing food safety controls have been elaborated and are awaiting endorsement by the Council of Ministers. Most regional health bureaux, under the Public Health Proclamation, have enacted regulations that fit their regional contexts.

The Meat Inspection Amendment Proclamation (No. 81/1976) and the Animal Diseases Prevention Control Proclamation (No. 267/2002) provide for the control of slaughterhouses and establishments as well as the safety of meat and meat products. These instruments are implemented by the Animal and Fisheries Resources Development and Regulatory Department of the Ministry of Agriculture.

By virtue of the national standard-setting mandate contained in Proclamation No. 413/2004, the Quality Standards Authority of Ethiopia (QSAE), which operates under the Ministry of Trade and Industry, has developed about 450 food-related standards, most of which have been translated into technical regulations. Currently, about 60 percent of the QSAE-approved standards fall under the category "Agriculture and Food Technology".

A number of institutions are assigned, via the proclamations establishing them, to undertake food safety inspections in the country. These include the Ministry of Health, the QSAE, the Ethiopia Health and Nutrition Research Institute and the Customs Authority. To strengthen collaboration, the existing Ethiopian Technical Committee has established the National Food Safety Council, a consultative body whose members are drawn from regulatory bodies, research institutes, industry, consumers and institutions of higher learning involved in food safety.

2.2. Ghana

In Ghana, the 1992 Food and Drugs Law (FDL) regulates the manufacture, importation, exportation, distribution, use and advertisement of foods, drugs, cosmetics, chemical substances and medical devices. It contains prohibitions against the sale of unwholesome, poisonous and adulterated foods and it prescribes standards for foods.

The FDL establishes an administrative authority, the Food and Drugs Board (FDB), under the control and supervision of the ministry responsible for health. The composition of the board draws from relevant departments and agencies of state and the private sector. The functions of the FDB as set out in Section 28 of the FDL include advising the ministry on all matters relating to the administration and implementation of the FDL.

A major defect of the FDL from the standpoint of *Biosecurity* is that it is void of any reference to international standards that should guide the FDB in the discharge of its duties. Schedule I of the FDL, which is linked to other national legislation on standard setting, makes reference to the publications of certain international bodies but omits the Codex Alimentarius Commission. Reportedly, a draft Food Bill was developed in 2006 to address this gap.

Authorized officers of the FDB have wide enforcement powers under the FDL for purposes of entering premises, opening and examining food receptacles and books and seizing and destroying unwholesome, poisonous or adulterated foods. Nonetheless, there is a gap in the legislation regarding meat inspection.

Under the FDL, both the FDB and the district/metropolitan assemblies have statutory functions in meat inspection. The meat inspection function has been exercised by public health officers by virtue of previous and current legislation on local government. Unlike these officials, whose mandate is expressly provided for in legislation, no specific mandate is accorded to veterinary officers of the Directorate of Veterinary Services (DVS) of the Ministry of Food and Agriculture in the area of meat inspection.

A revised draft Meat Inspection Bill was prepared in 2004 to divest public health officers of these functions and vest them in the DVS. The draft also makes provision for the appointment and qualifications of "veterinary inspectors". These include qualified and registered veterinarians and any other veterinary personnel appointed as inspectors pursuant to the law.

The Animals (Control of Importation) Ordinance, Diseases of Animals Act, 1961, a colonial statute still in force, bans the importation of animals into the country unless they are certified by a veterinary authority as free from disease. The ordinance is outdated and could be repealed by the draft Meat

Inspection Bill, which deals with importation and exportation of meat, meat products and animals.

Even though the appropriate international bodies have prescribed standards for inspections and the importation and exportation of meat products, there is no express reference to the OIE in the current legislation. Either the parent enactment could make a reference to these standards, or regulations could be passed incorporating them.

The Ghana Standards Board (GSB) is a statutory body that was established by the Standards Decree, 1967, and re-established by a new decree in 1973. The 1967 Decree grants the GSB a wide range of functions and powers on standard setting, implementation and enforcement. Standards cover the sale or manufacture of goods in the national interest as well as in the interest of public health and safety.

Another piece of legislation, the 1979 GSB Decree, added two specific functions to be exercised by the GSB in relation to food, namely: (1) prohibiting the sale or manufacture of foods, in the national interest; and, (2) prohibiting the importation into Ghana of foods which have not been certified by the GSB as compliant with its standards. Both the GSB and the FDB have statutory functions in the area of sale, manufacture, exportation and importation of food, and this has become a source of overlap and conflict between the two boards.

The 2006 draft Standards Bill establishes a National Standards Authority (NSA) as a body corporate. The bill re-enacts the provisions of the GSB decree and transfers the functions of the GSB to the NSA. The specifications for standards prescribed by law include "international or other overseas specifications", without explicit reference to WTO standards.

The draft bill, however, does not satisfactorily address the thorny issue of the NSA functions in the area of food *vis-à-vis* the FDB. Section 3(2)(c) of the draft bill states that if it is within the national interest the NSA is authorized to prohibit the sale or manufacture of any kind of goods. The NSA also has the power to prohibit the importation of goods that have not been certified as complying with the standards, and the definition of "goods" is wide enough to encompass food. Hence the draft bill in its present form conflicts with the mandate of the FDB which, as noted, has been established to control the manufacture, importation, exportation, distribution and use of food.

2.3. India

The Indian national case study notes that the SPS Agreement has prompted substantial changes, and not only in the food laws. At present, food safety legislation is still disparate, with several subordinate rules, regulations and orders having been enacted to deal with contingencies as they arose. The operative legislation, namely, the 1954 Prevention of Food Adulteration (PFA) Act, seeks to test only end products and does not foster the adoption of Hazard Analysis and Critical Control Point (HACCP) principles throughout the food chain.

The state governments and the union territories[4] are responsible for monitoring and implementing the provisions of the PFA Act and the PFA Rules, 1955. The latter were adopted by the Ministry of Health and prescribe maximum tolerance limits for pesticides and heavy metals in food products. The Directorate General of Health Services in the Ministry of Health and Family Welfare, which is the Codex Contact Point, is currently working to integrate Codex standards into the legislation.

The Ministry of Food Processing Industries (MOFPI) is in charge of the implementation of a number of food safety and quality provisions. For example, the Fruit Products Order of 1955 promulgated under Section 3 of the Essential Commodities Act of 1955 prescribes minimum norms for sanitary and hygienic conditions of manufacturing premises and also lays down product standards. MOFPI is closely associated with the Codex Contact Point in the Ministry of Health.

The Food Safety and Standards Act (FSSA), 2006, which seeks to consolidate the many pieces of legislation into one combined whole, is a serious attempt at implementing a food chain approach, promoting a continuous series of controls from the farm to the table. However, the FSSA excludes from its purview plants prior to harvesting and animal feed and hence does not control the contamination of food from pesticides and antibiotics at source. The FSSA does however establish a Food Safety and Standards Authority.[5]

---

[4] India is a federal republic which comprises 28 states and seven union territories.

[5] See Part VII on the institutional set-up.

In India, international standards, guidelines and recommendations are increasingly used to guide domestic as well as international trade in food. The Codex HACCP and food hygiene standards have been adopted by the Bureau of Indian Standards (BIS), an autonomous statutory body set up by the Bureau of Indian Standards Act, 1986. The BIS comprises members representing industry, consumer organizations, scientific and research institutes, technical institutions, central ministries, state governments and members of parliament. It provides for quality certifications, including food hygiene.

Inspection and certification for export are regulated under the Export (Quality Control and Inspection) Act of 1963. The Export Inspection Council (EIC) is the official certification body for exports operating under the act. Notably, the EIC is developing equivalence agreements on conformity assessment with its major trade partners. It is also developing standards for exports based mainly on Codex standards, but it also recognizes that an importing country may impose stiffer requirements.

Imported food is inspected at the ports of entry by personnel of the Collectorate of Customs. The Government of India through its various departments – Commerce, Health, Revenue and the Directorate General of Foreign Trade – is taking steps to streamline the inspection of imported food.

2.4. Kenya

In Kenya, the Food, Drugs and Chemical Substances Act (Chapter 254, 1970) makes provision for the prevention of adulteration of food, drugs and chemical substances. Foods for which there are prescribed standards must conform to such standards. Subsidiary legislation under the act makes provisions for food hygiene, and has addressed the issues of food labelling, additives and standards.

Meat control is also the subject of specific legislation. The Meat Control Act (Chapter 356, 1973) provides standards for slaughterhouses; storage and transportation of meat and meat products intended for human consumption; meat processing establishments; and import and export control over meat and meat products. Regulations specify standards to be observed in meat production as well as methods of packaging, labelling and transport. The Ministry of Agriculture implements both the Food, Drugs and Chemical Substances Act and the Meat Control Act.

The Standards Act (Chapter 496, 1974, as amended) is the main legislation for standards formulation and implementation in Kenya. Section 3 establishes the Kenya Bureau of Standards, whose functions inter alia are to make arrangements and provide facilities for the examination and testing of "commodities and any material substance from or with which they may be manufactured, produced, processed or treated". Those provisions are broad enough to cover food. The minister in charge of trade is empowered under the act to appoint inspectors who are mandated to, among other things, inspect and take samples of any commodity or any related material or substance.

Food is also regulated under public health legislation. The Public Health Act (Chapter 242, 1921, as amended) establishes a Central Board of Health, which is empowered to advise the Minister of Health on all matters affecting health. The act contains provisions that ensure the protection of foodstuffs intended for human consumption. Another significant provision on food safety is the requirement that local authorities ensure that water supplies, food and milk are wholesome.

2.5. Uganda

The Food and Drugs Act (Chapter 278, 1964) is the main piece of legislation on food safety in Uganda. The act makes provision for the prevention of adulteration of food, which is defined to include drink, chewing gum and other products of like use or nature, and articles and substances used as ingredients in the preparation of food or drink or of such products. It excludes water, live animals or birds, animal fodder or feed and substances used only as drugs (sect. 1). The act proscribes the use of any ingredient in the preparation of food sold for human consumption that would render the food injurious to human health (sect. 2) and prohibits false labelling or advertisement of food (sect. 5). Food in transit in Uganda may be examined by an authorized officer (sect. 9).

An authorized officer means a person authorized by the Minister of Health or a local authority with the approval of the minister. For the purposes of taking samples, an authorized person includes a police officer of or above the rank of inspector authorized to take samples. A veterinary surgeon registered under the Veterinary Surgeons Act (Chapter 277, 1966), in the service of the government or of a local authority, is deemed to be an authorized officer for the purposes of the inspection of animals intended for

slaughter and the examination and seizure of meat unfit for human consumption. A medical officer, a health inspector or a person having such qualifications as may be prescribed may undertake certain functions of the veterinary surgeon.

The Food Hygiene Advisory Committee is established under the act to advise the minister on any questions relating to the act that the minister may refer to it for its consideration.

The Uganda National Bureau of Standards (UNBS) Act (Chapter 327, 1983) is of relevance to food safety in that it establishes the UNBS under the general supervision of the minister responsible for commerce. The functions of the UNBS include the formulation of national standards and specifications for commodities, including food, as well as standards enforcement to protect consumers against harmful ingredients and dangerous components of commodities.

2.6. Viet Nam

In Viet Nam, food safety is mainly regulated by the 2003 Ordinance on Hygiene and Food Safety. The ordinance includes provisions to ensure hygiene and food safety in food production and trade as well as prevention and control of food poisoning and food-borne diseases. The ordinance establishes that individuals and legal entities manufacturing and trading in food must comply with three sets of regulations: (1) safety regulations on infrastructure, including facilities, water supply systems and wastewater treatment; (2) regulations on equipment, such as for processing, storage and transportation; and (3) regulations on personnel, such as employees' health and knowledge of hygiene and food safety principles. National standards of food hygiene and safety are established by the Ministry of Science and Technology in cooperation with the Ministry of Health.

Provisions on food export and import require import and export enterprises to obtain an authorization from the Ministry of Health, which certifies that the enterprises have an adequate food safety management infrastructure. In cases where the requirements are not met, food may be seized and disposed of.

In the area of prevention and control of food poisoning and food-borne diseases, the People's Committees at different territorial levels, the Ministry of Agriculture and Rural Development, the Ministry of Industry and the

Ministry of Health are all assigned a number of responsibilities. These range from the implementation of good manufacturing practices to the implementation and enforcement of food safety and hygiene standards and food safety emergency management.

Other laws, such as the 2000 Law on People's Health and the 1999 Ordinance on Consumer Protection, state the general duty of individuals and legal entities to follow food safety and hygiene standards.

III. PLANT HEALTH

3.1. Ethiopia

The Council of Ministers Regulations No. 4/1995 give the Ministry of Agriculture and Rural Development the general mandate for plant health. The ministry is made responsible for plant quarantine to prevent the spread of plant pests and to regulate the movement of plants, plant products or other articles into or from a specified area.

The ministry is further empowered to restrict the importation of certain plants and plant products by requiring import permits and phytosanitary certificates duly issued by the plant protection authorities of the exporting countries. The ministry has the responsibility for issuing phytosanitary certificates for export of plants and plant products.

The Plant Quarantine Regulations (Council of Ministers Regulations No. 4/1992) elaborate detailed provisions on import and export. The regulations prescribe that any plants or other articles, premises or conveyances found to be infected shall be treated or destroyed, as the case may be. Quarantine controls and documentary verification of phytosanitary certificates on all imported plants are required. Some plant species are prohibited from entering the country. The regulations also provide for the declaration of quarantine areas and the adoption of subsequent control measures.

3.2. Ghana

In Ghana, the major piece of legislation governing plants and plant protection is the Prevention and Control of Pests and Diseases of Plants Act, 1965. The act regulates the prevention of plant pests and also governs plant quarantine. It confers the general mandate for plant protection on the

Ministry of Food and Agriculture and provides for the appointment of plant quarantine officers. At the borders, officials of the Plant Protection and Regulatory Services Department carry out inspections on all imported plants and plant materials in accordance with the act.

The legal regime for plant protection is outdated, and the legislation does not measure up to IPPC standards. The shortcomings include the absence of provisions on the designation of a national plant protection organization, on risk analysis and on the exportation of plants, as well as insufficient financial penalties for violations.

Draft legislation was prepared with the assistance of FAO in the mid-1990s but has not yet been enacted. It is also somewhat out of date given the coming into force of the New Revised Text of the IPPC in 1997.

3.3. India

The Destructive Insects and Pests Act, 1914, continues to regulate the introduction and movement of any insect, fungus or pest which would be destructive to crops and crops only (not to areas such as forests). It has gone through several amendments over the years.

The act does not regulate the export and certification of plants and plant products. The enactment of the Plant Quarantine Bill, 2004, would repeal it and provide a comprehensive regulatory framework for quarantine pests. The bill establishes the Plant Quarantine Authority of India as the national plant protection organization, thus meeting India's obligation under the IPPC.

With regard to imports, the Plant Quarantine (Regulation of Import into India) Order, 2003, supplements the 1914 Act. The order classifies plants and plant products for import as: (a) prohibited; (b) restricted (i.e. subject to a special authorization regime in addition to ordinary import conditions); (c) requiring additional declarations and other import conditions; and (d) requiring phytosanitary certification for processing and industrial production. The central government, through the Joint-Secretary in charge of plant protection in the Department of Agriculture and Cooperation, can relax any of the conditions of the order for public interest reasons. The power to relax conditions on import permits and phytosanitary certificates has been delegated to officers in charge of plant quarantine stations.

There is generally a lack of enforcement of the existing legislation and an inability to follow the letter of the law (for instance, on phytosanitary certification). However, the current framework is in broad compliance with international standards, and the frequent updating of the Plant Quarantine Order suggests that the concerned ministerial department is trying to protect domestic plant health adequately while at the same time pay due attention to international trade requirements.

3.4. Kenya

In Kenya, the main legislation on plant health is the Plant Protection Act (Chapter 324, 1962, as amended). The act makes provision for the prevention of the introduction and spread of diseases destructive to plants. The main regulatory agents under the act are the Minister of Agriculture and the inspectors, including the Director of Agriculture and any other persons authorized by the director to enforce the act.

In the Plant Protection Act, the Minister of Agriculture is given regulatory powers in relation to:

(a) phytosanitary inspection and certification for imports and exports;
(b) disinfection or treatment of any plant or article likely to infect any plant with a pest or disease;
(c) imports through specified ports or places of entry;
(d) post-entry quarantine; and
(e) the movement of plants or classes of plants likely to be infected with any pest or disease into or within any specified place or area.

Under the act, inspectors are mainly appointed from staff of the Kenya Plant Health Inspectorate Service (KEPHIS). KEPHIS is a parastatal agency under the Ministry of Agriculture that was established by ministerial order under the provisions of State Corporations Act (Chapter 446, 1986). KEPHIS is the SPS Enquiry Point. Its mandate is to:

(a) coordinate all matters relating to crop pests and disease control;
(b) establish service laboratories to monitor the quality and levels of toxic residues in plants as well as soils and produce;
(c) advise the Director of Agriculture on appropriate seeds and planting materials for import and export;

(d) undertake inspection, testing, certification, quarantine control, variety testing and description of seeds and planting materials;
(e) undertake grading and inspection of plants and plant produce at the ports of entry and exit;
(f) develop and implement standards on both imported and locally produced seeds;
(g) approve all import and export licences for plants and seeds issued by the ministry responsible for commerce and industry, before such importation or exportation is carried out; and
(h) establish posts at convenient locations for quarantine, inspection and quality control of fertilizers and seeds.

