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GHANA COUNTRY STUDY*

Contents

* This chapter was prepared by George Sarpong.

I. INTRODUCTION

Biosecurity involves the management of biological risks in a comprehensive manner to achieve food safety and protect animal and plant life and health. It also addresses the associated environmental risks. The assumption is that all these sectors are inextricably linked and that the similarities in their regulatory frameworks demand a unified and coordinated approach.

As an issue of global importance, the different components of *Biosecurity* have been addressed in several international instruments, which were reviewed in Chapter 2. This chapter examines Ghanaian legislation in the light of these international instruments and addresses gaps/weaknesses in the Ghanaian regime against the backdrop of the relevant international dictates. The discussion proceeds along two broad but inter-related headings: (1) Ghana and the regime of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, and (2) the Convention on Biological Diversity (CBD), CBD-related instruments and Ghana. This chapter also examines the relevant constitutional and institutional bases for *Biosecurity* in Ghana. It draws conclusions and proffers a way forward for the *Biosecurity* regime in the country.

II. THE GHANAIAN REGIME ON *BIOSECURITY*

2.1. Ghana and the SPS regime

Various pieces of legislation exist on the statute books to address food safety, animal and plant health in Ghana.

2.1.1. Food safety

In the area of food control and safety, the 1992 Constitution and certain pieces of food safety legislation have a bearing on the subject. The Constitution, the fundamental law of the land, does not expressly address food safety. Some of its provisions, however, are relevant to the subject. Article 36(2)(b) of the Directive Principles of State Policy enjoins the state to take necessary steps to establish a sound and healthy economy whose underlying principles shall include affording ample opportunity for individual initiative and creativity in economic activities and fostering an enabling environment for a pronounced role of the private sector in the economy.

Furthermore, article 36(10) enjoins the state to safeguard the health, safety and welfare of all persons in employment, and to establish the basis of the full deployment of the creative potential of all workers. This provision, which is of significant relevance within the context of health and safety at work, is also relevant for present purposes. A law passed with the object of strengthening public health standards among street food vendors, for example, would be perfectly well in accord with this constitutional injunction since many a "person in employment" relies on street foods as a basis for sustenance.

In addition to the constitutional provisions noted above, the following pieces of legislation govern foods in Ghana:

- Food and Drugs Law, 1992 (PNDCL 305B); and
- Food and Drugs (Amendment) Act, 1996 (Act 523).

The Food and Drugs Board (FDB) has also proposed for adoption draft Food and Drugs Regulations, 2000. These are yet to be passed by Parliament but are being used by the FDB in its operations.

The Food and Drugs Law (FDL) was enacted to control the manufacture, importation, exportation, distribution, use and advertisement of foods, drugs, cosmetics, chemical substances and medical devices. Accordingly, the FDL contains prohibitions against the sale of unwholesome, poisonous and adulterated foods and also prescribes standards for foods.

The definition of "food" is rather wide under the law. Section 51 states that it includes "any article manufactured, sold or represented for use as food or drink for human consumption, chewing gum, water and any ingredient of such food drink, chewing gum or water". This definition is in consonance with accepted practice, as for example obtains under United Kingdom legislation.

The FDL has been amended by the Food and Drugs (Amendment) Act, 1996 (Act 523), whose purpose is to provide for the fortification of salt to alleviate nutritional deficiencies and to bring the provisions of the FDL in conformity with the Constitution. Act 523 expands on the definition of "food" to include "salt and any article manufactured, sold or represented for use as food or drink for human or animal consumption, chewing gum, water and any ingredient of the food, drink, chewing gum or water".

Section 27 of 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 is wide-ranging, drawn from relevant departments and agencies of state and the private sector. The functions of the FDB as set out in Section 28 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 the FDL is bereft of contents as regards the international standards that should guide the FDB in the discharge of its duties. Schedule I of the law makes reference to the publications of certain international bodies, but the list does not include those of the Codex Alimentarius Commission.[1] An amendment of the FDL would bring it in line with international practice on the subject.

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. Obstruction of an authorized officer or contravention of the provisions of the law is an offence punishable, upon summary conviction, by a fine or imprisonment. Individuals, corporations and partnerships are liable to sanctions under the law. Section 35 of the FDL mandates an authorized officer at any reasonable hour to inspect any animal intended for slaughter and to seize and inspect any meat which he or she considers unfit for human consumption.

2.1.2. Animal health

With regard to animal health, few statutes exist, one dating from the colonial era. Of relevance for present purposes are the:

- Animals (Control of Importation) Ordinance (Chapter 247); and
- Diseases of Animals Act, 1961 (Act 83).

A draft Meat Inspection Law, 1999, has also been proposed by the sector ministry although it is yet to be passed as an Act of Parliament.

The Disease of Animals Act gives the minister responsible for agriculture power to adopt measures to curb the outbreak of animal diseases. Veterinary

[1] For a discussion of the Codex Alimentarius, see Chapter 2, Part V.

officers have powers of inspection over animals. Thus by implication the draft law seeks to repeal Section 35 of the FDL. The powers exercisable by veterinary officers under Act 83, especially in the event of outbreak of diseases, are aimed at the control and avoidance of the spread of animal diseases, and hence safeguard human health since animals are sources of food.

Contravention of the provisions of the act constitutes an offence, and upon conviction, attracts imprisonment for a term not exceeding six months or to a fine not exceeding 50 pounds or to both. The applicable financial sanctions are, however, outdated and need to be revised. There is also the need to refer to and incorporate the OIE standards which are the international norms or benchmarks on animal health and animal diseases.[2]

The draft Meat Inspection Law was prepared as far back as 1999 to address the subject of meat inspection. An accompanying memorandum to the law provides justification for its enactment:

- the need to enact laws and regulations to protect consumers from chemical and biological agents harmful to human health;
- the need to entrust the responsibility for meat laws to a government department responsible for promotion of animal and human health – Veterinary Services is seen as best suited in this regard;
- the need to provide legal backing to veterinary personnel of the Ministry of Food and Agriculture (MOFA) to effectively carry out the meat inspection function;
- the need to ensure compliance of Ghanaian legislation with international standards and practices.

The draft legislation is in four parts: Part I deals with the controlling authority, appointment, qualifications and functions of veterinary inspectors. Part II deals with inspections, labelling and enforcement of the law. Part III deals with importation and exportation of meat and other animal products, and offences. Part IV addresses regulations and interpretation of the law.

Under Part I, the Veterinary Service Directorate (VSD) of MOFA is designated as the controlling authority responsible for the control of meat hygiene, including meat inspection, as well as all decisions relating to human health and animal health at admission of slaughter animals to the abattoir or

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

slaughterhouse, and ante-mortem and post-mortem inspections. These provisions are obviously designed to put to rest any controversy as regards the competent authority on the subject. The OIE has indicated that veterinary services departments should exercise responsibility for meat inspection. However, it should be kept in mind that the VSD alone cannot perform this function efficiently and effectively without the assistance or collaboration of officials from other ministries, departments and agencies.

Enforcement

Under the existing regime, both the FDB and the district/metropolitan assemblies have statutory functions in meat inspection. The draft law seeks to divest these bodies of these functions and vest same in the VSD. The justification for this proposal as contained in the memorandum is that VSD "is adequately equipped to undertake the task .... It has qualified staff that can detect diseases in animal[s], recognize normal and abnormal tissues in organs. There are over 700 … technical and professional staff spread throughout the country who can competently and completely take over meat inspection".

The draft in this part also makes provision for the appointment and qualifications of veterinary inspectors. These include a qualified and registered veterinarian and any other veterinary personnel appointed as inspector pursuant to the law. These are accorded wide inspection and enforcement powers under the act. Because the VSD does not have sufficient staffing, a convenient arrangement on the matter could be the sharing of responsibilities between officials of the VSD, public health officers and the FDB.

Part III of the draft law prohibits the importation and exportation of meat and meat products unless certain conditions are met. Meat and meat products cannot be imported unless they bear a certificate testifying that the products satisfy the requirements of standards prescribed by the appropriate authority in Ghana. In the case of exports, there is a similar prohibition unless the products are certified by the Director of Veterinary Services as meeting the prescribed standards set by the Ghana Standards Board.

The Animals (Control of Importation) Ordinance (Chapter 247), a colonial statute which is still in force, bans the importation of animals into the country unless certified by a veterinary authority that they are free from diseases. The ordinance is outdated and could be repealed since the draft

Meat Inspection Law deals with the subject of importation and exportation of meat, meat products and animals.

Even though standards for inspections, importation and exportation of meat products have been prescribed by the appropriate international bodies, there is no express reference to the OIE in the legislation. A reference to these standards could be made in the parent enactment, or regulations could be passed incorporating these standards. Another gap that needs to be addressed is the absence of legislation on animal feeds and veterinary drugs. These could be provided for by way of regulations made pursuant to the proposed law (as provision is made under the draft law for regulations) or by separate legislation addressing each of these topics.

A revised draft meat inspection law prepared in 2004 is an improvement on the 1999 draft. It provides for the appointment of inspectors, meat inspections, importation and exportation of meat and miscellaneous matters including advertising, seizures and regulations. The minister is given the power to make regulations on a wide range of matters including inspections; the registration of establishments and the licensing of operators; fees; and standards for imported meat products. However, the draft still suffers from a failure to refer to international standards as the basis for standard setting and enforcement.

2.1.3. Plant protection

The major piece of legislation governing plants and plant protection is the Prevention and Control of Pests and Diseases of Plants Act (1965). The main objective of the act is to consolidate, with amendments, the legal framework relating to the prevention and treatment of plant pests and that relating to plant quarantine. It has three parts: Part I on prevention and treatment of plant pests; Part II on plant quarantine; and Part III, with miscellaneous provisions.

Part I (sects. 1–8) places a ban on the keeping, selling, offering for sale or barter or distribution of any plant infested or infected with such pests as may be prescribed. Infested or infected plants may not be removed from any land except for the purpose of inspection by an inspector; destruction; or preservation of the produce of such plants for subsequent manufacture for sale or for seed. Provision is made under the act for the making of regulations by the minister on the prevention and eradication of plant pests and other relevant matters.

Part II of the Act (sects. 9–12) prohibits any person, except with a permit, from importing any plants, plant products, plant pests, soil, manure, grass, packing materials or any other material liable to harbour dangerous plant pests. Provision is made for regulations prescribing the conditions for the grant of a permit, examination of items imported under the permit and the prohibition and restriction of importation of such items. Inspectors have powers to seize items being imported in contravention of the act and to dispose of them.

Part III of the Act (sects. 13–17) makes it an offence punishable on conviction to a fine not exceeding 100 cedis or to a term not exceeding three months to contravene a direction, requirement, condition or prohibition imposed under the act. Provision is also made for compensation to occupiers of land or importers who may suffer pecuniary losses as a result of measures taken under the act.

Other relevant legislation is the Seed Inspection and Certification Decree, 1972, and the Pesticides Control and Management Act, 1996. Together with Act 307, they provide the legal and institutional bases for the coordination and regulation of plant protection activities in Ghana.

Enforcement

Within MOFA, the Plant Protection and Regulatory Services Department (PPRSD) is responsible for plant protection, plant quarantine, seed quality control and pest management. Officers of the PPRSD carry out phytosanitary inspections at all border points including the sea ports and the international airport. The Customs, Excise and Preventive Service (CEPS) officers, also stationed at the borders, are required to inform the plant quarantine officers if they notice any plant materials in imported shipments or baggage which they (CEPS) have inspected in the first instance. With regard to risk assessment, the PPRSD undertakes this function through the employment of a core of trained risk assessors drawn from MOFA, research institutions and the universities.

Proposal for reform of the law

The legal regime for plant protection is outdated, and the legislation has several drawbacks, and does not measure up to the standards of the new

revised text of the International Plant Protection Convention (IPPC).[3] The shortcomings include absence of provisions on risk analysis and exportation of plants, lack of adequate provisions on the duties of plant quarantine officers and on co-ordination among the various institutions involved in plant protection in the country as well as low financial penalties for violations.

Under the FAO Technical Co-operation Programme, a project, "Strengthening Plant Quarantine Capabilities: Republic of Ghana", was initiated in 1996. The main output of the project, a draft Plant Quarantine Act, was presented to the government for consideration and adoption. The draft act seeks to repeal the 1965 Plant Protection Act and replace it with a modern Plant Quarantine Act that will prevent the introduction and spread of plant pests in Ghana.

The 1996 draft act has itself been overtaken by the recent coming into force of the new revised text of the IPPC and needs to be updated to incorporate provisions and concepts of the new text, including an enhanced role for the national plant protection organization (PPRSD) in *Biosecurity*, such as through collaboration with the Ministry of Environment on living modified organisms and ecological risks.

2.2. Ghana, the CBD and CBD-related instruments

Ghana has not enacted specific legislation to domesticate the Convention on Biological Diversity (CBD).[4] However, several pieces of legislation along sectoral lines – fisheries, forestry, game and wildlife – exist on the statute books to address the subject. In general these are designed to ensure the conservation and sustainable utilization of these resources. For present purposes, two pieces of legislation, one on wetlands and a draft Biosafety Bill, are of direct relevance.

On wetlands, the Wetland Management (Ramsar Sites) Regulations, 1999 (LI 1659), have been passed to domesticate the Ramsar Convention. Under these regulations, six Ramsar sites have been designated, namely, Densu Delta, Keta Lagoon Complex, Muni-Pomadze, Owabi Wildlife Sanctuary, Sakumo and Songor. The regulations make provision for declaration of closed seasons and the designation of core areas, authorized activities, proscribed activities

[3] For a discussion of the IPPC, see Chapter 2, Part III.
[4] For a discussion of the CBD, see Chapter 2, Part VI.

and restricted activities in the designated areas. The regulations also makes provision for offences for contravention of its provisions and prescribes penalties in the form of fines, imprisonment or both, depending on the gravity of the infraction. The Wild Life Division of the Ministry of Lands, Forestry and Mines is the responsible implementing authority for the regulations.

The draft Biosafety Act, 2004, is designed to domesticate the Cartagena Protocol on Biosafety.[5] The draft act is the outcome of consultations and surveys involving the major stakeholders in the public and private sectors as well as the general public. Its objectives are to ensure, in accordance with the precautionary principle, an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have an adverse effect on the environment; and to establish a transparent and predictable process to review and make decisions on GMOs and related activities.

The draft's 44 sections and four schedules address all the requirements for the implementation of the protocol. Among other things, the draft act creates an institutional framework, the National Biosafety Authority (NBA), a corporate entity with perpetual succession, with representation drawn from both the public and private sectors. The functions of the NBA are to:

- receive, respond to and to make decisions on applications under and in conformity with the act;
- establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and any other matters covered by the act; and
- promote public awareness, participation and education concerning the activities of the NBA under the act.

The draft act creates a regulatory regime with accompanying regulations to address the handling of permits, monitoring and enforcement, approvals and appeals, public participation and information and finance. Decisions on GMOs are to be based on science – risk assessment – and the procedure is set out in the fourth schedule to the act to ensure transparency and predictability.

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[5] For a discussion of the protocol, see Chapter 2, Part VII.

Taking cognizance of the fact that biosafety is a multi-institutional activity that cuts across several sectors, the draft act does not re-invent the wheel: it employs the services of the existing regulatory agencies in the Technical Advisory Committee (TAC). The functions of the TAC are to act as the national advisory committee on matters concerning or related to the genetic modification of organisms, carry out risk assessment of applications at the request of the NBA and advise, upon request or on its own accord, the minister, the NBA, the ministries and appropriate bodies on matters concerning the genetic modification of organisms.

The inclusion of the regulatory agencies in the TAC should help ensure the much-needed coordination and cross-sectoral management required in such a multi-institutional endeavour. It should also help to address the overlaps, conflicts and gaps in mandates of the various regulatory agencies that now operate within the TAC. This kind of arrangement has much to commend itself especially for developing countries that lack the requisite capacity to create new institutions to address *Biosecurity*. Indeed an examination of the current institutional arrangements for *Biosecurity* reveals overlaps and conflicts in the mandates of the various institutions whose functions have a bearing on the subject, a situation that impedes its smooth operation.

2.3. The institutional basis for *Biosecurity* in Ghana

Biosecurity issues are not the responsibility of one ministry, department or agency (MDA) of state. Indeed, several MDAs have responsibility for, or are engaged in, activities in this area. These include:

Ministry of Food and Agriculture
- *Crops Services Directorate*
- *PPRSD*
- *VSD*

Ministry of Health
- *FDB*

Ministry of Lands, Forestry and Mines
- *Forestry Commission (Wildlife, Forest Products Inspection, Forest Services, and Timber Export Development Divisions)*

Ministry of Local Government, Rural Development & Environment
- *Environmental Protection Agency (EPA)*
- *district, municipal and metropolitan assemblies*

Ministry of Finance
- *Quality Control Division of Cocoa Marketing Board*
- *Cocoa Research Institute*

Ministry of Trade, Industry, Private Sector and Presidential Special Initiatives
- *GSB*
- *CEPS*

Ministry of Tourism and Diasporean Relations
- *Ghana Tourist Control Board*

Ministry of Education
Ministry of Fisheries
Ministry of Foreign Affairs
Ministry of Justice
Ministry of National Security
Ministry of Water Resources, Works and Housing

Under the Constitution, the executive power of state is vested in the President (art. 58). The MDAs are part of the executive arm of government. Departments, agencies and institutions such as EPA and CEPS are the creatures of statutes, and their functions or mandates are provided for in the enactments that established them. The Constitution also makes provision for the establishment of the:

- Lands Commission;
- Minerals Commission;
- Forestry Commission;
- Fisheries Commission; and
- such other commissions as parliament may determine.

These commissions are entrusted with responsibility for the regulation and management of the utilization of the respective natural resources and the coordination of policies in relation to them (arts. 258 and 59). Parliament has since enacted appropriate legislation to establish these commissions and other regulatory bodies. Of these, the most relevant for present purposes are:

- FDB and GSB – responsible for food and related safety matters;
- VSD – responsible for animal health and related safety issues;
- PPRSD – responsible for plant health and related safety matters;

- EPA – responsible for environmental regulation, including safety matters;
- CEPS – responsible for ports and borders in collaboration with the other agencies; and
- district, municipal and metropolitan assemblies which work with the regulatory agencies at the local levels of governance especially in monitoring and enforcement at markets.

These institutions are responsible for the fulfilment of Ghana's obligations under the WTO SPS regime: the PPRSD is the mandated national plant protection organization; the FDB and GSB are responsible for the Codex Alimentarius and the WTO Agreement on Technical Barriers to Trade, respectively; and the VSD is the responsible agency for the OIE. The overall regulatory/coordinating body, however, is EPA.

Environmental Protection Agency (EPA)

EPA was established pursuant to the Environmental Protection Agency (EPA) Act, 1994 (Act 490). Among its functions is the issuance of environmental permits and notices for controlling the volume, types, constituents and effects of waste discharges; prescription of standards and guidelines relating to pollution of water; and enforcement of environmental standards including ensuring compliance with established environmental impact assessment (EIA) procedures in the planning and execution of projects.

In pursuance of these functions, EPA officers embark on inspections in hotels and other industrial establishments to ensure maintenance of prescribed effluent standards and standards of hygiene generally. An issue that has serious implications for food safety is the contamination of food, in particular pesticides residues in food. The subject is addressed by the Hazardous Chemicals Committee (HCC) established pursuant to Section 10 of the EPA Act. The duties of the HCC are to:

- monitor the use of hazardous chemicals by collecting information on their importation, exportation, manufacture, distribution, sale, use and disposal;
- advise the board and the executive director of EPA on the regulation and management of hazardous chemicals;
- perform such other functions relating to such chemicals as the board or the executive director may determine.

The subject of pesticides is further regulated under the Pesticides Management and Control Act, 1996 (Act 528). Under Section 17, no person shall import, export, manufacture, distribute, advertise or sell any pesticides except in accordance with a licence issued under the act. The licensing regime is under the overall management and control of EPA.

A related problem is that of certification of agricultural exports as being free from pesticide residues for purposes of gaining access to foreign markets. This is an issue of extreme importance in view of the fact that in recent times, Ghanaian agricultural produce has been rejected in Europe on account of high residue levels. To date, no regulations have been enacted pursuant to Act 528 either on pesticide residues in food or on certification of agricultural produce as being free from residues.

With regard to cocoa, however, which is Ghana's major export crop, the Cocoa Research Institute of Ghana (CRIG) has the requisite facilities for vetting the effectiveness, toxicity and possible residues of pesticides that has been applied. CRIG works in close collaboration with EPA on the subject. In the event of a disagreement between CRIG and EPA with respect to residues on cocoa, an application cannot be granted. The GSB and the Ghana Atomic Energy Commission may also veto the registration of a pesticide. As in the case of other agricultural produce, there is the need to embody these standards in subsidiary legislation pursuant to Act 528.

2.4. Conflicts, gaps and overlaps

The current institutional arrangements for *Biosecurity* are bedevilled with gaps, overlaps and conflicts in the mandates of the various institutions whose functions have a bearing on *Biosecurity,* as illustrated below.

At the borders, PPRSD officials carry out inspections of all imported goods thought to consist of plants and plant materials. The PPRSD has 44 entry points around the country where their personnel are located. CEPS officers, also stationed at the borders, are required to inform PPRSD if they notice any plant materials in imported shipments or baggage which they (CEPS) have inspected in the first instance. The effectiveness of this collaboration depends on the particular border post in question. At Kotoka International Airport, the two services work well together. At Tema Port (the major sea port) by contrast, large shipments of plant materials are released into the country without the PPRSD inspecting the shipments or even being informed that the

shipments have arrived. Another problem facing both CEPS and the PPRSD is that there are several unapproved entry points into the country.

As part of the efforts towards improving the management of the country's borders, the Government of Ghana has decided to enhance the capacity of the Ghana Immigration Service (GIS) to perform more efficiently and effectively its responsibilities with respect to the entry and exit of persons to and from the country. This will enable GIS to deal with cross-border and travel-related crimes with a high degree of accuracy and efficiency. As part of the measures, a Border Patrol Unit has been established to intercept any illegal entries into the country. The idea is to manage immigration as an integral part of the national development agenda. These measures require a much closer collaboration between GIS and the other regulatory agencies operating at the borders.

The Ghana Tourist Control Board (GTCB) established by the Tourist Board Decree, 1973 (NRCD 224), as amended by the Ghana Tourist Control Board (Amendment) Decree, 1977 (SMCD 80), has among its functions the registration, classification, licensing and control of standards in hotel accommodation and catering enterprises. In pursuance of this function, officials of the GTCB conduct periodic inspections of hotels and catering businesses to ensure compliance with its standards. There appears to be little co-ordination/co-operation between officials of the GTCB, public health officials and FDB officials. In view of the implications of these inspections for food safety, there is the need for close collaboration and overall coordination between the GTCB and these regulatory agencies.

The meat inspection function is a source of conflict/overlap between the veterinary services and the public health officers (PHOs) of the metropolitan and district assemblies. The meat inspection function has been exercised by PHOs by virtue of previous and current legislation on local government. Unlike these officials whose mandates are expressly provided for in LI 1615, no such specific mandate is accorded to veterinary officers in the area of meat inspections. As noted, both the FDB and the district/metropolitan assemblies (local government institutions) have statutory functions in meat inspection. The draft law seeks to divest these bodies of these functions and vest same in the VSD, but makes provision for the inclusion of inspectors from the district assemblies in the meat inspection function.

Ghana Standards Board and the FDB

The Ghana Standards Board (GSB) was established by the Standards Decree, 1967 (NLCD 199), as a body corporate with perpetual succession. NLCD 199 was repealed by the Standards Decree, 1973 (NRCD 173). NRCD 173 continued the existence of the GSB as a body corporate with perpetual succession. Section 3 of NRCD 173 provides for a wide range of functions and powers of the GSB including:

- recommending to the ministry responsible for industries to prohibit the sale or manufacture of goods in the national interest as well as in the interest of public health and safety;
- maintaining the necessary machinery to ensure that goods prepared and manufactured for export are distinctly marked for export only;
- providing for the issuance of a certificate to the effect that goods comply with known requirements or standards in the country to which they are to be consigned, before the export of such goods is permitted; and
- recommending to the ministry responsible for trade to prohibit the importation into Ghana for the purposes of sale, use or human consumption, any goods unless the same have been certified by the GSB as complying with standards set up by the GSB.

