International Environmental
Law Research Centre

Report of a workshop on

Liability and Redress Under the Cartagena Protocol

Held in Mombasa, Kenya
22–26 September 2003

This report can be downloaded in HTML or PDF format from the workshop's website at
http://www.ielrc.org/activities/workshop_0309

Organised with the support of the Swiss Agency for Development and Cooperation (SDC)

International Environmental Law Research Centre
East Africa Office
PO Box 2394 KNH
Nairobi, Kenya
E-mail: nairobi@ielrc.org

Interdisciplinary Biosafety Network
RIBios
24 rue Rotschild
CP 136
1211 Geneva, Switzerland

Table of Content

I. BACKGROUND

One of the areas of focus of the International Environmental Law Research Centre and the Biosafety Interdisciplinary Network is biotechnology developments in the fields of agriculture and health. In principle, biotechnology can contribute to enhancing food security; reduce environmental pollution through reduction of pesticide use and contribute to alleviation of poverty, improved nutrition; biodiversity management.

Most of the Eastern African countries suffer from chronic food shortages and are among the poorest countries in the world. They have low agricultural production, low fertility, pest infestation, poor agronomic practices and other non-physical factors some of which can be addressed through biotechnology. Biotechnology development can only occur in the context of appropriate biotechnology and biosafety policies and strategies focusing on minimisation of risks and maximisation of benefits.

The Convention on Biological Diversity provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources. The Convention also addresses biosafety. The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. Articles 8(g) and 19, paragraph 3 seek to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health. Article 8(g) deals with measures that Parties should take at national level.

At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety. After years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was finalized and adopted in Montreal on 29th January 2000 at the extraordinary meeting of the Conference of the Parties (COP). The protocol came into force on 11th September 2003. The stated objective of the protocol is that in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, it seeks to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable of biological diversity, taking also into account risks to human health. At Article 27 the protocol mandates the COP serving as the protocol's Meeting of the Parties (MOP) at its first meeting, to adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress.

The following issues arise under Article 27:

- What kinds of loss or damage should be compensated?
- Who should pay for such loss or damage?
- In what circumstances?
- What remedies should be available for damage resulting from the transboundary movement of LMOs?

Is a specific international or national regime required to deal with the above issues and specifically setting out rules on liability and redress for damage resulting from the transboundary movement of LMOs?

One of the greatest missing dimensions in the context of biotechnology development in the East African region has been the absence of laws and policies geared towards addressing liability and redress in bio-technology. The need for mechanisms to address liability and redress cannot be overemphasised in light of the stated regional policy of embracing biotechnology. This demands overall direction and co-ordination of activities to ensure provision of a guiding legal framework to address liability and redress. East African states are firmly on-board the UNEP-GEF Biosafety Project and all have rudiments of a National Biotechnology Framework at different stages of development. Biotechnology frameworks comprise of policy, legal and regulatory systems to handle requests, detailed risk assessment procedures, mechanisms for monitoring and inspections and stakeholder participation.

Issues of liability and redress for biotechnology activities occasioning damage have so far not formed part of the draft and emerging national frameworks. The common law concepts of negligence, trespass, rule in Rylands versus Fletcher and nuisance provide a basis for dealing with liability in today's world. Provisions in other laws dealing with environment but not tailored to biotechnology and biosafety complement these concepts.

Recognising the need to put in place effective liability and redress policies for the region, the International Environmental Law Research Centre and the Biosafety Interdisciplinary Network organised a workshop on Liability and Redress in Mombasa, Kenya from 22-26th September 2003 with the support of the Swiss Agency for Development and Cooperation (SDC).

A. Objectives

The objectives of the workshop were to:

- Situate biosafety in broader biotechnology debates;
- Look at liability & redress legal regimes operative in the region;
- Identify gaps in those regimes;
- Suggest tenets of a biosafety liability & redress system; and
- Identify issues for further discussion & consensus

B. Expected Outputs

The expected outputs of the workshop were to:

- Further understanding of biosafety among workshop participants
- Map liability legal regimes in the region
- Link these to international discussions at MOP in Kuala Lumpur in Feb 2004
- Identify regional issues for further discussion within MOP & region
- Identify capacity needs
    - For COP/MOP discussions
    - For national & regional implementation of the Cartagena Protocol on Biosafety

C. Strategies Used to Achieve Objectives

The strategies used to achieve the stated objectives and outputs were:

- Plenary presentations; and
- Focus group discussions with facilitation.

