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CAPACITY-BUILDING FOR ENFORCEMENT OF NATIONAL BIOSAFETY REGULATORY FRAMEWORKS

1. INTRODUCTION

1. Paragraph 1 of Article 2 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. In this regard, most developing country Parties and Parties with economies in transition to the Protocol, with support from the Global Environment Facility (GEF), have developed national biosafety frameworks (NBFs). However, a majority have not yet embarked on their implementation and enforcement, largely due to lack of financial and human resources and institutional capacities.

2. In its decision BS-V/16, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) adopted a Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020. Operational objective 1.1 of the Strategic Plan is to enable all Parties to have operational national biosafety frameworks for the implementation of the Protocol and operational objective 2.1 is to further support the development and implementation of national regulatory and administrative systems.

3. Since the adoption and entry into force of the Protocol, at least 120 developing countries and countries with economies in transition have developed draft national biosafety frameworks with support from the Global Environment Facility (GEF). A few of those countries, including Brazil, Bulgaria, Burkina Faso, Cameroon, Iran, Kenya, Malaysia, Malawi, Mali, Mauritius, Namibia, the Republic of Moldova, South Africa, Viet Nam and Zambia, have enacted biosafety laws and some have elaborated accompanying regulations. However, most of the countries lack the necessary capacity to enforce their biosafety laws and regulations and to effectively implement the national biosafety frameworks in general. A study published by the United Nations University Institute of Advanced Studies (UNU-IAS) in 2008 noted that in many developing countries the policies have not yet translated into working institutional systems and that enforcement issues have not yet received adequate attention. In a few countries,

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operational manuals for implementation of the biosafety laws are still being developed. The study further noted that the implementation and enforcement of biosafety regulations would require institutional strengthening across the board.

4. This document reviews some of the existing measures and mechanisms for the enforcement of national biosafety laws and regulations. Section 3 of the document describes experiences from relevant initiatives aimed at strengthening capacity to implement and enforce environmental laws and requirements of multilateral environmental agreements. The last section identifies the capacity-building needs for the implementation and enforcement of biosafety laws, regulations and standards and possible actions for addressing those needs.

5. In the context of this document, enforcement is described as a set of actions undertaken to compel or encourage compliance with the biosafety laws and regulations and with the administrative rules/requirements (including conditions attached to permits and/or licenses). Enforcement encompasses monitoring and inspection to gather information needed to assess compliance with the laws and regulations, identify any violations and help return violators to compliance. It also encompasses investigation and prosecution of very serious violations of the law. Inspections, monitoring, and data collection are essential to developing an enforcement response and securing an enforcement response sometimes requires taking legal action.

2. NATIONAL BIOSAFETY ENFORCEMENT SYSTEMS AND MECHANISMS

6. A number of developing countries and countries with economies in transition have incorporated systems for monitoring and enforcement in their National Biosafety Frameworks (NBFs). The systems encompass a wide range of legal and administrative enforcement tools and various monitoring and enforcement functions. These include:

(a) Enforcement of national biosafety laws and regulations;

(b) Implementation of bilateral, regional and multilateral agreements and arrangements;

(c) Enforcement of rules and standards for LMO identification, handling, packaging, storage and transportation;

(d) Implementation and enforcement of measures and strategies to regulate, manage and control risks identified in a risk assessment;

(e) Enforcement of the final decisions made regarding the importation or release of LMOs, including any conditions attached to those decisions;

(f) Enforcement of domestic measures to detect and prevent illegal and unintentional transboundary movement of LMOs;

(g) Implementation of LMO traceability and monitoring and control systems for safe use of LMOs;

(h) Enforcement of requirements for contained use of LMOs, including approved protocols and standards for the operation of LMO laboratories, greenhouses and research facilities and activities related to LMOs and their derivatives; and

(i) Enforcement of other related measures including phytosanitary measures, food safety control and veterinary surveillance.

7. The nature and scope of the systems for monitoring and enforcement incorporated in the NBFs and the biosafety regulatory regimes varies significantly from country to country. For example, in Brazil the National Biosafety Law enacted in 2005 specifies the responsibilities of various national institutions in the implementation and enforcement of the law. The law also outlines some of the consequences for the administrative and criminal violations of the law. Some of the remedies specified include: warnings, fines, seizure of the LMOs and their derivatives, suspension of sales of LMOs and their derivatives, embargo of the LMO-related activity, partial or full interdiction of the business or undertaking, and suspension or cancellation of the registration, patent, license or authorization.