The Plant Protection Act is complemented by the Suppression of Noxious Weeds Act (Chapter 325, 1986), which provides that the Minister of Agriculture may, by notice in the gazette, declare a plant to be a noxious weed in any area. The inspectors, appointed by the Director of Agriculture, are granted powers of entry onto land for the purpose of ascertaining whether any noxious weed exists and, if so, to serve notice on the person in charge of the land. None of the legislation examined above refers to the IPPC or specifically to the mandate of the national plant protection organization.

3.5. Uganda

Uganda's legislation on plant health reveals an outdated framework that ought to be aligned with international requirements if it is to facilitate agricultural imports and exports. The Plant Protection Act (Chapter 31, 1976) was originally passed as an ordinance in 1937. The act has limited provisions on the prevention of the introduction and spread of diseases destructive to plants. Of course, the definition section does not reflect the modern concepts of plant protection even as first defined in the IPPC of 1951.

The existing plant protection administration is undersized and does not allow for the delivery of an efficient service. The penalties set in the legislation are outdated and have no deterrent effect. The review of the act started in 2001 led to the drafting of the Plant Protection and Health Bill of 2003.

The 2003 Bill attempted to fill the gaps by establishing a Technical Committee to assist the Commissioner and the Minister of Agriculture in carrying out the functions outlined for the Department of Crop Protection of the Ministry of Agriculture. The penalties were reviewed and currency points introduced to

make the penalties more realistic. The definition section was expanded to include modern terminology, drawing on the Glossary of Phytosanitary Terms (ISPM No. 5). However, the cost recovery in the draft bill, proposed in particular to enable rapid response to epidemics of quarantine importance, was not included in the final text. The 2003 Bill was found lacking in these respects and a revised bill was proposed in 2005.

The Plant Protection Bill, 2005, drafted with the assistance of FAO, proposes a new cost recovery mechanism to enable rapid response to epidemics of quarantine importance. It introduces pest risk analysis and strengthens the import and export control of plants, plant products and regulated articles. The Department of Crop Protection is designated as the National Plant Protection Organization (NPPO) and is responsible for the implementation of the act. To this end, the NPPO is in charge of surveillance of growing plants (including areas under cultivation and wild flora) and of plants and plant products in storage or in transport, in order to report the occurrence, outbreak and spread of pests, and to control those pests.

The Minister of Agriculture is authorized to appoint inspectors to enforce the act, from among officers of the NPPO or other competent persons. In addition, the minister may delegate certain functions, by statutory instrument, to any specified competent individual or institution, which includes designation of laboratories and competent scientists.

There are some overlaps in the legislative framework which the bill attempts to address in order to avoid institutional conflict and the resulting inefficiency. For example, Section 12 of the Agricultural Seeds and Plant Act (Chapter 28, 1994) authorizes the National Seed Certification Service (NSCS) to establish phytosanitary standards and practices for crops. The NSCS is further authorized to direct that seeds or plants harbouring pests and diseases be destroyed within a specified period of time and in a specified manner. Similar provisions are in the Cotton Development Act (Chapter 30, 1994), Section 12, with regard to the Minister of Agriculture in consultation with the Cotton Development Organization. On the other hand, under Section 36 of the National Forestry and Tree Planting Act, 2003, the minister responsible for forestry, the National Forestry Authority or a district council is authorized to prescribe the measures to be taken to control or eradicate pests in forests and forest products. To eliminate these potentially overlapping mandates, a clause in the 2005 Plant Protection Bill provides for the primacy of that bill in plant protection matters.

3.6. Viet Nam

The regulatory framework for plant health in Viet Nam is elaborate and comprehensive. The main piece of legislation is the 2001 Ordinance on Plant Protection and Quarantine. The ordinance provides for pest surveillance and control by generally referring to the management of injurious pests, including survey, detection, forecasting and warning of pest occurrence, development, distribution and damage. Government Decree No. 02/2007/ND-CP on Plant Quarantine requires the Ministry of Agriculture and Rural Development to develop a list of regulated pests, and refers to pest risk analysis as the basis for elaborating that list. Notably, the decree specifies the rights and duties of plant owners which include: (a) the right to be informed on pest status and assisted with pest control by the competent governmental bodies; (b) the duty to apply appropriate pest control measures as recommended by competent governmental bodies in order to contain a pest; and (c) the duty to report any pest of economic importance to competent governmental bodies.

The ordinance sets forth the mandate to designate areas in which an outbreak of a pest of economic importance occurs. The mandate lies with the Chairman of the People's Committee or the Ministry of Agriculture and Rural Development depending on the location of the outbreak. The ordinance states that when quarantine or alien pests are detected, the competent state bodies shall order appropriate measures to delimit and eradicate such pests and require the owners of regulated articles to apply those measures immediately.

Provisions on import controls, including issuance of import permits, inspection and treatment of consignments at points of entry and post-entry restrictions, are provided for in the ordinance and in the decree. In addition, the Ministry of Agriculture and Rural Development Decision No. 16/2004/BNN-BVTV sets forth, among other things, model documents for: (a) the import permit; (b) the application for phytosanitary inspection; (c) the declaration form at the point of entry; (d) the record of inspection for consignments and other regulated articles; and (e) the authorization to import.

Phytosanitary certification for export is mentioned in the ordinance while procedures for export inspections are regulated in the decree. With regard to the powers of quarantine officers, article 6 of the same decree empowers quarantine officers to enter any place where regulated

articles are found. Offences and penalties are regulated in subsidiary legislation, namely Decree No. 26/2003/ND-CP.

IV. ANIMAL HEALTH

4.1. Ethiopia

The Animal Disease Control Proclamation No. 267/2002 regulates the prevention and control of animal diseases. The proclamation tasks the Ministry of Agriculture and Rural Development with import controls on animals and animal products as well as animal movement restrictions. Import requirements are set forth, including import permits and inspections. The ministry is obliged to establish an emergency preparedness and epidemic surveillance system to contain the spread of animal diseases and prevent the introduction of exotic diseases into the country. The ministry is authorized to declare animal quarantine in areas infected by animal diseases of economic relevance and to order zoosanitary measures. With regard to exports, the ministry is responsible for international veterinary certification and the establishment of disease-free areas. The proclamation also sets out export conditions and procedures that exporters shall follow.

A set of regulatory instruments are in place for meat production and inspections. The Meat Inspection Proclamation No. 274/1970 confers a mandate on the ministry to control and regulate the production, processing and handling of livestock products. The Meat Inspection Amendment Proclamation No. 81/1976 mandates the ministry to issue regulations and establish criteria for livestock production for human consumption, including classification of products and inspection of processing facilities. The Meat Inspection Regulations No. 428/1970 lay down the requirements for setting up abattoirs and commercial establishments dealing with slaughtering, preparation and processing of livestock products for export from or import into Ethiopia.

As of 2003, the Government of Ethiopia has designed an export development strategy which pays particular attention to the promotion of meat and other livestock products. The government is building capacity to comply with international standards, particularly those emanating from the OIE. Within this context, a series of draft regulatory instruments are under development. These drafts incorporate *Biosecurity* concepts into the new legal framework, such as by streamlining import and export procedures and pooling resources to conduct risk assessment.

4.2. Ghana

In Ghana, the Disease of Animals Act, 1961, gives the Ministry of Food and Agriculture the power to adopt measures to curb the outbreak of animal diseases. The powers which may be exercised by veterinary officers of the Directorate of Veterinary Services under the act, especially in the event of an outbreak, are aimed at the control and avoidance of the spread of animal diseases. No reference is made to international standards. Given Ghana's membership in the OIE and its international obligations under the SPS Agreement, there is the need to refer to and incorporate the OIE standards, which are the international norms and benchmarks for animal health.

4.3. India

In India, the Livestock Importation Act, 1989, regulates the import of livestock and livestock products which may be affected by "infections" or "contagious disorders". These may be specified by the central government by notification in the gazette. Section 2(d) describes "livestock products" as including meat and meat products of all kinds, milk and milk products, embryos, ova and semen as well as any other animal product specified by the central government.

The Livestock Act empowers customs officials to carry out animal health inspections under Section 11 of the Customs Act, 1962. Section 3-A of the Livestock Act specifically states that the central government may by notification regulate, restrict or prohibit the import of "any livestock product, which may be liable to affect human or animal health".

The act empowers the state governments to make rules on the detention, inspection, disinfection or destruction of imported livestock and on the powers and duties of appointed persons. Based on this delegation of authority, several states have passed animal health legislation.

The Animal Quarantine and Certification Service within the Ministry of Agriculture is responsible for the implementation of the Livestock Act and for export certification. The Ministry of Environment and Forests is entrusted with the task of protection of wildlife health in sanctuaries and wildlife parks in accordance with the Wildlife (Protection) Act, 1972. Each state government has the power to protect the health of animals within its own boundaries and

has been empowered by the state enactments mentioned above to set up quarantine stations and testing for diseases.

In case of outbreaks or epidemics, the central government issues notifications and guidelines to control and monitor the disease, and has in several instances set up *ad hoc* monitoring committees. The Department of Animal Husbandry and Dairying has the task of monitoring and coordinating the various institutions that are engaged in animal health.

4.4. Kenya

In Kenya, the Animal Diseases Act, 2006, regulates animal health. The Director of the Veterinary Services Department (VSD) under the Ministry of Agriculture (now, under the Ministry of Livestock and Fisheries) appoints inspectors for the purpose of implementing the provisions of the act. The director is empowered under Section 5 to declare any area to be infected by a notifiable disease, and can extend, diminish or alter the borders of an infected area. The director may also declare areas free from notifiable diseases and may prohibit the movement of animals from one area to another.

Under the act, the VSD may regulate or prohibit for a period of time the importation or the exportation of animals. The minister is authorized to make animal health rules. Subsidiary legislation under the act elaborates rules on issuance of permits, tests required and certification for importation and movement of animals. It also deals with infected areas and prevention of the spread of disease. Rules have been promulgated under the act dealing specifically with foot-and-mouth disease as well as rinderpest and pig diseases. Those rules however do not directly refer to OIE benchmarks.

4.5. Uganda

The Animal Diseases Act (Chapter 38, 1964) is the main piece of legislation governing animal health. The act defines the animal species and lists the diseases to which it applies. Among other zoosanitary measures, the act provides that animal owners should notify a veterinary officer or administrative officer of any disease outbreak. Once he or she has ascertained the existence and nature of the disease, the veterinary officer must report the matter to the Commissioner of Livestock and Entomology and notify other animal owners in the area. The Cattle Traders Act (Chapter 43, 1964) subjects cattle trading to a licensing regime that is managed by veterinary officers.

4.6. Viet Nam

Legal provisions on the protection of animal health and life are found in several different laws, namely, the Fisheries Law of 2003, the Ordinance on Veterinary Controls of 2004 and the Ordinance on Livestock Breeds of 2004.

The Fisheries Law regulates activities related to aquatic animal and aquatic animal products such as breeding, processing, import and export. Activities that cause adverse effects to aquatic animal breeds are generally prohibited. The law establishes a list of aquatic animal species for which aquaculture is prohibited as well as list of chemicals that are banned in aquaculture. The law also envisages a series of measures that must be taken to protect the living environment for aquatic species as well as to preserve and develop rare aquatic species. The harvesting of rare species requires a permit from Ministry of Fisheries or provincial People's Committees, as do related activities.

Article 35 of the law states that the Ministry of Fisheries is responsible for developing and implementing: (1) standards for feed used in aquaculture; (2) zoosanitary measures in aquaculture; and (3) a list of banned chemicals in aquaculture.

The Ordinance on Veterinary Controls states that the Ministry of Agriculture and Rural Development and the Ministry of Fisheries are responsible for the prevention of animal diseases as well as the quarantine and treatment of infected animals. Article 23 of the ordinance provides that all animals and products of animal origin, when being transported out of districts, must be quarantined at departure. Articles 28 and 29 of the ordinance have regulations on quarantine for imported and exported animals and animal products. Article 26 establishes requirements for domestic transportation of animals and products of animal origin.

The law assigns the responsibility for the management of veterinary drugs and biological products, including microorganisms, to the Ministry of Agriculture and Rural Development, the Ministry of Fisheries and the People's Committees.

The Ordinance on Livestock Breeds has some provisions related to animal health and life. It generally prohibits activities that may harm safe animal breeding and regulates some zoosanitary aspects of animal breeding, multiplication and trading. Article 9 of the ordinance prohibits the export of

livestock species of genetic value. The Ministry of Agriculture and Rural Development is responsible for the management of agricultural livestock breeds while the Ministry of Fisheries is responsible for aquatic livestock breeds.

V. INVASIVE ANIMAL SPECIES

5.1. Ethiopia

The 1997 Environmental Policy of Ethiopia calls for action to restrict exotic species, including some potentially invasive plants, from biodiversity hotspot areas. Although the country does not have a stand-alone policy or specific legislation on invasive alien species (IAS), the policy provisions can serve as a basis for future action using the existing legislation on plant and animal health.

5.2. Ghana

In Ghana, the prevention of the introduction, control or eradication of alien species that threaten ecosystems, habitats or endemic species is not the subject of any specific piece of legislation. Nor has Ghana enacted legislation to implement the provisions of the CBD. However, several pieces of legislation along sectoral lines – fisheries, forestry, game and wildlife – exist on the statute books and are used to manage IAS.

5.3. India

The Biological Diversity Act, 2002, contains no provision to deal with IAS, and no mention is made of these species throughout the relevant Indian legislation. In the act, general duties are imposed upon the central government to develop strategies, plans and programmes for the conservation and promotion and sustainable use of biological diversity and to integrate these goals of conservation and sustainability into relevant sectoral, and cross-sectoral plans, programmes and policies.

5.4. Kenya

In Kenya, the Environmental Management and Coordination Act (No. 8 of 1999), establishes a legal and institutional framework for the management of the environment. Section 50 requires the National Environment Management Authority (NEMA) to prohibit and control the introduction of alien species into natural habitats. NEMA is expected to issue guidelines on this function but this is yet to be accomplished.

5.5. Uganda

Under the National Environment Act (Chapter 153, 2000), the National Environment Management Authority (NEMA) is responsible for the review and approval of environmental impact assessments. The list of activities for which the assessment is required includes the introduction of new crops and animals and the introduction of fauna and flora into ecosystems of natural conservation areas. Reportedly, neither NEMA nor the Uganda Wildlife Authority, which implements the Uganda Wildlife Act (Chapter 200, 2000), have an active programme of work on IAS.

5.6. Viet Nam

Like Ghana, Viet Nam does not have legislation systematically addressing IAS but rather manages them through sectoral instruments. Decree No. 58/2002/ND/CP on plant quarantine establishes that the import of all IAS of plant origin is prohibited. In specific cases where the import is for scientific purposes, permission from the Minister of Agriculture and Rural Development may be sought.

Decree No. 109/2003/ND/CP on the Preservation and Sustainable Development of Wetlands bans the introduction of new species which may damage ecosystems or modify the gene pool of animals. Article 6 of the 2003 Aquaculture Law states that the farming of new aquatic animal species requires a permit from the Ministry of Aquaculture.

The 2004 Ordinance on Plant Breeding prohibits the import, breeding and commercialization of IAS that may cause harm to human health, the environment or ecosystems. The 2004 Ordinance on Livestock Breeds contains similar provisions.

VI. BIOSAFETY

6.1. Ethiopia

In an attempt to implement its obligations under the Cartagena Protocol, Ethiopia developed the National Biosafety Framework, which is a set of policy, legal and operational documents that includes a draft Biosafety Proclamation. The draft proclamation establishes procedures of prior notification to and authorization by the Environmental Protection Authority

(EPA) for research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism (GMO) or products of a GMO. The proclamation initially envisaged a committee of experts from various regulatory agencies to advise the EPA but this has subsequently been abandoned.

The applicant is required to undertake risk assessment to identify potential risks of GMOs or products derived from GMOs on human and animal health and biological diversity, including socio-economic conditions, cultural norms and the environment in general. A GMO exporter is required to provide evidence of the advance informed agreement of the importing country. The EPA is required to make any application available to the public and technical experts and solicit their comments.

The draft proclamation also requires the identification, labelling and packaging of GMOs or their products subject to any authorization procedure prescribed under the draft proclamation. The EPA is tasked with establishing standards in this regard. The draft proclamation also regulates post-authorization monitoring and inspections.

Criminal sanctions are imposed on offenders who contravene mandatory obligations such as those on notification, risk assessment and compliance with standards.

6.2. Ghana

In Ghana, the draft Biosafety Bill, 2004, is designed to domesticate and implement the Cartagena Protocol. The bill is comprehensive, creating a regulatory regime with accompanying regulations to address permits, financing, monitoring and enforcement, approvals and appeals, public participation and information. Decisions on GMOs are to be based on risk assessment, and the relevant procedures are set out in the fourth schedule to the bill.

