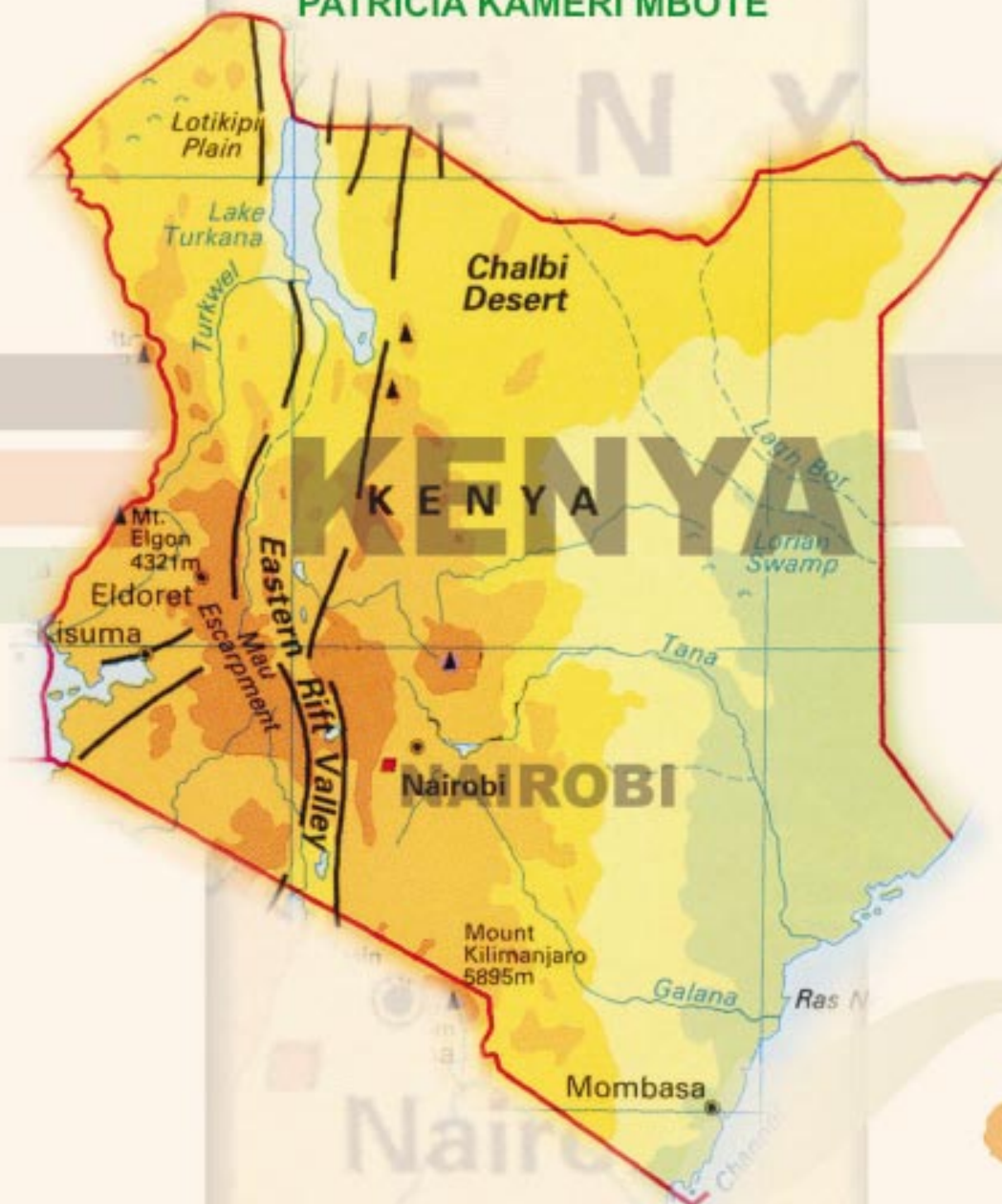




TOWARDS A LIABILITY AND REDRESS SYSTEM
UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

A REVIEW OF THE KENYA NATIONAL LEGAL SYSTEM

PATRICIA KAMERI MBOTE



ACODE Policy Research Series No. 8, 2004

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LIST OF ACRONYMS

1. ACODE Advocates Coalition for Development and Environment
2. AIA Advanced Informed Agreement
3. EMCA Environmental Management Coordination Act
4. BCH Biosafety Clearing House
5. CBD Convention on Biological Diversity
6. EA Environmental Assessment
7. EIAs Environmental Impact Assessments
8. IPRs Intellectual Property Rights
9. LMOs Living Modified Organisms
10. NEMA National Environment Management Authority
11. NCST National Council for Science and Technology - Kenya
12. NBC National Biosafety Committee
13. ICCP Intergovernmental Committee for the Cartagena Protocol on Biosafety
14. CoP Conference of the Parties

ACKNOWLEDGEMENT

The coming into force of the Cartagena Protocol on Biosafety on September 11, 2003 heralds a new beginning for further discourse and negotiations on the issue of liability and redress for damage arising out of the transboundary movement of Living Modified Organisms (LMO). Yet, already challenged and stretched in terms of capacity and expertise by the wide range of international and regional negotiations currently going on in many areas including trade, the commencement of the negotiations under article 27 of the Cartagena Protocol on Biosafety yet presents another challenge for policy makers and negotiators. The need to develop a better understanding of the current legal regime for liability and redress, mobilization expertise to inform the development of negotiating positions and the need to mobilize financial resources are critical defining factors in determining the ability of African countries to influence the forthcoming negotiations and define the scope and content of the future architecture of the regime to be developed under article 27.