Section 9 of the decree gave the board of the GSB power to make, alter or rescind rules on a wide range of matters, including providing for the amendment or revocation of any standard. NRCD 173 was subsequently amended by AFRCD 44, with the addition of two specific functions on food to be exercised by the GSB, namely: prohibiting the sale or manufacture of foods in the national interest; and prohibiting the importation into Ghana of foods which have not been certified by the board as complying with its standards.

From the above it is apparent that the GSB, like the FDB, has statutory functions in the area of sale, manufacture, exportation and importation of foods. It is these provisions which have become a source of overlap/conflict between the GSB and the FDB, the latter of which was established in 1992 to control the manufacture, importation, exportation, distribution, use and advertisement of foods, drugs, cosmetics, chemical substances and medical devices.

Apart from the overlaps, the existing laws on standards are also deficient in matters such as low fines for offences and low licence fees. Furthermore, even though in practice the standards sought to be implemented under the law are based on international standards such as the Codex Alimentarius, there is no explicit reference to any of these standards in any of the existing legislation.

A draft standards bill has been proposed to address the foregoing and other defects in the existing legal regime for standards. The draft bill establishes a National Standards Authority (NSA) as a body corporate with perpetual succession and enhanced powers of acquisition of land.

The draft bill re-enacts the provisions on the functions of the GSB under NRCD 173 as amended by AFRCD 44. The specifications for standards to be prescribed under the law include "international or other overseas specifications." In view of the fact that the WTO has prescribed the TBT Agreement as the source of international norms/benchmarks for goods other than those prescribed by the Codex Alimentarius, explicit reference to WTO standards would be appropriate.

A thorny issue that the draft bill does not satisfactorily address is the competence/functions of the NSA in the area of foods *vis-à-vis* the FDB. Under Section 3(2)(c) of the draft bill, the NSA is authorized to prohibit, in the national interest, the sale or manufacture of any kind of goods. It also has power to prohibit the importation of goods that have not been certified by the authority as complying with its standards. The definition of "goods" is wide enough to encompass foods. 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 foods.

The draft bill in its fourth schedule repeals the Standards Decree, 1973. It, however, continues in force any statutory instruments in force under the prior decree. The import of this provision is that certain regulations affecting foods would continue to remain in force. This calls for amendments to be made to the regulations, to remove all references to food, otherwise there will continue to be overlaps with the FDB. Further, in line with GSB's policy of developing voluntary standards in conformity with WTO guidelines, there is the need for regulations on certification of goods when the goods have been prescribed to have health and safety implications for consumers.

III. THE GHANAIAN *BIOSECURITY* FRAMEWORK: CONCLUSIONS AND THE WAY FORWARD

Biosecurity has assumed great importance in the twenty-first century owing to rapid technological advances and increased international trade. The international multilateral treaty regimes, including the WTO and the CBD, have prescribed or endorsed rules to address the subject. This chapter has assessed the existing Ghanaian constitutional, institutional and legislative frameworks in light of the relevant international standards. The discussion on the legislative framework was conducted along two broad but inter-related headings: Ghana and the SPS regime; and the CBD and CBD-related instruments and Ghana. Several results emerge from the study.

In relation to the SPS regime, several pieces of legislation exist which address food safety, plant and animal health. They, however, fall short of the standards prescribed by the relevant international bodies – Codex, the IPPC and the OIE. With regard to the CBD and CBD-related instruments, no single piece of legislation addresses the subject; there are several pieces of sectoral legislation on fisheries, forestry, game and wildlife. Indeed, the challenge faced by the government is how to implement these standards effectively given the limited resources available. However, specific legislation has been enacted to domesticate the Ramsar Convention on Wetlands, and comprehensive draft legislation has been prepared for the implementation of the Cartagena Protocol on Biosafety.

Some attempts have been made to revise existing legislation on food safety, plant and animal health. The outcomes have not been satisfactory: the proposed drafts do not measure up to the international norms prescribed by the SPS regime or they have been overtaken by subsequent developments on the subject. The draft Biosafety Act, 2004, designed to domesticate the Cartagena Protocol, however, is comprehensive and meets the objects and requirements of the protocol. Its institutional arrangement, involving the employment of all the existing regulatory agencies under the aegis of the NBA, points to a way of resolving the conflicts, gaps and overlaps in the Ghanaian regime on *Biosecurity*.

Biosecurity is not the responsibility of one agency of state; it involves several ministries, departments and agencies. The regulatory framework for *Biosecurity* is multi-sectoral in nature, but without an overall coordinating

body in Ghana. As a result, the regime is bedevilled with overlaps, gaps and conflicts among and between the regulatory agencies.

The challenge faced by Ghana is thus not only one of enacting legislation consistent with the prescribed international norms, but also ensuring a coordination of the regime so as to eliminate the various gaps, overlaps and conflicts. Indeed the need to implement WTO standards apart from the health implications for the population has serious implications for trade between Ghana and the North as well.

Even though developing countries now have preferential treatment in terms of lower or zero tariffs and non-tariff barriers for their products, similar concessions cannot be gained over sanitary and phytosanitary standards which are regarded as highly sensitive in view of their health implications. Once the standards are in place, the only options are either to meet those standards and export accordingly or drop the idea of exporting altogether. At the end of the day, no consumer would buy any agricultural product that does not conform to prevailing standards. Indeed, no such concessions can be gained even under the preferential concessionary arrangements under the ACP (African, Caribbean and Pacific Group of States)/European Union framework.

Ghana should thus strive to implement WTO rules in domestic legislation, in large part because they constitute treaty obligations assumed under the WTO. There are, however, constraints, including limited technical, human and financial resources. These constraints could be addressed by a programme of capacity building, through international and donor collaboration with organizations such as the WTO, the United Nations Environment Programme, FAO and the World Health Organization.

In the development of an appropriate legal framework for *Biosecurity*, two institutional options, in the light of the analysis, are worthy of consideration: the creation of a new body at a higher level, for example, under the Presidency, to exercise an oversight and coordinating role over *Biosecurity*; and the use of existing or proposed coordinating frameworks to address the subject.

The creation of a new body at a high level of state such as the Presidency to ensure coordination of, or to exercise oversight responsibility over, *Biosecurity* accords the issue proper attention. It will also prevent ministries from vying

with one another for resources and power. The creation of a bureaucracy to deal with the subject, however, is likely to entail significant costs.

The other option would be to enhance the functions of the proposed NBA to deal with *Biosecurity* as a whole. In this regard, the composition and functions of the NBA, its TAC and inspectorate could be enhanced to include representation from other *Biosecurity* agencies not represented in the NBA, such as national security and the GIS. Such a measure would be cost-effective. Indeed, the regulatory framework provided for under the draft Biosafety Act provides, with the necessary modification, a means of ensuring the much-needed coordination and cross-sectoral management required in such a multi-institutional activity as *Biosecurity*.

This kind of arrangement has much to commend itself for application by a developing country like Ghana that faces constraints in the creation of a new institution to address *Biosecurity*. Since the legislation is still in draft there will not be the requirement for any amendment to effect the proposed changes. They could be incorporated in the draft for appropriate parliamentary action.

7

INDIA COUNTRY STUDY*

Contents

* This chapter was prepared by Roopa Madhav and Adil Hasan Khan.

I. REFERENCE TO *BIOSECURITY* IN INDIA

In recent years, reference has been made in two policy documents to the need to bring about comprehensive legislation dealing with *Biosecurity* in India. The first such document was the May 2004 Report of the Task Force on Agricultural Biotechnology.[1] The report advised the Government of India to prepare a *Biosecurity* Compact in order to deal with the following issues:

- invasive alien species;
- sanitary and phytosanitary measures to avoid mycotoxins, salmonella and other forms of infection in food;
- food, environment and biosafety relating to genetically modified organisms (GMOs); and
- bio-ethical considerations in research.[2]

The report recommends setting up a task for the preparation of such a *Biosecurity* Compact.

Most recently, the Revised Draft National Policy for Farmers, issued in October 2006, includes among its ten major goals strengthening the "*Biosecurity* of crops, farm animals, fish and forest trees for safeguarding both the work and income security of farmer families, and the health and trade security of the nation".[3] The document calls for the creation of the National Agricultural *Biosecurity* System (NABS), with the following aims:

> "Safeguard the income and livelihood security of farmer families, as well as the food, health and trade security of the nation, through effective and integrated surveillance, vigilance, prevention and control mechanisms designed to protect the productivity and safety of crops, farm animals, fishes and forest trees."

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[1] *Report of the Task Force on Application of Agricultural Biotechnology,* by M.S. Swaminathan, Chairman, Task Force on Agricultural Biotechnology, May 2004 [hereinafter *Task Force Report*].

[2] *Id.*

[3] See Revised Draft National Policy for Farmers, *Serving Farmers and Saving Farming: Jai Kisan,* National Commission on Farmers, Ministry of Agriculture, Government of India, October 2006.

> "Enhance national and local level capacity in initiating proactive measures in the areas of monitoring, early warning, education, research, control and international cooperation."
>
> "Introduce an integrated *Biosecurity* package comprising regulatory measures, education, improved sanitary and phytosanitary measures and social mobilization."
>
> "Organize a coordinated National Agricultural *Biosecurity* Programme on a hub and spokes model, with effective home and regional quarantine facilities capable of insulating the major agro-ecological and farming systems zones of the country from invasive alien species of pests, pathogens and weeds as well as from the introduction and release of GMOs".[4]

Biosecurity was also added as an area of cooperation under the US-India Agricultural Knowledge Initiative in June 2006, which aims to address the issue, starting with threat posed to crops by invasive alien species up to averting the release of bio-agents of mass destruction.[5]

II. *BIOSECURITY* LAWS IN INDIA

India has a plethora of laws which deal with *Biosecurity* but it needs to be noted that they do not stem from an understanding of the term. The pieces of legislation have been enacted with differing objectives and public concerns in mind. Though disparate and scattered, these pieces of legislation serve an essential function in specifically addressing the sectoral concerns, and they carry forth the intent contained in the preambles. Likewise, the institutions, though numerous, have been established to serve the purposes of the original enactments.

2.1. Constitution of India

Though there is no specific reference or use of the term *Biosecurity* in the Constitution of India, a number of its provisions are of relevance to understanding the legal framework dealing with *Biosecurity* in the country. The Constitution is also the key to understanding how the general legal set-up works.

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[4] *Id.*

[5] See Fifth U.S.-India Agricultural Knowledge Initiative Board Meeting, Joint Deliverables, Washington, D.C., 14–15 June 2007, available at www.fas.usda.gov.

2.1.1. Directive Principles of State Policy

Part IV of the Constitution contains the Directive Principles of State Policy. Within these, article 47 is relevant and it, among other things, makes it the duty of the state to improve public health. Article 48 is also of relevance as it provides that the state shall endeavour to organize the agricultural and animal husbandry sectors on modern and scientific lines. Article 48A, which was inserted by the 42nd Amendment to the Constitution in 1976, requires the state to "protect the environment and to safeguard the forests and wild life of the country".

2.1.2. Fundamental rights

Part III of the Constitution of India contains the fundamental rights. Among these is the right to life, which is enshrined in article 21, and which has the most relevance for the legal framework for *Biosecurity*. Since the late 1970s, the Supreme Court, which is the highest court of the country, has progressively widened the scope of the rights granted under this article. This has been achieved by giving an expansive interpretation of the term "life". As a result of judicial interpretation, the right to life has become a sort of repository of various human rights. Some of the pertinent rights thus included are:

- the right to health;
- the right to a healthy environment;
- the right to pollution-free water and air; and
- protection against hazardous industries.

2.1.3. Federal scheme

Since India has a federal Constitution, it necessarily provides for a division of power and functions between the centre and the federal units (states). The Indian federal system leans slightly in favour of the centre while keeping a federal pattern and framework. The Constitution has created three functional areas regarding law-making by the two components of the federal system. These are:

- an exclusive area for the centre called the Union List;
- an exclusive area for the states called the State List; and

- a common or concurrent area in which both the centre and the states may operate simultaneously, though with the centre having overall supremacy, called the Concurrent List.

The relevant article of the Constitution in this regard is article 246, which creates this scheme of division and flexible sharing. The actual lists are provided in the seventh schedule of the Constitution. As far as *Biosecurity* is concerned the relevant entries are:

List I – Union List
Entry 28. Port quarantine, including hospitals connected therewith.
Entry 51. Establishment of quality standards for goods to be exported out of India or transported from one state to another.

List II- State List
Entry 6. Public health and sanitation; hospitals and dispensaries.
Entry 14. Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases.
Entry 15. Preservation, protection and improvement of stock and prevention of animal diseases; veterinary training and practice.

List III- Concurrent List
Entry 17A. Forests.
Entry 17B. Protection of wild animals and birds.
Entry 18. Adulteration of foodstuffs and other goods.
Entry 29. Prevention of the extension from one state to another of infectious or contagious diseases or pests affecting men, animals or plants.

2.1.4. International law

As per article 253 of the Constitution, the Indian Parliament has been given the power to enact any law to implement the international treaties, conventions or agreements entered into with other countries or even decisions made at any international conference, association or other body. This power is not affected by the subject matter of the legislation. That is, if India becomes a party to any international convention, parliament can enact a law to effectuate its obligations under the same, even if the subject matter of the enactment is specifically one that, according to the lists, falls within a different domain.

However, it must be kept in mind that the parliament's power to legislate in respect of an international treaty entered into by the state is not unlimited and is limited by other constitutional restrictions, e.g. fundamental rights.

2.2. Food safety

2.2.1. Legislation

Food Safety and Standards Act, 2006

The Food Safety and Standards Act consolidates the laws governing the food sector. The act 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 FSSAI shall 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 act defines "food" to mean any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum and any substance, including water, used in the food during its manufacture, preparation or treatment (sect. 3(j)).

Section 3(s) states that the "Food Safety Management System" means the adoption of Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), Hazard Analysis and Critical Control Point (HACCP) and such other practices as may be specified by regulation, for food businesses.

The FSSAI is to be assisted by several scientific panels and a central advisory committee in laying down standards for food safety and in its overall functioning. These standards will include specifications for ingredients, contaminants, pesticide residues, biological hazards and labels. The act empowers State Commissioners of Food Safety and other local-level officials to implement the law.

Every entity in the food sector is required to get a licence or registration from local authorities. Every distributor is required to be able to identify any

food article by its manufacturer, and every seller to identify any food article by its distributor. Any entity in the sector is bound to initiate recall procedures if it finds that the food sold has violated specified standards. The Commissioner of Food Safety (CFS) of each state, through food safety officers (FSOs), enforces the standards.

The act prohibits the use of food additives, processing aids, contaminants, heavy metals, insecticides, pesticides, veterinary drugs residue, antibiotic residues or solvent residues unless they are in accordance with specified regulations. Certain food items such as irradiated food, genetically modified food, organic food, health supplements and proprietary food cannot be manufactured, processed or sold without adhering to specific regulations.

For a specific district, the CFS of each state appoints a Designated Officer (DO), not below the level of Sub-Divisional Officer, whose duties include issuing or cancelling licences, prohibiting sale of food articles that violate specified standards, receiving reports and samples of food articles from FSOs and getting them analysed. The DO also has the power to serve an "improvement notice" on any food operator and suspend his or her licence in case of failure to comply with such a notice. The DO also investigates any complaint made in writing against FSOs. FSOs are appointed for a specified local area and their duties include taking samples of food articles, seizing food articles that are of suspect quality or inspecting any place where food articles are stored or manufactured.

The act has special provisions for food recall procedures. If a food business operator (i.e. anyone owning or carrying out a business relating to food) considers that a food item is not in compliance with the specified standards, he or she has to initiate procedures to withdraw the food in question and inform the competent authorities.

The act provides for a graded penalty structure where the punishment depends on the severity of the violation. Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food causing injury are punishable with imprisonment.

Prevention of Food Adulteration Act, 1954, and Rules, 1955

The Prevention of Food Adulteration (PFA) Act was enacted with the objective of assuring the quality and safety of food as well as encouraging fair trade practices. In effect, the statute sought to protect the consumer from the supply of adulterated food by specifying food safety and quality standards for consumer protection. The state governments and the union territories are responsible for monitoring and implementation of the provisions of the PFA Act and Rules.

According to the rules, no person shall manufacture, sell, store or distribute adulterated or misbranded food products not conforming to the prescribed standards. These standards apply to imported food as well as food domestically produced.

The institutional set-up under the PFA Act includes local food inspectors and public analysts, both at the municipal and state levels, their laboratory facilities, the four central food laboratories designated under the PFA Act and the central PFA Division under the Ministry of Health and Family Welfare (MOHFW). The Central PFA Division is also designated the National Codex Contact Point for India.[6]

The PFA Act provides for the inspection and certification of imported food. It prohibits the import of food which is adulterated, misbranded or which contravenes the provisions of the PFA Act or Rules. The important provisions which are required to be followed essentially while importing/clearing the food products are:

- authorized officers check imported food products;
- the custom collector checks imported food products; and
- authorized officers, on suspicion, may detain any imported food product and send the samples to the Central Food Laboratory for analysis.

MOHFW has prescribed maximum tolerance limits for pesticides and heavy metals in food products under the PFA Rules. MOHFW has also notified draft rules to amend the PFA Rules to regulate the sale and import of

[6] See Chapter 2, Part V for a discussion of the Codex Alimentarius Commission and Codex standards.

genetically modified or genetically engineered organisms obtained through modern biotechnology and to ensure mandatory labelling of all such products. The purpose is to provide correct information to consumers about the nature of food they purchase for consumption.

Essential Commodities Act, 1955

The Essential Commodities Act has been enacted to protect the interests of the general public through the control of the production, supply and distribution of and the trade and commerce in certain commodities. Section 3 of the act empowers the central government to issue control orders for regulating production, distribution, quality, movement and licensing pertaining to essential commodities. Similarly, exercising the powers delegated under the act, the state governments have issued a number of control orders to regulate various aspects of trading in essential commodities such as food grains, edible oils, pulses, kerosene, sugar, etc.

Other orders

Several orders were issued under Section 3 of the Essential Commodities Act addressing registration of manufacturers, hygiene in production, labelling and other requirements for specific foods. These include the Vegetable Oil Products (Regulation) Order, 1998, the Milk and Milk Products Order, 1992, the Meat Food Products Order, 1973 and the Fruit Products Order, 1955.

Export (Quality Control and Inspections) Act, 1963

The Export Act provides for the sound development of the export trade of India through quality control and inspection. It establishes the Export Inspection Council of India (EICI), which shall, *inter alia*, advise the central government regarding measures for the enforcement of quality control and inspection in relation to commodities intended for export.

Section 6 empowers the central government to (a) notify commodities that shall be subject to quality control or inspection; (b) specify the type of quality control or inspection to be applied to a notified commodity; (c) establish, adopt or recognize one or more standard specifications for a notified commodity; (d) prohibit the export of notified commodities that do not satisfy the quality control or inspection.

Bureau of Indian Standards Act, 1986

The Bureau of Indian Standards (BIS) is a statutory autonomous body set up by this enactment. It comprises members representing industry, consumer organizations, scientific and research institutes, technical institutions, central ministries, state governments and members of parliament.

The BIS provides for quality certifications. It has two kinds of certification schemes: (a) product certification; and (b) management systems certification. The product certification scheme has the primary objective of ensuring quality, safety and dependability for consumers, The scheme, although essentially voluntary, has been made mandatory for certain products such as drinking water, food colours and additives.

The management systems certification (MSC) activity of the BIS consists of a series of activities aimed at assessing the capability of an organization's management systems such as:

- Quality Management Systems – IS/ISO 9001: 2000;
- Environmental Management Systems – IS/ISO 14001: 2004;
- Occupational Health and Safety Management Systems – IS 18001: 2000;
- Food Hygiene – Hazard Analysis and Critical Control Point System – IS 15000: 1998; and
- the combination of two or more systems (integrated management systems).

The MSC activity provides third-party certification to organizations. The Indian Standard on Food Hygiene is technically equivalent to the Codex document on the subject (Codex ALINORM 97/13A).

The Ministry of Commerce and Industry (MOCI) has designated BIS as the enquiry point under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).[7] According to the TBT Agreement, the Enquiry Point issues notifications on proposed technical regulations and certification systems in India to the WTO in Geneva.

[7] See Chapter 2, Section 2.2 for a full description of the TBT Agreement

2.2.2. Institutions

In India, international standards, guidelines, and recommendations are increasingly used to guide domestic as well as international trade. (a) The Directorate General of Health Services (DGHS) in the MOHFW is working to integrate Codex standards into food laws as much as possible. (b) The EICI, the official certification body for exports, is developing standards for exports based mainly on Codex, but it also takes into account that an importing country may impose stiffer requirements. (c) The Codex HACCP and food hygiene standards have been adopted by the BIS. (d) As seen earlier, inspection and certification in India have a regulatory basis under the Export Act of 1963.

The main system of inspection and certification being followed by the EIC in the food sector is food safety management systems-based certification (FSMSC). The FSMSC is aligned with international standards on GMP, GHP and HACCP.

In addition to certifying food products in compulsory areas, the EIC also certifies other products for exports with a focus on the food sector. With the concept of equivalence having been recognized in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[8] as well as being encouraged at the international level by the Codex Alimentarius Commission, the EIC is emphasizing developing equivalence agreements on conformity assessment with its major trade partners.

The processed food exports from the country are handled by two apex-level agencies, namely the Agricultural and Processed Food Export Development Authority and Marine Products Export Development Authority. The Ministry of Food Processing Industries (MOFPI) is the nodal central government entity proactively involved with the food processing industry in regard to macro policy issues and planning for the sector.

MOFPI is in charge of the implementation of various food safety and quality concerns codified in numerous acts and other government measures. For example, the Fruit Products Order, 1955, promulgated under Section 3 of the Essential Commodities Act, prescribes minimum norms for sanitary and hygienic conditions of manufacturing premises and also lays down product

[8] See Chapter 2, Section 2.1 for a full description of the SPS Agreement.

standards. It is closely associated with the Codex Contact Point in the country, namely the Directorate General of Health Services.

With regard to genetically modified (GM) food, several central ministries and departments are involved in India's programme of food quality and safety and hence each one of them has a role to play in the activities related to GM foods in India. These include:

- the Ministry of Environment and Forests. This ministry holds the Secretariat of the Genetic Engineering Approval Committee, the apex body that gives approval for manufacture, sale, import and export of all genetically modified organisms (GMOs) and products thereof, including foodstuffs and additives using GMOs or cells;
- the Department of Health in the MOHFW. This department is responsible for implementation of the PFA Act under which the quality and safety of food is regulated;
- the Indian Council of Medical Research (ICMR). This is the apex body in India for the formulation, coordination and promotion of biomedical research under the MOHFW. ICMR acts as an advisory body for MOHFW on various issues including GM foods;
- the Ministry of Agriculture. This ministry comprises three departments, namely the Department of Agriculture and Cooperation, Department of Agricultural Research and Education/Indian Council of Agricultural Research (ICAR) and Department of Animal Husbandry and Dairying;
- MOFPI. This ministry supports the active participation of industry in the laying down of food standards as well as their harmonization with international standards. This ministry is also the licensing authority for processed fruits and vegetable industries; and
- MOCI. This ministry formulates the export policy of the country.

The Central Committee of Food Safety, a legal body under the PFA Act, the Central Fruit Products Advisory Committee and the concerned apex export promotion institutions under the MOCI regularly interact to update and amend existing domestic food laws.