The draft bill establishes the National Biosafety Authority (NBA). The functions of the NBA are, among others, to receive, respond to and make decisions on applications filed under the bill and to carry out inspections. Taking cognizance of the fact that biosafety is a multi-institutional activity that cuts across several sectors, the draft bill relies on the expertise of

existing regulatory agencies by establishing a Technical Advisory Committee (TAC), drawing its membership from those agencies.

The functions of the TAC are to: (a) act as the national advisory committee on matters related to genetic modification of organisms and specifically to carry out risk assessments at the request of the Board of the NBA; and (b) advise the NBA, ministries and appropriate bodies on matters concerning the genetic modification of organisms. Those matters include the introduction of GMOs into the environment, the conduct of specific activities or projects concerning GMOs, the contained use of GMOs, the importation and exportation of GMOs and the preparation of regulations and guidelines. The institutional arrangement proposed by the draft bill (establishment of the NBA and reliance on the existing regulatory agencies) points to a way of resolving the conflicts, gaps and overlaps in the Ghanaian regime on *Biosecurity*.

6.3. India

In India, several pieces of legislation, either in force or in draft, address GMOs. Food regulations cover labelling and other conditions for sale. The Ministry of Health and Family Welfare has notified draft rules to amend the Prevention of Food Adulteration Rules, 1955, and establish new labelling requirements. The draft rules establish that the manufacture, import, transport, storage, distribution or sale of raw or processed food or any ingredients of food, food additives or any food product that may contain genetically modified material in the country is subject to the approval of and conditions imposed by the Genetic Engineering Approval Committee (GEAC), constituted under the Environment Protection Act, 1986. In cases of import, the importer shall submit documents supporting the approval at the time of import.

The Plant Quarantine Order, 2003, seeks to regulate the import of GMOs of plant origin for the purposes of agricultural research or experimentation. The order requires a permit to be issued by the Director of the National Bureau of Plant Genetic Resources, subject to the approval of GEAC or the Review Committee on Genetic Manipulation (RCGM) within the Department of Biotechnology under the Ministry of Science and Technology.

The order does not cover imports for commercial purposes, which are subject to separate clearances set out in rules that were issued in 1989 by the

Ministry of Environment and Forests under the Environment Protection Act (EPA), 1986. The rules and their accompanying guidelines design a multi-layered decision-making structure involving six different bodies (including GEAC and RCGM) in two different ministries (Ministry of Science and Technology and Ministry of Environment and Forests) over four different phases (pre-research, research, commercial release and post-release).

In 2006, the Ministry of Commerce and Industry notified new regulations for the import of genetically modified products under the Foreign Trade (Development and Regulation) Act, 1992. According to these regulations:

- the import of GMOs/living modified organisms (LMOs) for the purpose of (i) research and development; (ii) food; (iii) feed; (iv) processing in bulk; or (v) for release into the environment is governed by the EPA and the related rules of 1989;
- the import of any raw or processed food or feed or any ingredient of food, food additives or food products that contain genetically modified material and are being used for industrial production, environmental release or field application is permissible only with the approval of the GEAC; and,
- institutes/companies wishing to import GMOs for research and development purposes must submit proposals to the RCGM.

The new regulations further provide that all GMO consignments have to carry a declaration to that effect at the time of import, with provision for penal action under the Foreign Trade (Development and Regulation) Act, 1992, in case of non-compliance.

A liability regime is in place under the EPA. Recently, some policy documents recommended the establishment of a National Biotechnology Regulatory Authority to combine the responsibilities of the several regulatory bodies currently empowered to manage biosafety.

6.4. Kenya

In 1998, prior to Kenya's ratification of the Cartagena Protocol, non-binding regulations were developed by the National Council for Science and Technology, which was established under the Science and Technology Act (Chapter 250, 1977). To date, they are the main regulatory instruments for GMOs in Kenya and require that the release of GMOs be preceded by the

approval of the National Biosafety Committee (NBC). The relevant regulatory authorities shall undertake risk assessment before making the decision to approve or deny approval for the import. For crops, KEPHIS is the relevant authority, advising the NBC on whether or not to allow imports and on what to do after the assessment.

The draft National Biosafety Bill, 2003, is an attempt to expand the coverage of the draft regulations and give a firm legal basis to biosafety regulation in Kenya. It seeks to align the draft regulations with the Cartagena Protocol. Section 5 of the draft bill establishes the National Biosafety Authority (NBA), whose functions are, among others, to:

(a) receive, respond to and make decisions on applications under the draft bill;
(b) identify national requirements for staff development and capacity building in biosafety; and
(c) keep a record of biotechnology and biosafety activities in Kenya.

The NBA is empowered to approve or reject applications as well as to determine whether or not to carry out risk assessments. The following are activities subjected to the written approval of the NBA:

(a) contained use involving GMOs;
(b) introduction of GMOs into the environment;
(c) importation and placing of GMOs on the market; and
(d) transportation of GMOs through Kenya.

Any decision made by the NBA is subject to review upon the request of a regulatory agency or any applicant where there is new scientific information relating to biosafety of the GMOs or where there has been a change of circumstances. The regulatory agencies are in charge of the following:

(a) monitoring applicants' activities to ensure that they conform to the law;
(b) informing the NBA of any new information aimed at enhancing the continued safe use of GMOs; and
(c) inspecting and evaluating activities involving GMOs.

The Minister of Science and Technology appoints biosafety inspectors, who have comprehensive enforcement powers under the draft bill.

A challenge for *Biosecurity* in Kenya is that permits with respect to GMOs have been issued on the basis of these draft regulations and not under legislation in force, since the process of promulgating the draft Biosafety Bill has been protracted. The bill has been under discussion since 2002, while an earlier draft Biosafety Bill of 1999 failed to win approval.

6.5. Uganda

The Uganda National Council for Science and Technology (UNCST), which is a statutory body currently under the supervision of the Minister of Finance, established the National Biosafety Council (NBC) with members from the specialized departments/authorities of the various line ministries. The NBC is tasked with evaluating applications for confined field trials of LMOs and referrals made by any department receiving applications for the import of LMOs (e.g. the Department of Crop Protection, for seeds). The decisions are made within the NBC, while risk assessment is carried out by the competent departments/agencies. The functions and procedures of the NBC are not legislated.

The UNCST has proposed the National Biotechnology and Biosafety Policy, 2006, which notes the inadequacy of the legal framework with respect to regulation of modern biotechnology and related issues. Existing provisions are scattered among several pieces of sectoral legislation and are applied by a number of statutory bodies, each concerned with the fulfilment of its own mandate. Despite Uganda's ratification of the CBD in 1993 and the Cartagena Protocol in 2001, the provisions of these agreements have not been fully incorporated into domestic legislation nor is there an institution that can address the concerns of both these international instruments. Under the Uganda Biosafety Bill of 2005, the UNCST is proposed as the competent authority for biosafety, with the ministry responsible for the environment as the national focal point to provide coordinated communication on behalf of all relevant ministries, departments and agencies. The provisions of the bill are under extensive and still internal revision by the sectoral institutions participating in the NBC.

6.6. Viet Nam

Biosafety is touched upon in some laws of Viet Nam, such as the 2005 Law on Environment Protection, Decree No. 109/2003/ND-CP on the Preservation and Development of Wetlands, the 2003 Ordinance on Hygiene and Food

Safety and the 2004 Ordinance on Livestock Breeds. These instruments generally intend to apply the existing legislative framework for conventional processes and products to biotechnology, GMOs and GMO products.

Decision No. 178/1999/QD-TTg on the labelling of domestic and import-export goods requires GMOs to be labelled as such.

In 2005, Regulations on the Management of Biosafety were promulgated by Decision No. 212/2005/QD-TTg under the 2005 Law on Environment Protection. According to the regulations, the Ministry of Natural Resources and Environment is the primary authority responsible for biosafety management at the state level. Other ministries such as the Ministry of Fisheries, the Ministry of Agriculture and Rural Development and the Ministry of Health are responsible for biosafety at the ministerial level. According to the regulations, enterprises shall obtain a biosafety certification upon adoption of risk management measures. For all other aspects of biosafety (e.g. authorization to import, risk assessment), the regulations lack detailed provisions.

A draft Law on Biodiversity is under development which contains a chapter on biosafety. Since the draft law is still subject to extensive revision, its provisions have an uncertain future.

VII. INSTITUTIONAL SET-UP

7.1. Ethiopia

In general terms, the current institutional framework in the five examined areas lacks the necessary coordination to implement a *Biosecurity* approach. Food safety matters fall within the mandate of several authorities. The leading government institutions responsible for food safety include the Ministry of Health (MOH), which implements the 2002 Public Health Proclamation, the Ministry of Agriculture and Rural Development (MOARD), the Quality Standards Authority of Ethiopia (QSAE), the Ministry of Trade and Industry and the Ethiopian Manufacturing Industries Association. Since 2002, these bodies have established a Technical Committee that implements international standards on food safety systems.

A number of institutions are assigned, under the proclamations establishing them, to undertake food safety inspections in the country. Some of these

institutions are the MOH, the QSAE, the Ethiopia Health and Nutrition Research Institute and the Customs Authority. To strengthen collaboration, the Technical Committee has established the National Food Safety Council, a consultative body of members drawn from regulatory bodies, research institutes, industry, consumers and higher learning institutes involved in food safety.

Reportedly, some conflicts exist between the MOH and the QSAE. While the MOH sees the role of the QSAE as merely procedural in the development and approval of standards, the QSAE claims not only a technical mandate for standards as a regulatory body but also an implementing role with respect to inspections and enforcement.

Animal health activities are carried out by the Animal and Fisheries Resources Development and Regulatory Department (AFRDRD) within the MOARD. Within the AFRDRD, the Veterinary Services Team is responsible for maintaining the safety of food products of animal origin.

The Crop Protection Department of the MOARD is responsible for plant health matters. It has a body of inspectors that are assigned to quarantine stations and border posts. Lack of capacity is accompanied by institutional conflicts. At present, there is a conflict between the Crop Protection Department and the Institute of Biodiversity Conservation (IBC). The latter is vested by the Proclamation on Access to Genetic Resources and Community Knowledge No. 482/2006 with the responsibility of granting access to genetic resources under certain conditions. Although the subject of the proclamation is access to genetic resources and not plant health, every export of plants or plant products is interpreted as constituting access granted on the germplasm embodied in those plants or plant products, thus requiring the consent of the IBC. This often leads to a conflict between the operating procedures of the two entities. A memorandum of understanding or a legislative instrument could resolve the conflict.

As seen above, the 2006 draft Biosafety Proclamation has the Environmental Protection Authority as the implementing institution.

7.2. Ghana

In Ghana, *Biosecurity* issues are not the responsibility of one ministry, department or agency of state. Instead, several bodies have responsibility for, or are engaged in, activities in this area. These include:

(a) the Ministry of Finance;
(b) the Ministry of Food and Agriculture (MOFA);
(c) the Ministry of Health;
(d) the Ministry of Local Government, Rural Development and Environment; and
(e) the Ministry of Trade, Industry, Private Sector and Presidential Special Initiatives.

Under each ministry, different departments, agencies and institutions operate. Among them:

(a) the Food and Drugs Board (FDB) and the Ghana Standards Board (GSB) are responsible for food safety;
(b) the Directorate of Veterinary Services (DVS) is responsible for animal health;
(c) the Plant Protection and Regulatory Services Directorate (PPRSD) is responsible for plant health;
(d) the Environmental Protection Agency (EPA) is responsible for environmental matters;
(e) the Customs and Excise Preventive Services (CEPS) is responsible for ports and borders in collaboration with the other agencies;
(f) district, municipal and metropolitan assemblies collaborate with the regulatory agencies at the local level especially in monitoring and enforcement at markets; and
(g) the Cocoa Research Institute operates independently from any other agency for quality control and export purposes under the Ministry of Finance.

Some of these departments/agencies, such as the EPA and CEPS, are statutory bodies, and their functions or mandates are provided for in the enactments that established them.

Three institutions are responsible for implementing Ghana's obligations under the SPS Agreement: the PPRSD is the mandated NPPO; the FDB and the GSB are the implementing agencies for Codex and the WTO TBT Agreement, respectively; and the DVS is the OIE contact point.

As highlighted earlier, the current institutional arrangements for *Biosecurity* in Ghana are bedevilled by gaps, overlaps and conflicts in the mandates of the

various institutions involved in *Biosecurity* activities. The border phytosanitary controls are within the mandate of the PPRSD but operative coordination with CEPS is problematic and not legislated. The meat inspection function is a source of conflict/overlap between the DVS, the FDB and the public health officers of the metropolitan and district assemblies. The relationship between the FDB and the GSB is another source of conflict.

The reported tensions between the FDB and the DVS arise from the draft Meat Inspection Bill. Under Part I of the draft bill of 2004, the DVS is designated as the authority responsible for the control of meat hygiene, for all decisions relating to human health and animal health at admission of slaughter animals to the abattoir and for ante-mortem and post-mortem inspections. Because the DVS does not have sufficient staffing, it cannot perform this function efficiently and effectively without the assistance or collaboration of officials from other ministries, departments and agencies.

Another competence conflict exists between the FDB and the GSB on food safety. The 2006 draft Food and Drugs Bill attempts, among other things, to deprive the GSB inspectors of any role with respect to food quality inspection (through a definition of "food" that explicitly offsets the ambit of the Standards Act). However, the 2006 draft Standards Bill retains the food inspection role of GSB inspectors.

With regard to plant health, implementation of the legislation is the responsibility of the PPRSD. The plant health officers carry out phytosanitary inspections at all border points including ports and the international airport. Officers of CEPS, also stationed at the borders, are obligated to notify the PPRSD of any inspected plant materials in imported shipments or baggage. However, in many cases shipments of plant materials are released into the country without PPRSD having inspected the shipments or even having been informed that the shipments have arrived.

As for biosafety, the Board of the National Biosafety Authority has representation drawn from both the public and private sectors. Draft biosafety legislation provides for sectoral representation on the Technical Advisory Committee (TAC), which would help ensure the much-needed coordination and cross-sectoral management required in such a multi-institutional endeavour as *Biosecurity*. It will also help address the overlaps, conflicts and gaps in the mandates of the various regulatory agencies that will operate within the TAC.

7.3. India

The *Biosecurity* legal and institutional framework in India is elaborate. A plethora of laws dealing with *Biosecurity* have been enacted with differing objectives and public concerns in mind. Along the same lines, the different legislative instruments are implemented by different institutions. Though disparate, the existing legislative instruments still serve an essential function in specifically addressing the sectoral concerns.

The following table provides a comprehensive overview of the institutional set-up of *Biosecurity* in India.

PARENT MINISTRY	INSTITUTION	FUNCTIONS
I. FOOD SAFETY		
1. Ministry of Agriculture	• Dept. of Agriculture & Cooperation • Directorate of Marketing & Inspection	• Standardization, grading & quality control of agricultural & allied produce; • Administration of Meat Food Products Order.
2. Ministry of Health & Family Welfare	• Central Committee for Food Standards and its • Sub-Committees for Framing of Rules/Standards of Food Articles	• Development of standards on, among other topics: (a) labelling; b) pesticide residues; c) food additives & contaminants; d) microbiology & hygiene; e) packaging.
3. Ministry of Food Processing Industries		• General competence for food safety.
4. Ministry of Commerce & Industry	• Dept. of Commerce • Agriculture & Processed Food Products Export Development Authority • Cashew Export Promotion Council • Coffee Board	• Promotion of HACCP and hygiene in the respective food sectors; • Audit and certification of the HACCP system through accredited certified bodies; • EIC is the official government inspection body for certifying food products for export. Its

PARENT MINISTRY	INSTITUTION	FUNCTIONS
	• Directorate General of Foreign Trade • Export Inspection Council (EIC) • Marine Produce Export Development Agency • Spices Board • Tea Board	certificate covers good manufacturing practices and HACCP, a combination of product specifications and requirements for manufacture, transport and shipping.
5. Ministry of Civil Supplies, Consumer Affairs, Food & Public Distribution	• Dept. of Food & Public Distribution • Dept. of Consumer Affairs • Bureau of Indian Standards (BIS)	• Certification; • Licensing of manufacturers.
II. ANIMAL HEALTH		
1. Ministry of Environment & Forests		• Protection of the health of animals in wildlife sanctuaries.
2. Ministry of Agriculture	• Animal Quarantine & Certification Service • Dept. of Animal Husbandry & Dairying	• Regulation, restriction and prohibition of the import of livestock which may affect human or animal health; • Coordination with state authorities.
III. PLANT HEALTH		
1. Ministry of Agriculture	• Dept. of Agriculture & Cooperation	• Regulation of domestic and international movement of pests, insects and fungi which might threaten agriculture; • Regulation of seed quality.
2. Ministry of Environment & Forests	• Conservation & Survey Division	• Regulation of access to and conservation of the biological resources of the country.

PARENT MINISTRY	INSTITUTION	FUNCTIONS
V. BIOSAFETY		
1. Ministry of Environment & Forests	• Conservation & Survey Division	• Provision of the regulatory framework for GMOs in India.
2. Ministry of Science & Technology	• Dept. of Biotechnology	• Provision of guidelines to be followed in the regulatory framework in the country.