8. In Ghana, the NBF and the draft biosafety bill provide for the enforcement of a biosafety regulatory regime through an inspectorate system. Inspectors will be given policing powers to ensure compliance. The Biosafety Bill requires licensing of specialized inspectors to take part in its enforcement functions. The Biosafety Bill and the National Biosafety Guidelines spell out the expected inspectorate functions. The National Biosafety Authority (NBA), proposed under the Biosafety Bill shall act as the executive body for the overall regulation of LMOs. Monitoring and inspection functions shall be handled by the regulatory agencies. The NBF envisages the need for the development of inspection materials or manuals to assist inspectors in ensuring compliance with the regulatory regime, the need to equip and develop and certify referral laboratories for cases involving verification and detection of LMOs, and the need to equip the cross-sectoral and dispersed inspectors with rapid diagnostic methodologies (kits) to assist in their work.

9. In Kenya, the Biosafety Act 2009 lays down legal and institutional frameworks for governing modern biotechnology in the country. The Act establishes a National Biosafety Authority which is responsible for the overall supervision and control of the development, transfer, handling and use of LMOs and empowers other regulatory agencies to enforce various provisions of the Act and relevant provisions in other legislation that are regulating biotechnology activities. The government has established a Coordination Structure for Biosafety Regulatory Agencies to foster a coordinated and harmonized approach to biosafety decision-making and enforcement of the biosafety law and regulations by the various agencies.[1] In addition, the government has developed a number of guidelines to facilitate the implementation and enforcement of biosafety laws, regulations, protocols and standards. These include: (i) national guidelines for release of LMOs into the environment; (ii) guidelines for monitoring and inspection of LMOs; (iii) inspection guidelines for contained use of LMOs in laboratories, greenhouses (Biosafety Level 1-3) and for animal units; and (iv) inspection guidelines for LMO field trials, including checklists that could help ensure effectiveness and consistency in the inspection of field trials.

10. In Liberia, the monitoring and enforcement component of the National Biosafety Framework (NBF) seeks to equip the Liberian government officials to ensure compliance with the Liberian Biosafety Regulations. Enforcement involves the use of administrative and legal tools to compel applicants to adhere to the permit conditions and to deter violations of the laws, rules and regulations. Various institutions shall have different enforcement functions, including inspections and enforcement of compliance with safety procedures. The inspectors shall have legal powers to: (i) enter premises of biotechnology permit holders with or without notice; (ii) take written records of activities therein; (iii) take samples of necessary materials for analyses; and (iv) review documents to ensure compliance. If an inspector establishes action of non-compliance that may pose risk to human health and the environment

[1] http://www.biosafetykenya.co.ke/documents/Coordination%20structure%20revised%20June%202009%20NBO.pdf

he or she shall institute the following measures as appropriate: (i) issue prohibition notice; (ii) order temporary suspension of all activities until the conditions for suspension are corrected; (iii) order the rectifying of any such established irregularities within a specified time period; (iv) order remediation and other measures for rectifying or reducing the consequences of adverse effects of the non-compliance activities; (v) bring administrative or judicial action against permit holders; and (vi) impose and collect fines for harm caused.

11. The Lithuanian NBF includes a detailed system for monitoring, control and enforcement of biosafety regulations. It outlines the monitoring and enforcement responsibilities of various institutions and proposes measures to be undertaken to facilitate effective monitoring, control and enforcement. Some of the proposed measures include the following:

(a) Preparation of the necessary orders and regulations for the enforcement of safety control and market surveillance of LMOs and LMO products;

(b) Development of the LMO laboratory infrastructure where all practical testing for LMOs and monitoring (and general surveillance) of LMOs could be executed;

(c) Preparation and employment of standard methodological sampling and evaluation techniques;

(d) Improvement of the knowledge of national experts in the field of biosafety with respect to monitoring environmental effects of LMOs usage, application of risk assessment procedures and making of conclusions; concretize and calculate financial resources of the LMOs monitoring;

(e) Inclusion of the LMO monitoring (surveillance) sub-programme in the state national biological diversity monitoring programme;

(f) Elaboration of methodological skills to promote quality assurance at different levels of monitoring and controlling processes, organizing specialized courses for personnel; and

(g) Improvement of coordination efforts with the customs department to regulate imports of LMOs.