The presentations revolved around:

- Rationale for liability and redress
- Liability and redress at the international level.
- Model liability and redress regime (Swiss law)
- Common law conceptions of liability and redress
- Available liability and redress statutory provisions in Kenya and Uganda
- Various stakeholders views

D. Structure of the report

This report is divided into four parts. The first part looks at the broad justification for biotechnology and biosafety issues and challenges of putting in place liability and redress regimes. The second part looks at the international law approach to liability and redress and the broad principles thereon. Part three looks at the common law concepts of liability and redress while Part four looks at the statutory approaches to liability and redress in Kenya Uganda and Switzerland. Part five is a conclusion and mapping of the way forward.

II. BROAD CONTEXT FOR LIABILITY AND REDRESS FOR BIOTECHNOLOGY

It is incumbent upon African countries, in light of their own priorities and circumstances, to determine how to engage in biotechnology. There is without doubt a need to grow food, fibre and feed in a more productive, profitable and environmentally sustainable manner and ways need to be found to maximise the benefits and minimise any potential risks, associated with biotechnology. It has been often pointed that Africa is already in the biotechnology revolution and the debate should not be whether or not the continent should go for the technology but what specific policies and institutions are required to enable it to maximise benefits and minimise risks associated with genetic engineering.

Policy decisions relevant to engagement in biotechnology include: Intellectual property rights (IPR); Biosafety; Trade; Food safety and consumer choice; Public research and investment and transboundary movement of living modified organisms (LMOs).

A. Intellectual Property Rights

In so far as intellectual property rights are concerned, this is a new policy area for many developing countries. The existence of IPR regulations is a requirement for private companies planning to spend large amounts of money on research and development (R&D) of GM products in any country. Patents, trademarks and breeders' rights are the means by which companies can recoup the investment they make in the development of new products. Without IPR, companies are unlikely to make R&D investments.

B. Biosafety

This too is a new policy area for many countries. Those that have signed the Cartagena Protocol on Biosafety are mandated to adopt regulations to put in place mechanisms for the evaluation of the environmental and consumer safety of GMOs and facilitate decisions on whether or not to allow a GMO to be used in a country.

C. Trade

Trade rules are well established under the World Trade Organization (WTO). The regulations are designed to encourage trade and reduce unfair protection and exclusion. Whether these regulations are actually benefiting poor nations is the subject of much international debate. Suffices it to say that they have implications for biotechnology development.

D. Food Safety and Consumer Choice

These regulations exist in many countries and deal with the wholesomeness of food. Food labelling requirements also address the issue of ingredients contained in food. They assist consumers and alert them to allergens, use and food composition. The international standards for food safety and labelling are determined by Codex Alimentarius. This organisation planned to release standards and labelling requirements for GM food in early 2002 but has not yet done so.

E. Public Research and Investment – Adaptation to Local Environment

While some applications of GM technology can be transferred to developing countries, the development of GM crops requires placement of the new traits in the best germplasm for the growing area. This often requires that modifications be bred into local germplasm. National breeding programmes are frequently the only source of specific germplasm and so need to get involved in identifying the most appropriate technology is transferred and tested in local conditions. This is especially true for crops that are not major commodities in the developed countries, like coconut, cassava, cowpeas, yam and sorghum. Getting involved in local crop improvement programmes can ensure that the outcomes are made available for the benefit of local people

F. Transboundary Movement of Living Modified Organisms

The movement of living organisms is largely covered by existing trade and pest control regulations. However, the Cartagena Protocol on Biosafety (CPB) has provisions specifically focussing on transboundary movement of LMOs and seeking to ensure that LMOs are not sent to countries without their approval and without a chance to review their human safety and environmental impact. Signatories to the CPB will have to bring their national legislation into line with the Protocol's requirements now that it is in force. For many this will mean the development of biosafety regulations.