As laid out in the transparency clause (art. 7) and further elaborated in Annex B of the SPS Agreement, the Trade Policy Division (TPD) of MOCI has been designated as the national notification authority (NNA) for the country. The NNA coordinates with different concerned ministries and departments for appointment of enquiry points.

Imported food is inspected at the ports of entry by personnel of the Collectorate of Customs. The Government of India through its various departments – Health, Revenue, Commerce and the Directorate General of Foreign Trade – has initiated several steps to streamline the checking of imported food. As noted earlier, the EICI is the official government inspection body certifying food products for exports.

2.2.3. Evaluation

Within the Indian context, the food safety legislative instruments are presently disparate, with several subordinate rules, regulations and orders having been enacted to deal with contingencies as and when they arose. The operative legislation, the Prevention of Food Adulteration Act, seeks to test only end products, and does not ensure the adoption of the principles of HACCP throughout the food chain.

The new enactment – the Food Safety and Standards Act, 2006, though not operational – seeks to incorporate HACCP principles. In seeking to consolidate these legislative instruments into one combined whole, it is a serious attempt at harmonizing legislation to comply with international standards. Some flaws in the legislation may be pointed out here. Both the organized as well as the unorganized food sectors are required to follow the same food law. The stringent norms relating to specifications, traceability and recall procedures are also extended to the informal food economy in the country. This may adversely affect street food sellers and stalls. The act excludes plants prior to harvesting and animal feed from its purview and hence does not control the entry of pesticides and antibiotics into the food at its source.

2.3. Animal health

2.3.1. Legislation

Among the pieces of central legislation the following are the main ones:

Wild Life (Protection) Act, 1972

The Wild Life (Protection) Act seeks to protect wild animals, birds and plants with a view to ensuring ecological and environmental security. Although this enactment does not specifically deal with the issue of animal health, two specific sections dealing with the preventive aspects of wildlife

health are worth noting. Section 32 states that no person shall use chemicals, explosives or any other substances which may cause injury to or endanger any wildlife in any wildlife sanctuary. Section 33A, introduced by an amendment to the act in 2000, mandates that the Chief Wildlife Warden shall take measures for the immunization against communicable diseases of livestock kept in or within five kilometres of a sanctuary.

Livestock Importation Act, 1898

The Livestock Importation Act, which was amended in 2001 by the Livestock (Importation) Amendment Ordinance, provides for the regulation of the import of livestock which is liable to be affected by infections or contagious disorders. The central government may regulate, restrict or prohibit any stock which may be liable to be affected by infectious or contagious disorders and any fodder, drug, stable-litter, clothing harness or fittings appertaining to livestock (sect. 3). The act empowers customs officials to act as though empowered under Section 11 of the Customs Act, 1962.

Section 3-A specifically states that the central government may by notification "regulate, restrict or prohibit in such manner and to such extent as it may think fit, the import into the territories to which this act extends or 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 other items as well as on the powers and duties of those they appoint.

2.3.2. Institutions

The Ministry of Environment and Forests (MEF) and the Ministry of Agriculture (MOA) are the key ministries in charge of animal health concerns regarding domesticated animals. The Department of Animal Husbandry and Dairying has been given the task of monitoring and coordinating the various institutions that are engaged with animal health. MEF is entrusted with the task of protection of wildlife health in sanctuaries and wildlife parks. Each state government has the power to protect the health of animals within its own boundaries and has been empowered by state enactments to set up quarantine stations and to test for diseases. In case epidemic outbreaks, 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 mandate of the animal quarantine and certification services within the MOA is to prevent the entry of livestock diseases into India by regulating the import of livestock and livestock-related products, and providing export certification for livestock and livestock products which are exported from India.

In order to provide referral services over and above the existing disease diagnostic laboratories in the states, one central and five regional disease diagnostic laboratories have been set up to strengthen the existing facilities. The Centre for Animal Disease Research and Diagnosis of the Indian Veterinary Research Institute, Izatnagar, is functioning as the central laboratory.

2.3.3. Evaluation

With regard to animal health, there is a need for a more effective centralized authority to monitor and coordinate the various activities of the state authorities. More effort at border control and monitoring is also needed. Further, there is need for a more sustained effort to ensure that the wildlife protection laws are strengthened to ensure protection of wildlife parks and sanctuaries and wildlife habitats.

2.4. Plant health

2.4.1. Plant quarantine legislation

Destructive Insects and Pests Act, 1914

The Destructive Insects and Pests Act is a pre-independence law which continues to regulate the introduction and movement of any insect, fungus or pest which could be destructive to crops. It has gone through several amendments over the years.[9]

Under the act, the central government can prohibit or regulate the import into India of any insects or articles (or classes thereof) likely to cause

[9] See Destructive Insects and Pests (Amendment) Act, 1930; Destructive Insects and Pests (Amendment) Act, 1938; Destructive Insects and Pests (Amendment) Act, 1939; Destructive Insects and Pests (Amendment and Validation) Act, 1992.

infection to crops, by issuing a notification in the gazette (sect. 3(1)). The act further empowers the government to regulate the transport of insects or articles likely to cause infection to crops from one state in India to another (thus providing for domestic regulation) (sect. 4(a)). The act also empowers state governments to make rules for specific purposes in order to aid the central government in fulfilment of the main tasks of preventing the spread of these pests (sect. 4(a)).

Plant Quarantine (Regulation of Import into India) Order, 2003

With this new Plant Quarantine Order, agricultural imports into India are now classified into one of the following categories and have to follow these procedures for import:

- *prohibited plant species*: These are plants/planting materials and countries from which import is prohibited. Justifications for the same are listed in Schedule IV (cl. 3(2));
- *restricted species*: These are plants and plant materials the import of which into India is restricted and permissible only with the recommendation of an authorized institution and an import permit with an additional declaration and special conditions as provided under Schedule V of the order (cl. 10(1)). Phytosanitary certification has to accompany the consignment as well (cl. 10(2));
- *species requiring additional declarations and special conditions*: The same as above except that no recommendation is required from issuing authorities; and
- *plant material imported for consumption or industrial processing*: These are plants/planting materials for which imports are permissible on the basis of a phytosanitary certificate, an inspection conducted by inspection authority and treatment as may be required (cl. 3(1)).

As per clause 14(1) of the order, 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 this order in the public interest. The powers for relaxing conditions of import permits and phytosanitary certificates for one-time exception have been delegated to officers in charge of plant quarantine stations.

(a) Permits

The notable feature of the order is that it has brought about a strict permit regime. An import permit is rather simply defined as "an official document authorizing the importation of a consignment in accordance with specified phytosanitary measures" (cl. 2(x)). No consignment of items regulated under the order is allowed into the country without a valid permit (cl. 3(1)).

Valid import permits can only be issued by the permit-issuing authorities, which are listed in Schedule X of the order. Distinct import permits are to be issued for special products, e.g. live insects and microbial cultures (cl. 7) and germplasm, transgenic or GMOs (cl. 6).

(b) GMOs

The order also seeks to regulate the import of GMOs of plant origin for the purpose of agricultural research or experimentation (cl. 6(1)-(3)). Such an import would require a permit to be issued by the Director, National Bureau of Plant Genetic Resources (cl. 6(1)). These permits will be issued subject to the approval of the Genetic Engineering Approval Committee (GEAC) or the Review Committee on Genetic Manipulation (RCGM), as the case may be (cl. 6(2)).[10] However, the order clearly provides that this does not cover imports for commercial purposes, which are governed by separate clearances.[11]

(c) IPPC: compliance and derogation

The order purports to promote harmony with the International Plant Protection Convention (IPPC)[12] through the following:

- phytosanitary measures under the order are to be based on justified scientific principles with pest risk analysis (PRA) as their cornerstone. The definition adopted for PRA is the same as that in

[10] See Section 1.7.

[11] Clause 8(3) provides that "bulk shipment(s) of transgenic plants or plant products or genetically modified organisms shall be dealt as per the provisions of the Rules for manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells made under [Sections 6, 8 and 25 of the Environment (Protection) Act]".

[12] See Chapter 2, Part III for an explanation of the IPPC.

the IPPC. As per clause 3(7), the guidelines for PRA have to be based on the standards established by the IPPC;

- the inspection and certification provisions (cl. 3, 8 and 10) under the order are in compliance with the requirements of article IV of the IPPC;
- under the definitions in the order, phytosanitary certificates are defined as "certificates issued in the model format prescribed under the IPPC and issued by an authorised officer at country of origin of consignment or re-export" (cl. 1(xix)). Article V of the IPPC is complied with in this regard;
- the restriction placed on the entry of certain plants and planting material by the order (cl. 3(14)) is in compliance with requirements for the same under the IPPC (art. VII (2)(d));
- the order is freely accessible to all, with a copy being available on the website of the national plant protection organization; and
- as per the notifications issued by the WTO Committee on Sanitary and Phytosanitary Measures, the order is "in line with the International Standards of Phytosanitary Measures of the [IPPC]".[13]

Plant Quarantine Bill, 2004

The Plant Quarantine Bill sought to establish the Plant Quarantine Authority of India (PQAI). The PQAI would be specifically established to meet India's obligation under the IPPC to establish a central regulatory agency for plant protection, a national plant protection organization. The bill seeks to bring about a comprehensive regulatory framework for prevention of the spread of quarantine pests both domestically as well as outside national boundaries. The bill seeks to finally repeal the Destructive Insects and Plants Act.

2.4.2. Pesticide legislation

Insecticides Act, 1968

Another relevant piece of legislation regarding plant health is the Insecticides Act and the rules framed thereunder. This legislation and its rules seek to ensure the availability of quality, safe and efficacious pesticides to the farming community and to manage risks to human health and the environment.

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[13] WTO Committee on Sanitary and Phytosanitary Measures Notification No. G/SPS/N/INDIA/12, 4 March 2004.

The act seeks to regulate the import, manufacture, sale, distribution, use and transport of insecticides (including herbicides, fungicides, rodenticides, etc.). The Ministry of the Agriculture (MOA) is the relevant ministry under the act. The Central Insecticides Board and Registration Committee along with the Directorate of Plant Protection, Quarantine and Storage in the MOA are the authorities concerned with the registration requirements and other related matters.

2.4.3. Seed legislation

Seeds Act, 1966

The relevant Indian enactment for seeds is the Seeds Act. This act provides for the regulation of the quality of only certain seeds, which are to be notified by the central government (sects. 5, 7). The main institution brought into being by this act is the Central Seeds Committee, which is constituted by the central government (sect. 3(1)). The primary function of this committee is to advise the central and state governments on matters arising out of the administration of this act (*id.*).

A relevant aspect to be kept in mind with regard to this act is that authorities created under it are entitled to act only in the case of seeds sold for agricultural purposes and not for human consumption. The relevant enactment for the latter is the Essential Commodities Act, 1955.

Seeds Bill, 2004

The Seeds Bill, 2004, is proposed as a replacement for the Seeds Act, 1966. As per Section 12 of the bill, all kinds and varieties of seeds have to be registered in the National Register of Seeds. No seed can be sold (for the purpose of planting) unless it is registered (sect. 13). The designated body for registration is the registration sub-committee (which comes under the Central Seeds Committee) (sect. 12).

One of the most controversial and for our purposes relevant provisions of the Seeds Bill is Section 15 which provides in effect for registration of transgenic seeds under the bill and as a result thwarts existing biosafety regulations.

For *Biosecurity* purposes, Section 18 provides the grounds for exclusion of certain varieties of seeds from registration. The grounds for such exclusion are if:

- "prevention of commercial exploitation of such kind or variety is necessary to protect public order or public morality or human, animal or plant life and heath, or to avoid serious prejudice to the environment" (sect. 18(1)); and
- it is "a kind of variety of seed containing any technology, which is harmful, or potentially harmful" (sect. 18(2)).

Section 36 of the bill deals with the import of seeds and it provides for the compulsory registration of all imported seeds (although the government may allow the import of an unregistered seed for research purposes). Further, all imports of seeds "shall be subject to the provisions of the Plants, Fruits and Seeds (Regulating of Import into India) Order, 1989, or any corresponding order made under Section 3 of the Destructive Insects and Pests Act, 1914".

2.4.4. Evaluation

Some basic themes emerge in an analysis of the plant quarantine framework in India. The Destructive Pests and Insects Act, 1914, along with the Plant Quarantine Order, 2003, seek to deal with this rather complicated issue. In certain areas there are obvious shortcomings while in others the current set-up can be said to be a success.

The obvious shortcomings of the Destructive Pests and Insects Act, 1914, are that its definition of plant protection is limited to crops – defined to include all agricultural and horticultural crops and all trees, bushes or plants – which leaves out any sort of protection for other areas, e.g. forests.

None of the enactments deal with the issue of exports and phytosanitary certification for exports. Thus, in case of exports the requirement of phytosanitary certification is not mandatory. This has resulted in cases where exporters have ended up exporting articles without seeking the requisite certification, due to an unawareness on their part of such a facility existing or an unwillingness to obtain the same. Some consignments have been returned, causing a loss of faith in Indian exports. Under the current set-up, officers notified under Notification 8-97/91-PP.I issued by the Ministry of Agriculture

(Department of Agriculture and Cooperation) on 26 November 1993, are authorized to inspect, fumigate or disinfect and grant a phytosanitary certificate.

The fact that the existing certification process might not be performing adequately is clear from the circular issued by the Ministry of Agriculture to the certificate-issuing authorities in May 2006, which pointed out a number of cases where although phytosanitary certifications had been issued by such authorities to certain consignments, these consignments had been rejected by the countries of import on phytosanitary grounds.[14] This theme of non-compliance with the existing framework and inability of the existing machinery to follow the letter of the law runs throughout India's *Biosecurity*-related legislation and the regulatory framework it creates.

With regard to monitoring imports of regulated articles, the frequent updating of the Plant Quarantine Order, 2003, suggests that the concerned department prioritizes this regulatory area. However, India does not seem to have put in place an adequate mechanism. For the system to work with a certain degree of competence, it has to put in place a paperless system that feeds into the existing national network of connected computer servers for customs purposes. A comprehensive border monitoring mechanism should also be put in place.

2.5. Invasive alien species

2.5.1. Legislation

The enactment of the Biological Diversity Act, 2002, was necessitated by virtue of India's signing and ratifying the Convention on Biological Diversity (CBD).[15] Though the CBD provides sufficient latitude to its members to pursue distinct approaches to national biodiversity laws, India chose to adopt the route of having stand-alone legislation on biodiversity.

With regard to *Biosecurity*, the Biological Diversity Act, 2002, only has limited relevance. To begin with, there is no provision in the act to deal with invasive alien species (IAS). In fact, no mention is made of these species throughout the legislation.

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[14] See *Circular Issued to Export Certification Authorities*, F. No. 18-53/2005-P.P.I (Pt.), Government of India, Ministry of Agriculture (Department of Agriculture and Cooperation), 2 May 2006, available at www.plantquarantineindia.org.

[15] See Chapter 2, Part VI for a full description of the CBD.

With regard to living modified organisms (LMOs), Chapter IX contains a very general provision which encumbers the central government to take measures "to regulate, manage and control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health" (sect. 36(4)(ii)).

Apart from these provisions, rather 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" (sect. 36(1)) and to integrate these goals of conservation and sustainable use of biological diversity into "relevant sectoral, and cross-sectoral plans, programmes and policies" (36(3)).

Under Section 38, the central government may also notify certain threatened species and "prohibit or collection thereof for any purpose and take appropriate steps to rehabilitate and preserve those species". Finally, Section 40 gives the central government the power to exempt certain biological resources from the provisions of the act, including "biological resources normally traded as commodities".

2.5.2. Institutions

The Biological Diversity Act, 2002, sets up a whole institutional framework for the protection and sustainable utilization of biodiversity in the country. These include the National Biodiversity Authority, State Biodiversity Boards in every state and Biodiversity Management Committees at local levels. This three-tier institutional framework and the relevant roles and responsibilities are further dealt with and elaborated in the Biological Diversity Rules, 2004.

2.5.3. Evaluation

The lack of adequate domestic regulation to protect biodiversity is an issue of great concern. The seriousness of the problem is compounded by the fact that India is a biodiversity-rich country with numerous agro-economic zones. The lack of domestic regulation is often blamed on the unwillingness of the state governments to comply with any strict regulations in this regard and the inadequacy of the existing enforcement machinery.

The issue of IAS for forest areas is not dealt with under the regulatory framework in place. The general view seems to be that this issue is a concern of the Ministry of Environment and Forests (MOEF) and should be dealt with by that ministry (possibly under the set-up created by the Biological Diversity Act).

2.6. Biosafety

For biosafety, the regulatory framework consists of rules issued in 1989 by the MOEF under the Environment Protection Act, 1986. These have been revised by guidelines issued in 1990, 1994 and 1998 (issued *vide* Rule 4(2) of the aforementioned rules). The fact that these were brought in place even before the Rio Summit in 1992 which adopted the CBD shows that India was one of the pioneers in this regard.

The 1990 Recombinant DNA Safety Guidelines and the 1994 Revised Guidelines for Safety in Biotechnology contain detailed guidance on containment and safe laboratory practices for GMOs in both the agricultural and pharmaceutical sectors. The 1998 Revised Guidelines for Research in Transgenic Seeds, Plants and Plant Parts, on the other hand, apply only to GMOs used in the agricultural sector.

The 1990 guidelines made one fundamental change from the 1989 rules *vis-à-vis* their treatment of the deliberate treatment of GMOs. Whereas such a release was permitted only under special circumstances under the rules (para. 9(1)), the guidelines permit them while focusing on assessing and managing possible environmental and health risks (para. 9).

2.6.1. Institutions

These rules and guidelines have put in place "multi-layered decision-making structures". What this means in practice is a multitude of bodies which come under two different ministries. The structure involves six different bodies which come into play over the four different phases a biotechnology product or organism has to undergo.

The first phase is pre-research, where the appropriate body is the Recombinant DNA Advisory Committee, which is constituted by and based in the Department of Biotechnology (DBT) of the Ministry of Science and Technology and is in charge of giving pre-research approvals. The second phase is the research phase for which the appropriate authority is the RCGM,

which is also constituted by and based in the DBT and which is charged with monitoring the research and experimental release of biotechnology products and organisms. A monitoring and evaluation committee (MEC) comprising scientists, agricultural experts and other officials nominated by relevant ministries has been formed under the RCGM.

The next phase is commercial release, which comes under the purview of the GEAC, which is constituted by and based in the MOEF and gives approval for such release from an environmental perspective. The last phase is post-release which involves the MEC, the State Biotechnology Coordination Committee and the District Level Committee. Apart from this, the Institutional Biosafety Committee is charged with implementing and monitoring safeguards at the research and development sites (under the supervision of the post-release-phase bodies).

2.6.2. Legislation

Shift from case-by-case to event-based approval

Until June 2006, the GEAC was following a "case-by-case" approval process for genetically modified (GM) crops. Under this system, every GM hybrid/variety had to undergo a minimum of three years of official trials before being approved. On 30 June 2006 as per a decision of the GEAC,[16] an "event-based approval system" has been put into place instead, which is supposed to speed up the whole process. An "event" refers to a specific gene construct that can be incorporated in a number of existing hybrids or varieties.

Import of GM products

On 7 April 2006, the regulation of importation of GM products was provided for under the Foreign Trade Policy, 2004–2009. MOCI, through the Directorate General of Foreign Trade, notified new regulations for import of GM products by amending Schedule I (Imports) of the ITC (HS) Classification of Export and Import Items under Section 5 of the Foreign Trade (Development and Regulation) Act, 1992. As a result of this notification:

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[16] Decision taken in the 69th meeting of the GEAC held on 30 June 2006, available at www.envfor.nic.in

> "The import of GMOs/LMOs for the purpose of (i) R&D; (ii) food; (iii) feed; (iv) processing in bulk; and (v) for environmental release will be governed by the provisions of the Environment Protection Act, 1986, and Rules, 1989.
>
> The import of any food, feed, raw or processed, or any ingredient of food, food additives or any food products that contain GM material and are being used either for industrial production, environmental release or field application will be allowed only with the approval of the GEAC.
>
> Institutes/companies who wish to import GM material for R&D purposes will submit their proposal to the RCGM under the DBT."[17]

Crucially, it is further provided that all GM 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.[18] These conditions were, however, kept in abeyance for three months via a notification issued by the Director General of Foreign Trade on 4 May 2006.[19] The United States filed notifications with the WTO the same month against this regulation,[20] seeking clarifications about the amendments and hinting at initiating action against India under the TBT and SPS Agreements.

Apart from this, the provisions of the Plant Quarantine Order, 2003, are applicable for the import of transgenic seeds (not for commercial purposes).[21]

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[17] Condition 18(a), (b) and (c) of Chapter 1A (General Notes Regarding Import Policy), Schedule-I (Imports) of the ITC (HS) Classifications of Export and Import Items, 2004–2009, inserted *vide* Notification No. 2 (RE-2006)/2004-2009, New Delhi, 7 April 2006, available at exim.indiamart.com.

[18] *Id.* Condition 18(d). This offers the crucial distinction between the 1989 Rules and these conditions, since such a declaration at the point of entry was totally voluntary under the rules. See Decision taken in the 66th meeting of the GEAC held on 2 May 2006, available at www.envfor.nic.in.

[19] Notification No. 4 (RE-2006)/2004-2009, New Delhi, 4 May 2006, available at dgft.delhi.nic.in.

[20] G/TBT/N/IND/12, 17 May 2006 and G/TBT/N/IND/17, 23 May 2006.

[21] See Section 1.5.1.

2.6.3. Evaluation

Though the existing rules and guidelines seek to delineate the various functions of the institutions in place, certain grey areas exist. Thus, while RGMC is supposed to administer experimental research and the GEAC supervises the deliberate release of transgenic crops, the question arises regarding under which function field trials would fall. Public interest litigation filed by a non-governmental organization forced amendments to the 1998 Biosafety Guidelines in September 1999 to the effect that the RCGM is now authorized to approve small experimental field trials for research.

A serious shortcoming of the existing regulatory set-up is that it fails to take into account other existing legislation concerning biotechnology. This includes: (a) the Seeds Act; (b) the *Biosecurity* Regulations (c) the Biodiversity Act; (d) the Protection of Plant Varieties and Farmers Rights Act; and (e) the Prevention of Food Adulteration Act.

To replace the GEAC with an autonomous statutory body, a National Biotechnology Regulatory Authority, along the lines of India's Atomic Energy Regulatory Board, is under discussion. The recommendation to create this authority was first made by the Task Force on Agricultural Biotechnology (chaired by M.S. Swaminathan) in its report of May 2004.[22] This call was repeated in the National Biotechnology Development Strategy, which was prepared by the DBT in 2005.[23] However, it must be borne in mind that no such demand for reform had emanated from the MOEF, which is the ministry responsible for the GEAC.

Some critical aspects need to be kept in mind while evaluating India's legal regulatory setup for biosafety *vis-à-vis* the requirements under the Cartagena Protocol on Biosafety.[24] India's existing regulatory framework is considered to be strict and one that provides for all adequate safeguards. This has meant that India has not been required to reform this set-up in order to bring about compliance with the Cartagena Protocol. The coming into force of the protocol has been considered an event that legitimizes the existence of the present framework. However, it must be pointed out that current Indian law does not provide any procedure for an advance informed agreement.

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[22] This task force was set up by the Ministry of Agriculture. See *Task Force Report, supra* note 1.
[23] See *National Biotechnology Development Strategy, Department of Biotechnology* - Ministry of Science and Technology, Government of India, launched on 31 March 2005.
[24] For a discussion of this instrument, see Chapter 2, Part VII.

The stringent nature of the regulatory framework when compared with international standards can be gauged by the requirement of agronomic analysis (socio-economic analysis) to be a part of the procedure of risk assessment (along with the usual ecological and human health safety evaluations).[25] This requirement is unique and is in addition to any framework generated solely under the Cartagena Protocol.