12. In Malaysia, the Biosafety Act 2007 includes a detailed section on the enforcement procedures and mechanisms. The Act specifies officers that may exercise enforcement powers under the Act, the investigation powers of the enforcement officers and the process and requirements for undertaking investigative searches with and without search warrants and for handling seizures. It also includes provisions regarding the collection of admissible evidence, including the powers and procedures for taking samples.

13. In the Republic of Moldova, the NBF developed in 2004 includes a component on enforcement and monitoring of activities connected with production, transportation, imports and exports and distribution of LMOs and LMO products. The NBF noted that the Law on Biosafety in effect then did not provide sufficient details regarding the powers for inspection and monitoring of compliance with the requirements with respect to LMOs or enforcement of laws and regulations. It also lacked clear or detailed provisions regarding the mechanisms for inspection and monitoring and for the enforcement of the law which has resulted in the decreased efficiency of the law. In this context, the NBF recommended the amendment of the law to introduce: (i) segregation of powers and functions of state authorities regarding the process of examination and decision-making; (ii) procedures and methodologies for

monitoring, inspection and control of the authorized LMOs and related activities; (iii) introduction of a new chapter regarding the BCH and the Biosafety Register; and (iv) development of procedures and methodologies for testing and assessment/management of biotechnology risks. The NBF also recommended the development of the following regulations, guidelines and manuals to facilitate the enforcement and implementation of the law: (i) procedures and internal documentation for the testing laboratory; (ii) procedures and methodologies for risk assessment in situations of contained use, deliberate release into the environment and placing on the market; (iii) guidelines and checklists for the examination of notifications and risks assessment; (iv) procedures, methodologies and requirements for packaging, labelling, storage and transportation; and (v) guidelines for monitoring of the LMO activities. The NBF also recommends the establishment of the state genetically modified organism (GMO) inspection system (and guidelines for relevant branches inspectorates), education and training in the field of living modified organisms (LMOs) for public servants; development of a methodology of calculation of costs and charges in the GMO regulation system; guidelines on customs procedures regarding imports and exports of LMOs and establishment of regulations regarding the handling of confidential information.

14. In Samoa, enforcement of the regulatory regime is provided through various criminal offences. A range of activities are prohibited including importing LMOs without notifications or approvals, failing to disclose or misrepresenting information relating to an LMO and fabricating risk assessments. The legislative framework empowers Environment Officers from the Ministry of Natural Resources and the Environment to inspect and monitor the use of LMOs. They are also empowered to enforce the legal framework by seizing and destroying LMOs that are in breach of the law. These enforcement powers complement, and do not affect existing powers to search and seize under quarantine, customs and excise laws.

15. In the United Kingdom, the Department for Environment, Food and Rural Affairs (Defra) is responsible for the control of the deliberate release of GMOs, and for national, European Union and international policy on the environmental safety of GMOs. The GM Inspectorate of the Food and Environment Research Agency (Fera) provides Defra with GM inspection and enforcement services for the deliberate release of GMOs in England and Wales.[2] The GM Inspectorate of the Science and Advice for Scottish Agriculture (SASA) performs the same duties for Scotland.[3] The aim of the two Inspectorates is to protect the environment and the public from any unapproved releases of genetically modified (GM) crop plants. Their key services are: (i) monitoring imports of conventional seed to reduce the risk of adventitious presence of GMOs and audit of seed importers and producers; (ii) case by case investigation of specific potential breaches of the GM legislation, including unauthorised releases of GMOs; (iii) inspection of deliberate release sites and undertaking management audits of deliberate release consent holders, (iv) undertaking research and development to underpin GM inspection and enforcement, including GMO testing and identification; and (v) giving advice to policy branches within the Government on GM crops and conduct research in support of this work. The two Inspectorates produce annual reports that detail their inspection and enforcement activities. These are available at: http://www.gm-inspectorate.gov.uk/reportsPublications and http://www.sasa.gov.uk/GM-annual-reports. In addition, Fera offers tailor-made training courses on GMO inspection and enforcement. Subjects covered include: practical field inspections, laboratory GMO testing, sampling for GMOs, seed auditing, enforcement procedures and regulatory aspects.