Food safety is under the umbrella of the Ministry of Health and Family Welfare, while the Directorate General of Health Services is the Codex Contact Point and works in collaboration with the Ministry of Food Processing Industries. As mentioned above, the official standard-setting authority is the BIS, which also has quality certification functions. Export certification is ensured by the EIC.

The Food Safety and Standards Act, 2006, establishes the Food Safety and Standards Authority of India (FSSAI), which is assisted by a central advisory committee, a scientific committee and several scientific panels. The Commissioner of Food Safety of each state enforces the standards through food safety officers. The FSSAI is mandated to lay down science-based standards for food articles, and seeks to regulate their manufacture, import, storage, distribution and sale to ensure availability of safe and wholesome food for human consumption.

The Commissioner of Food Safety of each state appoints a designated officer for a specific district whose duties include issuing or cancelling licences, prohibiting sale of food articles that violate specified standards, receiving reports and samples of food articles from food safety officers and having them analyzed.

With regard to animal health, the main authorities are the Department of Animal Husbandry and Dairying and the Animal Quarantine and Certification Service in the Ministry of Agriculture. However, wildlife management in protected areas falls under the Ministry of Environment and Forests. The need for a more effective centralized authority to monitor and coordinate the various activities of the state authorities is clear.

Plant health is under the Department of Agriculture and Cooperation in the Ministry of Agriculture. The Ministry of Environment and Forests has biodiversity-related functions that complete the *Biosecurity* framework.

Although there are a variety of institutions, there is a general appreciation of the sectoral work of the relevant institutions while the concept of a single agency is viewed with caution. A gradual upgrading of the legal framework, tailoring the mandates of existing institutions to carry out their *Biosecurity*-related tasks, may be the better approach for India.

7.4. Kenya

The institutional basis for *Biosecurity* is shared among different ministries and institutions in Kenya. These include:

(a) the Ministry of Agriculture, under which the Kenya Plant Health Inspectorate Service (KEPHIS) operates;
(b) the Ministry of Livestock and Fisheries, under which the Veterinary Services Department (VSD) operates;
(c) the Ministry of Environment, under which the National Environment Management Authority (NEMA) is established;
(d) the Ministry of Trade and Industry, which oversees the Kenya Bureau of Standards (KEBS);
(e) the Ministry of Education, Science and Technology, under which the National Council for Science and Technology (NCST) and the National Biosafety Committee (NBC) were created; and
(f) the Ministry of Health and its Central Board of Health.

In accordance with its technical mandate, each institution is responsible for Kenya's international obligations under the SPS Agreement.

To bring together the institutions responsible for different regulatory functions, a number of inter-ministerial coordinating committees have been established. The National Committee on WTO, for instance, gathers KEBS, KEPHIS and NEMA. The committee is established under the Ministry of Trade and Industry, and the ministries sitting on the committee act as focal points for sub-committees handling relevant WTO issues falling within their mandates. Another example is the Kenya Standing Committee on Imports and Exports.

The establishment of KEPHIS in 1996 has led to greater coordination of the phytosanitary aspects of *Biosecurity*. This has however been hampered by delay in amending the relevant laws to legitimize the role of KEPHIS. It is a matter of particular concern that a proposed bill to institutionalize KEPHIS, drafted with the assistance of FAO, is yet to be promulgated and continues to be debated. The central role of KEPHIS in the *Biosecurity* framework in Kenya suffers from the uncertainty of its legal basis. In fact, having been established by ministerial order and not by parliamentary-level legislation, it could, at least in theory, be dissolved or its role changed at any time by a new ministerial order.

Furthermore, there has been delay in amending the relevant sectoral laws to be implemented by KEPHIS. The Plant Protection Act (Chapter 324, 1962, as amended), the Suppression of Noxious Weeds Act (Chapter 325, 1986) and the Seeds and Plant Varieties Act (Chapter 326, 1972, as amended) all need to be amended to synchronize their provisions with the role of KEPHIS. Currently, there is room for conflict between the Ministry of Agriculture officers and KEPHIS officers in the performance of their duties. However, a positive trend is the involvement of officers from line regulatory institutions in related regulatory bodies such as the involvement of KEPHIS, the VSD and KEBS in NEMA and the NBC. This has assisted in coordinating various *Biosecurity* functions.

With regard to food safety, the Food, Drugs and Chemical Substances Act (Chapter 254, 1970) is implemented by the Ministry of Agriculture, which is also responsible for veterinary services. Under the Meat Control Act (Chapter 356, 1973), some of the inspectors' activities require consultation between the Ministry of Agriculture and the Ministry of Health. However, the limited human resources available in the ministries make those consultations rare and formal. Moreover, because the Meat Control Act deals with meat for export, the ministry responsible for trade and industry is also a relevant player in the implementation of the act, especially for export certification.

Recently, the need to streamline the food safety aspects of *Biosecurity* has been recognized and a Food Safety Committee set up, with the Agriculture Secretary as chair. The committee, launched on 4 May 2007, is the focal point for all food safety issues and draws its membership from the Ministries of Agriculture, Health and Trade, the Kenya Medical Research Institute, KEBS and the Kenya Agriculture Research Institute.

Food standards are established by KEBS, which was established under the Standards Act (Chapter 496, 1974). KEBS works closely with the main public bodies in the development and implementation of health standards on animals and animal products, plants and plant products and food safety. The main public bodies are KEPHIS, the VSD and the Ministry of Health. KEBS is the contact point for Codex and the International Organization for Standardization (ISO).

As for plant health, the regulatory agents under the Seeds and Plant Varieties Act include the Minister of Agriculture, seed analysts and KEPHIS. Ordinarily, KEPHIS seed inspectors perform tasks under the Plant Protection Act and the Suppression of Noxious Weeds Act. Under the latter act, local authorities are empowered to make by-laws regarding the eradication of any noxious weed from land within their areas, appointing inspectors and compelling owners or occupiers of land to eradicate any such weed from their land.

With regard to animal health, the Animal Diseases Act (Chapter 364, 1972, as amended) vests the VSD with the power to appoint inspectors. Reportedly, the mandate of KEPHIS includes the enforcement of standards for good husbandry and the control of animal diseases, although these powers do not appear in any legislative instrument.

In general, inspections are a problem arising mainly from scarcity of resources, which impedes the effective discharge of duties entrusted to the officers. For instance, while KEPHIS is required to provide border control with respect to plant materials (a function previously performed by airport staff of the Ministry of Agriculture), there are not enough inspectors to cover all entry points. Moreover, there are no inspectors of the VSD to inspect meat and meat products at the points of entry. Proposals to establish a single agency to encompass both KEPHIS and VSD have been made over the years but have not been implemented.

Environmental legislation is the most advanced in terms of institutional provisions. To ensure compliance, the Environmental Management and Coordination Act (No. 8 of 1999) establishes an elaborate institutional framework. Under the act, the National Environment Council is responsible for formulating policy on matters relating to environmental management in Kenya. It sets national goals and objectives and determines policies and priorities for the protection of the environment. It also promotes

cooperation among public departments, local authorities, the private sector, non-governmental organizations and other organizations engaged in environmental protection programmes. NEMA is the principal government institution responsible for the implementation of all policies relating to the environment. It is also responsible for dealing with environmental impact assessments, including from LMOs and IAS.

Similar to the situation in Ghana, the most detailed institutional provisions in Kenyan legislation appear in the draft Biosafety Regulations of 1998 and the draft National Biosafety Bill of 2003. The draft bill establishes the National Biosafety Authority, managed by a board drawing from the main agencies dealing with biosafety as well as other scientific experts and a consumer representative.

7.5. Uganda

As in the other countries studied, *Biosecurity* issues in Uganda are the responsibility of different ministries, state agencies or departments. The pieces of legislation which address food safety, plant and animal health are sectoral in nature, and different departments or regulatory agencies are responsible for their implementation.

The Ministry of Health (MOH) is the implementing authority of the Food and Drugs Act (FDA) (Chapter 278, 1964), but it is commonly recognized that its human and financial resources are extremely limited and food safety is not prioritized. Funding is sporadic, meaning that the MOH generally has a reactive approach to food safety issues. In practice, the MOH has been working with other agencies, on a case-by-case basis, in emergency situations (e.g. the European Union ban on fish from Uganda where MOH worked with the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) and the Uganda National Bureau of Standards (UNBS) to resolve the issues). A very advanced food chain approach is only implemented for fisheries products thanks to cooperation between the Fisheries Department and UNBS.

The Food Hygiene Advisory Committee, established under the FDA, and the minister, in conjunction with the local governments and authorized persons, are responsible for the prevention of the adulteration of food. UNBS, as the national standards body, sets and enforces standards, in some instances adopting standards from other jurisdictions or from international agencies for application in Uganda. Inspection of food imports is mostly done by UNBS agents at entry points.

With regard to animal health, the veterinary services division of the MAAIF is the main authority and the OIE contact point, while the fisheries arm of MAAIF handles aquatic life issues.

The Department of Crop Protection is responsible for phytosanitary and plant protection matters and will be designated the national plant protection organization once the Plant Protection Bill is enacted. The department also acts as the SPS Enquiry Point.

The National Environment Management Authority (NEMA) has a coordinating, monitoring and supervisory role and is the national focal point for the CBD and related instruments. The Uganda Wildlife Authority is the principal body responsible for wildlife management in Uganda, while the National Forestry Authority has similar responsibility with respect to forests. The Customs Department of the Uganda Revenue Authority, established in 1991, plays a crucial role in ensuring the legitimacy of imports and exports of regulated materials.

The Uganda National Council for Science and Technology (UNCST) is responsible for setting policy in all fields of science and technology and acts as the national focal point for the Cartagena Protocol. It is the competent authority for regulation and access to genetic resources, and is proposed as the competent authority to supervise and regulate the implementation of the draft policy on biotechnology and biosafety. Furthermore, it is proposed as the competent authority for biosafety under the draft Biosafety Bill of 2005, along with the ministry responsible for the environment. Notably, through its National Biosafety Council, UNCST is already a forum where sectoral authorities converge to deal with cross-cutting issues such as biosafety. This role suggests that UNCST may be the appropriate forum to start discussions on the implementation of a *Biosecurity* approach.

Each of the agencies mentioned above has inspectors in charge of ensuring compliance with the provisions of the applicable sectoral law. Certain laws also provide for delegation, enabling collaboration between departments and agencies. In appointing environment inspectors, NEMA is authorized to gazette persons employed as inspectors in other departments. NEMA itself, however, lacks the human resources to participate in activities of other ministries at the technical level.

Similarly, the phytosanitary service cooperates with the Customs Department in undertaking phytosanitary inspection at the various entry and exit points. Inspection of meat is undertaken by veterinary surgeons, medical officers or health inspectors authorized by the relevant minister or the local authority. However, most inspectors are only trained in their particular field of expertise and do not have sufficient capacity to effectively undertake inspection by delegation.

Finally it is worth noting that, although UNBS is the national standards body, other government units have the authority in law to set and enforce standards. For example, NEMA sets environmental standards, while the Directorate of Water Development sets water and water-related standards under the Water Act (Chapter 152, 1995).

7.6. Viet Nam

The institutional set-up of Viet Nam is characterized by a somewhat rigid division of responsibilities among the line ministries for each of the *Biosecurity* areas. The Ministry of Science and Technology is responsible for promulgating standards in all areas of *Biosecurity*, and is also the Codex Contact Point. The Ministry of Health is responsible for formulating and promulgating strategies and policies on food hygiene and safety as well as taking an oversight role in the prevention of food poisoning. It is in charge of the development of regulations on food hygiene and safety and their enforcement. In emergencies, it coordinates with the People's Committees at all levels as well as the concerned ministries to establish control measures.

The Ministry of Science and Technology issued Decision No. 25/2004/QD-BKHCN promulgating the statute of the Viet Nam Codex Commission. Pursuant to this decision, the Vietnam Food Standardization Committee acts as the Viet Nam Codex Commission, chaired by the Ministry of Science and Technology. The Directorate for Standards and Quality under the Ministry of Science and Technology is part of the Viet Nam Codex Commission and acts as the Codex Contact Point.

The Ministry of Agriculture and Rural Development (MOARD) oversees the production processes of food and the control of hygiene of imported food of animal origin. The Ministry of Fisheries (MOF) is responsible for aquatic products for domestic consumption and aquatic food products which are exported or temporarily imported for re-export. MOF, in coordination with other relevant ministries, is responsible for inspecting enterprises and

monitoring compliance with regulations on the quality and safety of imported and exported fish products.

MOARD establishes and implements quarantine measures for animals and plants, while MOF is responsible for sanitary measures on aquatic animals. In this regard, a resolution of the National Assembly adopted in August 2007 provides for the merger of the two ministries.

With respect to IAS and biosafety, the Viet Nam Environment Protection Agency takes the lead under the Ministry of Natural Resources and Environment, which hosts the focal point for the CBD and the Cartagena Protocol.

Viet Nam also has an inter-ministerial working group that coordinates SPS activities. Decision No. 99/2005/QD-TTg of the Prime Minister established the Viet Nam Sanitary and Phytosanitary Notification Authority and Enquiry Point, which serves as enquiry point and notification authority under the SPS Agreement.

VIII. CONCLUSION

This chapter has presented only a snapshot of the main areas of *Biosecurity*, to show the analysis as it has been carried out in the six pilot countries. The comprehensive reviews of the *Biosecurity* frameworks in each of the six countries are presented in Chapters 5–10.

The gap analyses presented here clearly demonstrate the methodology required to assess national frameworks for *Biosecurity*. The review requires an analysis of the legislation covering the main sectors of *Biosecurity* – food safety, plant health, animal health, invasive animal species and biosafety – assessing whether the legislation follows international standards and whether there are overlaps and gaps. Next the investigation must turn to the institutional set-up, examining which institutions are empowered to carry out *Biosecurity* functions and where there are any weaknesses, such as duplications of responsibilities or unclear mandates.

The analysis developed here is refined in the next chapter, which sets out in detail the methodology and its constituent steps. Application of this methodology should lead to a more comprehensive understanding of the national legal and institutional frameworks for *Biosecurity* and identification of any corrective action needed.

4

LEGAL METHODOLOGY

Contents

I. OVERVIEW

As can be seen from the review of the pilot case studies, a *Biosecurity* legal assessment consists of the following two steps:

1. an analysis of the legal framework covering the subject areas of *Biosecurity*;
2. a review of the mandates and functions of the various institutions responsible for *Biosecurity* controls.

Based on that analysis, policymakers will then need to consider the feasibility of taking three additional steps:

3. creating new agencies or establishing coordination mechanisms to implement a government-wide *Biosecurity* approach;
4. elaborating a legislative strategy to pursue the *Biosecurity* approach; and
5. implementing the strategy through new or amended legislation.

The next sections expand on the methodology to be applied in each of the five steps.

II. ANALYSE SECTORAL LAWS

The first step in the *Biosecurity* methodology will be an analysis of the existing legislative framework for *Biosecurity*. The logical division of subject areas for review is the following:

(a) food safety;
(b) plant health;
(c) animal health;
(d) invasive alien species; and
(e) biosafety.

Although every effort should be made to identify the main purpose of each statute so as to fit it into one of the subject areas above, the distinction between certain areas may be blurred, such as between animal health and food safety in cases of legislation covering animal products such as meat. The same can occur with plant health legislation and rules governing the export of fresh agricultural produce. Other laws, such as laws establishing a

national standard-setting authority (e.g. the Quality Standards Authority of Ethiopia, the Bureau of Indian Standards), may also need to be considered carefully as they may not fall neatly into one category. In fact, standard-setting is a typically cross-cutting mandate that intersects with the responsibilities of *Biosecurity* institutions, most frequently food safety, animal health and plant health authorities.

In each of the sectoral areas of *Biosecurity*, government officials interested in carrying out a review of the national legal framework should first collect and then analyse the various pieces of relevant legislation. The review of existing legislation should cover both parliamentary-level and subsidiary legislation. Typically, for food safety, animal health and plant health, there is one main parliamentary-level legislative instrument setting forth the general discipline (for instance, the Food and Drugs Law in Ghana or the Plant Protection Act in Uganda). This legislation often contains very brief provisions assigning the mandate for certain activities (for instance, quarantine inspections at border posts or certifications for export) to an authority.

The basic law is (or should be) accompanied by subsidiary legislation which specifies exactly how the assigned mandate is to be executed and provides some operational details (such as time frames for inspections, duties to notify competent authorities of arrival of consignments, model forms and certificates). It is necessary to look at those details, if provided for in subsidiary instruments such as ministerial regulations and orders, in order to carry out a comprehensive review of the strengths and pitfalls of the legislation in that sector. For instance, if a law has provisions on import requirements to be published in regulations but those regulations are either not present or outdated, the law may have little or no effect.

With regard to IAS, it is uncommon to find a single piece of legislation covering the subject. IAS can have different origins (plant or animal) and can be categorized in several ways. For instance, some IAS may qualify as plant pests and be regulated under phytosanitary legislation while others may not be regulated at all.