This paper was prepared as part of ACODE's effort to mobilize policy makers in the region to pay early attention to the need to undertake analytical work and generate information that can support future negotiating positions. Similar work was undertaken in Uganda and Tanzania and the papers focussing on these two countries will be published in these series soon. The papers were also presented and discussed at a policy dialogue workshop attended by senior governmental officials in Kenya, Uganda and Tanzania, national focal points for the Cartagena Protocol on Biosafety, leading personalities from civil society and legislators. The proceedings of the dialogue have now been published as ACODE Public Policy Dialogue Series, No. 1, 2004.

We would therefore like to first and foremost thank Dr. Patricia Kameri-Mbote for the wonderful work that she has done in putting together this paper. The paper is perhaps until now the most concise exposition of the current legal framework for liability and redress in Kenya. We hope that the information and analysis that has been provided will be useful in the process of formulating negotiating positions for the East African Community Member States. We are also grateful to the participants at the October 2002 public policy dialogue who provided valuable comments and recommendations that have helped in editing and finalizing this paper.

Finally, we would like to extend special thanks to the Rockefeller Foundation who provided the financial support for the research work, the organization of the policy dialogue and the subsequent publication of this paper.

1. Introduction

The coming into force of the Biosafety Protocol² charts out a new direction in the growth and development of modern biotechnology. It is a timely and vital development given that in a very short time frame, transgenic croplands have increased rapidly. This decade will witness many African countries adopt and commercialize transgenic crops. However, efforts to invest have to be guided by sound mechanisms for assessing risks and benefits. This is crucial to enable African governments to make informed choices and decisions.

The Protocol, an internationally binding legal instrument concluded by parties to the Convention on Biological Diversity (CBD), was the result of the work of the Ad hoc Working Group on Biosafety which was set up in 1995 and completed its work in 2000. The Protocol aims at comprehensively addressing concerns raised about biotechnology. These concerns include safe handling, use, and transfer of living modified organisms (LMOs).³ All Parties to the Protocol have the obligation to comply with its terms. However, the obligations set out in the Protocol do not fully align with the national needs and priorities of many African countries. The numerous areas of non-consensus within the Biosafety Working Group support the validity of this assertion.⁴ The Protocol contains not only elements of compromise but also provisions forced upon by some parties, particularly African States.⁵ The indefinite position on liability and redress is one such issue. However, most African States intend to implement the Protocol and some have begun putting in place mechanisms for biosafety.⁶ To provide a suitable framework for the implementation of the biosafety measures, parties are required to put in place relevant national legislation.⁷ For LMOs intended for direct use as feed, food or processing, only developed countries are obligated to put in place domestic regulatory frameworks while developing countries including those with economies in transition need only make decisions based on risk assessments.⁸ The challenge for African states is to put in place effective legal and administrative structures to implement the Protocol. African countries have been particularly concerned about the potential harmful impacts of biotechnology on their environment and most of them have put in place precautionary frameworks for biosafety.

2 See, Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes, Montreal, 2000.

3 These concerns are captured in the preamble paragraphs and Article 1 of the Protocol.

4 For a detailed analysis of the positions of the various interest groups comprising the Biosafety Working Group see: T.B.G. Egziabher, 'An Analysis of the Sixth Negotiation Session of the Biosafety Working Group, Cartagena, 14-23 February 1999 Report for the Like-Minded Group', (March 1999).

5 It is worth noting that the negotiation process was characterised by arm-twisting and threats and lacked effective participation and transparency as reflected in the documents produced after the Sixth Negotiation Session of the Biosafety Working Group in Cartagena. (See for instance: *ibid.*)

6 This is evident from the resounding response seen when the Protocol was opened for signature in Nairobi on 24 May 2000. At least 65 signatures were recorded on that day according to the UN. See IUCN Environmental Law Programme Newsletter (January-April 2000), at 5. Further African a number of African countries have already ratified the Protocol.

7 Protocol, Article 2(1).

8 *Ibid.*, at Article 11. Cf. R. Mackenzie, 'Cartagena Protocol on Biosafety: Overview' IUCN Environmental Law Programme Newsletter, (January-April 2000), at 1. See <<http://www.iucn.org/themes/law/index.html>

The objective of this paper is to review Kenya's legal system based both on legislation and common law. The main objective of the review is to analyse the adequacy and relevance of such regimes to liability and redress for damage caused by transboundary movement of Living Modified Organisms. It will seek to ascertain principles or provisions that can help form the country's and regional position in future negotiations for the elaboration of article 27. As a starting point, the paper will give an overview of the Protocol's main provisions. We view the Protocol as an environmental impact assessment aid and this position is borne out by the inclusion of "major developments in biotechnology including the introduction and testing of genetically modified organisms" in the Second Schedule of the Environment Management and Coordination Act (EMCA) as one of the projects that should undergo environmental impact assessment. We will look at Kenya's Constitution and other laws and identify the main liability regimes that exist under the domestic legal framework.

1.1. Overview of the Biosafety Protocol

The Convention on Biological Diversity was adopted in 1992 with three main objectives:

- 1 conservation of biodiversity,
- 1 sustainable use of genetic resources,
- 1 and fair and equitable sharing of the benefits arising from the use of the resources.

Under Articles 8 and 19 of the CBD, Parties are required to maintain, among other things, the means to regulate, control, and manage risks associated with the use and release of LMOs resulting from biotechnology.⁹ Based on these provisions, the management of environmental impacts on the conservation and sustainable use of biological diversity including risk to human health is a major concern of biosafety and the reason for being in the Protocol.