16. The above examples provide a glimpse of the general nature and scope of the existing systems for enforcement of the biosafety regulatory regimes. It is clear from the analysis that in general the

[2] http://www.gm-inspectorate.gov.uk/

[3] http://www.sasa.gov.uk/wildlife-environment/gm-inspectorate

existing mechanisms and measures for enforcement of national biosafety laws in many countries need to be strengthened.

3. EXAMPLES OF RELEVANT CAPACITY-BUILDING INITIATIVES FOR ENFORCEMENT OF ENVIRONMENTAL LAWS AND MULTILATERAL ENVIRONMENTAL AGREEMENTS

17. Over the last several years, a number of initiatives aimed at strengthening capacity to implement and enforce environmental laws and requirements of multilateral environmental agreements have been undertaken by various organizations in different countries and regions. Examples include: the United Nations Environment Programme's (UNEP) capacity-building activities in international environmental law[4]; the IUCN Environmental Law Programme (ELP)[5]; and activities of the International Network for Environmental Compliance and Enforcement (INECE)[6]

3.1. UNEP's Capacity-Building Programme in Environmental Law

18. Since its inception, the United Nations Environment Programme (UNEP) has played a prominent role in developing the capacities of countries in the field of environmental law. Its work encompasses provision of technical, legal and institutional advice, upon request, in establishing and enhancing their national environmental legislation and institutional frameworks, including for the implementation of multilateral environmental agreements; organization of trainings at international, regional and national levels; development of guidance and training materials; and dissemination of relevant information.

19. UNEP's Compliance and Enforcement unit provides technical assistance to Governments, particularly through the development of Guidelines on Compliance with and Enforcement of Multilateral Environmental Agreements, development of training manuals, organization of training workshops and provision of legal advisory services. In 2006, UNEP produced a "Manual on Compliance with and Enforcement of Multilateral Environmental Agreements (MEAs)" which highlights experiences and case studies of innovative approaches for the implementation and enforcement of MEAs.[7]

20. UNEP has also carried out a number of training activities for government in environmental law. The most prominent initiatives are the Global Training Programme in Environmental Law and Policy (GTPELP)[8] and the Judges Programme[9]. Other important activities include the promotion of environmental law education in national universities, training-by-attachment, and the internship programme. The GTPELP programme offers training in the field of environmental law to government officials working in the field of environmental management and legislation as well as other stakeholders, including judges, parliamentarians, legal officers, legal NGOs, enforcement officers, and academicians. The Judges programme aims at strengthening the capacity of judges, prosecutors, and other legal stakeholders in securing environmental governance, adherence to the rule of law and the effective implementation of national environmental policies, laws and regulations including the national level implementation of multilateral environmental agreements.

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[4] http://www.unep.org/law/Programme_work/index.asp

[5] http://www.iucn.org/about/work/programmes/environmental_law/

[6] http://www.inece.org/index.html

[7] http://www.unep.org/dec/MEA_Manual.html

[8] http://www.unep.org/Law/Programme_work/Training/global_training_prog.asp

[9] http://www.unep.org/Law/Programme_work/Judges_programme/index.asp

21. UNEP has also developed a series of environmental law training and guidance materials. These include: a UNEP Manual in Environmental Law, a Judicial Handbook on Environmental Law, Legal Drafters handbooks on specific topics, a Guidebook for Policy and Legislative Development on Conservation and Sustainable Use of Freshwater Resources, a Register of International Treaties and Other Agreements in the Field of the Environment and a Compendia of Summaries of Judgments in environment-related cases from around the world, a Lecturer's Manual for a Course on Compliance with and Enforcement of MEA, Judicial Training Modules on Environmental Law and a Judicial Handbook on Environmental Law. [10]

3.2. IUCN Environmental Law Programme

22. The IUCN Environmental Law Programme (ELP) is an integrated programme of activities that assists decision makers with information, legal analysis, advisory services, legislative drafting, mentoring and capacity-building at national, regional and global levels. The Programme also provides the opportunity and the forum for governments, non-government organizations and others to network and to share information and discuss ideas.