In biosafety, it is frequent to find biosafety laws, sometimes still in draft form, that are patterned after the Cartagena Protocol (see those examined in Chapters 8 (Kenya) and 9 (Uganda)). The regulation of living modified organisms may also be scattered in several pieces of legislation (see Chapter 10 (Viet Nam)).

Once the legislation is collected and classified according to its subject matter and status (parliamentary-level or subsidiary), policy-makers will have to evaluate the legislation in each of the *Biosecurity* areas. This evaluation has two parts. The first evaluates whether the legislation covers all the relevant sub-topics in that sector, as there are certain legislative provisions that must be present in order to build a comprehensive regulatory framework for that *Biosecurity* sector. The second looks at whether the legislation meets international obligations.

The next section provides a brief overview of the main sub-topics which should be addressed in each of the *Biosecurity* sectors.

2.1. Substance of sectoral laws

With regard to food legislation, the law should determine what kinds of food it regulates (e.g. foods of animal origin, street foods) and what harmful substances in food (e.g. food additives, pesticides, veterinary drug residues) it covers. The legislation should cover food hygiene by setting out the basic principles and rules to be followed by owners and operators of food establishments during the preparation, processing, manufacturing, handling, packaging, transportation, storage and distribution of food in order to guarantee a safe product fit for human consumption.[1] The food legislation should contain substantive provisions in these areas, stating for instance that food businesses shall follow hygiene rules and food manufacturers shall establish trace-back procedures.[2] Food legislation should also contain rules applicable to imported and exported food (such as the requirement to seek a permit from the competent authority).

Plant health legislation should be designed so as to guarantee that the government can create or function as an effective administrative and technical structure (the National Plant Protection Organization (NPPO)) for the implementation and enforcement of phytosanitary measures. The legislation should allow the NPPO to take action to control the introduction and spread of certain pests which will be listed in the legislation in accordance with risk analysis. Provisions for the establishment of quarantine areas are essential in order to contain outbreaks of quarantine pests.

---

[1] J. Vapnek and M. Spreij, *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, FAO Legislative Study No. 87, 2005, p. 86.
[2] *Id.* p. 173.

Phytosanitary legislation should also address the many aspects of the import and export of plants and plant products. For imports, the phytosanitary legislation should provide for the establishment of import requirements and phytosanitary measures based on scientific justification, including measures to be taken in emergency situations. With regard to exports, the legislation should provide for phytosanitary certification by the NPPO. Furthermore, the legislation should contain provisions allowing the NPPO to take action for detection, survey, containment and eradication of plant pests within the territory, and should provide for the establishment and maintenance of pest free areas.[3]

Animal health legislation should cover terrestrial as well as aquatic animals, and should set out a list of diseases and national pathogens based on risk analysis. The law or laws should charge the government with preventing and controlling these diseases and pathogens, through surveillance, monitoring, official control and stamping-out programmes. Other activities to be regulated include emergency action in case of disease and pathogen outbreaks as well as animal identification, traceability and movement. Animal health legislation should also permit the government authorities to establish buffer zones, free zones, zones of low disease prevalence and surveillance zones for zoosanitary purposes.

The legislation should also regulate the import of animals and animal products. The issuance of international veterinary certificates for the export of animals and animal products is another key regulatory area. In response to modern developments on animal welfare, the establishment of standards during the life of an animal as well as during its slaughter and destruction can be addressed in the legislation. Tangential but also important issues which may be regulated in separate laws or regulations are provisions on the import and export of animal feed as well as the manufacture, import, export, use, quality, suitability, packaging, labelling, transport, storage, sale and advertising of veterinary drugs.

The regulation of IAS may be found in several pieces of legislation, such as legislation on plant protection, biodiversity or nature conservation. The legislation will have to address prevention and containment of any introduction or invasion of IAS, covering risk management for those species.

---

[3] J. Vapnek and D. Manzella, *Guidelines for the Revision of Phytosanitary Legislation*, FAO Legal Paper Online No. 63, Jan. 2007, p. 11, available at www.fao.org/legal

As IAS is a cross-cutting subject, it will be important to ensure that the various pieces of legislation do not cause any overlap or conflict in oversight activities, for instance between plant health and biodiversity authorities.

With regard to biosafety, the legal framework should first define its scope (what activities and organisms are covered) and establish an authorization/ licence/permit system for those activities and organisms. The legislation should set out the necessary specifications for the system, such as the information to be provided by the applicants, requirements for applications and time limits for decisions.[4] The legislation may also set out simplified procedures for low-risk categories of living modified organisms (LMOs) as well as requirements for public consultation on permit applications. The legislation will also need to address risk assessment procedures and criteria, risk management conditions which may accompany the permit and post-approval monitoring and review. It should also address cases of unintentional releases of LMOs and emergency measures applicable in such circumstances.

2.2. Conformity with international obligations

The second objective of the legal assessment is to evaluate the conformity of the national legal framework with international dictates. In this exercise, the task will be to assess if and to what extent national legislation enables full compliance with the country's international obligations. This does not mean that international obligations need to be specifically spelled out in national laws. Rather, the task for national authorities is to develop national laws in light of and in harmony with the international instruments which are applicable at national level. Ultimately, what matters is how national measures are executed in practice and, in the case of the sanitary and phytosanitary measures, how transparently they are established and applied.[5] It is against this criterion and not through the literal transposition of clauses of international agreements into national laws that the domestic legal framework should be evaluated.

A few examples from the pilot case studies show provisions of national legislation that are clearly not in line with international standards. In the area of food safety, Schedule I of Ghana's Food and Drugs Law, 1992, makes

---

[4] R. Mackenzie, F. Burhenne-Guilmin, A. La Viña and J. Werksman, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN, 2003, p. 21.
[5] J. Vapnek and D. Manzella, *supra* note 3, p. 6.

reference to the publications of certain international bodies but the list does not include those of the Codex Alimentarius Commission, which is the internationally recognized source of international food standards under the World Trade Organization Agreement on the Application of Sanitary and Sanitary Measures (SPS Agreement). In the area of plant health, Ethiopia's Council of Ministers Regulation No. 4/1995 does not provide for the establishment of any pest list based on risk analysis, which is the cornerstone of the regulatory set-up of the International Plant Protection Convention (IPPC). With regard to animal health, the legislation of Uganda does not provide for any notification of diseases to the *Office international des epizooties* (OIE) based on which the OIE could circulate relevant information to the international community.

To carry out a detailed review of the sectoral areas and to evaluate their conformity with international standards, FAO has developed several documents and guidelines which can be of assistance:

- *Perspectives and Guidelines on Food Legislation*;[6]
- *Guidelines for the Revision of National Plant Protection Legislation*;[7]
- *Institutional and Legal Measures to Combat African Swine Fever*;[8]
- *Decision-Support Toolbox for Biosafety Implementation.*[9]

Other more general assessment tools contain useful guidance, including:

- *Phytosanitary Capacity Evaluation Tool*;[10]
- *Assuring Food Safety and Quality: Strengthening National Food Control Systems.*[11]

The websites of the main international organizations and instruments governing *Biosecurity* sectors will also have information and guidance for countries engaged in a detailed review of their national legislative framework for *Biosecurity.*

---

[6] J. Vapnek and M. Spreij, *supra* note 1.
[7] J. Vapnek and D. Manzella, *supra* note 3.
[8] J. Vapnek, *Institutional and Legal Measures to Combat African Swine Fever*, FAO Legal Paper Online No. 3, May 1999, available at www.fao.org/legal.
[9] *Decision Support Toolbox for Biosafety Implementation*, ISNAR/FAO, 2003, available at www.isnar.cgiar.org.
[10] Phytosanitary Capacity Evaluation Tool, FAO, 2005, available at www.ippc.int.
[11] *Assuring Food Safety and Quality: Guidelines for Strengthening Food Control Systems*, FAO/WHO, 2003. At the time of writing, FAO was also finalizing a *Biosecurity* Capacity Assessment Tool that is part of a *Biosecurity* Toolkit.

III. REVIEW INSTITUTIONAL MANDATES

Reviewing the legislation in each *Biosecurity* sector is only the first step in the assessment of the *Biosecurity* framework. Governments must look at the overall picture of controls on food safety, plant health and animal health to assess whether there is or can be created an efficient, integrated system to manage biological risks. The pilot case studies clearly bear out that the challenge is to foster coordination among regulatory bodies so as to eliminate gaps, overlaps and conflicts.

In each of the five sectoral areas of *Biosecurity*, it will be necessary to look closely at the institutions implementing the sectoral laws. In assessing the institutional mandates, there are four main issues to consider:

(1) what types of institutions carry out *Biosecurity* controls;
(2) whether the responsibilities of the different institutions are legislated and, if so, at what level (parliamentary-level or subsidiary legislation);[12]
(3) whether there are gaps or overlaps in the exercise of the functions; and
(4) whether institutions correct any overlaps or gaps in the legislation through *de facto* arrangements.

On the first issue, the Ghana study shows that, whereas the Food and Drugs Law establishes the Food and Drugs Board as a statutory body, the Prevention and Control of Pests and Diseases of Plants Act assigns the mandate for plant health control to the Ministry of Food and Agriculture in general, under which the Plant Protection and Regulatory Services Department (PPRSD) operates as an internal department without any specific legislated powers (see Chapter 6). This has implications not only for the different capabilities of the two institutions in terms of material and human resources, but also for the relative deference that other national authorities (such as customs) and the private sector (such as importers and exporters) accord the two bodies.

[12] The legal force of the legal instrument under which a body is established is important first because certain powers can only be provided for in primary legislation as they require parliamentary approval. Second, in principle, legal instruments can only be repealed by the same or higher-level instruments, hence a ministerial decree can easily be replaced by a new ministerial decree, for instance where a new minister is appointed, while a parliamentary-level law can only be amended by parliament.

Similarly, the Veterinary Services Department in Kenya remains a department of the government while the Kenya Plant Health Inspectorate Service (KEPHIS) is a state corporation with more autonomy and flexibility (see Chapter 8). In India, food safety is managed by a statutory body (the Food Safety and Standards Authority), while the main implementing authorities for plant and animal health (respectively, the Department of Agriculture and the Animal Quarantine and Certification Service) are ministerial departments (see Chapter 7). These may be deliberate choices by government to emphasize certain sectors over others, but to foster consistency across *Biosecurity* subject areas may require a closer look at such institutional anomalies.

On the second issue (level of legislation), the Kenya study highlights that some of the responsibilities that KEPHIS exercises at present do not have a basis in law while others are set out only in subsidiary instruments (see Chapter 8). The chapter notes that a parliamentary act establishing KEPHIS as a statutory body and defining its overall mandate is still being debated.

On the third issue (gaps and overlaps), the question is whether certain regulatory functions fail to be implemented by any institution or, conversely, whether there are areas where two or more institutions overlap. An example of the first case is Uganda, where the Food and Drugs Act tasks the Ministry of Health with food hygiene standard-setting and controls, but it is presently not implementing these responsibilities (see Chapter 9). For the second type of problem, the meat inspection dispute between Ghana's Food and Drugs Board and the Directorate of Veterinary Services of the Ministry of Food and Agriculture is exacerbated by conflicting legislative provisions.

In carrying out the assessment of the various *Biosecurity*-related institutions, it may be useful to look at the following *Biosecurity* functions:

(a) diagnostic services;
(b) quarantine services;
(c) surveillance and monitoring;
(d) emergency action;
(e) inspection services;
(f) scientific research and advice;
(g) enforcement.

The task will be to determine whether the institutions are empowered by the law to carry out all of these functions in each *Biosecurity* sector. For instance, plant health legislation may impose a duty on customs officials to notify the arrival of plants or plant products to plant health authorities, and they do so routinely, but no such duty is set forth in animal health or food safety legislation and no such notification takes place. This is a clear gap in *Biosecurity* controls as a whole. The function-based analysis will also assist in devising legislative solutions to improve the integration of *Biosecurity* controls among the sectoral authorities.

The final step is to look beyond how the legislation creates or empowers the different institutions to any other arrangements in place. In many cases there may be written agreements (such as memoranda of understanding) or even informal arrangements between two or more institutions to correct specific gaps or overlaps in mandate or functions. For instance, although neither Ghana's Prevention and Control of Pests and Diseases of Plants Act nor any subsidiary legislation provides for consultation with environmental authorities, the PPRSD has taken initiative and regularly involves academic environmental experts in the pest risk assessment of certain plants and plant products (see Chapter 6). A similar example is the Department of Crop Protection in Uganda, which regularly involves environmental experts appointed with the concurrence of the National Environment Management Authority for its pest risk analysis in the absence of any internal memorandum formalizing the arrangement (see Chapter 9). Similarly, the National Biosafety Council of Uganda receives and acts upon applications for the import of LMOs of plant or animal origin referred to it by the Department of Crop Protection and the Veterinary Services Department, without specific authorization under any legal text.

IV. CONSIDER CREATION OF A NEW AGENCY/ COORDINATION MECHANISM

Having identified the weaknesses and gaps in the legislative and institutional frameworks, governments will next need to consider possible solutions in order to integrate *Biosecurity* functions and rationalize the *Biosecurity* framework. One option is to create a new body at a supra-ministerial level, for example under the Presidency or the Council of Ministers, to implement a *Biosecurity* approach. Another option is to use existing legal and institutional frameworks while establishing a coordinating mechanism to exercise an oversight role.

The creation of a new body along the lines just mentioned has the merit of according the subject the attention that it deserves at the highest level of government. This should enhance its effectiveness and prevent "inter-ministerial jealousies", since *Biosecurity* would not be under the control of just one ministry. The unified agency would have responsibility for end-to-end *Biosecurity,* overseeing pre-border and border activities, incursions and eradications and pest and disease management. The agency would also coordinate with any authority responsible for biodiversity protection in relation to IAS and to biosafety.

The prominent role of the lead agency, of course, does not mean that it would work alone. From time to time, it may need to delegate tasks to other departments or units where there is specialized knowledge. It should also develop systems to protect wider interests in *Biosecurity* and improve connections among the agricultural, environmental and health sectors.

The creation of a new agency has the advantage of mitigating the problem that in some countries, not all *Biosecurity* sectors are at the same stage of development. For instance, in some sectors there may be critical gaps in baseline knowledge while others may lack diagnostic and treatment tools and equipment. Where centralization into a new agency occurs, capabilities, in terms of material resources and intellectual capital, could be maximized through resource pooling (e.g. at the border posts) instead of having isolated units with minimal staffing and equipment addressing narrow sectoral concerns. Although the idea of creating a new institution may be daunting, it can actually be well suited to developing countries and small states with resource constraints.

Despite the potential advantages, the creation of a new institution to address *Biosecurity* may still not be possible in some national contexts. There may be political resistance, for instance due to the historical separation of certain sanitary and phytosanitary functions or due to particularly powerful ministers resistant to loss of influence. And despite the potential advantages of resource pooling, there is no doubt that creation of a new agency entails heavy financial, logistic and manpower requirements which many countries can ill afford. Thus, another option is establish a coordination mechanism to oversee existing line agencies. Such a mechanism – a board, council or committee – would be the repository of information as well as the mechanism for disseminating information to all relevant actors. The board or council would be given certain powers to oversee the entire framework and

would have the authority to require certain actions by line agencies to ensure effective *Biosecurity* controls.

This solution would of course require line agencies to cede some control to the overall coordinating mechanism, and the regulatory framework may have to be modified to guarantee the much-needed coordination inherent in such a multi-institutional activity as *Biosecurity*. The biosafety area is a good example of successful cooperation in three of the countries examined in this study (namely, Ghana, Kenya and Uganda): each used existing institutions while creating an oversight body for biosafety issues, drawing on the implicated ministries and agencies on the national scene.

As for the actual implementation of *Biosecurity* controls, efficiency in the application of such measures depends on standardized risk assessment and management procedures, which, in turn, rely on science. Identifying the right advice is the key to making good decisions. Scientific input from the best-positioned experts, no matter which institution they serve, must be relied upon, bolstered by public and stakeholder input. Laws can assist in the establishment of science-based criteria for sanitary, phytosanitary and zoosanitary measures as well as procedures to ensure that those criteria are applied.

V. DEVISE LEGISLATIVE STRATEGY

Having identified the weaknesses and gaps in the existing legislative and institutional frameworks and having decided upon the institutional set-up to be pursued, the next step is to identify a legislative strategy to implement the necessary changes. Elaborating the strategy will require extensive consultations to verify the feasibility of legislative change. It is important to understand the context in which legislative change will take place, to have a realistic understanding of how open to change decision-makers are in a particular setting.

Several considerations will affect the design of a legal strategy for the particular country. The first is the legal system. Each country has its own history, politics, traditions, legislation, institutions and resources. Any new legislation must be conceived with these factors in view, in order to ensure that the proposed legislation reflects national needs and national circumstances.

Apart from the formal legal system, the role of law in society varies enormously from country to country. In some countries, adopted legislation may be generally effective, while in others it may have little impact, mainly because of lack of resources for implementation and enforcement. The absence of necessary political will to support certain recommendations may also be related to the manner in which the law is perceived by public authorities. Much-needed collaboration among authorities may fall victim to institutional jealousies, turf-defending behaviour and passive resistance of government officials or stakeholder groups.[13] These constituents may feel their interests can be better protected through new sectoral legislation that is promoted autonomously and not as part of a collective and comprehensive *Biosecurity* approach.