There is broad agreement that the aspect of biosafety that requires close inspection and lengthy deliberation concerns the ability to actually bring into effect the regulatory mechanism put in place on paper. There are three shortcomings in the Indian context in this regard: (i) the basic lack of technically trained manpower and adequate machinery (both quantitatively as well as qualitatively); (ii) lack of interest in strictly enforcing the laws in place. The regulatory framework tends to prefer being pragmatic (in the sense of flexibility) rather than being strict, a tendency that can be noted in other areas examined in this chapter as well. It appears that extraneous concerns weigh heavily on decisions as to enforcement of the regulatory system. (iii) There is also a perceptible lack of coordination in the system in place, with various ministries contending for a greater role in the process.

Of particular relevance for the previous point is that the Biosafety Clearing-House mechanism provided for under article 20 of the Cartagena Protocol has been established and is functioning in India. In this regard the MOEF is currently implementing a Global Environmental Facility/World Bank-funded project on capacity building in the context of the protocol. One of the areas where capacity is sought to be developed in this context is the strengthening of the legislative framework and operational mechanisms.

III. CONCLUSIONS

This analysis of the *Biosecurity* legal framework has been undertaken applying the FAO definition of *Biosecurity*.[26] The primary elements that constitute *Biosecurity* cover the introduction of plant pests, animal pests and diseases and zoonoses, the introduction and release of GMOs and their products and the introduction and management of IAS and genotypes.

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[25] See Guideline 6 of the Revised Guidelines for Research in Transgenic Plants, 1998.

[26] *Biosecurity in Food and Agriculture*, FAO Committee on Agriculture, 17th Session, Rome, 31 March–4 April 2003, available at ftp.fao.org/unfao.

The concept of *Biosecurity* being nascent, evolving as it is with progress in science and technology, it has not been incorporated as an integrated whole into legislation in India. So the approach here is essentially piecing together sectoral pieces of legislation that have a different historical background, in an attempt to test their feasibility against emerging concerns around *Biosecurity*. At the outset, therefore, it is important to acknowledge this limitation and the essential pitfalls in rereading the enactments with a different prism.

The *Biosecurity* legal framework of India is presently evolving. The existing framework on sectoral issues relating to *Biosecurity*, both on the statute books and the institutional structures, is both disparate and elaborate. This review sets out to map this elaborate framework, keeping in mind the historical context and continuing relevance. It also alludes to the proposed changes to the existing framework and the newer pieces of legislation that are on the drawing board of the relevant legal departments.

The challenges for implementation of the *Biosecurity* regime in India are immense, given the size and geographical variations within the country. Lack of trained manpower and the resources for scientific research are additional challenges that loom large. In some of the other countries that have undertaken a similar exercise, there is a suggestion to consolidate existing legislation and create a single agency to deal with *Biosecurity* concerns. However, this approach needs more careful consideration in the Indian context. The motivations behind the existing legal framework and the focus of work of the respective institutions differ vastly. Besides, the *Biosecurity* concerns do not necessarily override the pre-existing purposes behind the sectoral legislative instruments and the institutions set up under them. An altogether new legal framework, with institutions tailored to carry out the tasks of protecting and promoting *Biosecurity* within the delimitations of their respective mandates, could perhaps be a more effective approach.

It may be stated that currently, there is no clear indigenous understanding of the concept of *Biosecurity*. The draft National Policy for Farmers, put together by the National Commission on Farmers, refers to a "National Agricultural *Biosecurity* System", which discusses the concept at some length. The approach contained in this document is narrower than the definition adopted by FAO in its COAG document.[27]

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[27] See *id.*

More importantly, the concept of *Biosecurity* needs to be viewed more broadly from the perspective of public policy on health, environment and sustainable development. Evolving international standards are driven by interests that may not be consistent with a broader *Biosecurity* approach.

The various standards that are being prescribed to ensure *Biosecurity* provide a broad template for compliance. However, the politics behind the standard setting are of equal importance. Standards and technical regulations for *Biosecurity* may be viewed from the two different intents with which they are put in place. The two primary purposes are: the promotion of trade, and the promotion of public policy objectives. Although there are several fundamental differences between them, they both depend on the same quality assurance institutions and are governed by many of the same legal regimes. Although many of the weaknesses that exist in these institutions and legal regimes do not create problems in the context of trade promotion, they do create problems in the context of public policy promotion.

Finally, it is important that the focus of legislation, including legislation dealing with *Biosecurity* concerns, be directed towards protecting and conserving the environment, and ensuring the health of the country's people, flora and fauna. While trade concerns are important and should run a parallel course, there is an urgent need to keep the focus on the broader concerns as expressed in CBD and the Rio Declaration, particularly the fundamental rights to clean environment, food, health and life.

8

KENYA COUNTRY STUDY*

Contents

* This chapter was prepared by Patricia Kameri-Mbote.

I. INTRODUCTION

This chapter is divided into three parts. After this introduction, part II lays out the normative and institutional framework for *Biosecurity* in Kenya. It looks at the constitutional basis for *Biosecurity*, SPS-related and food safety laws and institutions and laws on biodiversity and biosafety.

Part III analyses the adequacy of the *Biosecurity* framework and notes that there are overlaps that need to be addressed. It is clear that Kenya has considered the need to synergize the *Biosecurity* framework. The establishment in 1996 of the Kenya Plant Health Inspectorate Service (KEPHIS), a parastatal agency under the Ministry of Agriculture, began a process of bringing the phytosanitary aspects of *Biosecurity* under one rubric. This process is still ongoing. Similarly, the promulgation of a framework environmental law, the Environmental Management and Coordination Act (EMCA) in 1999, and the establishment of the National Environment Management Authority (NEMA) as a coordinating institution under it, is a further step towards coordinated performance of *Biosecurity* functions.

It is, however, a matter of concern that the Biosafety Bill is still in draft form and genetic modification activities in Kenya have been proceeding only on the basis of draft regulations prepared in 1998. Part IV comprises a conclusion and recommendations where the basic issues for consideration in reviewing and framing a national *Biosecurity* legal and institutional framework in Kenya are outlined.

II. *BIOSECURITY* LAWS IN KENYA

Although Kenya has a host of statutes dealing with *Biosecurity*, it is notable that the purposes of these acts are as varied as the acts themselves. The framework environmental law, the EMCA, for instance, establishes the legal and institutional framework for the management of the environment and for matters connected and incidental thereto as its main purpose. The Biosafety Bill for its part has as its main objective ensuring an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have an adverse effect on the environment; and to establish a transparent and predictable process to review and make decisions on such GMOs and related activities. While it is not clear whether the GMO bill is promulgated under

EMCA, it is clear that EMCA's mandate extends to biosafety. In discussing the legal framework, therefore, we divide the laws into three categories.

The first category comprises laws that provide the context within which *Biosecurity* occurs. This includes the Constitution. The second category addresses SPS-related and food safety laws. The third category analyses laws related to biodiversity management and biosafety.

2.1. Constitutional anchorage for *Biosecurity*

Kenya's Constitution does not contain explicit *Biosecurity* provisions. It does, however, place importance on the right to life, and experts argue that the right to life encompasses the right to a clean and healthy environment.[1] It protects individual fundamental rights and freedoms which are relevant to ensuring the integrity of biological resources and food safety. These include the right to life and the right to the protection of the law, which appear in Chapter V of the Constitution. These rights provide the necessary context for implementing *Biosecurity*. It is instructive to note that the Constitution also provides for the right to sue and therefore provides a means of ensuring *Biosecurity* through legal interventions.

The stalled constitutional review process was expected to define a more explicit constitutional basis for securing environmental integrity. All the drafts generated during the process explicitly required the state to "ensure the respect and integrity of natural processes and ecological communities, including conservation of habitats and species; ensure sustainable exploitation, utilization, management and conservation of the environment and natural resources and the equitable sharing of the accruing benefits; and prevent pollution and ecological degradation" (draft Proposed National Constitution of 2005, sect. 87). The drafts also included explicit provisions on the right to a healthy environment. Section 88 provides that every person has a duty to:

(a) ensure ecologically sustainable development and use of natural resources;
(b) respect, protect and safeguard the environment;
(c) prevent or discontinue an act which is harmful to the environment;

[1] *Environmental Management in Kenya: A Guide to the Environmental Management and Coordination Act* (G.M. Wamukoya and F.D.P. Situma, eds.), Centre for Research and Education in Environmental Law, Nairobi, 2000.

(d) direct the appropriate authority to take measures to prevent or discontinue an act or omission which is harmful to the environment; and
(e) maintain a clean, healthy and safe environment.

Section 89 on conservation of the environment provides that in the utilization and management of the environment, the state shall protect genetic resources and biological diversity; establish systems of environment impact assessment, environment audit and monitoring of the environment; and ensure that the environmental standards enforced in Kenya are in harmony with accepted international standards. An institutional framework, the National Environment Commission, was also provided for in the drafts to oversee the implementation of these provisions (sect. 92). All these provisions have implications for *Biosecurity* in Kenya and provide the context within which it is anchored.

Even though the constitutional review process is yet to be completed, it is noteworthy that the provisions on the environment are not among the contested ones.[2] It is expected that when the review process is completed, these provisions will be part of a new Constitution.

2.2. Sanitary- and phytosanitary-related legislation

Sanitary and phytosanitary (SPS) measures are measures that protect human, animal and plant health. Kenya has a number of laws that deal with these measures by regulating animal and plant health, food safety and related issues of packaging, importation, exportation, manufacture, distribution and use thereof. The following laws are in place:

- Seeds and Plant Varieties Act (Chapter 326), 1972;
- Plant Protection Act, (Chapter 324), 1962;
- Pest Control Products Act, (Chapter 345), 1983;
- Suppression of Noxious Weeds Act, (Chapter 325), 1986;
- Animal Diseases Act, (Chapter 364), 1972; and
- Cattle Cleansing Act, (Chapter 359), 1937.

One discernible factor in these laws is the overlapping mandates of regulatory agencies. Indeed, in 2003, an attempt was made to come up with

[2] Report of the Committee of Eminent Persons, 2006.

one law amalgamating the Seeds and Plant Varieties Act, Plant Protection Act and the Suppression of Noxious Weeds Act. This idea was abandoned but it is expected that once the revision of the Seeds and Plant Varieties Act is completed, the other statutes will need to be amended to align their objectives with those of this act as well as to consolidate the roles of KEPHIS in the phytosanitary area.

2.2.1. Plant health

Seeds and Plant Varieties Act (Chapter 326), 1972

The Seeds and Plant Varieties Act deals with, among other things, the imposition of restrictions on the introduction of new seeds and plant varieties; the importation of seeds; and the prevention of injurious cross-pollination.

The regulatory agents under the act include the minister for the time being responsible for agriculture, seed analysts and KEPHIS. Established under the provisions of State Corporations Act (Chapter 446), 1996, KEPHIS is responsible for implementing phytosanitary and quarantine measures. It is the national focal point for SPS. The roles of KEPHIS include:

- coordinating all matters relating to crop pests and disease control;
- establishing service laboratories to monitor the quality and levels of toxic residues in plants as well as their soils and produce;
- advising the Director of Agriculture on appropriate seeds and planting materials for import and export;
- undertaking inspection, testing, certification, quarantine control, variety testing and description of seeds and planting materials;
- undertaking grading and inspection of plants and plant produce at the ports of entry and exit;
- enforcing standards for good husbandry and the control of pests and diseases;
- developing and implementing standards on both imported and locally produced seeds;
- approving all importation and exportation licences for plants and seeds issued by the ministry responsible for commerce and industry before such importation or exportation is implemented;

- implementing the national policy on the introduction and use of genetically modified (GM) plant species, insects and micro-organisms and regulating imports of GM seeds; and
- establishing posts at convenient locations for quarantine, inspection and quality control of fertilizer and seed, and monitoring agricultural inputs and their environmental effects.

To enable it to discharge its duties under the bill, KEPHIS is granted the power to appoint seed inspectors, seed analysts and plant examiners.

With respect to seeds, the minister is required to consult representatives of the organizations having a substantial interest in the matter being regulated (sect. 3). Seed regulations under both the draft bill and the current act seek to control and regulate seed production, processing, testing, certification, and marketing by:

(a) ensuring that reliable and adequate information is afforded as to the nature, condition and quality of seeds intended for sale;
(b) preventing the sale of seeds which are deleterious, which have not been produced in specified conditions, which have not been tested for purity or germination or which are of a variety of which the performance has not been subjected to trials;
(c) requiring the registration and/or deregistration of persons growing any specified crop for the main purpose of seed production, or of persons selling any seed;
(d) supporting plant inspectors in preventing the spread of plant diseases by seeds;
(e) providing for seed certification, processing, sampling, testing and marketing;
(f) regulating the descriptions under which seed is sold;
(g) regulating, controlling or prohibiting the import or export of seeds;
(h) charging fees for services rendered by KEPHIS under the act or the Seed Regulations;
(i) prescribing the national obligations for seed crops; and
(j) providing for the filing of appeals.

These regulations may also address packaging, bags, trays or other containers in which seeds may be sold as well as the requirements for the marking of such containers; prohibit the selling of uncertified seeds; and require seed dealers to maintain records on seed transactions. Furthermore, KEPHIS has power

under the draft bill to limit the importation of seeds in certain situations, such as where the seeds are unsuitable in Kenya because they are of a type developed in countries with different climatic or other conditions (sect. 15).

In order to maintain the purity of seeds, KEPHIS is further given the authority under the draft bill to restrict the growing of seeds in any area in Kenya in order to isolate them from crops that might cause injurious cross-pollination.

Plant Protection Act (Chapter 324), 1962

The Plant Protection Act makes provision for the prevention of the introduction and spread of diseases destructive to plants. Pests are defined as any animal or vegetable organism inimical to the growth or existence of living plants or injurious to plant products and any other agent capable of producing a communicable disease of plants (sect. 2). The main regulatory agents under the act are the minister for the time being responsible for agriculture and inspectors who comprise the Director of Agriculture and any other persons authorized by the director, mainly from KEPHIS.

Under the act, inspectors are authorized to enter any land or building other than a dwelling house for the purpose of discovering pests or diseases in any plants, upon informing the occupier or owner (sect. 5).

The minister can order a prohibition or restriction or can regulate the importation and exportation of any plants and the soil, packages, coverings or wrappings thereof and any other article, animal or insect likely to infect any plant with any pest or disease. In carrying out this role, the minister is authorized to and has made rules for a variety of measures which can be taken (sect. 3).

Owners and occupiers of land are obligated to take the measures required by the minister and which are reasonably necessary for eradicating, reducing or preventing the spread of any pest or disease (sect. 4). Persons who knowingly introduce any pest or disease into any cultivated land or who wilfully obstruct or interfere with an inspector are guilty of an offence (sect. 7).

The minister may, if he or she thinks fit, order compensation to be paid out of public funds to any person whose plants or other articles are destroyed pursuant to the act (sect. 6). The main compliance mechanism established

under the act is through the use of criminal sanctions (sect. 9). Inspectors are insulated against any suit, prosecution or other legal proceeding for anything done in good faith and without negligence (sect. 10).

Pest Control Products Act (Chapter 345), 1983

The Pest Control Products Act regulates the importation, exportation, manufacture, distribution and use of products intended for the control of pests and of the organic function of plants and animals. Under Section 5, the act establishes the Pest Control Products Board (PCPB) whose functions include:

(a) assessing and evaluating pest control products;
(b) considering applications for registration of pest control products; and
(c) advising the minister on all matters relating to the enforcement of the provisions of the act and its regulations (sect. 6).

The enforcement of regulatory mechanisms established under the act is the responsibility of inspectors and analysts. Under Section 8 of the act, the minister responsible for agriculture is obligated to appoint suitably qualified persons as inspectors and analysts. Inspectors have the power to enter any place or premises for the purposes of carrying into effect any of the provisions of the act; in instances where they reasonably believe a pest control product to which the act applies is or has been manufactured, stored, sold or used; and where they reasonably believe there is material that is contaminated by a pest control product or which is used or capable of being used in the manufacture of a pest control product.

They also have power to examine any pest control product or material found in any place or premises or to open any package found in the premises which they believe contains any pest control product or material and take samples thereof; require any person to produce books, shipping bills, bills of lading, documents containing instructions or other documents or papers relevant to the performance of their duties, for the purpose of obtaining copies or extracts (sect. 9). Inspectors have the power to seize and detain any pest control product in the performance of their duties and may, under the orders of the court or with the consent of the person in possession of the products, dispose of the product (sect. 10).

Any person who refuses entry to an inspector acting under this section or obstructs him or her in making an entry or inspection or who, without reasonable excuse, fails to produce any pest control product or material for examination or any required document, is guilty of an offence (sect. 9(4)). The main compliance mechanism established under the act is criminal sanctions (sect. 12).

Suppression of Noxious Weeds Act (Chapter 325), 1986

The Suppression of Noxious Weeds Act provides that the minister of agriculture may by notice in the gazette declare a plant to be a noxious weed in any area, which may consist either of the whole of Kenya or of one or more districts or portions thereof.

Local authorities are empowered under Section 10 to make by-laws for securing the eradication of any noxious weed from land within their areas; for compelling owners or occupiers of land to cause any such weed to be eradicated from their land; and for such purposes, by-laws may appoint inspectors.

The act also creates the office of the inspector (a person authorized in writing by the Director of Agriculture to perform the duties of an inspector under this act in an area specified by the director, and a person appointed by or under by-laws made by the relevant local authority). The inspector may at all reasonable times enter upon land for the purpose of ascertaining whether any noxious weed or other weed exists thereon.

If an inspector finds upon land within a declared area any plant which has been declared to be a noxious weed, he or she may, by notice in writing to the person responsible for the land, require that person to clear the land of the noxious weed within a time specified in the notice. The notice shall state the particular noxious weed which has been found upon the land, and, as far as practicable, the portion or portions of the land on which the noxious weed has been found. If the person responsible fails to clear the land within the time specified in the notice, an inspector may, upon receiving a written authority from the director, enter, with or without assistance, upon the land and eradicate any noxious weed found there. Any expenses incurred in eradication shall be a civil debt recoverable summarily from the person responsible at the suit of the director. Failure to comply with this notice is an offence under the act.

2.2.2. Animal health

Animal Diseases Act (Chapter 364), 1972

The Animal Diseases Act provides for matters relating to the diseases of animals. It covers stock, ruminating animals, dogs, cats, rabbits and captive wild animals. Persons possessing animals infected with a notifiable disease (defined in Section 2 of the act) are required to keep the animal tied up in an enclosed place separate from uninfected animals.

The Director of the Veterinary Services Department (VSD) under the Ministry of Agriculture is to appoint inspectors for the purpose of implementing the provisions of the act. The director is empowered at Section 5 to declare any area "an area infected by a notifiable disease"; "to extend, diminish or alter … an area declared to be an infected area"; to "declare an infected area to be free from a notifiable disease"; and to "prohibit the movement of animals from one … area to another".

Once an area is declared to be infected:

- no stock shall be moved from or into it without the director's written permission;
- no animal shall be moved from the area unless it has been disinfected and treated in the manner required by the director;
- all stock in the area shall be herded as far as possible from any public road and shall not graze on any road reserve;
- the director may require the owner or person in charge of the animal to isolate the animal from other animals within the infected area or to remove the animal from the area;
- no person shall leave any such area without having complied with such reasonable precautions for preventing the spread of the notifiable disease as may be required by the veterinary officer or inspector in charge of the area; and
- the carcasses of all animals infected with the notifiable disease shall be disposed of in accordance with general or specific instructions issued by a veterinary officer or inspector.

Section 8 allows the director to prohibit for such time as he or she thinks necessary, or to regulate, the importation or exportation of all animals or any specified kinds of animals, or of carcasses, meat, hides, skins, hair, wool,

litter, dung, semen, live viruses capable of setting up infections in animals, sera, vaccines and other biological or chemical products intended to be used for the control of animal diseases.

Under Section 14, the director or inspector has power to enter any land, building, shed, van, truck or other premises or container to search for infected animals or their products such as meat, carcasses and hides. Subsidiary legislation under the act elaborates rules on issuance of permits, tests required and certification for importation and movement of animals; infected areas; and prevention of spread of diseases. Under the act, rules dealing specifically with birds; foot and mouth disease; rinderpest; and pig diseases have been promulgated. It is an offence punishable by law for any person to contravene the provisions of the act.

Cattle Cleansing Act (Chapter 359), 1937

The Cattle Cleansing Act provides for the cleansing of cattle. The responsibility for this is bestowed on the Minister of Agriculture as well as the Provincial Agricultural Board. Where the board has recommended to the minister that any area within that province should be a cattle cleansing area, the minister may, if he or she is satisfied that it will be of general benefit to the stock owners in the area, declare that area, or any part thereof, to be a cattle cleansing area.

Inspectors appointed under the act have the power and authority under Section 7 to inspect and count any cattle at any time. Further, a land owner in a cattle cleansing area on whose land cattle are kept is required to satisfy the inspector that there is adequate provision of facilities for the dipping or spraying of cattle and sufficient quantities of effective tick-destroying agents. It is unlawful under the act for any cattle owners to refuse or fail to submit their cattle for cleaning in accordance with the provisions of the act.

Under Section 10 of the act, where a land owner on whose land cattle are kept is absent from Kenya and does not have a representative or agent in Kenya with authority to carry out the terms of the act, any veterinary officer may authorize the due performance of these requirements. Any expenditure incurred in such circumstances shall be recoverable by the director as a civil debt.

2.2.3. Food safety

With respect to food safety, the relevant laws include:

- Food, Drugs and Chemical Substances Act (Chapter 254), 1970;
- Meat Control Act (Chapter 356), 1973;
- Standards Act (Chapter 496), 1974; and
- Public Health Act (Chapter 242), 1921.

Food, Drugs and Chemical Substances Act (Chapter 254), 1970

The Food, Drugs and Chemical Substances Act makes provision for the prevention of adulteration of food, drugs and chemical substances. Section 3 prohibits the sale of food containing anything poisonous or harmful; food that is unwholesome or not fit for human consumption, poisonous or which consists of filthy, putrid, disgusting, rotten, decomposed or diseased substances or foreign matter or which is adulterated. It is an offence under the act to label, package, treat, process, sell or advertise any food in a manner that is misleading or deceptive as regards its nature, value, substance, quality or composition (sect. 4).

Further, foods for which there are prescribed standards must conform to such standards, and labelling, packaging, selling or advertising such foods in a manner that misleads as to the conformity with the set standards is an offence (sect. 5). It is also an offence to sell, prepare, package, convey, store or display for sale any food under unsanitary conditions (sect. 7). The act makes it an offence to use or dispose of chemical substances in a manner likely to cause contamination of food or water for human consumption (sect. 24).

Subsidiary legislation under the act makes provisions for food hygiene, providing for licensing of premises used for sale, preparation, packaging, storage and display for sale of any food; prescribing conditions for growing and harvesting food; covering construction of food plants and facilities and other health measures to be taken in food plants. Subsidiary legislation under the act has addressed the issue of food labelling, additives and standards.

Meat Control Act (Chapter 356), 1973

The Meat Control Act provides standards for storage and transportation of meat and meat products intended for human consumption, slaughterhouses

and places where meat is processed, as well as import and export control over meat and meat products. Regulations made under the act require the licensing, control and regulation of slaughterhouses and premises where meat is processed for human consumption. They also specify standards to be observed, additives to be used and methods of packaging and labelling; require inspection of slaughterhouses and meat and meat products; and establish standards to be observed in storing and transporting meat and in transporting animals intended for slaughter.

The act is under the ministry responsible for veterinary services and some of the duties under it require consultation with the minister responsible for health. Moreover because it deals with meat for export, the ministry responsible for trade and industry is also a relevant player in the implementation of the act.

Standards Act (Chapter 496), 1974

The Standards Act is the main legislation on standards formulation and implementation in Kenya. Section 3 establishes the Kenya Bureau of Standards (KEBS), whose function, *inter alia,* is to make arrangements and provide facilities for the examination and testing of commodities and the substances used to manufacture, produce, process or treat them. In a nutshell, KEBS seeks to ensure the safety of products and ingredients.