Article 19 of the CBD is the basis upon which negotiations for the Biosafety Protocol were initiated. Contrary to suggestions that the negotiation process of the Protocol started in 1996, Veit Koester, the person hailed as 'the father of the Protocol'¹⁰ contends that the process began way back in 1991 at the promulgation of the CBD.¹¹ The advance informed agreement (AIA) procedure (which is central to biosafety) is envisaged by the CBD at Article 19.3, which provides:

The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, *in particular, advance informed agreement*, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that
may have effect on the conservation and sustainable use of biological diversity.¹²

9 CBD, Articles 8(g) and 19.

10 See n. 7 above, at 4.

11 V. Koester, 'Excellence in the art of the possible', *IUCN Environmental Law Programme Newsletter*(January-April 2000), at 6.

12 Emphasis added to underscore the relevance of the AIA principle on which the biosafety regime should be founded.

The AIA procedure enables countries importing LMOs to undertake risk assessments for all initial shipments of LMOs into their countries.¹³ This principle, coupled with the precautionary approach, allows countries to refuse importation of LMOs whose safety is uncertain due to insufficient scientific evidence. The backbone of the decision-making process is the undertaking of risk assessments. To facilitate this procedure, a clearing house mechanism is established under Article 20 of the Protocol and capacity building provisions in Article 23 of the Protocol are incorporated representing important requirements for the Protocol's implementation.

1.2 Main Requirements of the Protocol

The main requirements of the Protocol focus on risk assessment, risk management and risk communication. However, there are exemptions to these rules. The Protocol provides for the exemption of certain pharmaceuticals¹⁴ from its scope explicitly stating that this provision is 'without prejudice to the right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import . . .',¹⁵ Along similar lines, Article 6 explicitly exempts LMOs in transit and those destined for contained use from AIA procedure. Parties also are given leeway to regulate the transport of LMOs through their territory and to undertake risk assessments prior to making decisions on importing LMOs destined for contained use. This includes the right of the importing Party to set standards for contained use within its jurisdiction under which, for instance, Kenya and Zimbabwe (which are each experimenting with LMOs) have put in place standards for contained use.

Article 7 of the Protocol focuses on the application of the AIA procedure. Article 7.1 refers only to initial transboundary movements and not to subsequent movements of LMOs. This provision is also subject to the right of a Party to require all LMO movements to undergo the AIA procedure.¹⁶ However, Article 7 does provide exemptions for importation of LMOs intended for use as food or feed, or for processing without AIA procedures being followed.¹⁷ Under Article 8, the exporting Party must notify or require the exporter to notify the importing Party of the initial shipment of LMOs to be imported. The exporter is responsible for accuracy of information in notification. To realize this goal, the exporting Party is required to take necessary and appropriate legal measures to implement this obligation.¹⁸

13 As discussed below, it is possible for a Party to require that both first and subsequent imports of LMOs be subjected to the AIA procedure.

14 The exemption covers the transboundary movement of LMOs, which are pharmaceuticals for humans and are regulated by other international regimes.

15 Article 5 of the Cartagena Protocol.

16 Article 7 read together with Articles 5 and 6 of the Cartagena Protocol.

17 Special procedures of LMOs intended for use as food or feed, or for processing are made under Article 11 of the Cartagena Protocol. These simply require notification to Parties through the Biosafety Clearing House. The end result is essentially to lay responsibility on importers to regulate and communicate that regulation to the Party of export. For further details on this point see: A. Cosbey, & S. Burgiel. , 'The Cartagena Protocol on Biosafety: An analysis of results,' An IISD Briefing Note, Winnipeg, Canada, (2000).

18 Protocol, Article 8.2. Cf. Art. 11.2.

Article 13 of the Protocol provides for a simplified procedure of notification of importation of LMOs. This simplified procedure allows states to export LMOs without a written permit, if the importing Party consents. In effect, this system corrodes the AIA procedure as it alienates further opportunities to check accuracy of decisions. Article 10(3)(a) of the Protocol enjoins Parties to inform exporters on how they intend to deal with subsequent imports. The time extension for decision-making under the AIA procedure shall be fixed by the importing Party.¹⁹ The reasons for disapproval of imports are required to be given by the would be importing Party.²⁰

Article 12 of the Protocol allows exporters to request a review of decisions not to import LMOs. Importing Parties must be able to respond to this request within 90 days. Considering Africa's implementation in light of limitations in capacity, it would require great efficiency in the flow of information especially from a Biosafety Clearing House (BCH) to make informed decisions. The BCH is the mechanism set out by the Protocol to facilitate the exchange of scientific, technical, environmental and legal information on and experience with LMOs and thus assist parties in implementing the Protocol. Article 19 of the Protocol on capacity building is designed to address some of these needs. National capacity building is one of the critical tools in implementing AIA procedures. Technical assistance and training, however, are not always forthcoming despite the fact that such commitments are increasingly being included in international legal instruments. Articles 19 and 20 make provisions for technical assistance in the Protocol's implementation to developing countries. The Global Environment Facility has also put in place mechanisms to assist countries in meeting their obligations under the Protocol.

Article 15.3 of the Protocol provides that a Party can require the exporter to carry out and bear the costs of a risk assessment. Given the fact that most African countries lack the capacity to undertake risk assessments, one can foresee situations whereby these countries are likely to rely on exporters' assessments. Three major issues arise from such scenarios.

First, countries that rely on exporters to do the assessments will almost never develop their own capacity in that area.