Another important consideration in the design of nationally tailored legislative strategies is the government's policies and priorities. In every country, a variety of policies, strategies and priorities of national, regional or international provenance affect the development of national legal frameworks. In some situations, governments are obligated to incorporate certain policies in their national legislation, while in others they may do so voluntarily. Hence, undertaking an assessment of national *Biosecurity* legislation entails understanding the level of commitment that the government has with respect to *Biosecurity* in the context of other relevant policies.

As happens with laws, policies have varying degrees of importance in different countries and this will be an important consideration in elaborating a legislative strategy. If a decentralization policy or decentralization law is extremely influential, this will affect the design of the legislation in fundamental ways. Thus, in any new legislative framework for *Biosecurity* control, local authorities might be given significant regulatory powers, while the central authority would retain those of a more limited scope or be in charge of setting the guiding principles and policies.

Rarely, governments may have explicit policies on *Biosecurity* which will naturally guide the legislative strategy to implement a *Biosecurity* approach. Other policies, although not expressly referring to *Biosecurity*, may have an impact on the legislative strategy. These would include the overall agricultural policy as well as policies regarding the environment, land use and trade. Good governance policies, such as access to information, participation

[13] J. Vapnek and D. Manzella, *supra* note 3, p. 10.

in decision-making, transparency and accountability of regulatory authorities will also affect the legislative design, as will policies on government structure and reform. For instance, if government policy does not encourage the establishment of new institutions, the legislative strategy will focus on establishing coordinating mechanisms to oversee existing institutions working in *Biosecurity* rather than proposing a new *Biosecurity* agency.

A *Biosecurity* approach puts traditionally sectoral institutions into a broader scheme of efficient management of risks to food and agriculture. It calls for inter-institutional cooperation and integration of functions, requiring strong commitment by the entire government and not only by individual ministries or agencies. Ideally, a *Biosecurity* approach will be implemented through comprehensive legislation, formulated in a participatory fashion, making it strong enough to change existing institutions and institutional behaviours.

VI. IMPLEMENT THE STRATEGY THROUGH NEW OR AMENDED LEGISLATION

The final step will be to identify the legislation that will be needed to implement the changes agreed upon by government policy- and law-makers, and then to prepare that legislation. Legislation will be needed toward two ends: first, to make substantive changes in the *Biosecurity* sectors, and second to change institutions or create new ones. For the first task, an example is where the plant protection law is outdated, an updated text will be needed to permit the government to carry out *Biosecurity* effectively with respect to phytosanitary issues. Or as another example, the absence of a biosafety law will call for the preparation of a new draft. If the assessment of sectoral legislation has revealed substantive deficiencies in several regulatory areas, amendments to the different pieces of legislation or the preparation of new legislation in those areas can be folded into a comprehensive legislative package and tabled before the legislative bodies.

Legislative change to empower new institutions or modify the functions of existing ones is the second area for action. As noted earlier, this may require the creation of a full-fledged *Biosecurity* agency or the establishment of a coordinating mechanism – although in some cases, governments may opt for some combination of the two, possibly to foster increased coordination as an intermediate step on the way to a fully autonomous *Biosecurity* agency. And although legislation may very well be needed, in some national contexts the development of memoranda of understanding between ministerial entities or

autonomous agencies may be sufficient and may be a quick and practical solution to institutional overlaps and gaps. Though without any legally binding force, these memoranda may establish a good working relationship between institutions and pave the way for coordinated action.

VII. CONCLUSION

The step-by-step methodology can be summarized as follows:

A. Analyse the legal framework covering the subject areas of *Biosecurity*
A.1 Collect and classify the legislation according to its level (parliamentary or subsidiary) and subject area (food safety, animal health, plant health, IAS, biosafety)
A.2 Evaluate the legislation
A.2.1 Find gaps in the substance of the sectoral laws
A.2.2 Determine compliance with international standards

B. Review the mandates and functions of the various institutions responsible for *Biosecurity* controls
B.1 Identify the legal status of the institutions
B.2 Examine the legislated mandate of the institutions and compare it with the effective mandate
B.3 Identify gaps and overlaps among the activities of the institutions
B.4 Assess *de facto* arrangements to correct the gaps and overlaps of point B.3

C. Consider the feasibility of creating a new agency or establishing a coordination mechanism to implement a government-wide *Biosecurity* approach

D. Elaborate a legislative strategy to pursue a *Biosecurity* approach
D.1 Consider the local context
D.2 Identify the legislative changes needed

E. Implement the strategy through new or amended legislation
E.1 Elaborate legislation on substantive *Biosecurity* sectors
E.2 Prepare legislation to implement institutional change with regard to point C

The methodology will naturally result in different recommendations for different countries. *Biosecurity* does not carry a one-size-fits-all solution; rather, it can be achieved in a variety of ways. The main objective is to provide countries with:

- a detailed understanding of the strengths and weaknesses of the legal and institutional framework for *Biosecurity*;
- plans for the implementation of necessary legislative and institutional change;
- an enabling framework of laws and regulations for the implementation of core Biosecurity functions in line with international legal requirements; and
- an organization or system with the mandate to perform controls and manage biological risks in food and agriculture.

The key is to choose solutions which are suitable for the time, the place, the policy context and the legal system of the country.

REFERENCES

FAO. 2007. *Guidelines for the Revision of Phytosanitary Legislation*, by**.** Vapnek, J. & Manzella, D. FAO Legal Paper Online No. 63, January 2007, available at www.fao.org/legal.

FAO. 2005a. *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, by Vapnek, J. & Spreij, M., FAO Legislative Study No. 87, Rome.

FAO. 2005b. *Phytosanitary Capacity Evaluation Tool*, available at www.ippc.int.

FAO. 2004. *The Legal Regime for the Control of Invasive Alien Species (IAS) in Ghana*, by Sarpong, G., Legal Paper Online No. 40, December 2004, available at www.fao.org/legal.

FAO. 2002. *Law and Sustainable Development Since Rio: Legal Trends in Agriculture and Natural Resource Management,* FAO Legislative Study No. 73, Rome.

FAO. 1999. *Institutional and Legal Measures to Combat African Swine Fever*, by Vapnek, J. FAO Legal Paper Online No. 3, May 1999, available at www.fao.org/legal.

FAO/WHO. 2003. *Assuring Food Safety and Quality: Guidelines for Strengthening Food Control Systems*, Rome.

ISNAR/FAO. 2003. *Decision Support Toolbox for Biosafety Implementation*, available at www.isnar.cgiar.org

IUCN. 2003. Mackenzie, R., Burhenne-Guilmin, F., La Viña A., & Werksman, J. *An Explanatory Guide to the Cartagena Protocol on Biosafety*, Bonn.

5

ETHIOPIA COUNTRY STUDY*

Contents

* This chapter was prepared by Wondwossen Sintayehu Wondemagegnehu.

I. INTRODUCTION

This chapter contains an assessment of the existing system of *Biosecurity* in Ethiopia and its ability to accommodate international standards on plant and animal health, as well as food safety requirements. After this introduction, the chapter gives an overview of the legal and policy foundations that underpin the development of the *Biosecurity* laws and policies in the country.

In Ethiopia, there are some attempts to adopt specific regulatory provisions in scattered sectoral laws to realize the demands under each of the relevant international instruments. The National Biosafety Framework, which is currently being developed, is the only comprehensive document that focuses on one of the international agreements, the Cartagena Protocol.[1] It has a comprehensive vision of biosafety and has provided the impetus for the drafting of a biosafety law and a number of directives.

This chapter also examines the mandates of regulatory institutions involved in the development and issuance of standards, such as the Drug Administration and Control Authority, the Ministry of Health, the Ministry of Agriculture and Rural Development, the Quality and Standards Authority of Ethiopia, the Ethiopian Health and Nutrition Research Institute, the Environmental Protection Authority and the Customs Authority.

Various laws existing in the country have empowered these agencies to undertake inspections of food quality, issue procedures and standards against risks of plant and animal diseases and thereby enhance human health and environmental sustainability. But as the laws were not initiated in a coordinated fashion and also owing to the low level of awareness on matters related to *Biosecurity*, the institutions are not functioning up to expectations. Some of the agencies, as will be seen below, lack either the necessary mandate or the requisite sectoral integration and coordination. This chapter analyses the exact lacunae in their mandates or the points of overlap in their functions.

The chapter goes on to outline the legislation in force and draft legal texts relevant to *Biosecurity*. The chapter discusses laws on seeds, plant protection and quarantine, pesticides registration, animal disease control and food

[1] This instrument is discussed in Chapter 2, Part VII.

safety, in particular in the areas where they are relevant to *Biosecurity*. There are gaps in the existing laws which exist either because of the complex law-making process in the country and lack of appropriate law-making capacity or the reluctance to adopt draft texts through the appropriate law-making channels. The chapter concludes by indicating the possible way forward in order to foster *Biosecurity* in Ethiopia.

II. POLICY AND LEGAL FOUNDATIONS OF *BIOSECURITY* IN ETHIOPIA

2.1. Constitutional provisions

The incorporation of environmental right provisions into the Constitution is recent in Ethiopia.[2] In 1995, the Constitution introduced environmental rights as fundamental and inalienable to the people.

There are no provisions in the Constitution that are directed at food safety or animal and plant health. However, some of the human rights provisions can be construed as incorporating the basic tenets of *Biosecurity*. The right to a "clean and healthy environment" is one of the rights that Ethiopian citizens are accorded as part of the fundamental and inalienable human rights (art. 44). What constitutes a clean and healthy environment is not explained in the Constitution. But a healthy environment requires protection of flora and fauna from organisms, chemicals, pests and invasive species. A clean and healthy environment cannot be ensured where minimum requirements of plant and animal health are absent. Thus, the protection of the environment against harmful substances or practices stems from the construction of these constitutional provisions.

A corresponding duty is imposed on the government to refrain from negatively affecting the health and development rights of the people (art. 92) and to promote those rights by issuing relevant protection schemes. All actors (state agents and non-state actors alike) shall respect the constitutional safeguards that are in place to ensure the balance between economic development and environmental protection (art. 43). The Constitution also provides for the improvement of the livelihood of the people of Ethiopia. Ethiopians also enjoy a right to be consulted on the adoption of policies and the implementation of

[2] The Constitution of the Federal Democratic Republic of Ethiopia, Proclamation No. 1/1995.

projects affecting their communities. Prior informed consent of those communities is a pre-condition to the implementation of such projects.

Ethiopian citizens also have a right to be protected from undue displacement from areas where they live. In the event that this is compulsory (for instance, in case of health emergencies), people are entitled to monetary or non-monetary compensation, including relocation with adequate state assistance.

As stated above, these constitutional provisions are not specific to food safety or the protection of animal and plant health. However, they do lay down the basic conceptual framework for the setting of *Biosecurity* norms in the sectors of human health, environment and plant and animal health.

2.2. Policy coverage

2.2.1. Environment

In addition to incorporation of environmental issues in the Constitution, the framework of environmental protection in Ethiopia involves the formulation of an overarching environmental policy. The policy outlines principles to be followed in order to ensure the respect for environmental values, taking into account the economic, social and cultural circumstances of the country. The policy provisions relevant for *Biosecurity* in Ethiopia are discussed below.

The Environment Policy of Ethiopia (EPE) was approved by the Council of Ministers in 1997. The overall EPE goal is "to improve and enhance the health and quality of life of all Ethiopians and to promote social and economic development through the sound management and use of natural, human made and cultural resources and the environment as a whole so as to meet the needs of the present generation without compromising the ability of future generations to meet their own needs".[3]

In the EPE goal, there are features pertinent to the enhancement of human health and the protection of animals and plants from pests and diseases. For one thing, the policy targets as an ultimate goal the protection of the health and quality of life of the people. Though this goal does not provide for a list of the activities identified as harmful to

[3] Environment Policy of Ethiopia, 2 April 1997.

human health, it can be inferred from the specific policy provisions that some elements of *Biosecurity* are instrumental to achieving the goal.

Principles of intra- and intergenerational equity are echoed in the policy in the sense that Ethiopian nationals have the right to utilize available natural resources, while at the same time they have the duty to conserve them for the use of future generations. Conservation of biodiversity and ecosystems appears in the policy. The policy also prohibits causing harmful and irreversible consequences to the natural and cultural heritage of the country.

The EPE contains sectoral and cross-sectoral elements that are of significance to *Biosecurity*. Under the sectoral policies, the most relevant aspects are those dealing with genetic, species and ecosystem biodiversity; human settlements, urban environments and environmental health; control of hazardous materials; and cultural and natural heritage. At the cross-sectoral level, EPE tries to link thematic issues like environment and population, community participation in decision-making, tenure and access rights to land and natural resources, and the importance of environmental impact assessment (EIA) and community participation in decision-making. EIA has a particular significance to ensure that the Ethiopian people and environment are safeguarded from alien elements that negatively affect the food system, ecosystems or any component of the environment. Owing to the importance of the EIA tool to a *Biosecurity* approach, this will be explored at more length later in this chapter.

The EPE envisages measures to develop and disseminate sustainable technologies to enhance agricultural production. This section of the policy can be the basis for regulating products of modern biotechnology under the draft National Biosafety Framework, particularly as regards the intentional release of such products into the environment.

There is a policy provision stating that ecosystems should be safeguarded from possible biological contamination through quarantine legislation. The possibility that some animals or plants may be infected with diseases and pests is also articulated in the policy for future action.

The EPE urges actions for the restriction of exotic species from biodiversity hotspot areas, thereby limiting the spread of some potentially invasive plants. Though the country does not have a stand-alone policy or specific legislation on invasive alien species, this policy element can be used as a basis for future

actions. The possible adverse effects of invasive alien species on biodiversity are also recognized under the water resources conservation section of the EPE. Its objective is to ensure that any proposed introduction of exotic species into water ecosystems is subject to detailed ecological studies and EIA. It also recognizes that natural ecosystems, particularly wetlands and upstream forests, are fundamental to rendering ecosystem services and hence deserve conservation. As with invasive alien species, despite this policy statement there is no law in place governing conservation and utilization of fisheries resources.

The policy goals laid down in the EPE seem to reflect the government's commitment to conserve natural resources and protect the environment. However, it is clear that this commitment has to be substantiated through detailed and enforceable rules. The EPE has a mechanism for its periodic revision, although no initiative has been taken in that respect after the adoption of the policy.

In spite of the policy foundation, the quarantine laws of the country are far from meeting international standards. The problems emanating from the movement into and out of the country of organisms that can be categorized as plant pests and animal diseases remain without an adequate legislative response.

2.2.2. Biodiversity

Ethiopia has a national policy on biodiversity and research which was adopted in April 1998. The objectives of this policy are to ensure that genetic resources and ecosystems as a whole are conserved, developed, managed and sustainably utilized. Biodiversity conservation and development programmes should be duly integrated into the country's agricultural, health, industrial and overall national economic development strategies and plans. Promoting regional and international cooperation in biodiversity conservation, development and sustainable use is also another policy goal.

Some elements of the biodiversity policy can be construed to encompass the environmental aspects of *Biosecurity* (in particular, the loss of genetic diversity that may result from pests and diseases). The policy was initiated under the auspices of the Institute of Biodiversity Conservation and Research (IBCR), now the Institute of Biodiversity Conservation. The mandate to carry out research was removed and is now being undertaken by the Ethiopian Agricultural Research Institute, which seems to have assumed all tasks of research and development that used to be carried out by the IBCR. This

overlap in mandates has caused the research component of the policy to lose efficacy. These policies will be discussed later in this chapter with respect to their relevance to *Biosecurity*.

III. INSTITUTIONAL AND LEGAL REGIME OF *BIOSECURITY* IN ETHIOPIA

3.1. Institutional framework

3.1.1. Crop Protection Department

Ethiopia joined the International Plant Protection Convention (IPPC)[4] on 20 June 1977. The Ministry of Agriculture is the responsible body vested with the power to coordinate all efforts as regards compliance with this instrument. This ministry was reorganized in 2004 and renamed the Ministry of Agriculture and Rural Development (MOARD). Its mandate includes all measures necessary to:

- conduct quarantine controls on plants, seeds, animals and animal products; and
- prevent outbreaks of animal diseases and plant pests.

The Crop Protection Department is the national plant protection organization (NPPO) of Ethiopia. It has the following three divisions:

a. *Pesticide Registration and Control Team*: The team is composed of a few experts mainly tasked with registering agricultural inputs. They operate under the Pesticide Registration Decree No. 20/1990 which regulates pesticide import permits;

b. *Crop Protection Laboratory and Quarantine Team*: This division is responsible for ensuring that all imported and exported agricultural products are inspected and verified as free of any injurious insects, pests, diseases and noxious weeds. With a federal mandate, the division oversees the functioning of a number of quarantine stations. The stations currently functioning are those at Bole Airport, Dire Dawa, Metema, Moyale and Nazareth (Central Rift

[4] The IPPC is discussed in Chapter 2 Part III.