Section 6 of the act creates the National Standards Council mandated to declare any specification or code of practice framed by KEBS to be a Kenyan standard. Members of the council include the Chair, public officers and other persons with knowledge of industrial or commercial standards (appointed by the minister responsible for trade).

The minister is empowered under the act to appoint inspectors who are mandated at all reasonable times to inspect and take samples of any commodity or material or substance being used in its manufacture, production, processing or treatment. They can also open containers.

KEBS works closely with three main public bodies in the development and implementation of health standards on animal and animal products, plant and plant products and food safety. These are KEPHIS, DVS and Ministry

of Health. KEBS is the contact point for the Codex Alimentarius Commission[3] and the International Organization for Standardization (ISO).

KEBS also has technical committees to deal with different issues and to assist in the development of standards. These committees comprise 12–15 members drawn from industry, regulatory authorities, the Weights and Measures Department, consumer organizations, institutions of higher learning, research organizations and non-governmental organizations.

KEBS is a member of the National Biosafety Committee and has a memorandum of understanding with NEMA.

Public Health Act (Chapter 242), 1921

The Public Health Act makes provision for securing and maintaining health. The act establishes a Central Board of Health (sect. 3), which is empowered to advise the Minister of Health on all matters affecting health. It contains provisions that ensure the protection of foodstuffs intended for human consumption (sects. 127–28). Another significant provision for food safety relates to the requirement that local authorities ensure that water supplies, food and milk are in good condition.

2.3. Biodiversity management and biosafety

Kenya ratified the Convention on Biological Diversity (CBD)[4] in 1994, which provided the impetus for the crafting of a framework environmental law to provide the normative and institutional anchorage for the conservation, sustainable use and equitable sharing of benefits emanating from biodiversity in consonance with the CBD's objectives.

2.3.1. Environmental Management and Coordination Act

The framework law, the Environmental Management and Coordination Act (EMCA), No. 8 of 1999, provides for the establishment of a legal and institutional framework for the management of the environment and for matters connected and incidental thereto. The promulgation of this act was aimed at ensuring that there was an overarching legal framework to guide environment

[3] For a discussion of Codex, see Chapter 2, Part V.
[4] For a discussion of this convention, see Chapter 2, Part VI.

management in the country and to provide coordination within and among the various sectoral laws and agencies dealing with environmental matters.[5] Section 3 of the act declares the right of every Kenyan to a clean and healthy environment as well as the corresponding duty to safeguard and enhance the environment. The entitlement to a clean and healthy environment includes access by any person in Kenya to the various public elements or segments of the environment for recreational, educational, health, spiritual and cultural purposes.

Section 5 lays out the principles of sustainable development which underpin the act. These are:

(a) the principle of *public participation* in the development of policies, plans and processes for the management of the environment;
(b) the *cultural and social* principles traditionally applied by any community in Kenya for the management of the environment or natural resources insofar as these are relevant and not repugnant to justice and morality or inconsistent with any written law;
(c) the principle of *international co-operation* in the management of environmental resources shared by two or more states;
(d) the principles of *inter-generational and intra-generational equity*;
(e) the *polluter-pays* principle; and
(f) the *precautionary* principle.

These principles undergird the attainment of *Biosecurity*.

Protection of the environment

EMCA provides for the protection and conservation of various ecosystems. For instance, it bars the introduction of animals whether alien or indigenous into lakes or wetlands (sect. 42(c)) or the deposit of any substance likely to have an adverse environmental effect on a river or lake (sect. 42(e)). To ensure sustainable management of such ecosystems, EMCA provides for the development of a management plan that addresses, among other issues, prevention and control of pollution, guidelines for access to and exploitation of resources and the overall management of biodiversity (sect. 42(3)).

[5] C.O. Okidi & P. Kameri-Mbote, *The Making of a Framework Environmental Law in Kenya,* ACTS Press, Nairobi (2001).

Section 50, dealing with the conservation of biological diversity, deserves special mention. It requires NEMA, the body charged with coordinating all matters relating to the environment in Kenya, to prohibit and control the introduction of alien species into natural habitats. It is expected that NEMA will issue guidelines on this function but this is yet to be accomplished.

NEMA is also mandated to issue guidelines for the sustainable management and utilization of genetic resources for the benefit of the people of Kenya. These include guidelines on access to genetic resources, the sharing of benefits derived from the genetic resources, biosafety measures necessary to regulate biotechnology and measures necessary to regulate the development, access to and transfer of biotechnology (sect. 53). Under this provision, NEMA has drafted two sets of regulations, some dealing with access to genetic resources and others dealing with biosafety. The former have not been promulgated while the latter informed the development of the draft Biosafety Bill which has not been finalized.

Environmental impact assessment

Environmental impact assessment (EIA) is a process which enables the examination, analysis, and assessment of proposed projects, policies or programmes and the integration of environmental issues into development planning in order to maximize the potential for environmentally sound and sustainable development. The EIA process, as argued by Hunter and others, should ensure that before granting approval (1) the appropriate government authorities have fully identified and considered the environmental effects of the proposed activities under their jurisdiction and control and (2) affected citizens have an opportunity to understand the proposed project or policy and to express their views to decision makers".[6]

EMCA identifies the areas in which an EIA must be carried out, which include biosafety.

Environmental audit and monitoring

Under EMCA, NEMA is charged with the responsibility of ensuring that environmental audits are carried out for all activities likely to have significant

[6] D. Hunter, et al., *International Environmental Law and Policy*, Foundation Press, New York, 2003, p. 367.

effects on the environment (sect. 68). It is also mandated to monitor all environmental phenomena with a view to making an assessment of any possible changes in the environment and the possible impacts; and the operation of any industry, project or activity with a view to determining its immediate and long-term effects on the environment (sect. 69). Under this mandate, NEMA can ensure plant and animal health by protecting the integrity of the environment which comprises their habitat.

Regulatory institutions

To ensure conformity with its provisions, EMCA puts in place an elaborate institutional framework. The National Environment Council (NEC) is a top policy-making body under the act charged with the responsibility of formulating policy on matters relating to environment management in Kenya, setting national goals and objectives and determining policies and priorities for the protection of the environment; and promoting co-operation among public departments, local authorities, private sector actors, non-governmental organizations (NGOs) and other organizations engaged in environmental protection programmes. Those who sit on the council include two representatives of public universities in Kenya, two representatives of specialized research institutions, three representatives of the business community and two representatives of NGOs active in the environmental field. As already noted, NEMA is the principal government institution responsible for the implementation of all policies relating to the environment.

The Public Complaints Committee (PCC) is set up under Section 31 of the act. It is investigates complaints relating to environmental damage and degradation generally and it has powers to investigate NEMA. It can also initiate investigations on its own without waiting for a complaint to be made. The mandate of the PCC is wide enough to cover animal and plant health. Some of the complaints that have been brought to the PCC include concerns about the introduction of alien species and their impacts on plant and animal health.

The National Environment Tribunal (NET) is established under Section 125 of EMCA. The tribunal is set up to hear appeals from administrative decisions taken by organs responsible for enforcement of the provisions of EMCA which encapsulate diverse aspects of plant and animal health

Established under Section 70 of EMCA, the Standards and Enforcement Review Committee is required, among other things, to advise NEMA on

water quality procedures and standards and discharge of effluents into the environment; air quality and emission standards; standards for waste disposal and management, hazardous waste, pesticides and toxic substances. These standards have direct and indirect implications for plant and animal health as well as food safety.

Compliance and enforcement mechanisms

EMCA contains provisions for compliance and enforcement, thus contributing towards the achievement of *Biosecurity*. These mechanisms include:

1. Environmental restoration orders requiring restorative action, preventing harm to the environment, payment of compensation for harm to the environment and levying charges commensurate with costs of restoring degraded environments (sects. 108–111).
2. Environmental easements for facilitating the conservation and enhancement of the environment through the imposition of obligations in the form of environmental conservation orders in respect of the use of land (preservation of flora and fauna; preservation of water flow, open space, scenic view among others) (sects. 112–115).
3. Fiscal incentives and disincentives to induce or promote proper management of the environment. These include customs and excise waivers, tax rebates, tax disincentives to deter bad environmental behaviour and user fees.
4. Criminal sanctions.

2.3.2. Biosafety legislation

The Cartagena Protocol on Biosafety[7] is a protocol to the CBD which has been ratified by Kenya. It had already become apparent during the negotiations for the CBD that further work was required towards a biosafety protocol.

Prior to the ratification of the protocol, Kenya had developed *Draft Regulations and Guidelines for Biosafety in Biotechnology for Kenya* in 1998 under the UNEP-GEF Pilot Project on the development of national biosafety frameworks. These were issued by the National Council for Science and

[7] For a discussion of this instrument, see Chapter 2, Part VII.

Technology (NCST) established under the Science and Technology Act, Chapter 250 (1977). They are the main instrument for regulating GMOs in Kenya to date and require that the release of GMOs be preceded by the approval of the National Biosafety Committee (NBC). Membership in the NBC includes representatives of relevant institutions (KEPHIS, NEMA, KEBS, DVS) and line ministries (environment, health, agriculture, education, science and technology). The Office of the Attorney-General is also represented, to provide advice on relevant emerging legal issues. The relevant regulatory authorities must undertake risk assessments, and thus require information from applicants such as a description of the GMOs and their intended uses in Kenya.

For crops, KEPHIS is the relevant authority, advising the NBC on whether or not to allow imports and what to do after the assessment. The guidelines provide that it is an offence to import GMOs without prior approval of the NBC. Penalties for offences under the biosafety regulations were left to be made by the minister. In order to do this the minister requires powers conferred upon him or her by an act of parliament. To date, this has not been done although there are some prescribed penalties in draft form under the proposed National Biosafety Bill.[8]

The main aim of the regulations is to enhance effectiveness in the use of new products and to ensure safety regarding human health and the environment. They require institutions carrying out work on genetic modification to establish institutional biosafety committees. These committees are required to advise their respective institutions on drawing up proposals that take cognizance of applicable biosafety measures and advise them on activities that should be brought to the attention of the NBC. The applicant is expected to make an application in the prescribed form detailing all information on the proposed work and send the form to the NCST as the secretariat of the NBC. The NBC should acknowledge receipt within 30 days and verify the information for completeness using a checklist, whereupon it may request additional information from the applicant within 60 days. Deliberation must be within 90 days and the decision to approve or deny approval communicated within 210 days.

[8] The proposed penalties may not achieve the desired goals as they are relatively lenient. For example, someone who imports GMOs without the advance informed agreement of the country of import may only be liable to a fine not exceeding fifty thousand shillings (about €530 at today's prices). Under such circumstances potential violators may find it convenient to commit the offence and pay the fine.

The NBC gives approvals for GMO events while KEPHIS gives permits where plant materials are involved. The NBC approval is predicated on the applicant satisfying phytosanitary conditions and getting a permit from KEPHIS. KEPHIS appoints technical experts to coordinate risk assessments on behalf of the NBC where plant materials are at issue.

There is also close collaboration between VSD and NBC. For instance, the application by a private company to use GM soya for piglets was referred to the NBC by VSD. Similarly, the PCPB referred to the NBC an application made to it regarding a GM biopesticide for use in rose farming.

The draft National Biosafety Bill is an attempt to give a firm legal basis to biosafety regulation in Kenya. It seeks to align the draft regulations with the Cartagena Protocol. The main objective of the draft biosafety bill, issued by the NCST under the Science and Technology Act within the auspices of the Ministry of Education, Science and Technology, is to ensure an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have an adverse effect on the environment; and to establish a transparent and predictable process for review and decision-making on such GMOs and related activities (sect. 4).

Section 5 establishes the National Biosafety Authority, the board of which comprises:

(a) a Chairperson, who shall be an eminent scientist, appointed by the minister responsible for science and technology matters;
(b) three other members comprising experts in biological, environmental and social sciences;
(c) the Permanent Secretaries in the ministry responsible for science and technology and the Ministry of Finance;
(d) the Director-General of NEMA;
(e) the Managing Director of KEBS;
(f) the Managing Director of KEPHIS;
(g) the Director of VSD;
(h) the Secretary to the National Council for Science;
(i) the Chief Public Health Officer;
(j) the Director of Agriculture; and
(k) a representative of the consumer information network.

The functions of the authority as enumerated under Section 7 include to:

(a) receive, respond to and make decisions on applications under the bill;
(b) establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and other matters covered by the bill;
(c) establish contact and maintain liaison with other countries and organizations dealing with biosafety;
(d) establish a database for the purpose of facilitating collection and dissemination of information relevant to biosafety;
(e) identify national requirements for manpower development and capacity building in biosafety;
(f) maintain a directory of experts in biotechnology and biosafety;
(g) keep a record of biotechnology and biosafety activities in Kenya;
(h) advise institutions and persons on mitigation measures to be undertaken in case of accident; and
(i) promote awareness and education among the general public in matters relating to biosafety.

The authority is further granted powers 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 authority:

(1) contained use involving GMOs;
(2) introduction of GMOs into the environment;
(3) importation and placing of GMOs into the market; and
(4) transportation of GMOs through Kenya.

Any decision made by the authority is subject to review upon the request of a regulatory body or any applicant in situations where new scientific information relating to biosafety of the GMOs is discovered or there has been a change of circumstances. Any applicant who, having knowledge of such information, withholds it from the authority, commits an offence under the bill. Furthermore, failure to adhere to any of the requirements on approvals constitutes an offence.

Any person aggrieved by any decision made by the authority has the right of appeal to an Appeals Board established under Section 26 of the bill. It is also noteworthy that the bill identifies regulatory agencies responsible for different issues. These are contained in the first schedule and include the

Ministry of Health, VSD, KEBS, KEPHIS, the Kenya Industrial Property Institute, the Kenya Wildlife Service, PCPB and NEMA. They are in charge of the following:

- monitoring of applicants' activities to ensure that they conform to the bill;
- informing the authority of any new information aimed at enhancing the continued safe use of GMOs; and
- inspecting and evaluating activities involving GMOs.

Biosafety inspectors are appointed by the minister responsible for science and technology, and are accorded a variety of powers. In addition to criminal sanctions, the draft bill anticipates the use of other means of redress or damage resulting from GMOs. It provides at Section 42 that "liability and redress for any damage that occurs, as a result of activities subject to this Act, shall be addressed by applicable laws". There is concern, however, that this provision is not adequate because the applicable laws predate biotechnology activities and may not cover all kinds of damage likely to arise from them.[9]

III. ANALYSIS OF ADEQUACY OF *BIOSECURITY* LEGAL FRAMEWORK

3.1. Institutional fragmentation and conflicting mandates

It is clear from the above analysis that Kenya has many laws dealing with *Biosecurity*. The challenge of implementation and coordination of the various laws however remains. At both the normative and institutional level, there are overlaps which create room for conflict. Additionally, many of these institutions may perform their duties within narrow confines and thus fail to consider national imperatives for cohesion and synergies.

From the analysis above, it is clear that the institutional basis for *Biosecurity* is dispersed among different ministries and institutions. These include:

1. Ministry of Agriculture
   - KEPHIS
   - PCPB

[9] P. Kameri-Mbote, *Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System*, East African Law Journal, 2004.

2. Ministry of Livestock Development and Fisheries
   - VSD
   - Department of Fisheries
3. Ministry of Health
   - Department of Public Health
   - Public Health (Standards) Board Central Board of Health
   - Central Board of Health
   - Medical Department
4. Ministry of Education, Science and Technology
   - NCST
   - NBC
5. Ministry of Local Government
   - Local authorities
6. Ministry of Trade and Industry (MOTI)
   - KEBS
   - National Committee on the World Trade Organization (WTO)
7. Ministry of Environment
   - NEMA
   - NEC
   - NET
   - PCC
8. Ministry of Finance
   - Customs and Excise Department, working with KEPHIS and KEBS at points of entry
9. Ministry of Justice
10. Ministry of Tourism.

To bring together the institutions responsible for different regulatory functions, a number of inter-ministerial coordinating committees have been established. For instance, there is an inter-ministerial committee to advise the government on all matters pertaining to the WTO. This committee later metamorphosed into the National Committee on WTO which includes governmental as well as non-governmental actors. It includes the Attorney-General, the Office of the President, MOTI, and the Ministries of Finance, Planning and National Development, Health, Agriculture, Foreign Affairs, Labour and Human Resources, Environment and Natural Resources, Information and Communications and Transport. The ministries act as the focal points for sub-committees handling relevant WTO issues and each line

ministry handles its core issues. KEBS, KEPHIS and NEMA are also represented on the committee. The coordinating ministry is MOTI.

On a positive note, the establishment of KEPHIS in 1996 has led to greater coordination of the phytosanitary aspects of *Biosecurity*. This has however been hampered by the delay in amending the relevant laws to entrench the role of KEPHIS. It is particularly a matter of concern that the proposed bill to institutionalize KEPHIS is yet to be promulgated and continues to be debated.[10] Given the centrality of KEPHIS in the *Biosecurity* framework in Kenya, its lack of a definitive status, being an institution established only through a in a ministerial order that, at least in theory, could be revoked creates uncertainty that does not augur well for *Biosecurity*.

The Plant Protection Act, Suppression of Noxious Weeds Act, Seeds and Plant Varieties Act and Agriculture Act 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. One example is where a Seed Committee chaired by the Agriculture Secretary and comprising seed sector stakeholders made a decision which was against the Seeds and Plant Varieties Act yet KEPHIS was expected to implement it.

Another positive trend is the involvement of officers from line institutions in related regulatory bodies such as the involvement of KEPHIS, VSD and KEBS in NEMA, the NBC and the National Committee on WTO. This has assisted in coordination of various *Biosecurity* functions.

There is a need to examine the legal status of the various institutions involved in *Biosecurity*. VSD remains a department of the government while KEPHIS is a state corporation with more autonomy and flexibility. This perhaps reflects the emphasis the government places on agriculture. Given the constant change in line ministries where there is sometimes a livestock ministry and other times the ministry's functions are brought together with agriculture, it is important to create VSD as an autonomous body like KEPHIS. It could for instance be brought under an SPS regulatory regime that has divisions dedicated to the roles that KEPHIS and VSD currently play. Proposals to establish one such agency, the Kenya Animal and Plant

[10] A version of the bill was tabled for discussion at a meeting on 3 May 2007, four years since the last draft was finalized and presented to the ministry.

Health Inspectorate Service (KAPHIS) to encompass both KEPHIS and VSD, have been made over the years but they are yet to materialize.

The food safety aspect of *Biosecurity* also needs to be streamlined. For instance, the biosafety regime needs to be harmonized with the Food, Drugs and Chemical Substances Act, the Standards Act and the Public Health Act. The roles of the Ministry of Health, the Ministry of Agriculture, KEBS and VSD need to be synchronized and rationalized. This need has been recognized and a Food Safety Committee set up with the Agriculture Secretary as Chair, to provide guidance on synergies. This committee 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 Agricultural Research Institute. It was launched on 4 May 2007.

This raises a broader issue of the diverse inspection functions. Under most of the laws discussed above, there is provision for inspectors. This function needs to be coordinated so that training and the inspection function are carried out in a systematic way. Currently, inspectors are few and this hampers the effective discharge of the 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 VSD inspectors to address meat and meat products at the points of entry.

Another challenge for *Biosecurity* is the operation on the basis of drafts with regard to biosafety. Kenya has ongoing work on GMOs, but the permits have been issued only on the basis of draft regulations, as noted above. The process of promulgating a biosafety law has remained protracted. Attempts to come up with a National Biosafety Act in 1999 failed. There is currently, as was pointed out above, a draft Biosafety Bill which has been the subject of discussion since 2002.

It is worth noting that Kenya also has a biotechnology policy promulgated in December 2006 which seeks to provide a framework for safe development and application of biotechnology. There is also an ongoing process to develop a national biotechnology strategy. The policy framework needs to be supported by a law and a national strategy to mainstream the application of biotechnology in national development. In the absence of a finalized law, the

NBC continues to consider applications and allow work on GMOs on the basis of the draft regulations.

As Kenya refines its *Biosecurity* framework, it has to contend with the imperatives of regional integration. Membership in sub-regional and regional groupings will have implications for the efficacy of the framework put in place. Kenya is a member of the East African community, one of whose objectives is harmonization of laws and standards to facilitate the creation of a common market. This has implications for the national *Biosecurity* framework. Similarly, membership to the Association for Agricultural Research in Eastern and Central Africa, which is currently working on harmonizing seed and biosafety laws, will have implications for Kenya's national framework and institutions.

3.2. Proposals for reform

It is widely recognized that there is need for greater institutional synergy. The historical separation of SPS functions calls for sensitization of stakeholders and consensus building on the benefits of the establishment of a single agricultural regulatory authority, which could also address *Biosecurity*. The draft Agriculture Sector Reform Bill, 2006, sets out to reorganize and update the legal and regulatory environment in the agricultural sector by consolidating roles in three proposed agencies:

1. the Agriculture Development Board;
2. the Livestock Development Board; and
3. the Agriculture Sector Regulatory Authority (ASRA).

The proposed ASRA draws its membership from a wide array of actors including the Ministries of Livestock and Fisheries, Agriculture, Health and Treasury, the universities, the Agriculture Development and Livestock Development Boards, the Kenya Association of Manufacturers and two representatives from the agribusiness sector.

The objective of the bill is laudable and its timeliness cannot be gainsaid. Currently, the agricultural sector is governed by over 130 pieces of legislation, 60 of which regulate and control various commodity sectors. Many of these laws are outdated and in need of repeal or amendment. The consolidation of legislation is seen as a way of fast-tracking and updating laws in a context where legislation takes a long time to go through

parliament.[11] The Law Reform Commission, the national body charged with reviewing, updating and drafting new laws, is currently developing many bills. It has been historically inactive but has in the last five years developed a strategy for law reform. The demand for new laws far outstrips the capacity of the commission and drafters in the Attorney-General's chambers. Consequently, many draft laws are being generated by the sector that still require amendment, review or overhaul.

This legislative initiative presents an opportunity to mainstream *Biosecurity* and to provide a coordinated institutional framework for its implementation. There is no reference to *Biosecurity* in the Strategy for Revitalizing Agriculture (SRA) 2004–2014 concluded in 2005,[12] although it can certainly be read to embrace *Biosecurity*. The SRA identifies six interventions to reverse the decline in the agriculture sector and position it competitively in the global arena:

(a) review and harmonization of the legal, regulatory and institutional framework;
(b) restructuring and privatization of non-core functions of parastatals and ministries;
(c) improving the delivery of research, extension and advisory support services;
(d) improving access to quality inputs and financial services;
(e) improving access to both domestic and external markets; and
(f) formulating food security policy and programmes.

These interventions have direct and indirect implications for *Biosecurity*. Part 2.3.4. on animal health and plant protection services is of direct relevance. It seeks to revamp animal health and plant protection services in order to increase production through:

(a) reviewing and enforcing laws on delivery of animal health, fish and plant protection services;
(b) building capacity for laboratory analysis for diagnosis and remedial action;
(c) ensuring development and maintenance of infrastructure for the control of livestock and plant diseases; and

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[11] Cabinet memo on Consolidating Legislation in the Agricultural Sector, 2007.
[12] Republic of Kenya, Ministry of Agriculture, Ministry of Livestock and Fisheries Development and Ministry of Cooperative Development and Marketing, Livestock and Fisheries Development, *Strategy for Revitalizing Agriculture 2004–2014*, February 2005.

(d) enforcing sanitary, phytosanitary and zoosanitary measures to prevent introduction and spread of new pests and diseases.

The opportunity to include *Biosecurity* is there in the anticipated changes but it requires clarification and articulation. First, it is not clear from the draft Agriculture Sector Reform Bill how the existing regulatory institutions will interface with the proposed ones. Will they be absorbed in the ASRA? Second, it is not clear how the authority will be structured to perform all the regulatory roles currently dispersed in different agencies. Third, it is not clear how the regulatory roles will be linked to regulatory agencies in other sectors that have relevance for the agriculture sector. Failure to clarify and articulate synergies will confound an already complicated scenario.