1. Why are GMOs regulated?

The necessity to carry out safety checks on GMOs has been recognised from the outset of biotechnology. This is to make sure that in transferring the genes, no unwanted characteristics are obtained. When the first GMOs were ready for commercial release, governments independently reviewed the safety of GMOs before approving their release. Independent assessments of GMO safety are known as biosafety reviews and are routinely carried out on all new GMOs before they are released into the environment. Because GMOs are living organisms, they are able to reproduce and spread once released. Thus, in addition to determining the safety of food derived from GMOs, the biosafety process also needs to investigate what impacts these GMOs may have on the environment. In order to take these decisions, countries need to have biosafety regulations that enable both the assessment of risk and decision making based on safety and non-safety issues.

The biosafety review process is largely a paper exercise, where governments ask local experts to assess the safety data accumulated by the applicant and determine whether enough information is present to assess the safety and impact of the GMO. Where important information is missing, the applicant is asked to collect the data before the review process proceeds. Where risk is identified, the chance of the hazard happening and the ability to manage the risk are assessed. The risks are then weighed against the benefits and a decision is taken on the overall safety of the GMO on its release in the environment. This scientific biosafety assessment is passed back to government where the final decision is taken and approval is given or withheld for release and use of the GMO.

2. Steps towards establishing a biosafety framework

A national policy on the use of modern biotechnology should be established to guide decisions taken about the use of GMOs. The development of a national biosafety framework should follow extensive consultation to ensure public awareness and input. Consultations within existing departments of environment, agriculture and health will ensure that the infrastructure is cross-sectoral efficient, cost-effective and capable of being implemented. An interim framework can be implemented using biosafety guidelines and an existing permit system for approvals while the legislation for the final framework is being modified or developed.

Implementing the biosafety administration will be facilitated by capacity-building in both the handling of GMO applications and biosafety review training. Reasonable fees charged to applicants can cover an efficient review process.

3. Components of an effective biosafety framework

When faced with applications for use of GMOs, governments need to implement an effective biosafety framework to ensure a science-based review of the safety issues and a review of other factors important in making a national decision. With hindsight, the following components are considered desirable in a national biosafety framework:

- A single entry point for applications, whether for GM plants, animals or micro-organisms;
- An efficient biosafety administration for processing of applications (two people once applications reach about 40 a year);
- A mechanism for ensuring confidential handling of commercial information;
- Access to a trained pool of scientific expertise to independently assess the safety of each application on a case-by-case basis;
- A call for public input into the application;
- A single, transparent national decision-making body that can take into account the scientific risk assessment recommendations, the benefits, the public input and any national needs and priorities when making decisions;
- Development of a decision document that clarifies the safety issues of each GMO, the conditions attached to specific releases and the reasons why decisions were made; and
- Access to an inspectorate that can monitor whether release conditions are adhered to.

a) Components of an interactive national biosafety framework

- Acknowledge receipt of the application;
- Assess what the applicant requires approval for and the nature of the GMO;
- Select a group of scientists with the relevant expertise to review the safety of the proposal (about 5 scientists are needed for each proposal, depending on what the GMO is and what it will do);
- Publicise the application and call for public input;
- Schedule a meeting for the scientific group to review the application and make recommendations to the national decision making body regarding the activity, missing data, the possible risks and acceptable risk management procedures;
- Where information is missing or clarification is needed, schedule a meeting with the applicant and the scientific review panel;
- Call a decision-making meeting when the scientific and public input is available;
- Once a decision had been made, prepare a decision document on the findings of the review and make this publicly available;
- Notify the applicant and issue a permit where necessary; and
- Schedule an inspection of the release site during and after the activity

G. Liability and Redress Challenges

There is a major challenge of linking GMO's to liability and redress issues. There is uncertainty as to the impact of GMOs on the environment. Due to this uncertainty, proving causation of damage could be quite sticky, causation being a precursor to liability and redress. The uncertainty is coupled with the gap on knowledge on the interaction between GMOs and the environment. During the period of 1990 – 1995 only a few countries had adopted GM crop policies and even today the issues are not clearly developed.