Valley). Among these, it is only the Bole Airport and Moyale stations that carry out import inspections. The rest are performing only inspections for export;

c. *Crop Protection Division*: This division controls migratory pests such as African Army worm, locust, etc. It has a federal mandate as it looks only at transregional issues.

Inspectors are assigned to each of the quarantine stations listed above in paragraph b. Inspectors are empowered to search, inspect, analyse, treat and seize any infested or infected plants, plant products and articles. The inspectors are not properly trained and, being few, do not have the capacity to monitor all the movements of plants and plant materials across the borders. In most instances, inspection is primarily carried out through visual observation.

None of the quarantine facilities in Ethiopia is adequately equipped. With the exception of those at Moyale and Nazareth, none has any laboratory facilities. Most of the stations also lack basic facilities such as greenhouses or fumigation centres.

Some laboratory equipment is found in the different agricultural research institutions. For instance, the Holeta and Melkassa Agricultural Research Centres have independent laboratory facilities. The Ethiopian Agricultural Research Institute has a laboratory facility that undertakes molecular marker techniques to characterize local poultry. The Sebetta Laboratory is serving as the National Animal Health Diagnostic Centre and has laboratory equipment for this purpose. Some of the science universities in the country such as the Biology Department of Addis Ababa University and Haromaya University have laboratories destined to fulfil the research needs of their students. To cope with these capacity constraints, it has been proposed to establish a central laboratory to employ equipment scattered in the many sectoral agencies.

The lack of capacity is also accompanied by institutional conflicts. With regard to plant health, there is a conflict between the Crop Protection Department of MOARD and the IBC. The latter is the national institution established in 1976 with responsibility for coordinating efforts to stop the rate of genetic erosion by promoting conservation activities. It is vested by

law with the responsibility of granting access to genetic resources under certain conditions.[5] Although the ambit of its authorizing law is access to genetic resources and not plant health, all plant material ready for export is interpreted as access granted on the germplasm, thus requiring a permit from the IBC. This often leads to a conflict between the operating procedures of the two entities. A memorandum of understanding or a legislative instrument would go far to resolving the conflict.

There is no official quarantine pest list kept within the Crop Protection Department. Nor has there been so far any attempt to designate a pest free area in Ethiopia. Regarding pest risk analysis, there are no defined or elaborate procedures that would enable the country to comply with the demands of the IPPC. Most of the international standards developed under the IPPC are not being implemented in the country.

3.1.2. Animal and Fisheries Resources Development and Regulatory Department

The Animal and Fisheries Resources Development and Regulatory Department within MOARD is currently empowered to undertake regulatory functions relating to livestock development in the country. Animal and animal products are inspected by this department. There are four animal quarantine stations in the country, namely, at Afar, Dire Dawa, Nazareth and Bole Airport. There are veterinarians, senior inspectors and junior inspectors assigned at each of these posts. At the veterinary inspection post of Bole Airport (which is the main port of exit for animal products via air shipment), two veterinarians and four senior inspectors are assigned to inspection in order to control the movement of animal products. Apart from these there is a national animal health diagnostic centre (Sebetta Laboratory) in the town of Sebetta which is in the vicinity of the capital city.

There is generally a lack of integration in terms of plant and animal inspection activities at the ports of entry and exit. Apparently, the only quarantine station that is common both to plants and animals is the post at

[5] Proclamation on Access to Genetic Resources and Community Knowledge No. 82/2006. This proclamation prescribes procedures for facilitating access by foreign users to the plant and animal resources of Ethiopia. It also provides an institutional mechanism for equitable sharing of the benefits arising from their utilization.

the Bole Airport. Laboratory and inspection facilities are also scattered, which leads to mismanagement.

Within the Animal and Fisheries Resources Development and Regulatory Department, the Veterinary Services Team is responsible for maintaining animal health and the safety of food products of animal origin. There is, however, a serious constraint to the efficient functioning of the team. When compared to the overall importance of the livestock sector, particularly to the livelihoods of the nomadic community living in the Afar and Somali regions, the staffing levels within the department are too low[6] and personnel often lack the requisite skills. It is often commented that the country has the lowest animal health care coverage in the entire sub-Saharan community[7].

The OIE Terrestrial Animal Health Code specifies the guidelines for safe animal and animal product trade.[8] These guidelines specify that livestock products must originate from countries or specified geographical areas (zones) of a country that are free from major animal diseases capable of causing economic losses or human diseases. In compliance with these requirements, Ethiopia attempted to designate a disease free zone covering the regions of Afar, Borena and Ogaden with a view, among other things, to maximizing profits from the rich livestock resources in these parts of the country.[9] The designation has not proven to be effective as the community is mainly made up of nomadic pastoralists and diseases will not be contained outside of the disease free zone as intended. Currently, there is no disease free zone officially communicated to the OIE.

---

[6] See *Ethiopia Trade and Transformation: Synthesis, Diagnostic Trade Integration Study,* available at www.integratedframework.org, according to which this veterinary services team consists of only eight professionals and a total of about 500 veterinarians, 800 para-veterinarians and 3 400 animal technicians. These experts manage a network of about 930 clinics, 650 animal health posts and ten diagnostic laboratories. The private veterinary sector is weak, with a total of 57 private veterinarians, 64 private clinics and about 150 private animal health assistants.

[7] See *id.*

[8] The OIE, or World Organization for Animal Health, is discussed in Chapter 2, Part IV.

[9] NEPAD-CAADP Bankable Investment Project Profile Preliminary Options Outline, *Live Animal and Meat Export* (NEPAD Ref. 05/08 E), Volume V of VI, January 2005, p. 12.

3.1.3. Environmental Protection Authority

The Environmental Protection Authority (EPA) is an autonomous public institution of the federal government. It has the role of coordinator among environmental protection agencies at the federal and regional levels. EPA formulates policies, strategies, laws and standards for the environment and enforces them. Article 6 of the proclamation establishing the EPA[10] includes the powers and duties to:

- coordinate measures to ensure that the environmental objectives provided under the Constitution and the basic principles set out in the environmental policy of Ethiopia are realized;
- prepare environmental policies, strategies and laws and upon approval, monitor and enforce their implementation;
- establish a system of environmental impact assessment (EIA);
- review EIA reports of such projects and notify its decision to the concerned licensing agency, and audit and regulate their implementation;
- set environmental standards and ensure compliance with them;
- formulate policies, strategies, laws and programmes to implement international environmental agreements to which Ethiopia is a party; and
- coordinate, promote and as may be appropriate, carry out research on environmental protection.

EPA operates at the federal level while all eleven regions of the country (including the autonomous cities of Addis Ababa and Dire Dawa) have established respective environmental bureaux to enforce environmental standards.[11] Though all the core responsibilities listed under the provisions of this law are not specific to *Biosecurity*, they have a bearing on aspects of it. The term "environment", as defined in Proclamation No. 295, in itself

[10] EPA Establishment Proclamation No. 9/1995. A proclamation is an act of Parliament while a regulation is a pronouncement of the Council of Ministers. A directive on the other hand is a subsidiary instrument that is adopted by the competent executive agency.
[11] Proclamation No. 295/2002 (Proclamation to provide for the Establishment of Environmental Protection Organs). Under article 15(2), regional states are responsible for ensuring the implementation of federal environmental standards or, as may be appropriate, issuing and implementing their own no less stringent standards.

embodies elements of protection of human, animal, and plant life. According to article 2(3), it consists of:

> "the totality of all materials whether in their natural state or modified or changed by humans, their external spaces and the interactions which affect their quality or quantity and the welfare of human or other living beings, including but not restricted to land, atmosphere, weather and climate, water, living things, sound, odour, taste, social factors, and aesthetics."

The EPA has initiated the drafting of a number of laws. The EIA system operational in Ethiopia is one of the creations of this institution and is a key tool in achieving environmental sustainability and the enhancement of animal and plant health. The law on EIA and its implementation practice will be discussed later in this chapter.[12]

3.1.4. Drug Administration and Control Authority

The Drug Administration and Control Authority (DACA) was established as a semi-autonomous regulatory agency through Proclamation No. 176/1999 with the objective of ensuring safety, efficiency and quality of drugs and regulating their production, distribution and use. DACA has the power to set standards and ensure their observance, to control the quality of raw materials and packaging and to monitor drugs and set standards for traditional medicine practitioners and users. Along with these functions, inspectors are empowered to search any premises, conduct inspections, seize documents and take samples of materials. DACA performs import and distribution controls through a system of registration and import permits.

3.1.5. Ethiopian Health and Nutrition Research Institute

The Ethiopian Health and Nutrition Research Institute (EHNRI) was established by Council of Ministers Regulations No. 4/1996. The major objectives of the institute are:

---

[12] See Section 3.2.9.

- to conduct research on the causes and spread of diseases, on nutrition, on traditional medicines and medical practices and on modern drugs;
- to support activities for the improvement of health in the country; and
- to contribute to the development of health science and technology.

Apart from general research duties, EHNRI is vested with powers and duties that are relevant to food safety. It is, for instance, expected to undertake studies on the causes, health impacts and distribution of food-borne diseases and conduct nutritional science and technology research on food items.

3.1.6. Ministry of Health

The Ministry of Health (MOH) is one of the executive organs of the government established through Proclamation No. 4/1995. The mandate of MOH, as outlined under article 22 of the proclamation, includes:

- determining standards to be maintained by health services;
- determining the required qualifications of professionals engaging in public health services at various levels;
- devising and following up the implementation of ways and means of preventing and eradicating communicable diseases;
- undertaking necessary quarantine controls to protect public health; and
- undertaking studies with a view to determining the nutritional value of foods.

The responsibilities of MOH regarding food safety and protection of public health are further elaborated in the Public Health Proclamation (Proclamation No. 200/2002). The goals of this proclamation as stated in its preamble are:

- to bring about attitudinal change in society through the primary health care approach with a view to solving most of the health problems of the country; and
- to promote the health of the society for future generations.

In order to achieve these objectives, the proclamation has provided for specific rules on food quality control and provisions on applicable food standards in the country. According to article 2(1), food quality shall be ensured through compliance with biological, chemical and physical standards set nationally and internationally.

A number of important terms are defined in the same article. "Food" is defined to mean any substance whether processed, semi-processed or raw which is intended for human consumption and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of food, but it does not include tobacco, cosmetics or substances used only as drugs.[13] "Food additive" is a substance added to food to improve its taste, colour, preservation or appearance and which is considered to become a component of food. Minimum requirements of food quality are set under articles 8 and 9 of this proclamation which are discussed at length later in this chapter.

In order to ensure compliance with the law, inspectors are assigned duties and responsibilities such as the power to:

i. enter and inspect any premise where the inspector has sufficient reason to believe that there exists a situation endangering public health;
ii. seize any article or material which is the result of any act committed contrary to law or used for the commission of the illegal act or has any connection with the commission of the illegal act;
iii. order that the premises remain closed for a limited period of time;
iv. take, where necessary, samples of articles, materials or goods from any premises or building, or any sample of air from within the premise or from the compound;
v. cause the destruction of articles, materials or goods found in any premises or building where there is sufficient reason to believe that such goods are dangerous to health, or that they cause or can cause another danger;

[13] This mainly tracks the Codex definition.

vi. request any information from any person which the inspector believes can give any information relevant for the investigation; and
vii. cause the institution of prosecution by the authorized organ.

3.1.7. Quality and Standards Authority of Ethiopia

The Quality and Standards Authority of Ethiopia (QSAE) was first established in 1970 as the National Standard Body. In 1998, it was re-established through Proclamation No. 102/1998, which was later amended by Proclamation No. 413/2004.

The QSAE is an autonomous federal organ operating under the Ministry of Trade and Industry (MOTI), whose major task is to approve Ethiopian product standards, including for crops and animal products. The modalities of operation of the institution and the main elements of its standard-setting activity are discussed later in this chapter.[14]

3.1.8. Institute of Biodiversity Conservation

As noted earlier, the Institute of Biodiversity Conservation and Research was established in 1976 and underwent gradual evolution, with its mandate and name undergoing frequent change. Initially, it was established as the Plant Genetic Resources Centre of Ethiopia and was focused on the collection and *ex situ* conservation of crop plants with high research and economic importance. The centre gave priority to crop types facing immediate danger of extinction and genetic erosion.

The institute was renamed the Biological Diversity Institute in 1994 and was tasked with, among other functions, conserving genetic resources and providing germplasm for the improvement of crops, acquiring new germplasm from other countries, documenting indigenous community knowledge and establishing field gene banks and botanical gardens.

In 1998, it was renamed the Institute of Biodiversity Conservation and Research (IBCR) through Proclamation No. 120/1998. Under this proclamation the institute has the power to initiate policy and legislative proposals and survey genetic diversity and distribution. It can also undertake

[14] See Section 3.2.8.

ex situ and *in situ* activities to conserve biological resources and implement international conventions, agreements and obligations on biodiversity. It is now the focal point for the Convention on Biological Diversity (CBD).[15]

The IBCR was restructured by Proclamation No. 381/2004 into a semi-autonomous entity under MOARD and assumed its current name – the Institute of Biodiversity Conservation (IBC). The IBC has various powers and duties relevant to *Biosecurity* and in particular, its environmental aspects. These include:

- cooperating with the concerned federal and regional authorities with respect to protection of biodiversity;
- encouraging and supporting public participation in the conservation, development and use of biological resources; and
- developing regional and international cooperation on biodiversity conservation and research activities, based on international agreements and national legislation.

3.2. Legal framework

3.2.1. Plant protection

MOARD is given the mandate for plant health by virtue of Council of Ministers Regulation No. 4/1995. Under this law MOARD shall assume the duty to establish quarantine of plants to prevent the spread of plant pests and to regulate the movement of plants, plant products or other articles into or from a specified area. Once the plant species are identified and the infested or infected materials isolated, MOARD can also treat it or in the worst case scenario dispose of it at the expense of the owner. This process limits the possible damage that would result from inappropriate disposal of the infected plants or plant products.

MOARD is further empowered to restrict the importation of certain plants which do not have import permits and phytosanitary certificates duly issued by the plant protection authorities of the exporting countries. MOARD has the responsibility for issuing phytosanitary certificates for export of Ethiopian plants and plant products.

---

[15] This convention is discussed in Chapter 2, Part VI.

The Plant Quarantine Regulations (Council of Ministers Regulations No. 4/1992) further detail the provisions on import and export. The regulations prescribe that any plant or other articles, premises or conveyances found infected shall be treated or destroyed, as the case may be. Quarantine controls and documentary verification of phytosanitary certificates on all imported plants are required. Some plant species are prohibited from entering the country. For others there are restrictions and a permit should be secured from MOARD before they may be imported. The regulations also provide for the declaration of quarantine areas and subsequent control measures.

The regulations are silent with regard to surveillance of pests within the country. They contain a list of quarantine pests which is not updated and includes pests that have been endemic in the country for a long time. For instance, parthenium is a weed which is endemic to South and North America but is reported to have been noticed in Dire Dawa, Hararghe and eastern Ethiopia as from 1988.[16] It was supposedly imported from subtropical North America "as a contaminant of grain food aid during the 1980s famine"[17] and subsequently spread in the country.

3.2.2. Seed and variety release

According to its preamble, the Seed Proclamation[18] is intended to achieve increased crop production by enabling farmers to use high quality seeds, particularly for improved varieties, and making those seeds available on the market. The proclamation does not directly deal with plant health. However, article 14 provides that any seed produced and processed locally, imported or exported shall be of a variety registered by the National Agricultural Inputs Authority (NAIA) and shall conform to the requirements and standards of the country.

Phytosanitary inspections of seeds are undertaken before the variety is released. However, as seed is also one of the plant parts subject to the quarantine regulations, there is often a conflict in mandate between the

---

[16] *Invasive Alien Species: A Tool Kit of Best Prevention and Management Practices*, R. Wittenberg and M.J.W. Cock (eds.), IUCN, 2001, p. 86.
[17] *Id.*
[18] Proclamation No. 206/2000.

National Agricultural Inputs Department of MOARD, which replaced the NAIA as Ethiopia's seed authority, and the Crop Protection Department.

There is a *de facto* legal instrument[19] that puts in place the applicable procedure regarding seed development and release in the country. Under this procedure, the National Variety Release Committee approves the release of hybrids and varieties developed by governmental and private institutions, makes the necessary arrangements to conduct quality tests in collaboration with other agencies and registers the released varieties and hybrids.

3.2.3. Agricultural inputs

NAIA was established under Proclamation No. 288/2002 with the mandate of regulating agricultural inputs (plant seeds, fertilizers and pesticides). NAIA was established with the basic purpose of ensuring increased production and productivity of the agricultural sector. The restructuring of the Ministry of Agriculture has eliminated the autonomy of the NAIA and made it a department within MOARD. The Agricultural Inputs Department of MOARD has the task of ensuring the health of all agricultural inputs. The department is mandated to inspect the quality of seeds, fertilizers and pesticides to be released on the local market or those to be exported or imported.