IV. CONCLUSION AND RECOMMENDATIONS

Kenya has in place an elaborate *Biosecurity* legal and institutional framework. This framework has been refined over time and continues to evolve. There is recognition of the need to amend laws to ingrain elements of *Biosecurity* from the agriculture, health and environmental angles. While there is a framework environmental law, the drafting of the implementing regulations of that law is ongoing. For instance, it is expected that regulations on alien and invasive species will be put in place. This chapter has captured the framework as it grapples with these changes.

The implementation of the framework is a challenge. It was not easy to ascertain, in carrying out the present review, the extent of conformity with existing regulations. Furthermore, since most of the laws and institutions have functions other than *Biosecurity*, it was not possible to rate the effectiveness of the normative and institutional frameworks. For instance, the emphasis on trade of agricultural products and exports of meats seems in some cases to override concerns for national *Biosecurity*. In addition, the emphasis on certain kinds of products leaving out others can compromise *Biosecurity*. There is, for instance, evidence that game meat consumption has gone up in Kenya in the last ten years, but because dealing with game products is illegal, most of such meat finds its way to the marketplace without the requisite inspection. This is an example of the difficult context that can compromise the implementation of even the best normative and institutional framework for *Biosecurity*.

At another level, the framework still has normative and institutional overlaps as new laws and institutions are put in place. The challenge is to ensure that these laws and institutions seek to achieve the same objectives. There are many international instruments which Kenya has ratified and whose implementation is in the nascent stages, and the challenge of synergizing these *inter se* as well as with national development imperatives will continue. Membership in international, regional and sub-regional bodies will also influence the evolution of the national *Biosecurity* framework.

Capacity to implement an effective national *Biosecurity* framework is another issue of concern. It is not helped by the overlaps which can lead to bureaucratic delays as each body looks to the other to act. It could also drain necessary capacity from implementation which instead must deal with conflicts. While it may not be possible to contain all elements of *Biosecurity* in one law or institution, there is a need for a focal point to ensure that the overall objectives are not compromised by actions within any one function in the framework. Such a focal institution would be the repository of information as well as the mechanism for dissemination of that information to all relevant actors. It needs to be able to oversee the entire framework and have the authority to require certain actions on the part of all actors to ensure more synergy and cooperation.

At a broader level, inter-institutional rivalries have hampered the development of a coherent *Biosecurity* normative and institutional framework. This raises the need for awareness raising among stakeholders and engagement in consensus building to ensure buy-in by all stakeholders. The SRA and accompanying reforms provide an opportunity for consensus building and banking on political good will. It is worth noting that within this framework, an inter-ministerial Cabinet committee has been established to work with the Agriculture Sector Coordinating Unit and technical committees to fast-track the thematic interventions identified under the SRA.

9

UGANDA COUNTRY STUDY*

Contents

* This chapter was prepared by Judy Obitre-Gama.

I. INTRODUCTION

Biosecurity measures in agriculture are needed to protect agricultural production systems and those dependent on these systems. Producers and others dependent on agriculture can see their livelihood destroyed by animal and plant pests and diseases or damage to the environment such as impacts resulting from invasive alien species. Measures are needed to protect human health, particularly of vulnerable groups that can be exposed to severe health risks, which B*iosecurity* attempts to prevent. *Biosecurity* seeks to protect the environment, promote sustainable production and build consumers' confidence in agricultural products. Public awareness of environmental issues and human dependency on biodiversity have resulted in numerous commitments to achieving sustainable development, and achieving these will require an effective approach to *Biosecurity*.

This report appraises legislation and policy in Uganda on *Biosecurity* comparing the national framework with the international regime on *Biosecurity*. It concludes by proposing a way forward for an effective *Biosecurity* legal regime in Uganda.

II. NATIONAL LEGAL REGIME ON *BIOSECURITY*

2.1. Constitution

Constitution of the Republic of Uganda, 1995

The Constitution, as amended in February 2006, in the National Objectives and Directive Principles of State Policy, provides that the state shall protect important natural resources including fauna and flora on behalf of the people of Uganda (Objective XIII). The state commits itself to promote sustainable development and the rational use of natural resources so as to safeguard and protect the biodiversity of Uganda (Objective XXVII).

The right to a clean and healthy environment is enshrined in article 39 while article 245 requires parliament to pass laws for the protection and preservation of the environment.

2.2. Environment and wildlife

National Environment Act (Chapter 153), 1995

The objective of the National Environment Act (NEA) is to provide for sustainable management of the environment and to establish an authority as a coordinating, monitoring and supervisory body for that purpose.

The National Environment Management Authority (NEMA) is established under the act as the principal agency in Uganda responsible for the environment. NEMA is required to ensure the integration of environmental concerns into overall national environmental planning through coordination with the relevant ministries, departments and agencies of government; and initiate legislative proposals, standards and guidelines on the environment in accordance with the act. NEMA is mandated to ensure the observance of proper safeguards in the planning and execution of all development projects, including those already in existence that have or are likely to have a significant impact on the environment. In a similar vein, NEMA shall review and approve any environment impact assessment (EIA) or statement submitted in accordance with the laws of Uganda.

Accordingly, an EIA shall be undertaken by the developer where the lead agency, in consultation with NEMA, is of the view that the project proposed may have an impact, is likely to have a significant impact or will have a significant impact on the environment. The list of projects that must have an EIA is contained in the third schedule to the act. The list includes the introduction of new crops and animals (item 8), and the introduction of fauna and flora into ecosystems of natural conservation areas (item 13). The minister on the advice of the board of directors of NEMA may amend the schedule.

NEMA, in consultation with the lead agencies, is enjoined to take all measures to ensure that biodiversity is conserved *in situ*, where possible, and *ex situ* where not. Further provision for preservation of wildlife *in situ* is made in the Uganda Wildlife Act (see below). The NEA stipulates that access to genetic resources shall be regulated in order to sustainably utilize genetic resources for the benefit of the people of Uganda.

National Environment
(Access to Genetic Resources and Benefit Sharing) Regulations, 2005

The Access to Genetic Resources and Benefit Sharing Regulations define genetic resources as genetic material of actual or potential use or value and includes their derivative products and intangible components, while "access" is defined to mean the obtaining, possessing and using of genetic resources for purposes of research, bio-prospecting, conservation, industrial application or commercial use. The regulations prescribe the procedures for access for these purposes.

The regulations apply to access to genetic resources or parts thereof, whether naturally occurring or naturalized, whether in *in situ* conditions or *ex situ* conditions, including genetic resources bred for or intended for commercial purposes within Uganda or for export. Excluded from the application of the regulations are the exchange of genetic resources that are certified to be purely for food or other consumptive purposes as prescribed by the relevant laws; the transit of genetic resources through Uganda; exchange by a local community *inter se* for consumptive purposes; and access to genetic resources derived from plant breeders as defined by laws relating to plant breeding and plant varieties. Where access to genetic resources is likely to have a significant impact on the environment, an EIA shall be carried out prior to the conclusion of a material transfer agreement.

The Uganda National Council for Science and Technology (UNCST), which is established under the Uganda National Council for Science and Technology Act, Chapter 209, 1990 (see below), is designated as the competent authority for the purpose of fulfilling the object of the regulations. UNCST is enjoined to coordinate all activities of lead agencies relating to access to genetic resources in accordance with these regulations and the NEA; and submit to NEMA reports relating to the implementation of these regulations. NEMA, however, retains the function of initiating the formulation of national policy on access to genetic resources; developing guidelines for access to and export of genetic resources; collaborating with lead agencies in carrying out public awareness campaigns, designing capacity building programmes; ensuring compliance with and enforcement of these regulations; developing guidelines for the export of genetic resources and benefit sharing; and advising on access to genetic resources outside protected areas.

Uganda Wildlife Act (Chapter 200), 2000

The Uganda Wildlife Act provides for the sustainable management of wildlife which is defined to include any wild plant of a species native to Uganda. Any species of plant whose natural range does not now or did not in the past include a specific part of Uganda or the whole of Uganda is referred to as an alien species (sect. 1) and the act does not authorize the introduction of alien species of plants or animals into wild habitats within Uganda (sect. 2). Though a wild habitat is not specifically defined, it is construed to refer to a wildlife conservation area declared as such by statutory instrument (sects. 17 and 18).

This act is intended to promote the conservation of wildlife in Uganda in order to maintain the biological diversity that exists for the benefit of the people of Uganda. This includes the protection of rare, endangered and endemic species of wild plants (sect. 2). The minister responsible for wildlife may, by statutory order, declare any species of wild plant or wild animal as a protected species under the act (sect. 27). Use of resources in wildlife protected areas is permitted by the Uganda Wildlife Authority (UWA) in instances where a permit is issued to an applicant specifying the extent and duration under which such applicant has access to the resources stated in the permit (sect. 23).

The UWA is established under the act to, inter alia, ensure the sustainable management of wildlife conservation areas; develop and implement policies in the field of wildlife management; establish policies and procedures for sustainable utilization of wildlife by and for the benefit of the communities living in proximity to wildlife; control the development of tourist facilities in wildlife protected areas; and promote the conservation of biological diversity ex situ and contribute to the establishment of standards and regulations for that purpose.

UWA is authorized to delegate any of its functions in writing to a lead agency, a committee or any public officer. In performing its functions, UWA shall coordinate with lead agencies involved in the field of wildlife management. A lead agency includes any ministry, department, parastatal agency or public officer in whom the law vests functions related to the management of wildlife or wildlife conservation areas and includes a local government council.

2.3. Plants and seeds

Plant Protection Act (Chapter 31), 1976

The Plant Protection Act was originally passed as an ordinance in 1937. The scope of the act can be gleaned from the long title which limits the act to the prevention of the introduction and spread of diseases destructive to plants. The definition section is very limited and is an indicator of the purpose of the act. The act precedes the International Plant Protection Convention (IPPC)[1] of 1951 so arguably it does not take any international considerations into account. The administrative structure was limited to the size of the service required. Over time, the structure became too small and the budget too restrictive to allow the operation of an efficient and effective service. The penalties imposed were found to have no deterrent or actual value. For these reasons, *inter alia,* the act was reviewed in 2001 and the Plant Protection and Health Bill, 2003, was drafted.

The 2003 bill attempted to fill in the gaps identified in the Plant Protection Act by establishing a Technical Committee to assist the commissioner and the minister in carrying out the functions outlined for the Department of Crop Protection in the ministry responsible for agriculture. The penalties were reviewed and currency points introduced to make the penalties more realistic. The definition section was expanded to include newer terms used in phytosanitary service, drawing on the Glossary of Phytosanitary Terms of the new revised text of the IPPC (1997). The thrust of the bill was to protect plant health and the natural environment and comply with international standards on plant protection in order to enhance the international reputation of Ugandan agricultural products, especially exports. The cost recovery proposed in the draft bill particularly to enable rapid response to epidemics of quarantine importance was not included in the final text of the bill. The 2003 bill was found lacking in these respects and a revised bill was proposed in 2005.

The Plant Protection Bill, 2005, seeks to consolidate and reform the law relating to protection of plants against pests; to prevent the introduction and spread of pests that may adversely affect Uganda's agriculture, the natural environment and the livelihood of the people; to ensure sustainable plant and environmental protection; and to regulate the export and import of plants and plant products and the introduction of new plants in accordance with

[1] For a discussion of this convention, see Chapter 2, Part III.

international commitments on plant protection. The bill proposes a cost recovery mechanism to enable rapid response to epidemics of quarantine importance. It introduces pest risk analysis and strengthens the import and export controls of plants, plant products and regulated articles. The objective of the bill is to protect and enhance the international reputation of Ugandan agricultural products, and to entrust all plant protection regulatory functions to the government through the national plant protection organization (NPPO).

The department responsible for plant protection within the Ministry of Agriculture is designated as the NPPO and is responsible for the protection of the plant resources of Uganda from pests that exist in the country or could be introduced into the country. The NPPO is responsible for the implementation of the act. To this end, the NPPO is responsible for carrying out surveillance of growing plants, including areas under cultivation and wild flora, and of plants and plant products in storage or in transport, for the purpose of reporting the occurrence, outbreak and spread of pests, and of controlling those pests.

The NPPO is mandated to enforce the act and any other legislation relating to plant protection that the minister may identify; and to establish procedures for accreditation of any quarantine station, official analyst, official laboratory or any other person or institution from the public or private sector involved in phytosanitary matters. The minister is to appoint a Plant Protection Technical Committee to advise the commissioner on all technical matters arising from the administration of the act and on any other related issues. The commissioner shall be the head of the NPPO and responsible for the day-to-day administration of the act. The commissioner is defined to mean the commissioner responsible for plant protection or any other commissioner or competent person assigned by law to administer the act.

The minister is authorised, from time to time, to appoint by notice in the gazette, officers of the NPPO or other competent persons to be inspectors for the purposes of the act. In addition, the minister has powers, by statutory instrument, to prescribe functions under the act that may be delegated to any specified competent individual or institution, including designation of laboratories and competent scientists. Delegated individuals or institutions shall be required to comply with instructions that may from time to time be issued by the minister; report on their activities to the NPPO on a periodic basis as may be determined by the minister; and assist in and cooperate with the NPPO in attaining the purposes of the act.

A perusal of related laws reveals that there are overlaps that should be addressed in the bill to avoid institutional conflict and the resultant inefficiency it engenders. 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 any particular crop as the need arises. 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. The Cotton Development Act (Chapter 30, 1994), in Section 12, mandates the minister responsible for agriculture, in consultation with the Cotton Development Organization, to direct that any cotton seed or plant harbouring or likely to harbour any cotton pest or cotton disease be destroyed. A provision is proposed in the Plant Health and Protection Bill, 2005, to address this anomaly and ensure that the principal authority for all phytosanitary matters is assigned by law to the NPPO.

National Forestry and Tree Planting Act, 2003

The National Forestry and Tree Planting (NFTP) Act contains provisions that are contrary to the purpose of establishing an NPPO with principal responsibility for phytosanitary services in Uganda. Under Section 36 of the NFTP Act the minister responsible for forestry, the National Forestry Authority or a district council is authorized to notify the public through the mass media of the existence of plant and livestock pests or diseases dangerous to forests or forest produce and prescribe the measures to be taken to control or eradicate those pests and diseases. Section 92(2)(g)–(i) empowers the minister by statutory instrument to issue regulations that may provide for the notification of plant and livestock pests and diseases dangerous to forests and forest produce and the measures to be taken to control or eradicate the notified pests or diseases; and the introduction of alien and exotic species.

While the authority to notify the public of plant pests or diseases as stipulated in the NFTP Act may not in itself be inconsistent with the revised text of the Plant Protection Bill, particularly if that notification enables the NPPO to improve in the efficient delivery of service, the prescription of control and eradication measures, and the authorization for the introduction of alien or exotic species (particularly as pertains to the phytosanitary health and safety of such species) are matters that are within the exclusive domain of the NPPO. To solve any mischief that may be occasioned by the aforementioned sections of the NFTP Act, a new clause was introduced in the

revised bill that stipulates that any law existing immediately before the coming into force of this act relating to plant protection shall have effect subject to such modifications as may be necessary to give effect to the bill; and where any such law conflicts with the bill, the provisions of the bill shall prevail. It is hoped that this clause will preserve the role of the NPPO as the government agency charged with the responsibility for all phytosanitary matters.

Agricultural Seeds and Plant Act (Chapter 28), 1994

The Agricultural Seeds and Plant Act provides for the promotion, regulation and control of plant breeding and variety release; multiplication, conditioning, marketing, importing and quality assurance of seeds and other planting materials. The National Seed Industry Authority established under the act is responsible for advising government on national seeds policy; constantly reviewing the national seed supply; and coordinating and monitoring the public and private seed sector in order to achieve the national seed programme objectives (sect. 3). The NSCS is responsible for the design, establishment and enforcement of certification standards, methods and procedures in the seed industry (sect. 6); while the variety release committee reviews and maintains the national variety list including the approval of new varieties of seeds, and approves variety release and entry of seeds into the seed multiplication programme (sect. 5). All biosafety issues are referred to and handled by UNCST in accordance with the law.

The Seed and Plant Bill, which was assented to and should be gazetted as an act of parliament shortly, will repeal Chapter 28. The bill establishes a National Seed Board (NSB), with the department of Crop Protection providing the secretariat. The Variety Release Committee is maintained under the bill. Seed import permits shall be issued by the NSB. Risk assessment in terms of plant health is done by phytosanitary services. The seed import permit constitutes a "no objection" to import seeds, subject to phytosanitary measures.

2.4. Animals

Animal Diseases Act (Chapter 38), 1964

The Animal Diseases Act defines animals that are within its ambit to mean all stock, camels and other ruminating animals, cats and dogs (sect. 1(a)); and disease to mean any disease contained in the list under Section 1(d). All

diseased animals or animals suspected to be infected by disease must be separated from the other animals by the owner or caretaker of the animals; and a veterinary officer or administrative officer should be notified accordingly (sect. 2). The veterinary officer notified must, once he or she has ascertained the existence and nature of the disease, report the matter to the Commissioner of Livestock and Entomology (sect. 3). An administrative officer shall, on being satisfied as to the existence of a disease affecting stock (cattle, sheep, goats, horses, mules, donkeys and poultry) within his or her area of jurisdiction, cause all owners and occupiers of farms and owners of stock in the neighbourhood to be notified of the disease (sect. 4).

All diseased or suspect animals or any animal which has been in contact with a diseased animal or has been exposed to the infection or contagion of disease shall be slaughtered on the instruction of the veterinary officer or administrative officer and the carcass disposed of according to such instruction.

Cattle Traders Act (Chapter 43), 1964

The Cattle Traders Act provides for the regulation of cattle trading in Uganda which can only be undertaken once a licence in the prescribed form has been issued by a veterinary officer indicating the area(s) of operation of the cattle trader (sect. 2). The licence shall be valid up to 31 December (sect. 7) and shall not be renewed if the applicant has, inter alia, been convicted of an offence under the Animal Diseases Act. A cattle trader is defined as any person who trades in cattle for the purposes of resale or slaughter (sect. 1).

Animal Breeding Act, 2001

The Animal Breeding Act provides for the promotion, regulation and control, marketing, import and export and quality assurance of animal and fish genetic materials. It makes general provision for the implementation of the national breeding policy in Uganda and other matters connected therewith.

The Director of Animal Resources is charged with various functions. Under Section 4, the director should promote optimum animal genetic resource management, conservation and sustainable use commensurate with Uganda's needs and environmental protection. The Commissioner of Animal Production and Marketing is responsible for registration of animal genetic resources and related activities (sect. 6(1)), while the Commissioner of Fisheries Resources is responsible for the register of fish breeding and

related activities (sect. 6(4)). "Animals" are defined to mean all livestock, camels, donkeys, rabbits, poultry, other ruminating and pseudo-ruminating animals, fish and any other animal that the minister may by statutory instrument so declare (sect. 3).

No imports or exports of animal breeds and genetic material shall be done without obtaining a permit from the Commissioner of Livestock and Entomology (sect. 7). A list of suitable breeds for widespread use is contained in the third schedule to the act, and any breed not appearing in that schedule shall only be allowed into the country for restricted use on designated locations and experimental stations or specialized production units as approved by the director (sect. 8(1)). The director shall sanction imports and exports based on verified documentary evidence of the material being free of the disease agents and prohibited hereditary defects specified in the fourth schedule to the act (sect. 8(4)). A sample of all genetic materials defined to be semen, ova, eggs and embryos shall be submitted to a national depository for examination and future reference (sect. 9). The National Animal Genetic Resources Centre and Data Bank established under Section 13 is identified to serve as a national gene depository and examination centre for genetic materials (sect. 15(2)), among other functions. All genetic materials must conform to the national biosafety standards set by UNCST and UNBS (sect. 9).

2.5. Food

Food and Drugs Act (Chapter 278), 1964

The Food and Drugs 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 prohibits the use of an ingredient that renders food injurious to human health in the preparation of food sold for human consumption (sect. 2) and prohibits false labelling or advertisement of food (sect. 5). Food in course of transit 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, 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 the 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 functions similar to the veterinary surgeon.

A committee known as 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 committee is appointed by the minister to hold office for such period as may be stipulated. The membership of the committee includes persons qualified to represent the interests of the public generally in relation to matters of food hygiene and related matters; and representatives of persons carrying on any trade or business affected by the operation of the act. Based on the draft Food and Nutrition Policy, the Food and Drugs Act is in the process of review through a participatory process with the involvement of the ministry responsible for agriculture in order to expand its scope from matters concerning human health to the whole food chain.

Public Health Act (Chapter 281), 1964

According to the Public Health Act, construction and regulation of buildings used for storage of foodstuffs must take into account public health concerns (sect. 101). The minister responsible may make rules for any purpose having as their object the preservation of health or the prevention of disease (sect. 104).

Uganda National Bureau of Standards Act, Chap 327

This act provides for the establishment of a national bureau of standards, the standardization of commodities and matters related thereto. A commodity is defined under the act to mean any article, product or thing which is or will ultimately be the subject of trade or use. The Uganda National Bureau of Standards (UNBS) is established as a body corporate under the general supervision of the minister responsible for commerce. The functions of UNBS include the formulation of national standard specifications for commodities; the promotion of standardization in commerce, industry, health, safety and social welfare; the endorsement or adoption of any

international or other country's specification with or without modification as suitable for use in Uganda; the enforcement of standards in the protection of the public against harmful ingredients, dangerous components, shoddy material and poor performance; and the ability to seek membership of any international organization connected with standardization.

The governing body of UNBS is the National Standards Council (NSC), whose function is to declare standard specifications, certification marks and codes of practice and to do all things incidental thereto. The executive director of UNBS with the approval of the NSC may appoint standards inspectors to inspect and test any commodities and processes.

2.6. Biosafety

Uganda National Council of Science and Technology Act (Chapter 209), 1990

The Uganda National Council for Science and Technology (UNCST) is established as a body corporate under the general supervision of the minister responsible for planning and economic development. The functions of UNCST as stipulated in Section 4 of the act include:

- to advise on and coordinate the formulation of an explicit policy in all fields of science and technology;
- to assist in the promotion and development of indigenous science and technology through, *inter alia*, technology transfer and adaptation, as well as establishment of research and experimental development institutions, pilot plants and other testing grounds and standardization and quality control centres;
- to assist in the rationalization of the use of foreign science and technology;
- to act as a clearing house for information on research and experimental development taking place in scientific institutions, centres and other enterprises and on the potential application of their results;
- to work in close cooperation with and coordinate all scientific and technological activities of persons, institutions, sectors and organizations; and
- to carry out any other function incidental or conducive to these functions or as the minister may assign to it.

UNCST is authorized under Section 5 of the act to do all such things to facilitate its work or that are conducive or incidental to better carrying out its

functions. In this vein, UNCST may establish any specialized committees, research councils or organizations and carry out experimental and development activities or other scientific and technological services. UNCST may establish and maintain relationships with national, regional and international organizations and agencies as it may deem appropriate. There is established under the act a specialized committee on natural sciences whose mandate includes bio-science (sect. 15(1)(e)) and whose functions include advising UNCST on all policy matters on bio-science in the country; and advising on the assignment of scientific and technological responsibilities to different institutions or persons.

Represented on UNCST are the ministry responsible for agriculture, animal industry and fisheries; the ministry responsible for environment protection; the ministry responsible for health; UNBS; universities and eminent scientists in the field of agriculture and allied sciences, medical science and natural science.

UNCST 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 living modified organisms (LMOs) and acting on referrals made by any department receiving applications for the import of LMOs (e.g. the Department of Crop Protection for seeds). While the decisions are made within the NBC, risk assessment is carried out by the competent departments/agencies.