Another handicap identified is the definitional problem of damage. Issues of product and liability standards, identification of persons liable for damage and time limits for bringing claims were identified as challenges requiring attention in the development of a liability and redress regime. One view was that to the best of the current knowledge, GM foods and crops are as safe as conventional ones because the approval process requires many tests over a period of many years. Nutritionists and other scientists, the workshop participants were told, do not know of any unresolved safety issues. That GM food and crops are being improved to provide better nutrition to consumers was a reason to call the liability and redress system into question.

III. LIABILITY AND REDRESS IN INTERNATIONAL LAW

A. State Responsibility

It's a trite general principle of international law that states are responsible for activities within their territories that cause transboundary damage. The *locus classicus* in international law jurisprudence is the Trail Smelter Arbitration that concerned the pollution of Washington in the US by a smelter across the border in Canada. Indeed this principle was later encapsulated in the International Law Commission draft rules on state responsibility where it is proposed at Article 1 that "every wrongful act of a state entails the international responsibility of that state".

There are several defences available to states in avoiding responsibility. They include:

- Acts of war;
- Where acts complained of are wholly caused by a third party with intent to cause damage;
- Discontinue wrongful conduct;
- Guarantees of non-repetition;
- Full reparation for injury caused; and
- Prevent repetition and specify future conduct (Trail Smelter case)

B. Civil Liability

There are various schemes and treaties that govern the conduct of international relations. They include:

1. Nuclear energy schemes principles

Under nuclear energy schemes, liability is absolute. Liability is channelled exclusively to the operator of a nuclear installation or ship. Limitations may be placed on the amount of compensation payable and the duration. Payment is up to a prescribed limit supported by compulsory insurance or security held by the operator and guaranteed by the state.

2. The Council of Europe Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, 1993

This Convention was negotiated with a view to ensuring adequate compensation for damage resulting from activities dangerous to the environment (Art. 1). Dangerous activity was defined to include GMOs which, as a result of the properties of the organisms, pose a significant risk to man, the environment or property (Art. 2). Damage was defined to include loss of life, personal injury, loss or damage by impairment of the environment (limited to costs of measures of reinstatement), cost of preventive measures (Art. 7)

3. Limitations of liability schemes in public international law

There is very limited case law reported. Indeed, the Trail Smelter Arbitration still blazes the trail as the only arbitral resolution touching on state responsibility. Case law is uncommon as states prefer resolving disputes through negotiations. Consequently, there has been limited development of principles relating to liability (and limited focus on environment). It is worth noting that state responsibility is concerned with state to state obligations since it is only States that are actors on the international scene. Private individual concerns can only be articulated internationally through States as they are not recognised as actors on the international level save for the internationally recognised non-state actors.

Increasingly, emphasis in international environmental law is being laid on preventive measures as an alternative. Other schemes have emerged to supplement and strengthen customary international law liability provisions. These include the Polluter Pays Principle (PPP). Other treaties such as the Basel Convention, at Article 4.3, have criminalised some activities.

4. GMOs: liability issues in international law

States are to take all appropriate measures to prevent significant harm (cf. ILC liability draft Art 3). Preventive measures include assessment of overall advantages of social, economic and technical character as well as assessment of means to prevent such harm or restore the environment (cf. ILC liability draft, Art. 10). There can be liability for any environmental damage (cf. 1992 oil pollution, Art. III).

To prevent damage, disincentives for the introduction of GMOs through the use of biosafety clauses in intellectual property laws can be introduced as it has been done, for instance, in Thailand.

5. “Reverse” liability of farmers

Liability may attach to farmers simply because they own land on which grows GMOs that cause damage. There is need to establish a linkage between real property and intellectual property. It is also critical to link biosafety to patents in that patent holders be made liable for their product’s biosafety.

6. Discussion

As a general principle of customary international law states are liable for acts that have transboundary effects occurring within their territories. However the nitty gritty of state responsibility are not developed.

IV. THE COMMON LAW APPROACH TO LIABILITY AND REDRESS

A. The Role of Common Law in Dealing with Liability and Redress for Biotechnology Activities

Common law comprises rules of customary law which have been recognised by English courts. The common law system is built on precedents and centres on individual decisions; it has built up its principles by gradual growth from case to case. In East Africa, the common law is a colonial legacy. Colonial governments sought to extend to English settlers the same rights and privileges they enjoyed in England. The common law was and still remains a significant part of this package of rights and privileges. Common law was adopted in the colonies in the East African region through a reception clause which, in Kenya's case is, for instance, the Judicature Act, Chapter 8 of the Laws of Kenya. It provides that courts are to apply "the substances of the common law" but only to the extent that Kenya's circumstances and its inhabitants permit. Indeed, the common law constitutes a significant source of law for Kenya, since it is the applicable law in the absence of legislation. Uganda has equivalent legislative provisions domesticating the common law in light of the common East African colonial legacy.