23. The ELP has contributed to the implementation of MEAs through regular advice and technical assistance on legal issues to the MEA Secretariats – in particular: the Convention on Biological Diversity (CBD), the Convention on International Trade in Endagered Species of Wild Fauna and Flora (CITES), the Convention on Migratory Species of Wild Animals (CMS) and the Ramsar Convention on Wetlands (Ramsar) – and production of studies and analysis of MEA implementation issues. For example in 2003 it produced an "Explanatory Guide to the Cartagena Protocol on Biosafety". The ELP has also provided technical assistance to a number of developing countries upon request ranging from review, diagnosis and preparation of inventories of existing legislation, to identifying measures for strengthening national legislation, and assisting in drafting new legal instruments. It has also contributed to national and regional capacity-building in environmental law through seminars, workshops and training courses. For example in the mid-1990s, a "Train the Trainers" Programme in environmental law was implemented. It involved the conduct of courses for law professors teaching environmental law in the Asia-Pacific Regions at the University level and resulted in a two-volume set of training materials for the region.

24. Finally, the IUCN Commission on Environmental Law provides an international network of some 700 environmental law specialists from 120 countries. This pool of experts can be easily accessed, and their expertise can be used to assist in promoting compliance and enforcement of environmental laws around the world.

3.3. Capacity-Building Activities of the International Network for Environmental Compliance and Enforcement

25. The International Network for Environmental Compliance and Enforcement (INECE) is a global network of more than 4,000 environmental compliance and enforcement practitioners dedicated to raising awareness of compliance and enforcement, developing networks for enforcement cooperation, and strengthening capacity to implement and enforce environmental requirements. Since its establishment in 1989, INECE has undertaken a number of initiatives aimed at promoting active compliance with and enforcement of environmental laws and regulations. For example, to date it has organized eight International Conferences for Environmental Compliance and Enforcement. The ninth conference will be held 20-24 June 2011 in British Columbia, Canada.

[10] http://www.unep.org/DEC/Information_Resources/Publications.asp

26. INECE maintains forums designed to facilitate communication between persons with common interests in environmental enforcement relating to the various topics. Currently there are ongoing discussions on environmental compliance inspections, citizen participation in environmental enforcement, enforcement indicators, illegal logging, and on enforcement and compliance issues relating to water, wildlife, hazardous waste, pesticides and the ozone layer.[11]

27. Furthermore, INECE provides access to a number of environmental compliance training resources, including an inspector training curriculum based on international good practice.[12]

28. The examples highlighted above, and other similar initiatives, provide useful experiences and resources that could be used to strengthen the capacities of Parties to the Cartagena Protocol to implement and enforce their biosafety laws and regulations. They also present opportunities for collaboration. The meeting of the Parties to the Protocol may wish to invite the institutions implementing the above initiatives to develop similar programmes dedicated to strengthening capacities to implement and enforce their biosafety laws and regulations.

4. STRATEGIES FOR STRENGTHENING NATIONAL BIOSAFETY ENFORCEMENT CAPACITIES

29. Lack of national capacity, in particular a lack of capacity to implement and enforce national biosafety laws, regulations and standards, is one of the biggest obstacles to the effective implementation of the Cartagena Protocol on Biosafety. As noted above, most developing country Parties and Parties with economies in transition have developed draft national biosafety frameworks and some have enacted biosafety laws and regulations. However, many of them lack the capacity to implement and enforce their national biosafety laws and frameworks. Some of the challenges encountered include:

(a) lack of effective institutional mechanisms;

(b) inconsistency and lack of clarity of the biosafety regulatory frameworks;

(c) lack of human and financial resources;

(d) lack of awareness and understanding of biosafety issues and requirements by government officials (including inspectors, customs officers, police, prosecutors, judges and others) responsible for enforcing the biosafety laws and by the stakeholders.

(e) lack of political goodwill and commitment to implement and enforce the relevant regulatory frameworks; and

(f) lack of effective coordination and information exchange among the relevant national institutions.