Second, the assessment may not be sound if the exporter (who has an interest in the assessment) not only selects but also pays the assessor.

Third, handling liability and redress becomes problematic where the exporter's assessment is formed on the basis of the importing country.²¹ Any litigation would take place in the

19 Ibid., at Article 10(3)(d).

20 Ibid., at Article 10(4)

21 J. Mugabe, 'From Cartagena to Nairobi: Towards an African agenda on the biosafety protocol,' Background paper for panel discussion at the 5th Conference of Parties to the Convention on Biological Diversity, Nairobi, (May 10, 2000).

exporting country inviting problems related to interpretation and undue pressure on weaker Parties.

Although the scope of the AIA procedure is limited by the Protocol's list of exemptions, countries may still regulate the LMOs contained in the exemptions.²² Ruth MacKenzie notes that 'the right of countries of import to regulate more strictly and even to extend regulations to cover these exempted activities is recognized in various provisions of the agreement'.²³

1.3 Article 27 - Liability and Redress

Liability and redress was a recurrent theme in the negotiation of the Cartagena Protocol on Biosafety to the CBD. Negotiators were unable to reach consensus on details of a liability regime during the negotiations for the Protocol. An enabling clause included in the Protocol states as follows:

"The Conference of Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of ongoing processes in international law on these matters, and shall endeavour to complete this process within four years". Article 27.

Liability and redress was one of the issues addressed by the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) in accordance with the work plan of ICCP adopted by the COP to the CBD at its fifth meeting²⁴. ICCP was requested to elaborate "a draft recommendation on the process for elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs including *inter alia* (a) review of existing and relevant instruments; and (b) identification of elements for liability and redress." At its second meeting, ICCP considered a review of existing relevant instruments and identification of elements provided by the secretariat and requested governments and organizations to submit further information on national, regional and international measures and agreements in the field of liability and redress for damage resulting from transboundary movements of LMOs.

22 Five types of LMOs are exempted from AIA. They include most pharmaceuticals, LMOs in transit, LMOs for contained use, LMOs for direct use as feed, food or processing, and LMOs declared by the Parties. These exemptions are discussed above.

23 See n. 7 above, at 4.

24 Decision V/1, annex, section B, item 1

2. Operationalizing article 27 of the Cartagena Protocol: The International Context

2.1. International Law

Liability and redress issues have to be seen within a broader context. It is a difficult issue to address in an international context because the rules are enforced in a national context and different countries have had systems of liability and redress based on other areas of law. In international law, liability is normally associated with the obligation to provide for compensation for damage caused to persons, property, and the environment. Rules of state responsibility at international law form the fundamental basis of liability and redress in international law. States are generally responsible for breach of their obligations under international law as stated succinctly by Ian Brownlie:

*“Today one can regard responsibility as a general principle of international law, a concomitant of substantive rules and of the supposition that acts and omissions may be categorized as illegal by reference to the rules establishing rights and duties. Shortly, the law of responsibility is concerned with the incidences and consequences of illegal acts, and particularly for payment of compensation for loss caused. However, this, and many other generalizations offered on the subject, must not be treated as dogma, or allowed to prejudice the discussion, which follows. Thus the law may prescribe the payment of compensation for the consequences of legal or excusable acts, and it is proper to consider this aspect”.*²⁵

In the area of the environment, the principles that states are responsible for breach of the obligation not to cause environmental harm (Principle 21 of Stockholm Declaration) and have a “responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment...” (Principle 2 of Rio Declaration) are the basis for liability.²⁶

Some international agreements have provided for liability regimes. These include nuclear liability and oil pollution damage regimes, transboundary movement of hazardous wastes and their disposal (Basel and Bamako Conventions). Under the Bamako regime, it is notable that a technical group has been working on a liability regime with a view to getting a Protocol in place. It has been considering such issues as scope of liability (should it extend only to actual shipment); what standard of liability should be applied (strict, joint, several); parties liable: generators, exporters, persons in control of waste at time of release, required insurance or other financial guarantees and creation of an international fund for emergency response actions.

²⁵ Ian Brownlie, *Principles of Public International Law* (4th ed. 1990).

²⁶ For a more detailed discussion on state liability under international law, also see: Springer, A. L., (1983). *The International Law of Pollution: Protecting the Global Environment in a World of Sovereign States*. Quorum Books. Westport & London.

Liability and redress in the context of the Protocol relates to what would happen if the transboundary movement of LMOs resulted in damage. One issue that has dogged the discussions has been whether parties should develop a regime suited specifically to LMOs or whether they should include damage caused by LMOs within a broader purview namely, damage to biodiversity or damage to the environment and including specificities on LMOs.

2.2. Regional Efforts to Confront the Liability and Redress Issue

At the regional level, the Bamako Convention represents an example of a regime under which there are attempts at establishing a liability and redress regime.

The position articulated by the African countries during the negotiations for the Protocol favoured a stringent liability regime. In line with this stance, a meeting of African Biosafety Experts held in Addis Ababa in June 1999 drafted a Model Biosafety Law. Under this law, risk assessment is defined as

“evaluation of the direct and indirect risk to the environment, biological diversity and health, including to the socio-economic conditions and ethical values of the country which may be posed by the import, contained use, release or placing on the market of the genetically modified organism or of a product of genetically modified organism. This may include the evaluation of secondary and long-term effects.”

This is a very broad definition which requires the assessment of risk on a multiplicity of levels.