UNCST, through its parent ministry, the Ministry of Finance and Economic Planning, has proposed the National Biotechnology and Biosafety Policy, June 2006. The policy defines the concepts of biotechnology and biosafety and the status of these concepts in Uganda. Biotechnology is defined as any technique that uses living organisms or substances therefrom to make or modify a product, improve plants or animals or microorganisms for specific purposes; and biosafety as the safe development, transfer and application of biotechnology and its products. The policy notes that the Uganda Biosafety Framework, 2000, by which various institutions have undertaken research in agricultural biotechnology and molecular biology, has limitations. The lack of an explicit biotechnology and biosafety policy has meant that national strategies and priorities in biotechnology development have not been proposed, and biotechnology considerations have not been integrated into the overall national development policy and planning framework.

The policy notes the inadequacy of the legal framework with respect to regulation of modern biotechnology and the issues that it raises. The legal provisions that exist are found in various 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 Convention on Biological Diversity in 1993 and the Cartagena Protocol in 2001,[2] the provisions of these treaties have not been fully transformed into local laws nor is there an institution that can singularly address the concerns of these treaties.

The policy seeks to enable Uganda to realize the full potential of biotechnology through the formulation of a specific biotechnology and biosafety policy which defines the institutional, legal and regulatory regime for the promotion of biotechnology development and lays emphasis on infrastructure development, research, public awareness, human resource capacity development and the promotion of commercial/industrial development. The application of bioethics is required while government is encouraged to effectively integrate indigenous knowledge in the development and application of modern biotechnology. The policy proposes a monitoring and evaluation framework to continuously monitor and assess both the sector and system performance on the basis of measurable parameters.

III. INSTITUTIONAL BASIS FOR *BIOSECURITY* IN UGANDA: GAPS AND OVERLAPS

Biosecurity, as defined earlier in this report, is a strategic and integrated approach to analysing and managing risks in animal and plant life and health, food safety and biosafety. Issues arising within the *Biosecurity* framework are therefore cross-cutting and are the responsibility of different ministries, state agencies or departments.

The Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) is responsible for animal health matters under its veterinary services division, while its fisheries arm handles aquatic life issues. Several inspectors of the veterinary services have recently received training on risk analysis but still face constraints in terms of equipment (e.g. laboratories).

[2] For a discussion of these instruments, see Chapter 2, Parts VI and VII.

The Department of Crop Protection is responsible for phytosanitary and plant protection matters and will be designated the national plant protection organization once the new law is enacted. The department has recently received technical assistance from FAO, which has resulted in the updating of the national pest list (still to be gazetted) and the effort to establish pest free areas for bananas.

The Ministry of Health (MOH) is the implementing authority of the Food and Drugs Act but it is commonly recognized that its human and financial resources are extremely limited and food safety is not prioritized. In practice, MOH has been working with other agencies on a case-by-case basis in instances where there have been emergencies (e.g. the European Union ban on fish from Uganda where MOH worked with MAAIF and UNBS to resolve the issues).

Inspection of food imports is mostly done by UNBS or its agents at entry points. Funding for food safety is sporadic although MOH seeks to have a systematic approach to food safety to address not only the final product stage but the production stage as well. Currently, MOH has a reactive approach to these matters. There is a very advanced food chain approach only for fisheries thanks to the cooperation between the Fisheries Department and UNBS.

Various other ministries are involved in *Biosecurity* matters mainly as supervisors of state agencies. The Ministry of Water and Environment houses the Wetlands Inspectorate which is the focal point for the implementation of the provisions of the Ramsar Convention. Agricultural research is undertaken by various agricultural research institutes that constitute the National Agricultural Research Organization, and by universities. Seed policy, certification standards and variety approval and release are the function of the National Seed Industry Authority.

NEMA as the principal agency responsible for the environment has a coordinating, monitoring and supervisory role. NEMA is the national focal point for the CBD and related instruments. The Uganda Wildlife Authority is the principal organ responsible for management of wildlife in Uganda. The National Forestry Authority has similar responsibility with respect to forests. 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. The Uganda Revenue Authority, through

its customs department, plays a crucial role in ensuring the legitimacy of imports and exports of regulated materials. The Food Hygiene Advisory Committee and the responsible minister, in conjunction with the local governments and authorized persons, are responsible for the prevention of the adulteration of food.

UNCST is responsible for policy in all fields of science and technology. It is the competent authority for regulation and access to genetic resources, and is proposed in the draft policy on biotechnology and biosafety as the competent authority to supervise and regulate the implementation of the policy. Further, it is proposed as the competent authority for biosafety under the proposed Uganda Biosafety Bill, 2005, 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.

MAAIF through its crop protection and animal industry departments is responsible for the IPPC and OIE, respectively; and UNBS is responsible for the Codex Alimentarius.[3] The Department of Crop Protection also acts as SPS Enquiry Point but has no visibility at the moment. It is advisable that this be addressed in the near future. NEMA and UNCST are the national focal point and competent authority for the CBD and Cartagena Protocol, respectively.

Each of the agencies mentioned above has inspectors charged with the duty of ensuring compliance with the provisions of each sectoral law. There are mechanisms in some laws authorizing delegation to related departments, thus enabling collaboration between departments and agencies. NEMA in gazetting environment inspectors is authorized to gazette persons employed as inspectors in other departments as environment inspectors, and such inspectors have been appointed. NEMA, however, lacks of human resources to participate in all 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 of Uganda whose borders are porous. 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 the particular field of their employment and do not have sufficient capacity to effectively undertake inspection by delegation.

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[3] For a discussion of the Codex Alimentarius, see Chapter 2, Part V.

Though UNBS is the national standards body, other government agencies or departments have the authority in law to set and enforce standards. NEMA sets environmental standards while the Directorate of Water Development sets water and water-related standards under the Water Act (Chapter 152, 1995).

Biosecurity as a concept has not been specifically addressed by policy or law in Uganda. NEMA as the principal agency responsible for the environment appears best placed to perform the umbrella role in biosecurity. NEMA already acts as a coordinating agency in various standing policy committees that are established (e.g. biodiversity, environment) and this focal point role is well accepted by other ministries. UNCST has the scientific and technical capacity to carry out the functions of a competent authority. Granted that UNCST at the moment is leaning towards biotechnology and biosafety, it could be persuaded to embrace *Biosecurity* as a whole.

The Plan for the Modernization of Agriculture (PMA) was approved by Cabinet in 2001, and includes the strengthening of plant and animal health controls. Nine ministries are directly involved with PMA whose main function is the commercialization of agriculture in order to eradicate poverty in Uganda. The PMA process of mainstreaming issues involves a Stakeholders Forum, a Steering Committee comprised of Permanent Secretaries and the PMA Secretariat. The PMA operates through consensus building through annual reviews of the PMA. All the responsibilities for implementation of the PMA remain with the ministries. The Stakeholders Forum and the Steering Committee seem to be the appropriate bodies where stakeholders and policy makers can be sensitized to *Biosecurity*.

It is important to create public awareness about *Biosecurity* and what the cost of a disease outbreak would be to the country. This would engender better understanding and policing of already existing laws, and improve the efficiency of mandated institutions even more.

IV. CONCLUSIONS AND WAY FORWARD

The National Biotechnology and Biosafety Policy is in the final stages of consideration in the Ministry of Finance. The institutional framework proposed in the policy reflects some of the institutional overlaps that exist in the current operations as pointed out in the review of the national legal regime. A National Biosafety Act is proposed but is still in the initial stages of formulation. The underpinning philosophy of the act is that biosafety is a

cross-sectoral activity spanning from food safety, plant and animal health to environmental protection and thus requiring operative coordination among the authorities. *Biosecurity* has the same characteristics. Uganda has the opportunity to incorporate in policy and law an appropriate coordination mechanism for *Biosecurity*.

Biosecurity is not the responsibility of one agency of state; as seen above, it involves several ministries, departments and agencies. Accordingly the regulatory framework for *Biosecurity* must be multi-sectoral in nature with an overall coordinating body. Any other formulation would engender institutional rivalry and conflict leading to paralysis.

Several pieces of legislation which address food safety, plant and animal health have been discussed. The legislation is sectoral in nature particularly since different departments or regulatory agencies are responsible for the implementation of each law. The Plant Protection Act has been reviewed to bring it in conformity with the IPPC and may be further reviewed to ensure compliance with new developments in *Biosecurity*. The National Environment Act as the framework law on the environment does concern itself with CBD matters though there are sectoral laws in force that address CBD matters in greater detail, for instance the Uganda Wildlife Act. The proposed National Biosafety Act which seeks to domesticate the Cartagena Protocol is being formulated under the ministry responsible for science and technology which at the moment is the Ministry of Finance. This in itself poses a challenge since the Ministry of Finance has as its priority the fiscal matters of state and macro- and other economic issues. The elaboration of a new Food Act is at a very early stage. All these efforts show a certain degree of commitment to aligning the national legal framework to international dictates. In that respect, *Biosecurity* may become the guiding principle for legislative upgrading and give new impetus to the various legislative initiatives.

In the development of an appropriate legal and institutional framework for *Biosecurity*, it is recommended that the National Biosafety Act serve as a means of ensuring coordination and cross-sectoral management in *Biosecurity*. The government policy does not encourage the establishment of new institutions at the moment. In the circumstances, it is better to encourage the various institutions to carry out their mandates with *Biosecurity* in mind. In that regard, the cross-sectoral coordination that is being promoted for biosafety represents the ideal occasion to mandate the various institutions to embrace *Biosecurity* as a whole.

10

VIET NAM COUNTRY STUDY*

Contents

* This chapter was prepared by Duong Thanh An.

I. INTRODUCTION

FAO uses the term *Biosecurity* in relation to sanitary, phytosanitary and zoosanitary measures applied in food and agriculture regulatory systems. For FAO, *Biosecurity* broadly describes the process and objective of managing biological risks associated with food and agriculture in a holistic manner. *Biosecurity* is a holistic concept of direct relevance to the sustainability of agriculture, food safety and the protection of the environment, including biodiversity. This chapter reviews Viet Nam's legislation in the five areas of *Biosecurity*, namely, food safety, plant health, animal health, IAS and biosafety.

II. VIET NAM'S LEGISLATION ON *BIOSECURITY*

2.1. Food safety

In Viet Nam, food safety is regulated mostly by the 2003 Ordinance on Food Hygiene and Safety and other related laws, namely, the 2000 Law on People's Health, the 2003 Fisheries Law and the 1999 Ordinance on Consumer Protection.

Ordinance on Hygiene and Food Safety (2003)

The Ordinance on Food Hygiene and Safety (OFHS) establishes a regulatory regime for food safety in Viet Nam. It 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.

In the area of food production and trade

According to the OFHS, production and trade in food include farming, harvesting, treating, processing, packaging, keeping in storage and transporting. The ordinance provides for: (1) standards for hygiene and food safety; (2) regulations on conditions of food production and trade; (3) regulations on food processing; (4) regulations on storage and transport of food; and (5) regulations on export and import of food.

The Vietnamese standards on hygiene and food safety include national standards, ministerial standards and local standards. National standards are established by the Ministry of Science and Technology (MOST) in cooperation with the Ministry of Health (MOH) and other related ministries.

Ministerial standards are established by other ministries, such as the Ministry of Agriculture and Rural Development (MOARD), while local standards are developed by authorized food production enterprises in accordance with national and ministerial standards. Organizations and individuals producing and trading in food are required to publish the standards that they follow.

The OFHS provides that organizations and individuals shall comply with three sets of regulations:

- safety regulations on infrastructure, such as locations, water supply systems and waste water treatment;
- regulations on equipment, such as processing, storage and transportation facilities; and
- regulations on personnel, such as employees' health and knowledge of hygiene and food safety principles.

Enterprises that produce and trade in fresh food are required to ensure that the production and trading places are clean and isolated from polluted areas. They are also responsible for applying appropriate methods of storage and transport.

Regulations on food export and import require enterprises to obtain an authorization from public authorities certifying that they have adequate food safety management infrastructure. Where the requirements are not met, food may be seized and disposed of.

Decree No. 163/2004/ND-CP of the Government of Viet Nam dated 7 September 2004 provides for the implementation of the OFHS. The responsibilities of various ministries are specified in articles 21–29 as follows:

- MOH is responsible for formulating and promulgating strategies and policies on food hygiene and safety. Also, MOH must assume the lead in coordinating with other ministries and ministerial departments in: (1) implementing food safety controls in the retail sector and testing pesticide residues in food; (2) inspecting and testing on food hygiene; and (3) carrying out research, training, international cooperation and awareness raising.
- MOARD is responsible for the production process, including processing, slaughtering, preservation and transport as well as for veterinary controls on imported food of animal origin.

- The Ministry of Fisheries (MOF) is responsible for aquatic products for domestic consumption and aquatic products which are exported or temporarily imported for re-export.
- The Ministry of Industry (MOI) is responsible for food products originating from establishments under its management.
- The Ministry of Trade is responsible for food safety controls in the retail sector and, in coordination with other ministries and ministerial departments, for the regulation of food businesses.
- MOST is responsible for standard setting, quality controls and licences, in coordination with MOH.
- The Ministry of Culture and Information is responsible for the regulation of food advertising and for awareness raising on food safety, in coordination with MOH.
- The Ministry of Finance is responsible for the collection of fees and charges and the inspection of food for import in collaboration with MOH and in accordance with customs legislation.
- The People's Committees at the different territorial levels are required to assist state authorities with the implementation of food safety and are responsible for implementing good manufacturing practices and building models of community participation in the management of food hygiene and safety.

In addition, all the ministries shall formulate and promulgate regulations in their respective areas of competence in coordination with MOH.

In the area of prevention and control of food poisoning and food-borne diseases

When food poisoning occurs or food-borne diseases occur at a specific location, the local People's Committee is responsible for applying measures to prevent the transmission of disease and informing the public. In cases where the outbreak is in a large area and seriously threatens public health, emergency regulations must be taken into account.

Additional responsibilities to be assumed by the relevant ministries are as follows:

- as for prevention, MOARD and MOF shall implement good manufacturing practices in order to ensure hygiene and safety for

agricultural and aquatic products before they are marketed, while MOI has the same responsibilities for food production sites;

- MOH is responsible for the implementation and enforcement of food safety and hygiene standards as well as the management of food safety emergencies.

Food producing and food trading organizations as well as individuals shall observe food safety and hygiene regulations and standards. In cases of food poisoning or food-borne diseases, they must immediately report to the local health administrations and take remedial measures as instructed. For penalties, depending on the seriousness of violations, individuals and legal entities shall be sanctioned administratively or through penal liability and shall pay compensation.

Law on the Protection of People's Health (2000)

Although the Law on the Protection of People's Health mostly regulates issues of public health protection, it also deals with some aspects related to food hygiene and safety. First, the law states that Vietnamese citizens have the right to health protection as well as the right of access to safe and wholesome food.

Second, article 7 provides for regulations on hygiene of food, water and alcohol. Enterprises that produce, process, store or transport these items must follow certain hygiene standards. The use of chemicals for food processing and preservation without the permission of MOH is prohibited. Individuals who have transmissible diseases are banned from activities in direct contact with food.

Third, hygiene in animal farms, an important factor of food safety, is also covered by article 11 of this law. It prohibits slaughtering, trading in and consuming livestock or poultry that may bear transmissible diseases.

Fisheries Law (2003)

The Fisheries Law has some regulations related to food safety. Chapter VI regulates processing activities of aquatic products for which the following two requirements are set out:

- processing enterprises of aquatic products are required to have their own storage areas as well as processing and hygiene equipment which shall meet certain technical and hygiene standards. Also, the use of additives and chemicals that are in a banned list is prohibited; and
- enterprises that process, import or export aquatic products are responsible for ensuring conformity with processing and product standards.

MOF, in coordination with other relevant ministries, is responsible for inspecting facilities and monitoring compliance with regulations relating to quality and safety of imported, exported or domestically produced aquatic products.

Ordinance on Veterinary Controls (2004)

The Ordinance on Veterinary Controls provides for standards on slaughter to ensure the safety of food of animal origin. Article 8 provides that all activities of slaughtering in slaughterhouses which do not meet certain hygiene standards are prohibited Also, the slaughtering of infected animals and the trading in infected food of animal origin are prohibited.

With regard to oversight of slaughter, the ordinance has three main prescriptions:

- all slaughtered animals must be inspected to make sure the standards on hygiene and food safety are met;
- slaughterhouses and processing places must meet standards of hygiene and safety;
- slaughterers must be in good health and bear no transmissible diseases as well as undergo periodic health check-ups by local public health authorities.

Article 7 of the ordinance provides that veterinary standards include Vietnamese standards, professional standards, corporate standards and international standards applicable to Viet Nam. MOST is responsible for promulgating Vietnamese standards while MOARD and MOF promulgate professional standards. Corporate standards are developed by private establishments operating in the sector.

Ordinance on Consumer Protection (1999)

Among the objectives of the Ordinance on Consumer Protection are the protection of the health of the general public. It reaffirms the duty of individuals and enterprises to follow hygiene standards and establishes administrative and criminal offences and penalties. Pursuant to the ordinance, MOH, MOF and MOARD are the implementing authorities.

Other instruments

Decree No. 21/2006/ND-CP of the Government of Viet Nam dated 27 February 2006 promulgated regulations on the trade in and use of nutrition products for children. The objective of the decree is to ensure that all children are protected from unsafe nutrition products. MOH is required to cooperate with other relevant ministries to promote the use of breast milk. All nutrition products for children must comply with standards developed in accordance with food safety laws.

Decision No. 43/2006/QD-TTg of the Prime Minister dated 20 February 2006 approved the National Action Plan on Hygiene and Food Safety to 2010. The plan aims to ensure food safety in order to protect human health and facilitate socio-economic development. Eighty percent of national standards are expected to be in conformity with international standards by 2010.

Decision No. 21/2007/QD-BYT of MOH dated 12 March 2007 promulgated regulations on the health of operators directly in contact with food during the processing of pre-packaged food and trading in instant food.

Assessment of the legislation

The above analysis shows a relatively complete regulatory framework covering the main areas of food safety. In particular, it is worth noting that the government is committed to progressively achieving compliance with international standards in order to protect human health and promote trade.

However, it must be noted that, although laws are in place, the regulatory activities have limited impact on the general food safety situation in the country and the implementation arrangements are not efficient. This might be caused by the following factors:

First, general laws are in place but the implementing regulations are inadequate or unapplied. Below are some illustrative examples:

- manufacturers of and traders in meat and meat products, eggs and egg products and other food products are obliged to obtain a licence and a certificate from MOH. However, street food vendors are not subject to the regime. Moreover, MOH has authorized local medical centres to issue health and professional certificates to food dealers. However, many of those centres lack capacity to implement this function effectively;
- the state authority responsible for the management and inspection of food safety is MOH, while the state authority responsible for performing quality controls is MOST. This division of responsibilities has led to undesirable results and harmed efficient food safety management as the two ministries do not coordinate on a regular basis;
- the maximum administrative penalty of 15 million dong for the production of and trading in unsafe or poisoned food is low (approximately €660 at current rates), given the financial capability of major food enterprises;
- the national food safety standards are permissive and many low-quality food items have entered the market with negative and uncontrolled consequences on food safety; and
- under the Ordinance on Consumer Protection, consumers who purchase products not conforming to regulations and standards can only file a complaint with the Association of Consumer Advocates, which is a non-state entity without any power to adjudicate disputes or order compensation.

Second, the coordination of activities among government authorities on food safety is still weak. Since food comes from multiple origins, food safety is related to the management functions of several governmental sectors such as public health, veterinary services and fisheries. However, the clarification of their precise responsibilities along the food chain, from primary production to consumption, has not been achieved yet. The laws contain general provisions that are subject to interpretation. As a result, in the implementation phase the activities of the sectoral authorities overlap. In some cases, those authorities claim a more extended mandate for food safety than is established in the relevant legislation. In some other cases

(e.g. food emergencies), there are gaps in regulatory activities. Besides, many authorities have limited enforcement and infrastructure capabilities.

Finally, there is not enough information on food safety channelled to the public, hence citizens lack necessary information to become "knowledgeable consumers".

2.2. Animal health

Legal provisions on the protection of animal health and life are found in different laws, as follows:

Fisheries Law (2003)

The Fisheries Law regulates activities related to aquatic animals and aquatic animal products, such as breeding, processing, import and export. Activities that cause adverse effects on aquatic animal breeds are generally prohibited. The law establishes a list of aquatic animal species for which aquaculture is prohibited as well as a list of chemicals that are banned in aquaculture. The law envisages a series of measures to protect the living environment for aquatic animals as well as to preserve endangered species. Aquaculture of endangered species requires the permission of MOF or the provincial People's Committee.

Individuals who breed aquatic animal species shall comply with regulations on breeding and the use of chemicals. The law also speaks of animal health measures to prevent the outbreak of or to control the spread of animal diseases in aquaculture environments.

Article 35 of the law states that MOF is responsible for developing: (1) standards for feed used in aquaculture; (2) zoosanitary measures in aquaculture; and (3) the list of banned chemicals. The responsibilities for prevention and control of animal diseases in aquaculture environments are assigned to MOF and the provincial People's Committees.

Ordinance on Veterinary Controls (2004)

Article 9 of the Ordinance on Veterinary Controls provides for:

- surveillance and control;

- animal quarantine and zoosanitary inspections;
- programmes on control and eradication of animal diseases and zoonoses; and
- quality control of products of animal origin, animal feed, veterinary drugs, veterinary biological products and microorganisms.

All activities that cause adverse effects on animal health are prohibited, including non-compliance with regulations on disease prevention, disposal of carcasses and movement of infected animals and animal products. MOARD and MOF are responsible for the prevention and control of animal diseases, including the treatment of infected animals. The government is mandated to establish a National Steering Committee for animal disease prevention and control, upon request of MOARD or MOF.

MOARD, MOF, the People's Committees at different territorial levels, government veterinarians, customs officials and officials of transport authorities are collectively assigned the responsibility for animal quarantine. Animal quarantine includes the quarantine of domestic animals and animal products, animals and animal products for import and export as well as animals and animal products in transit. Article 23 of the ordinance provides that all animals and animal products must, when being transported out of their district of origin, be quarantined at departure. Also, articles 28 and 29 of the ordinance have regulations on quarantine for imported and exported animals and animal products. Article 26 establishes requirements for animals and animal products for domestic transportation.

The ordinance gives the responsibility for the management of veterinary drugs and veterinary biological products, including microorganisms, to MOARD, MOF and the People's Committees.

Ordinance on Livestock Breeds (2004)

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 and multiplication. Article 9 of the ordinance prohibits the export of livestock species of genetic value. MOARD is responsible for the state management of agricultural livestock breeds while MOF is responsible for aquatic livestock breeds.

Assessment of the legislation

As presented above, the regulatory framework on animal health and life assigns responsibilities to authorities and individuals in general terms, for instance by assigning the mandate for certain activities to ministries or by setting forth a general prohibition of harmful conduct. In cases where individuals do not comply, administrative and criminal offences and penalties are in place. The criminal law of Viet Nam (1999) contains applicable provisions, such as those in articles 158 and 187.

Certain shortcomings of the legislation can be identified:

- the legal dictates are of a very general nature and some powers of public authorities (e.g. inspections by veterinarians) and duties of individuals (e.g. duties of animal owners) are not legislated;
- small animal husbandry is very relevant in Viet Nam but some key regulatory activities, such as inspection of cattle and slaughter, do not reach small household farms;
- the task force of veterinarians and animal health inspectors within MOARD is still deficient, with limited professional knowledge and infrastructure; and
- information exchange between MOARD and the local People's Committees is not efficient and, in cases of epidemics, this causes delays in control measures.

2.3. Plant health[1]

In addition to the phytosanitary legislation listed in Chapter 3,[2] two other laws, not specific to plant health, contain scattered provisions referring to plant quarantine. The Law on Environment Protection (2005) generally prohibits the import of plants without an import permit, the issuance of which is administered by plant health legislation. The 2004 Law on Forest Protection and Development refers to regulations on the prevention and eradication of plant pests and requires individuals to execute control measures in accordance with the guidelines of state authorities. The law also refers to import and export requirements that are established in plant protection legislation.