30. As countries move from policy development to implementation of national biosafety frameworks, there is a need to strengthen the institutions and improve skills of personnel (including inspectors, customs officers, police officers, prosecutors, judges and others) involved in the monitoring and enforcement of biosafety. Although personnel in existing government institutions (including police,

[11] http://www.inece.org/forums.html

[12] http://www.inece.org/forumsinspector.html

sectoral inspectorates, the judiciary and others) have experience in their traditional fields, many of them have limited experience with activities involving LMOs, and environmental law enforcement in general.

31. The following are examples of the some of the measures that could be taken to enhance capacity-building for enforcement of national biosafety regimes:

(a) Policy and law reform - identification of weaknesses and gaps in existing biosafety-related policies, laws and regulations to enhance their clarity so as to minimize the scope for conflicting interpretations of the various provisions; improve their consistency and ensure their compatibility/complimentarity with other national legal frameworks; and to enhance their workability, enforceability and adaptability.

(b) Development of implementing regulations and technical guidelines for regulators, providing details on how the biosafety laws would be implemented in practice and spelling out the roles and responsibilities of the various regulatory agencies in a country;

(c) Training of inspectors and members of the National Biosafety Committees (NBC) on inspection and enforcement requirements for LMOs;

(d) Building the legal capacity of relevant government institutions – ensure that each country has adequate and effective legal instruments, administrative policies and institutions;

(e) Production and distribution of relevant technical documentation and guidelines (including biosafety inspection and enforcement manuals with specific guidelines or checklists and practical case studies on relevant approaches to biosafety inspections and enforcement strategies successfully used in other countries);

(f) Helping the regulated community to better understand their responsibilities under the law and to comply with the law through training and dissemination of relevant information;

(g) Facilitating public involvement in the implementation and enforcement of biosafety laws and regulations (this involves ensuring that citizens have access to the courts in terms of open-standing provisions and access to information and financial and other resources to be able to effectively enforce the laws and policies);

(h) Mobilizing academic institutions to deliver training and education in biosafety law. Increasing the ability of academics in the region to deliver training and education in the field of biosafety law is a key component of long-term capacity-building for government and non-government organizations. Existing human resource limitations, combined with a high turnover of personnel within many government institutions severely constrains the ability of governments to effectively respond to environmental challenges;

(i) Establishment of regional and subregional biosafety enforcement networks to facilitate coordination and exchange information and expertise. These networks could also be used to facilitate capacity-building in enforcement of biosafety laws, regulations and standards. For example they could be used to: strengthen environmental law implementation and enforcement; facilitate collaboration and information exchange; build government and non-government institutional capacity; identify regional priorities and building consensus; and overcome challenges of limited resources.

32. Other measures that could be undertaken to enhance operational capacity to enforce biosafety laws and regulations include the following:

(a) Creation of specific institutional bodies to enforce biosafety laws and regulations and/or re-alignment of existing institutions;

(b) Designation of staff dedicated to enforcement of biosafety laws and regulations and improvement of staff performance and commitment, for example through training and recognition of enforcement achievements;

(c) Training of enforcement officials and civil society in the requirements of the national biosafety regulatory frameworks and in techniques for monitoring, detecting and reporting of illegal biosafety activities;

(d) Development of reporting and monitoring systems for biosafety-related crime or non-compliance.

(e) Fostering inter-agency linkages, communication and cooperation in the enforcement of biosafety laws and regulations. Inter-agency cooperation is essential to the success of any law enforcement effort. This requires establishment of regular and systematic communication and exchange of information among law enforcement agencies.

(f) Establishing partnerships between the public institutions and civil society or private sector bodies to monitor compliance with, and increase transparency in the enforcement of, biosafety laws and regulations.

33. The successful implementation of the Protocol is to a large extent dependant on the effective enforcement of the national biosafety regulatory frameworks. However the latter cannot be achieved without adequate technical, financial and human resource capacities at the national level. In this regard, Parties may wish to consider undertaking, as appropriate, the above-mentioned measures in order to enhance their capacities for implementation and enforcement of their national biosafety regimes and the Cartagena Protocol in general.