2.2.1 Standard and Incidence of Liability

Article 14 which specifically addresses the issues of liability and redress imposes strict liability for any harm caused by GMOs or products of GMOs imported, made in contained use, released or placed on the market. It requires that such harm be fully compensated. It further provides that liability shall attach to the person responsible for the activity which results in the damage, injury or loss as well as the provider, supplier or developer of the genetically modified organism or products of the genetically modified organism and that if there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.

Liability shall also extend to harm or damage caused directly or indirectly by the GMO or product of the GMO to the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community or communities. Such harm includes the following: disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to the biological mass, and damage to the economy of an area or community.

2.2.2 Remedies

In the case of harm to the environment or biological diversity, Article 14 provides that compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.

Article 15 proposes the institutions of criminal sanctions against persons who import, release, place on the market or make contained use of, any genetically modified organism or products of a genetically modified organism without the written approval of the competent authority; violate any conditions attached to the grant of approval under this Act; fail to furnish any information as required by the provisions of this Act; provide false, misleading or deceptive information in order to secure an approval; does not label, package or identify any GMO; labels, packages or identifies any GMO or products of a GMO in a manner that is false, misleading or deceptive and exports a GMO or products of a GMO without the advance informed agreement of the importing country. On limitation of actions, the article provides that any action in respect of the harm caused by a genetically modified organism or products shall lapse only after a reasonable period from the date on which the affected person or the community could reasonably be expected to have learned of the harm, taking due account of:

- (a) the time the harm may take to manifest itself; and
- (b) the time that it may reasonably take to correlate the harm with the genetically modified organism or products of the genetically modified organism, having regard to the situation or circumstance of the person or community affected.

2.2.3 Locus Standi

Under Article 14.7, any person or group of persons may be entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision of this Act, including any provision relating to damage to the environment and biological diversity; relating to socio-economic:

- (a) in that person's or group of persons' interest;
- (b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
- (c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;
- (d) in the public interest; and
- (e) in the interest of protecting the environment or biological diversity.

To promote public interest litigation on issues of GMOs and the protection of the environment, the Article provides that no costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

3. The Legal and Institutional Framework for Biosafety in Kenya

Liability and redress have to be considered within the broader context of legal regimes in a country. For liability to arise, there has to be a set standard. The standard set under the Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

The Protocol thus focuses on safe handling, transportation and release of biotechnology. It adverts to the fact that even with the greatest safety measures taken, damage may occur for instance, where LMOs are for contained use or released for experimental purposes or in a market context. Further more, transboundary movement may be intended or unintended (cross-border movement of LMO in use in one country given that borders are political fixations and there is no firm wall and the ecosystem may be one making movement across the border very easy).

The question as to who should be liable and what standards of liability should attach to specific acts becomes critical. In reviewing the Kenyan laws on these issues, we will look at the Constitution, environmental law provisions that pertain to adverse impacts on the environment and general laws on civil liability under the law of tort.

3.1. Broad Legal Provisions

3.1.1 Constitutional Law

In a national context, it is imperative that the supreme law of the land provides the parameters for one to get a remedy when their rights are infringed. Kenya's operative constitution does not contain explicit environmental provisions.²⁷ 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.²⁸

²⁷ Act No. 5 of 1969 (last amended in 1992 and rev in 1998).

²⁸ Environmental Management in Kenya: A Guide to the Environmental Management and Coordination Act, 2 (G.M. Wamukoya and F.D.P. Situma eds ,Centre for Research and Education Environmental Law 2000).

This would entail a positive obligation on others to ensure that the environment is wholesome and cover adverse effects of LMOs that would impinge on this right. The constitution also includes the right of access to the High Court for redress regarding enforcement of fundamental individual rights and freedoms. The constitution defines "person" to include "any body of persons, corporate or unincorporate."²⁹ Judicial decisions confirm that "person" includes "corporate person."³⁰ In the Draft Bill of the Constitution, 2002, the rights to an environment that is safe for life and health and to compensation for damage arising from the violation of the rights are included in the Bill of Rights (Article 63). This is accompanied by the right to access justice through independent tribunals in respect of these rights (Article 67). Chapter 12 of the draft Bill contains a duty to safeguard the environment and adoption of the precautionary principle in protecting the environment. (Article 239)

It is apt to state that the constitutional provisions provide a legal basis for the promulgation of a liability and redress system under the laws of Kenya.

3.1.2 Environmental Management and Coordination Act (EMCA)

The EMCA provides for the right of every person to a clean and healthy environment. It also makes it every person's obligation to protect and manage the environment.³¹ Any person may bring an action in the High Court to enforce the right to a clean and healthy environment. Redress may be sought if the right has been violated, is being violated, or is likely to be violated. In judging the dispute, the court must be guided by the principles of sustainable development, such as public participation in the development of policies, plans, and processes for environmental management.³²

Under the EMCA, environment impact assessments (EIAs) are required to be undertaken for projects specified under the second Schedule to the Act. As pointed out above, biotechnology including the introduction and testing of genetically modified organisms is one of the projects included in the schedule. Further, the EMCA overcomes most of the limitations on standing to sue. It explicitly provides that an aggrieved person need not show special damage or particular injury beyond that which is suffered by other affected people.³³ In effect, this provision grants to every person the right to protect the environment. This promotes public interest litigation in environmental matters.

29 Supra n. 25 at § 123.

30 Shah Vershi Devshi and Co. Ltd. v. The Transport Licensing Board , 289 EALR (1971).

31 Environmental Management and Coordination Act (1999) [hereinafter EMCA],

32 Ibid . § 3(3).

33 Ibid. § 3(4).

Environmental impact assessment is undertaken by the project proponent at her or his own expense but must be conducted by experts authorized by National Environment Management Authority (NEMA). NEMA is empowered to set up a technical advisory committee to advise it on Environmental Assessment (EA). Lead agencies may submit written comments on EAs at NEMA's request. These agencies comprise organizations and institutions vested by law with controlling or managing the environment. This tallies with the AIA procedure under the Protocol.