3.2.4. Pesticides

The pesticide regulatory instrument is a Council of Ministers decree enacted in 1990 (Regulation on Pesticide Registration, Council of Ministers Special Decree No. 20/1990). It lays down a scheme of control to minimize the adverse effects of pesticides on human beings, animals, plants and the environment. "Pesticide" is defined as any substance or mixture of substances intended to prevent, destroy or control any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products, animal foodstuffs or substances

[19] National Variety Release Procedures and Mechanisms, adopted on November 2001 by the National Authority for Inputs in Agriculture. These procedures and mechanisms are in place and have been used by the National Variety Release Committee for over a decade without any challenge to their authority by individuals or legal entities.

which may be administered to animals for the control or insects, arachnids or other pests in or on their bodies. The decree prohibits the manufacture, import, sale and use of unregistered pesticides in Ethiopia.

There are no official standards or criteria nationally adopted to regulate the registration process in cases of import. There also appears to be a mandate conflict on the registration of veterinary drugs for import. These drugs are perceived by MOARD to be included within the wider definition of pesticides, whereas DACA considers them no different from human drugs and claims competence to regulate them. An inter-ministerial committee was assigned the responsibility to resolve the conflict. Currently, the registration of all forms of veterinary drugs is performed by DACA, which issues import licences. It also keeps a list of registered veterinary drugs and registration guidelines. There is a perceived need to upgrade the status of this list to be an enforceable law.

3.2.5. Animal health

Animal disease control is dealt with under Proclamation No. 117/1998. The Animal Marketing Authority (AMA) was established in the proclamation with the objective of promoting the domestic and export marketing of animal products and by-products through increasing support and improving quality. In order to achieve these goals, the AMA has the power to issue quality control directives on exportable or importable animals, animal products and by-products and to follow-up on trading activity. It also has to ensure that the exportable items meet international standards.

The AMA has been dissolved and there is no later authority assigned to take over its function. The activities it used to undertake are now being followed up by the Animal and Fisheries Resources Development and Regulatory Department within MOARD.

In 2003, the Ethiopian Government designed an export development strategy which gives particular attention to the promotion of labour-intensive production and processing for export. Meat, livestock, hides and skins are priority export commodities within this strategy. In order to win on the competitive international market, the government is building capacity to comply with the different international standards, particularly those emanating from the OIE.

Legal instruments regulating animal diseases, livestock development and meat inspection are summarized hereunder.

The *Animal Disease Control Proclamation No. 267/2002* mainly deals with the prevention and control of diseases; outbreak notification; establishment of quarantine stations; entrance and exit ports for export of livestock and livestock products; international animal health sanitary certification; and animal movement permits. MOARD is authorized by this proclamation to declare by public media an area infected by a notifiable animal disease (art. 4). This notice should specifically indicate the infected area, the type of disease and the measures to be taken. Specific actions which can be taken in relation to an infected area are set out in article 5. MOARD is also assigned the mandate to extend, diminish or otherwise alter the limits of a declared infected area.

The law also incorporates provisions stating the conditions under which animals, their products or by-products are exported. Article 12 states the requirement to keep animals for export in a quarantine station for a specified period. Animals for export shall also originate from an area that is free from notifiable animal diseases and be accompanied by a movement permit. Persons who transport export animals, animal products and by-products are required to comply with transport requirements and use designated exit posts.

The importation of animals and their products should follow similar requirements under article 13 of the law. The importer should obtain an entrance permit by applying to MOARD stating the type of product, country of origin, quantity, means of transport, date of arrival, port of entry and transit countries prior to importation of animals, animal products and by-products. Imported items should be checked at the port of entry by an animal health officer.

There is also a provision on animal movement and the requirement of a permit for such purposes. Article 14 states the duty to obtain an animal movement permit from the animal's place of origin in order to transport animals from woreda to woreda[20] or from region to region. The animal movement permit should indicate the animal's place of origin, destination, route, type and number of animals, health status and other necessary details.

[20] A "woreda" is a lower administrative unit while a "kebele" is the lowest.

The *Meat Inspection Proclamation No. 274/1970* confers a mandate on MOARD to control and regulate the production, processing and handling of livestock products.

The *Meat Inspection Amendment Proclamation No. 81/1976* mandates MOARD to issue regulations and establish criteria for livestock production for human consumption, including classification of products and inspection of processing facilities.

The *Meat Inspection Regulations No. 428/197* are issued under Proclamation No. 274. They establish the requirements for setting up abattoirs and commercial establishments dealing with slaughter, preparation and processing of livestock products for export from or import into Ethiopia.

There are also a series of draft legislative instruments:

The *Draft Regulations for Animal Diseases Prevention and Control* set rules for disease reporting, investigation and surveillance mechanisms at federal and regional levels. They also set the modalities for the control of disease outbreaks.

The *Draft Regulations for Controlling Movement of Animals and Transportation of Animal Products and By–products* set the mechanisms to prevent the spread of infectious diseases.

In addition to this, a series of guidelines, which are non-binding instruments issued by MOARD, have been prepared for:

Meat inspection, hygiene and construction of export abattoirs: These guidelines were approved in 2000 to set the standards of good practice.

Operational procedures of export abattoirs: These guidelines set out the procedures for examining animals destined for slaughter and for implementing sanitary measures in abattoirs.

3.2.6. Food safety

In Ethiopia, the leading government institutions responsible for food safety include MOH, MOARD, the QSAE, MOTI and the Ethiopian Manufacturing Industries Association. These institutions work together in

organizing training workshops, setting standards and drafting regulations. Since 2002, these bodies have established a Technical Committee that implements food safety assurance systems in accordance with the international market requirements, supported by the United Nations Industrial Development Organization.

Although there is no comprehensive food safety policy in the country, safeguarding the public from communicable and infectious diseases is clearly addressed in different policies such as the National Health Policy that gives due emphasis to prevention and control of the major health problems of the country, which would include problems arising from food safety.

As noted in Section 3.1.6., the Government of Ethiopia has issued Public Health Proclamation No. 200/2002 which gives general powers on public health matters to MOH. The proclamation establishes an advisory board at the federal level and regional health bureaux at the regional level for the purpose of advising MOH on the implementation of the proclamation. This task inherently includes food safety since it is one of the important factors in ensuring public health.

There are minimum requirements set under this law to ensure national food quality control (art. 8). Accordingly:

- it is prohibited to prepare, import, distribute or make available to consumers any food which is unhygienic, contaminated, unwholesome or mislabelled and does not meet the standards of food quality;
- any food intended for human consumption should meet the standards of food quality and be labelled and preserved in a healthy manner;
- any person who produces or distributes salt for human consumption shall ensure that it meets the standard requirement of iodine content; and
- no person shall use any testing laboratory unless it is registered by the health authorities.

It is a requirement under the law that a person engaged in any activity of selling, producing for sale, storing, preparing or preserving food intended for human consumption should meet the standards set by MOH. Regarding

water quality control, it is prohibited to import, produce or distribute to the public bottled mineral water or plain water unless its quality is verified.

Based on this proclamation, draft food safety regulations are completed and awaiting endorsement by the Council of Ministers. Most regional health bureaux have enacted their own regulations that fit their regional context based on this proclamation.

Committees consisting of government representatives, food manufacturers, food traders, food scientists, food inspectors, medical and veterinary experts, consumers and other stakeholders set food standards. These standards can be company, national, regional or international depending on the scope of their application. The QSAE has developed about 450 food-related standards, most of which have been implemented and have been made technical regulations by Regulation No. 13/1990. Standards are the technical basis for food safety inspection activities. Food products are inspected and controlled through third-party certification schemes.

A number of institutions are assigned, through the proclamations establishing them, to undertake food safety inspections in the country, including MOH, QSAE, EHNRI, DACA and the Customs Authority. There are overlaps in the exercise of those functions that are hampering the effectiveness of controls. For instance under MOH Proclamation No. 4/1995, one of the functions of MOH as regards ensuring public health is undertaking quarantine controls. This, however, is a duty assigned to MOARD under other laws. The task of setting food quality standards, assigned to MOH, is also another problematic issue as it also falls within the mandate of QSAE. The latter is in fact in the process of developing food quality standards to be applied nationally.

Coordination of activities at the lower level of the hierarchy remains to be established and strengthened. Responsibilities and mandates are not clearly defined, demarcated or streamlined, resulting in insufficient coordination of activities, duplication of efforts, misuse of human resources and waste of meagre financial resources allocated to the sectors. In order to overcome these problems, the existing Technical Committee has established the National Food Safety Council whose members are drawn from regulatory bodies, research institutes, industry, consumers and higher learning institutes involved in food safety.

3.2.7. Biosafety

Ethiopia is a party to both the CBD and its Cartagena Protocol. In an attempt to implement the obligations under the protocol, the country implemented a UNEP/GEF-funded biosafety project which resulted in the National Biosafety Framework (NBF). The NBF includes a draft Biosafety Proclamation.

According to the preamble, the objective of this draft proclamation is to enable the country to benefit from the advantages of modern biotechnology, by managing the possible risks occasioned as a result of the application of the technology on human and animal health, biological diversity and the environment. The precautionary principle, which requires the employment of cost-effective safety actions to prevent potential harm even in the absence of conclusive scientific evidence, underpins the draft proclamation.

The draft proclamation establishes procedures of prior notification to and authorization by the EPA for research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, feed or for processing of any genetically modified organism (GMO) or products thereof. EPA is designated to be the responsible authority for the approval (or rejection) of applications. The proclamation initially envisaged a committee of experts from various regulatory agencies to advise the EPA but this concept has subsequently been abandoned.

The applicant is required to undertake risk assessment to identify potential risks of GMOs or derived products on human and animal health and biological diversity, including socio-economic conditions and cultural norms and the environment in general (art. 9). A GMO exporter is required to provide evidence of the advance informed agreement of the importing country. EPA is not precluded from taking more restrictive actions or prohibiting the intended export (art. 13). EPA is required to make any application available to the public and technical experts and solicit their comments.

The draft proclamation also provides for the identification, labelling and packaging of GMOs or their products, with the EPA tasked with establishing standards in this regard. Post-authorization monitoring and inspections are also regulated in the draft proclamation. Criminal sanctions

are imposed on offenders who contravene the mandatory obligations of the proclamation such as those on notification, risk assessment and compliance with standards.

The draft proclamation contains the basic provisions that are required in order to implement the obligations of the Cartagena Protocol. If approved, it would be an important tool within the national *Biosecurity* system to manage risks to the environment and human health arising from GMOs.

3.2.8. Product quality standards

As seen above, the QSAE currently sets standards for agricultural products and is empowered to ensure compliance with them. The standards are harmonized with the pertinent standards of other countries so that they will not constitute trade barriers under the World Trade Organization Agreement on Technical Barriers to Trade.[21]

To monitor compliance, the QSAE acts at three levels: local manufacturing, import and export. Any organization engaged in the food manufacturing business will give samples of the products to the laboratory of QSAE for inspection. Routine inspections on the premises are also conducted on a quarterly basis. In the case of imports, the QSAE issues pre-import authorizations and inspects at ports of entry, with sampling and laboratory testing if necessary.

For exports, the QSAE operates a permit system for food exporters. Inspections on food items for export are carried out mainly on oil seeds and pulses. The QSAE does not inspect the content of manufactured products but only verifies compliance with labelling requirements. The QSAE is also responsible for setting plant and animal health standards but their implementation is left to the responsible units within MOARD.

3.2.9. Environmental impact assessment

The Environmental Impact Assessment (EIA) Proclamation No. 299/2002 entered into force in December 2002. The proclamation tasks EPA with the elaboration of a series of projects and activities for which an EIA is required.

---

[21] This agreement is discussed in Chapter 2, Section 2.2.

It establishes criminal penalties in cases of false representations in an EIA report (art. 8). Though not specifically addressing *Biosecurity* issues, this law is used to manage environmental risks for imports of invasive plant and animal species. A person desiring to engage in such an import business is required to produce a clearance from the regional environmental agencies. It is only when an authorization is secured that an import is allowed (art. 3(3)).

The steps generally followed are that the applicant prepares an EIA study which is subsequently reviewed by the competent regional environmental agency. After review of the EIA report, the environmental agency will decide either to approve or refuse the proposed request. This decision is expected to be followed by the issuance of a licence or permit by the rendering agencies (art. 3(3)). These agencies should check the environmental clearance in advance of granting any form of permit or operational authorization.

The Crop Protection Department and the Animal Inspection Department of MOARD should follow this mandatory provision of the law. This, however, does not seem to be taking place. The ports of entry and exit that perform quarantine functions only examine the physical items subject to movement and do not require any environmental clearance for shipment to or from the country. This is an example of a lack of interagency cooperation. MOARD has its own recently established in-house Environmental Management Unit. This unit is mandated, under article 14 of Proclamation No. 295/2002, to ascertain that environmental standards are complied with.

The implementation of the EIA proclamation is further hampered by a number of other constraints. The list of projects and activities that need to undergo compulsory EIA procedures is not in place yet and, as a consequence, it is unclear whether a certain import requires EIA or not. This is one grey area that needs to be clarified. The procedures for undertaking EIA studies (including the qualifications of the expert that can undertake an EIA study or the composition of panels of experts) are not set forth in law. The existing law also provides that the EIA review process include participation of the affected communities (art. 14) but so far there is no record of such consultation undertaken. Moreover, the EPA reviewers of EIA studies often lack proper training.

IV. *BIOSECURITY* ASSESSMENT AND RECOMMENDATIONS

Although *Biosecurity* does not appear in any policy document in Ethiopia, the different sectoral policies of Ethiopia provide the necessary policy foundations for a *Biosecurity* approach. For instance, the EPE, although not in a detailed manner, provides for the need to control the introduction of pests or invasive alien species (IAS) into ecosystems. The existing policy provisions can be employed as the basis for the development of legislation. However, as regards other *Biosecurity* components, there is no on-going initiative for the upgrading of legislation. Sectoral legislation in the area of animal disease, plant pest control and quarantine regulations is not comprehensive. The laws generally are not harmonized with respect to the mandates of the implementing institutions. This often leads to conflict rather than cooperation.

Seen in this light, the overall legal system of *Biosecurity* in Ethiopia is only at a rudimentary level. It is full of gaps that render it incomplete compared to dynamic developments in the international arena. Many of the *Biosecurity*-related international instruments are not yet fully domesticated. For instance, as seen above there is no IAS law to give effect to the obligation of Ethiopia under article 8 of the CBD.

Draft legislation on biosafety has been prepared. However, the drafting of the biosafety proclamation as well as the National Biosafety Framework was the result of technical assistance under UNEP/GEF. After the assistance ended, the draft has not proceeded through the legislative process. A similar situation inheres with regard to other draft legislation of relevance to *Biosecurity*:

- draft Regulations for Animal Diseases Prevention and Control; and
- draft Regulations for Controlling the Movement of Animals and the Transportation of Animal Products and By–products.

These draft documents should be finalized and undergo the necessary approval process. One opportunity that these drafts avail is the possibility of incorporating *Biosecurity* concepts into them, such as the streamlining of import and export procedures or the pooling of resources to conduct risk assessment. In this regard, an entry point is the NBF.

The status of some legal instruments should also be revisited. Some *Biosecurity* instruments are mere guidelines that are subject only to voluntary compliance. These should be given more legal weight and be transformed into directives, which are enforceable but easier to approve than regulations or proclamations. Included in this category are the guidelines on meat inspection, hygiene and construction of export abattoirs.

The gaps in the EIA system in Ethiopia should be given attention as EIA is essential to control the damage that may be caused to flora and fauna as a result of imports. At present, the implementation of this important tool demands adopting subsidiary regulations to put the prescriptions of the law into action. For instance, as stated earlier, the activities and projects that require a full-scale EIA should be listed and a mechanism be devised to coordinate the working procedures of the environmental agencies especially at the ports of entry.

Most of the institutions engaged in the management of animal and plant health as well as food safety are constrained by conflicts and overlaps in mandate that seriously lessen their effectiveness. *Biosecurity* is not currently being handled by a single institution. Understandably, this is due to the multidisciplinary nature of the subject. However, the present situation has created lacunae in the implementation not only of international standards but also of the laws in force within the country. The handling and implementation of *Biosecurity* obligations is generally a task scattered within a wide array of agencies. In order to implement the food quality standards, plant life and animal health standards of the Codex Alimentarius,[22] OIE and the IPPC, there is a need to improve this institutional infrastructure.

Owing to the sectoral orientation of the agencies handling *Biosecurity* in Ethiopia, interagency cooperation is very poor. This can be solved by the assignment of an oversight body at a higher level vested with the task of supervising the implementation of *Biosecurity*-related activities. An interagency committee composed of the major institutions involved (EPA, MOARD, MOH, EHNRI, DACA, QSAE) can be formed to address *Biosecurity* issues in the country. It is important to make such a committee accountable to a higher-level political authority such as the Prime Minister's office, to give it more power and efficacy.

---

[22] The Codex Alimentarius is discussed in Chapter 2, Part V.

The disease surveillance and quarantine system of the country is constrained because of the unwise use of limited resources such as laboratories, laboratory equipment and the necessary personnel. One urgent response would be to pool the country's meagre human and technological resources and establish a centralized system for risk assessment and risk management. This would also ensure the necessary synergies among different experts and the reliability of the risk analysis process. Legislation could be adopted in this regard to consolidate all the scattered surveillance and quarantine activities undertaken by the sectoral agencies and the regional states.