[1] This part of the report draws from FAO, *Technical Assistance in Phytosanitary Legislation, Vietnam*, 2005.
[2] See Chapter 3, Section 3.6.

Institutional mandate of the Plant Protection Department

The Plant Protection Department (PPD) was established in 1961 as the authority responsible for plant protection and plant quarantine matters in Viet Nam. It is affiliated with MOARD. The actual mandate of the PPD is set forth in Decision No. 88/2003 of MOARD.

The three main areas of the PPD's mandate are: (1) plant quarantine; (2) plant protection; and (3) pesticides management. With regard to plant quarantine, article 5(b) of Decision No. 88 speaks of: (a) administration of plant quarantine activities; (b) elaboration of the list of quarantine pests for approval by the minister responsible for agriculture; (c) control of pest outbreaks; (d) phytosanitary inspection for imports and exports; and (e) treatment of consignments.

Under article 5(a), PPD exercises the following responsibilities in connection with plant protection: (a) surveillance for the purpose of reporting the occurrence of pests; and (b) proposals to the minister for the declaration of quarantine areas.

General responsibilities affecting phytosanitary activities include scientific research; policy-making for trade in plants and plant products; international cooperation and representation of the country in international fora; implementation of relevant international agreements; and training of staff.

The mandate of "Plant Quarantine Agencies" is set forth in article 5 of Decree No. 02/2007/ND-CP on Plant Quarantine. Those provisions make an important addition to the PPD mandate, namely, the designation and management of pest free areas.

Surveillance and pest control

Article 9 of the Ordinance on Plant Protection and Quarantine (2001) generally refers to the management of injurious pests, including survey, detection, forecasting and warning of pest occurrence, development, distribution and damage.

Article 10 specifies the rights and duties of plant resource owners which include: (1) the right to be informed on pest status and assisted with pest control by the competent governmental bodies; (2) the duty to apply

appropriate pest control measures as recommended by competent governmental bodies in order to contain a pest; and (3) the duty to report any pest of economic importance to competent governmental bodies.

Declaration and management of quarantine areas

Article 11(2) of the ordinance sets forth the mandate for designation of areas where an outbreak of a pest of economic importance occurs. The mandate lies with the Chair of the People's Committee or MOARD depending on the territorial extension of the outbreak. As for management of affected areas, article 12(1) tasks MOARD with ordering and implementing control measures in collaboration with local authorities. Provisions made in article 16 of the ordinance state the duties of individuals to report and cooperate in the implementation of control measures in cases of pest outbreaks.

With regard to emergency action, article 11(1) of the ordinance provides that, when a pest outbreak is reported, the relevant organizations shall inspect promptly and assist the owner of the plant resources with pest control. Article 17 states that when quarantine or alien pests are detected, competent plant health authorities shall decide upon appropriate measures to delimit and eradicate such pests and request the owners of regulated articles to undertake those measures immediately. Those provisions appear open to interpretation in cases of emergency (i.e. in situations where prompt phytosanitary action is undertaken in a new or unexpected phytosanitary situation without full technical justification).

Import controls

Article 14 of the ordinance generally describes phytosanitary activities related to imports, which include inspection, detection, treatment and monitoring of the status of the consignment after import. Article 18(1) prescribes that all regulated articles for import are subject to phytosanitary inspection while article 22 sets forth a corresponding duty for importers and establishes that, in cases where a quarantine pest is detected, the plant health authority can order re-export, destruction, observation or treatment of the consignment. In terms of article 13(d) of Decree No. 02 on Plant Quarantine, MOARD is responsible for issuing permits for the import of certain beneficial organisms to be specified in a list.

Article 19 of the ordinance sets out criteria for the import of seeds as follows: (1) seed imports are subject to strict inspection and monitoring by the plant health authority; (b) movement of consignments shall be traceable; (c) seeds that are imported for the first time shall be grown in a designated place for phytosanitary testing and shall be released only after certification of freedom from quarantine pests.

List of regulated pests and articles

Article 15 of the ordinance and article 7(1) of the decree provide that MOARD shall publish and regularly update the list of quarantine pests and the list of regulated articles. Decision No. 88 tasks the PPD with elaboration of these lists.

Decision No. 117/2000 of MOARD contains the list of quarantine pests of Viet Nam, which are divided into two categories: (a) pests of potential economic importance and not present in Viet Nam; and (b) pests of potential economic importance which are present in the territory but not widely distributed. These definitions mainly track the terminology and concepts of the new revised text of the International Plant Protection Convention.[3]

Decision No. 56/2001 of MOARD provides the list of regulated articles for import, export, re-import and re-export including plant seeds, plants and parts thereof, plant products, insects, diseases, weeds, soil and other materials harbouring pests, and means of conveyance.

Phytosanitary certification for export

Article 20 of the ordinance and article 15 of the decree indicate that phytosanitary inspection for export and re-export shall be carried out on regulated articles in cases where it is so required by commercial contracts or international agreements to which Viet Nam adheres or where so requested by the exporter. In cases of non-compliance with the phytosanitary requirements of the importing country, phytosanitary certification shall be refused until the exporter properly treats the consignment.

[3] For a discussion of this instrument, see Chapter 2, Part III.

Article 16 of the decree specifies the procedures for export inspections, while article 17 mandates the plant health authority to monitor the status of consignments after certification and prior to export.

With regard to consignments in transit, article 21 of the ordinance prescribes mandatory phytosanitary inspection and action in cases of infestation while articles 18 and 19 of the decree detail procedures for inspection of consignments in transit.

Miscellaneous

With regard to powers of quarantine officers, article 6(3) of the 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.

Assessment of the legislation

The legislation in place comprehensively covers most of the operational areas of the PPD at present. Its mandate, as set out in Decision No. 88, is well reflected in the substantive provisions of the ordinance. The ordinance also has a prescriptive force in that it imposes duties on individuals (e.g. duty to notify the presence of a pest, duty to apply for permits and certificates, duty to pay fees).

However, the functioning of the PPD may suffer from a number of shortcomings arising from the legislative framework. At first glance, the absence of parliamentary-level legislation is striking, in terms of protection of rights as well as definition of institutional and individual responsibilities. A well-grounded legislative framework establishing predictable rules for phytosanitary controls cannot be established without parliamentary-level legislation.

The provisions for administration of the ordinance and the decree do not directly task the PPD with any responsibility. This may not be efficient in light of the designation of the PPD as the national plant protection organization for Viet Nam, which is a requirement of the IPPC.

At the level of substantive provisions, the legislation provides for some key principles (e.g. pest risk analysis) and regulatory areas (e.g. pest free areas)

which are dealt with in the international agreements. With the recent adoption of the decree, controls on imports and exports, which are important regulatory areas from the perspective of international trade, are disciplined with clarity.

2.4. Invasive alien species

Invasive alien species (IAS) are not systematically addressed in Viet Nam's legislation. Some IAS have been imported for commercial purposes but it is only in relation to some of them that the National Environment Agency has conducted an assessment of their impacts on biodiversity and the environment. The concept of IAS also appears sporadically in regulations on biodiversity, plant and animal health.

Decree No. 58/2002/ND/CP of the Government of Viet Nam dated 3 June 2002 includes provisions on plant quarantine. article 16 establishes that the import of all IAS of plant origin is prohibited. In specific cases where the import is for scientific purposes, the permission from the Minister of Agriculture and Rural Development may be sought.

Decree No. 109/2003/ND/CP of the Government of Viet Nam dated 23 September 2003 contains provisions on the preservation and sustainable development of wetlands. In this decree, the introduction of new species which may endanger the ecosystem or alter the gene pool of animals and plants in these areas is banned.

Article 6 of the Fisheries Law (2003) states that the farming of new aquatic animal species without permission from MOF is prohibited. Individuals and organizations may farm aquatic animal species that appear in a list of permitted species.

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

The Ordinance on Veterinary Controls (2004) provides that all animal species that cause harm to human health, animal, environment, and ecological system are subject to quarantine.

The Law on Forest Protection and Development (2004) establishes a permit system for exploitation activities in protected forestry areas. The permit system could operate to manage IAS in those areas.

Thus, the laws of Viet Nam sporadically address IAS in different instruments. Accordingly, the institutional responsibilities are assigned to different state authorities without any overarching authority. It is critical to develop a new framework to manage and effectively control IAS under a designated authority responsible for their management. Specifically, this institution should be responsible for investigating, categorizing and conducting surveillance of IAS. The authority should also be tasked with the development of risk assessment procedures to evaluate applications for the import of IAS.

2.5. Biosafety

Until 2004, the issue of management of genetically modified organisms (GMOs) was not properly addressed in Viet Nam's legislation. It was sporadically touched upon in some laws, such as Decree No. 109 (referred to in the preceding section), the Ordinance on Animal Breeding, the Ordinance on Plant Breeding, Decision No. 178/1999/QD-TTg on the Labelling of Domestic and Import-export Goods and the Ordinance on Hygiene and Food Safety. Most of those laws generally mentioned GMOs simply to include them within the scope of the legislative instrument, but contained no specific directives on this issue.

Regulation of biosafety in environmental legislation

The Law on Environment Protection (2005) includes several provisions on biosafety. The purpose of those provisions is to extend and apply the existing legislative framework for conventional processes and products to biotechnology, GMOs and GMO products. Article 87 provides as follows:

- individuals and legal entities that manufacture and trade in GMOs and their products shall comply with the laws on biodiversity, food hygiene and food safety, plant and animal breeding and other related laws;
- Individuals and legal entities are only permitted to carry out research, manufacture, trade in, use, import, export, storage and transportation of GMOs and their products which are included in a list. Those activities shall be in compliance with legislation in place; and

- genetically modified animals, plants and microorganisms for import shall be quarantined.

Regulations on the management of biosafety were promulgated by Decision No. 212/2005/QD-TTg of 26 August 2005. The regulations provide for several areas of biosafety management, from research, manufacturing and trade, to importation, exportation, storage and transportation of GMOs.

The Ministry of Natural Resources and Environment (MONRE) is the principal authority responsible for management of biosafety at the state level. Other ministries, such as MOF, MOARD and MOH, are responsible at the ministerial level. According to regulations issued in 2005, enterprises shall obtain a biosafety certification for their risk management measures. For all other aspects of biosafety (e.g. authorization to import, risk assessment), the regulations lack detailed provisions.

MONRE has a coordinating role *vis-à-vis* the other ministries. With regard to conservation and biodiversity, Decree No. 109 regulates the prevention of adverse effects of GMOs on wetland ecosystems. Article 7 prohibits "the introduction of new species into wetland ecosystems which may cause ecological unbalance or modify the gene pool of local animals and plants". In the implementing Circular No. 18/2004/TT-BTNMT, there is no specific directive on how to manage biosafety in those ecosystems.

It is clear from the above that biosafety has been integrated into the Law on Environment Protection and other subsidiary legislation in the area of environment law, but in very general terms without any operational detail or implementation arrangements.

Regulation of biosafety in plant and animal legislation

The plant and animal legislation of Viet Nam follows the same approach as the environmental laws, which means applying legislation developed for conventional agriculture to biotechnology. The Ordinance on Animal Breeding and the Ordinance on Plant Breeding state that activities of research, selection, manufacturing, trading in, import and export of genetically modified animal and plant varieties shall be in compliance with applicable laws.

The 2001 Ordinance on Plant Protection and Quarantine does not directly regulate GMOs. However, pest risk analysis carried out by the PPD under the ordinance and in accordance with international standards may cover GMO plants and plant products. All other regulatory activities of the PPD could apply to genetically modified plants and plant products as well.

Regulation of biosafety in food safety legislation

Under the Ordinance on Hygiene and Food Safety, the issue of products and food originating from GMOs is sporadically covered. Article 20 provides that products and food originating from GMOs must clearly be labelled as such in Vietnamese. Decision No. 178 on Labelling (referred to above) provides some directives to implement the ordinance.

Ministries and their departments have promulgated other legal directives on labelling. MOF and MOARD promulgated Circular No. 03/2000/TT-BTS on 22 September 2000 and Circular No. 102/2001/TT-BNN-KHCN on 26 October 2001, respectively. These directives provide that food originating from GMOs must be labelled clearly in Vietnamese.

Currently, a draft Law on Biodiversity is under development. It covers biosafety in that it provides that MONRE is the designated implementing authority for the Cartagena Protocol.[4]

III. ASSESSMENT OF LEGISLATION

It is clear from the above that Viet Nam does not have a single law which covers the whole *Biosecurity* issue. Instead, provisions on *Biosecurity* are found in different laws and regulations which address specific areas of *Biosecurity*. The institutional mandates of the ministries that play a role in the *Biosecurity* scenario are briefly summarized below.

MOARD plays the most important role in the area of animal and plant health. It establishes and implements quarantine measures for animals and plants. In the food safety area, it is responsible for the production processes of food and the management of hygiene of imported food of animal origin. In addition, it serves as enquiry point and notification

[4] For a discussion of this instrument see Chapter 2, Part VII.

authority under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures.[5]

MOF is responsible for sanitary measures for aquatic animals and animal products. In the food safety area, it is responsible for aquatic animal products for domestic consumption and aquatic animal 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 aquatic animal products. According to a recent resolution of the National Assembly, from August 2007 MOF will be merged with MOARD.

MOST is responsible for promulgating standards in all areas of *Biosecurity*. It is also the Codex Contact Point.[6]

MONRE is responsible for the management of biosafety at the overarching state level. The Environment Protection Agency that operates under its hierarchy is the focal point for the Convention on Biological Diversity[7] and the Cartagena Protocol.

MOH 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 cases of emergencies, it coordinates with the People's Committees at the different territorial levels as well as the concerned ministries to establish control measures.

In short, in the five areas of *Biosecurity*, the existing laws of Viet Nam have tasked several ministries with the performance of functions. In terms of substantive regulation of *Biosecurity*, the plant health framework seems to be the most advanced. The legislation captures the principles and the key regulatory areas according to international dictates. In light of the WTO SPS requirements by which Viet Nam has recently become bound, it is critical to have enabling laws and regulations in the other areas of *Biosecurity*. *Biosecurity* is the guiding concept that can bring together the existing and future legislative efforts in order to manage trade in agricultural products in a manner respectful of the SPS dictates while at the same time protective of the natural resources of the country.

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[5] For a discussion of this agreement, see Chapter 2, Section 2.1.
[6] For a discussion of the Codex Alimentarius, see Chapter 2, Part V.
[7] For a discussion of this convention, see Chapter 2, Part VI.

11

CONCLUSION

Contents

I. LESSONS LEARNED

Biosecurity is an evolving concept not only because of progress in science and technology that brings new opportunities and new risks to food and agriculture but also because of how the approach is perceived and implemented in different countries. Governments give varying degrees of priority to international trade and to the protection of agricultural resources from sanitary and phytosanitary threats, thus *Biosecurity* is addressed differently in different jurisdictions. In some countries, *Biosecurity* functions as a specific objective of agricultural policies and laws, and governments take specific action to synchronize sectoral authorities and responsibilities; in other countries interest in a *Biosecurity* approach can simply point to the need to protect agricultural health and food safety against trade liberalization without requiring any immediate action. What is agreed is that the path to a shared perception of *Biosecurity* and its legal framework is still long.

On the legislative side, *Biosecurity* does not appear as an integrated whole in any of the pilot countries. Rather, *Biosecurity* is addressed through sectoral regulatory instruments that may have arisen in different historical contexts and because of specific needs. In Chapters 5–10, the national legal consultants examined these legislative instruments in an attempt to evaluate their compliance with international norms and their effectiveness at coordinating action against biological risks. The consultants essentially pieced together the sectoral regulatory instruments of different scopes and examined them from a new angle, assessing how well these pieces of legislation embrace *Biosecurity*. Their work reveals gaps in certain sectors as well as the absence of a consistent approach to *Biosecurity* overall.

At the institutional level, the national studies show that coordination is often lacking among government bodies involved in *Biosecurity* matters, and inter-institutional conflicts are common. This is an issue in the six countries reviewed and argues for some corrective action. If the main goal of *Biosecurity* at national level is to integrate the animal health, plant health and food safety sectors, the national studies reveal that this dimension of *Biosecurity* is not being successfully achieved.

Regardless of whether the governments of the pilot countries have overtly committed themselves to the implementation of a *Biosecurity* approach, the case studies reveal that all six countries are making efforts to align their legislation with international dictates in some or all of the areas that

constitute *Biosecurity*. In that respect, *Biosecurity* has in some fashion already become the guiding principle for legislative upgrading. Greater understanding can provide further impetus and coherence to many legislative initiatives already under way.

At the international level, *Biosecurity* is not defined in any single legal text, instead covering a range of subjects and implicating several international instruments. Governments may wish to consider all these instruments under the *Biosecurity* rubric in order to implement their international obligations in a coordinated manner. This should help countries protect their natural resources for food and agriculture more effectively.

II. THE WAY FORWARD

The rapid growth of international trade in agricultural products calls for prompt action at the national level to avoid biological risks. As can be seen from the preceding chapters, any legislative and institutional reform must be supported at the political level. This is particularly true in a cross-cutting area like *Biosecurity* which requires a coherent approach.

In some countries, even where a comprehensive policy and clear strategy may be adopted, legal reforms may be blocked for years at the final drafting stage before draft legislative instruments are submitted to parliament (for primary legislation) or to the relevant minister or ministers (for subsidiary legislation). Where no political reasons are hindering adoption of the text, there may be staffing problems among the legal personnel in charge either of drafting the necessary legislation or of checking its consistency with the domestic legal system.

This problem has been noted in Kenya, where the Law Reform Commission has been trying to consolidate the legislative framework for agriculture, which consists of more than 130 legal instruments. The consolidation of legislation (i.e. the reduction in the number of legislative enactments by merging several instruments dealing with common issues into one piece of legislation) is seen as a way of fast-tracking and updating laws in a context where legislation takes a long time to pass parliament. This is also a perfect opportunity to review the laws through the lens of *Biosecurity*.

Another important task at national level will be to evaluate the actual capacity of the institutions that will be called upon to enforce *Biosecurity*

legislation. Without such an assessment, the application of the legal methodology contained in this study and the development of a strategy for legislative and institutional reform risks becoming a theoretical exercise. Capacity-building and provision of essential resources, based on a real assessment of existing institutions and capacities, are likely to be essential to the implementation of an effective *Biosecurity* approach.

On a more practical note, two final observations can be made. First, it appeared from the national consultations and from the authors' extensive experience in FAO member countries that *Biosecurity* is not a particularly popular or well-understood concept as yet. It is often confused with biosafety, which has been the subject of an international convention as well as capacity-building initiatives worldwide. This suggests that an important next step will be to carry out awareness-raising activities at national and regional level. Only where governments and stakeholders understand the concept of *Biosecurity* and see the benefits it can be expected to provide will there be the will to make institutional and legislative change.

National consultations will also be essential to build consensus around the most sensitive aspects of any proposed reforms, which will in turn encourage compliance once the reform is undertaken. Moreover, widespread consultations facilitate the circulation of draft legislation among relevant parties, which permits it to be modified in light of inconsistencies with other draft legal instruments being proposed in related areas. All these elements contribute to the design of feasible reforms, suited to the needs and realities of each country wishing to implement a *Biosecurity* approach.

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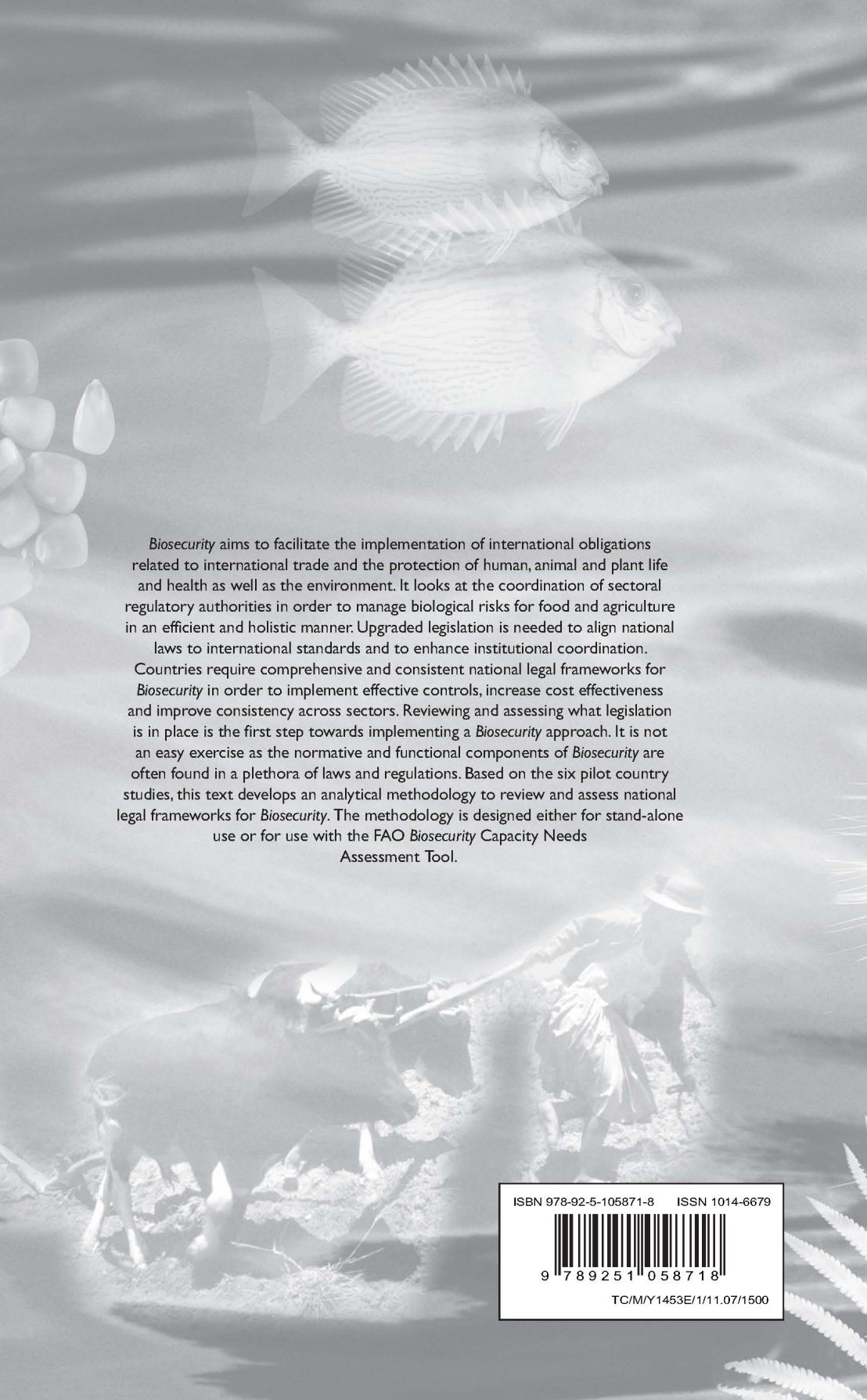

Biosecurity aims to facilitate the implementation of international obligations related to international trade and the protection of human, animal and plant life and health as well as the environment. It looks at the coordination of sectoral regulatory authorities in order to manage biological risks for food and agriculture in an efficient and holistic manner. Upgraded legislation is needed to align national laws to international standards and to enhance institutional coordination. Countries require comprehensive and consistent national legal frameworks for *Biosecurity* in order to implement effective controls, increase cost effectiveness and improve consistency across sectors. Reviewing and assessing what legislation is in place is the first step towards implementing a *Biosecurity* approach. It is not an easy exercise as the normative and functional components of *Biosecurity* are often found in a plethora of laws and regulations. Based on the six pilot country studies, this text develops an analytical methodology to review and assess national legal frameworks for *Biosecurity*. The methodology is designed either for stand-alone use or for use with the FAO *Biosecurity* Capacity Needs Assessment Tool.

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