The act imposes on project proponents the obligation to conduct EIAs and grants all persons the right to participate in the EIA process.³⁴ Project proponents have to submit reports to NEMA. If, after studying the report, the authority is convinced that the proposal will result in significant environmental impact, an EIA must be undertaken. No other licensing authority can lawfully issue a license for a project for which an EIA is required under the Environment Management and Coordination Act. As mentioned above, EIAs must be conducted by experts authorized by the authority. Only a license issued by the director general of NEMA will be valid.³⁵

To promote public involvement, the act requires that the general public, including potentially project-affected persons, be notified of the intention to carry out an EIA. The notices must contain a summary of the project, the location in which the project is to be carried out, and the place at which the EIA report may be inspected.³⁶ The time limit within which public comments may be submitted should not exceed 60 days. To afford reasonable opportunity for comments to be submitted, the time limit may be extended. Provision is made for the general public, on payment of a prescribed fee, to inspect the register of EIA experts. NEMA also has powers to set up a technical advisory committee on EIAs and to require the developer to provide additional information to ensure the accuracy and adequacy of reports.³⁷

On conclusion of the review, if the authority decides that the project may proceed, it issues an environmental impact assessment license. The license may be given with conditions, and the authority may give other directives at any stage of the project. The register of EIA licenses is maintained by the authority as a public document and, as mentioned, is open to inspection on payment of a fee. It is important to note that the requirement for payment of a prescribed fee may impede public participation if members of the public are unable to raise the fee, which, in many cases, is likely.

34 The scheduled categories of projects that must undergo EIA are broadly defined. They include urban development, major roads, storage dams, river diversions, aerial spraying, mining, clearance of forest areas, irrigation, use of pesticides, processing and manufacturing industries, electrical infrastructure, waste disposal, nature conservation areas, and major developments in biotechnology, such as the introduction and testing of genetically modified organisms. The minister responsible for environmental matters has powers to amend the schedule after consultations with key actors in the environment field.

35 See *supra* n. 28 at § 58.

36 *Ibid.* at § 59.

37 *Ibid.* at § 60.

The act provides that EIAs shall be carried out in accordance with regulations and guidelines issued by NEMA and that EIA reports shall be available for public scrutiny and input.³⁸ Section 53 of the Act provides a basis for promulgating biosafety regulations. (See Box)

Access to Genetic Resources

- (1) The Authority shall, in consultation with the relevant lead agencies, issue guidelines and prescribe measures for the sustainable management and utilization of genetic resources of Kenya for the benefit of the people of Kenya.
- (2) Without prejudice to the general effect of subsection (1), the guidelines issued or measures prescribed under that subsection shall specify
 - (a) appropriate arrangements for access to genetic resources of Kenya by non-citizens of Kenya including the issue of licences and fees to be paid for that access;
 - (b) measures for regulating the import or export of germplasm;
 - (c) the sharing of benefits derived from genetic resources of Kenya;
 - (d) biosafety measures necessary to regulate biotechnology;
 - (e) measures necessary to regulate the development, access to and transfer of biotechnology; and
 - (f) any other matter that the Authority considers necessary for the better management of the genetic resources of Kenya.

3.1.3 Civil Liability under the Law of Tort

Tortious liability arises from the breach of a duty primarily fixed by law towards persons generally whose breach is redressable by an action for unliquidated damages. The law of torts defines the obligations imposed on a person to his fellows to provide for compensation for harms caused by breach of the obligations. Tort has been said to be concerned with loss adjustment and judged by its success as a compensation system. The primary issue to be determined is who should bear the relevant loss or should the loss lie where it falls? In determining whether the loss should be shifted to a defendant, a relevant issue is whether the conduct of the defendant warrants such shifting. Since tort concerns situations where one person's conduct causes or threatens to cause harm to the interests of others (broadly defined), it provides a basic infrastructure for building a liability and redress system.

There are differing standards of liability, namely, strict which makes a specific person responsible regardless of fault, but offers limited justifications. The second one is based on absolute liability which makes a person liable regardless of fault and allows no justifications/excuses and fault based liability where there is need to prove negligence on part of person responsible for damage.

³⁸ Ibid. at §§ 58 (7) and 59

Liability can also be attributed to several persons where the cause of loss is attributable to a number of persons. However, most torts require that the plaintiff have suffered damage and it is for this damage that the law gives compensation. There is also a fundamental requirement that the damage should have been caused by the Defendant's tortuous act or omission.

The "but for" test is applied to establish the causative link, namely, *the D's wrong is a cause of the damage if the damage would not have occurred if his wrongful act or omission had not taken place*. This test can be problematic in situations where there is multiplecausation.

3.2. National Biosafety Laws

At the national levels, competent national authorities, national focal points, and advisory groups (in the form of committees or commissions to serve as an oversight mechanism)³⁹ must be established to facilitate the implementation of the Protocol's obligations at national levels. There is need to develop harmonized approaches to the risk assessment of products of modern biotechnology. National committees on biosafety need to publish expert reports on safety considerations, concepts and principles for risk assessment as well as information on field releases of transgenic crops and a consideration of traditional crop breeding practices. Safety considerations for genetically engineered organisms should include the issues relevant to human health, the environment and agriculture, which might be considered in a risky assessment.

The institutions that will need to be created will be essentially scientific bodies with the capacity to conduct risk assessments. They should be comprised of experts from government, private agencies and other institutions, which should work together in close association with competent national authorities in areas such as information dissemination. The problem of expenses could be solved partly through the levying of fees from applicants augmenting the resources available to the national institutions. In addition to undertaking risk assessments and management, national bodies will need to provide systems by which countries provide AIA. They will administer requests for AIA, issue import and export permits, monitor compliance (through a compliance information system), and serve as points of contact and for liaison with the Secretariat. They will also perform other functions required by the Protocol such as facilitating public awareness.

³⁹ J. Richter, *et al.*, (eds.), *Biotechnology for Crop Protection: Its Potential for Developing Countries*, (German Foundation of International Development (DSE), 1998).

National legislation should authorize established institutions to perform prescribed administrative functions required by the Protocol. A Party may designate one institution to perform all the functions required,⁴⁰ which will provide the advantage of efficiently allocating the use of scarce resources with particular reference to financial constraints.⁴¹ These institutions should be given legal authority and clear mandate in all aspects of biosafety, including authority for institutional collaboration.

National guidelines and/or regulations (including policies and strategies) should be put in place. These regulations ought to focus on building the capacities of the Parties in risk assessment and management. Systems for environmental impact assessment and risk assessment should emphasize scientific, technical and infrastructural capacity. Such capacity would be enhanced through access to the latest technologies in those areas. For handling and transport, specific procedures could include rules on standards such as on labelling requirements and guidelines for contained use. This will be particularly important in respect of cases where the Party of import is required to undertake proactive regulation. An example of such a case is Article 11 of the Protocol regarding the shipment of agricultural commodities. The legal measures should include Intellectual Property Rights (IPR) policies. These ought to meet the standards preferred for foreign biotechnology transfers and investments. IPR policies should serve also to meet the confidentiality requirements of the Protocol.

On the whole, the basis of national legal and administrative regimes should be based on the precautionary principle, prior informed consent or advance informed agreement, public participation and consultation, access to information (without prejudice to the protection of confidential information), access to justice (through compliance, liability, and compensation systems), and enforcement procedures and sanctions. The legal and administrative regimes may be built upon the existing mechanisms or based on new frameworks. The establishment of biosafety oversight capacity within existing regulatory structures would help strengthen those institutions. Information sharing, coordination, and institutional synergy can achieve this. It is anticipated that most countries that lack any biosafety regulations will enact new legislation to create biosafety bodies within the administrative structures of government departments. These regimes must provide for effective enforcement mechanisms and provide means of action by any person to secure the enforcement of rights under the Protocol. This includes relaxing the requirements of *locus standi* as well as recognizing interests such as community rights.

40 Protocol, Article 19.1.

41 See n. 20 above.

Many countries in Africa have either put in place or are in the process of putting in place biosafety policies and laws to comply with the requirements of the Protocol. For instance, under their Science and Technology institutions, countries like Kenya and Uganda have managed to develop biosafety guidelines and policies. What is pending is the putting into force of legislation concerning existing policies. Enforcement of guidelines and policies is difficult without appropriate laws. With the exception of lead countries such as Zimbabwe⁴² and South Africa⁴³, none of the African countries has managed to put in place a biosafety law. In the rest of Africa, framework legislation on biosafety is lacking and most countries depend on science and technology laws and policies for overall guidance.⁴⁴

3.3. Recent National Efforts to Address Biosafety Issues in Kenya

The National Council for Science and Technology (NCST) of Kenya was designated by the Government to lead the implementation of biosafety measures in the country. In 1998 *Regulations and Guidelines for Biosafety in Biotechnology for Kenya* were published by the NCST.⁴⁵ These guidelines require that the release of LMOs be preceded by the approval of the National Biosafety Committee (NBC). The authorities are supposed to undertake risk assessments before making the decision to approve or deny approval of the import. In order to do so they should be provided with enabling information such as description of the LMOs and its intended uses in Kenya.⁴⁶ The guidelines provide that it is an offence to import LMOs without prior approval of the NBC. Penalties for offences under the biosafety regulations were left to be made by the Minister. To do this the Minister requires the powers to be conferred upon him 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.⁴⁷

The Proposed Kenya Legal Framework for Safety in Biotechnology forms the basis of the National Biosafety Act first raised in 1999.⁴⁸ Under the proposed framework, an exporter of LMOs or related products is required to provide to the NCST or the competent authority a written AIA of the competent authority of the importing country.⁴⁹

42 Government of Zimbabwe, Research Act Cap. 10:22, *Research (Biosafety) Regulations* Statutory instrument 20/2000, 2000

43 Republic of South Africa, *Genetically Modified Organisms Act*, Government Gazette, 1997.

44 Idah Sithole-Niang and Julius Mugwagwa, *Agricultural Biotechnology Assessment in Sub-Saharan Africa: Country Specific Study-Zimbabwe*, (Draft Study commissioned by the African Centre for Technology Studies, 2001), (on file with the author).

45 Republic of Kenya, *Regulations and Guidelines for Biosafety in Biotechnology for Kenya*, (National Council for Science and Technology (NCST), 1998).

46 See for instance: *Ibid.*, at Annex F.

47 It seems that the proposed penalties may not achieve the desired goals as they are relatively lenient. For example, a person who imports LMOs without the AIA of the country of import may only be liable to a fine not exceeding fifty thousand shillings. (See: Clause 15 of the NCST, 1999, UNEP/GEF, Pilot Biosafety Enabling Activity Project: Kenya Biosafety Framework .. In such circumstances one may find it convenient to commit the offence and pay the fine.

48 The legislation is yet to be passed by Parliament into law.

49 See NCST, 1999 n. 58, Clause 13.

The exporter is also required to comply with other regulations on foreign trade in LMOs. Before approving the export, the importing country is empowered to consider other relevant concerns it may have. Significantly, the provisions of the proposed regime preclude the export of LMOs or their products that have been banned under the laws of the country of export. In practice the NBC in Kenya applies relatively high standards in screening GMOs and is slow in approving imports of GMOs and related products.⁵⁰

Under the National Biosafety Act, 1999 no person shall import release, make contained use or offer for sale genetically modified organism or product for a genetically modified organism without approval of the council/ competent authority.

Any person who intends to import release used in contained conditions or offer for sale genetically modified organisms or their products shall submit an application in prescribed form to the Council/Competent Authority.

The proposed Kenya Legal Framework for safety in Biotechnology adopts the Model Law provisions on liability and redress, including strict liability, provisions for costs of reinstatement, rehabilitation or clean-up and preventive measures incurred.

50 R.L. Paarlberg, 'Governing the GM crop revolution: Policy choices for developing countries', Food, Agriculture, and the Environment Discussion Paper 33, (International Food Policy Research Institute, December 2000).

4. Conclusion and Recommendations

Biosafety is about risk assessment and management. Consequently the framework and efficacy of biosafety laws and institutions dealing with liability and redress will to a great extent depend on the capacity of countries to put in place mechanisms for risk assessment and management. Risk assessment can be defined as the identification of potential environmental adverse effects or hazards, and determining, when a hazard is identified, the probability of it occurring.⁵¹ Article 16 of the Protocol stipulates that Parties must establish appropriate domestic mechanisms to regulate, manage and control risks associated with LMOs. If a potential hazard or adverse effect is identified, measures must - be taken to minimize or mitigate it. The ecological risks, policy makers and regulators need to assess include the potential for spread of traits such as herbicide resistance from genetically improved plants to unmodified plants (including weeds), the build up of resistance in insect populations, and the potential threat to biodiversity posed by widespread monoculture of genetically improved crops.⁵²

Risk management on the other hand refers to the methods applied to minimize potential hazards or adverse effects, which have been identified during a scientifically based risk assessment. Management actions should be based on, and be in proportion to, the results of the risk assessment. There are different ways of managing hazards or adverse effects identified in these assessments including confinement, restricted use, provision of guidance, technical support and advice and record keeping.⁵³

The basic requirements of the Protocol as outlined above include the advanced informed agreement (AIA) mechanism; the precautionary approach; risk assessment and management; and the clearing house mechanism. Although the Protocol only makes reference to the precautionary principle in its preamble, textual analysis evinces incorporation of the principle throughout the Protocol.⁵⁴ The principle is operationalized through decision-making procedures which are based on sound science and rigorous risk assessment and management. The specific legal and administrative mechanisms that Parties are required to institute are supposed to cover the related but separate fields of development, handling (including packaging and identification), transport, use, transfer, and release of LMOs.⁵⁵

51 Organisation for Economic Co-operation and Development, *Safety Considerations for Biotechnology: Scale-up of crop plants*, (OECD, 1993). Ibid 52.

53 Organisation for Economic Co-operation and Development, *Recombinant DNA safety Considerations. Safety Considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA technique*, (OECD, 1986).

54 See: Protocol, Articles 12, 15 and 16.

55 Ibid., Article 2.2.

It is anticipated that regulations on AIA, precautionary principle, risk assessment and management, and capacity building will be incorporated into national legislation. The main objective of these legal and administrative mechanisms should be to ensure that the activities stated above are undertaken in such a safe manner that any adverse effects arising therefrom are reduced or prevented. The risks relate not only to biodiversity but also to human health. All decisions are to be based on risk assessments. The assessment of such risks should be done in accordance with sound science based on the available information.

It is our view that the rudiments of a liability and redress system are there in Kenyan laws and what needs to be done is to refine it to cover LMOs. The biosafety regulations in their definition of risk assessment already intimate what issues one should look for, namely risk identification, risk-source characterization, exposure assessment and risk estimation.

The general objectives of the liability and redress regime will be to protect human health, protect property against degradation generally from the effects of LMOs and protect the environment/ecosystem integrity. Since the Protocol flows from the Convention on Biological Diversity, the primary focus should be on effects to biodiversity and human health. In developing countries such as in East Africa where indigenous knowledge is an essential component or embodiment of biodiversity, damage caused by LMOs to indigenous knowledge and loss of indigenous species should be taken into account. In assessing harm, regards should be had to adverse effects that are actual and significant.

Another important issue that should be addressed by any future liability and redress regime is causation. As already indicated, causation has always at the centre of any civil law actions whether based on nuisance, negligence or the Rule in Rylands Versus Fletcher. However, it has been argued elsewhere that the rules or causation employed in such cases may not be suitable for a liability and redress regime for LMOs. Consequently, developing new regime on liability and redress regarding transboundary movement of LMOs will need to set new standards for determining causation. The standard should be such that in the case of damage occurring, LMO trait should be evidence of the chain of causation from the transboundary movement of the LMO to the damage that has been caused. Further more, in addition to damage or compensation, the proposed regime should require preventive action or reinstatement where feasible. Clean up or restoration should be provided for as remedies while a regulatory regime for risk management and monitoring should be considered and integral part of the redress mechanisms to be established.

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