The common law arm that deals with liability and redress is the law of tort. Torts are defined as civil wrongs. A civil wrong is said to be a breach of legal duty which affects the interest of an individual to a degree which the law regards as sufficient to allow that individual to complain on their own account. There are three torts that were discussed at the workshop and found to be relevant in biotechnology debate of liability and redress. These are the tort of negligence, nuisance and the rule in Rylands Vs Fletcher.

1. Negligence

Negligence protects interests in physical and mental health, reputation, property interests, economic relationships and public rights. To establish negligence the following ingredients have to be proven:

- Existence of what in law is "a duty of care situation", namely, a situation in which the law attached liability to carelessness;
- Secondly there has to be breach of the duty of care by the defendant, that is, failure to measure up to the standard set by the law;
- A casual connection between the defendant's careless conduct and the complained of damage has to be established; and
- The damage has to have been foreseeable, that is, not so unforeseeable as to be too remote.

a) Reasonableness

The defendant will be in breach of the duty of care if his or her conduct falls below the standard required by the law. The applicable standard is that of a reasonable and prudent person. But that leaves an important question unanswered: what level of care will be reasonable in any particular situation?

The common law has provided some useful guidance: First, the standard of care expected of the reasonable person is generally objective. It does not take into account the weaknesses or inexperience of the defendant in question. Second, the common law requires courts to do a cost benefit analysis: Is it reasonable (or fair) for the defendant to bear the cost of a particular form of precautionary conduct in light of the level of protection and benefit it will confer on the plaintiff and others? Third, community values will be taken into consideration. Courts will be influenced by the evidence of practice within the community. But this is to be balanced against the reasonable expectations of the community.

b) Foreseeability

The foreseeability test is not one of the actual foresights of the defendant. Instead, it is what the court determines to be foreseeable, after reviewing the evidence and trying to do justice. Why is this a good test? It is flexible and leaves a large element of discretion to courts. This is good because it enables courts to raise standards of expected behaviour by insisting on better precautions being taken in advance. Thus it enables justice to be done according to the merits of each individual case.

c) Negligence and the Protocol

The transboundary movement of LMOs could have a number of effects on ecosystems such as the crossing of introduced traits; herbicide resistance into wild relatives of the LMO; toxic effects produced on other organisms in the environment or on humans or livestock affected via the food chain. A number of questions arise:

- Who should be liable in these situations? Manufacturers, exporters, operators, exporting states, states of origin?
- Who owes a duty of care?
- What constitutes damage? Any degree of change of biodiversity?
- Thresholds? Is the damage foreseeable?
- Will "state of the art" defence be appropriate?
- Should liability be strict? So that it does not matter that the defendant was not negligent.

These questions cannot effectively be addressed in the abstract. They are best dealt with in the context of specific cases. This makes the tort of negligence a suitable regime for addressing them. The tort of negligence can therefore effectively deal with the liability of manufacturers, exporters and operators. In these cases, it would be relatively easy for courts to determine whether there are duties of care situations. Indeed, torts of such a character would be actionable if committed in Kenya, for instance, notwithstanding their lack of basis for founding an action in other jurisdictions. The idea of imposing liability on states for the acts of private entities is bound to be problematic. The State Action Doctrine is a doctrine of customary international law that seeks to establish, in accordance with international law, actions or omissions attributable to the state as an international actor. The basic principle is that for acts or omissions to be attributed to the state at international level, they have to have been undertaken by members or an organisation or agency of the state. Attribution, even in instances involving recognised state organs, is problematic where they have exceeded their competence or acted in outright contravention of municipal law.

The tests of reasonableness and foreseeability make the tort of negligence a potentially effective tool for liability and redress for handling, transfer and use of LMOs. In particular, two features of LMOs make the tort unknown of negligence an appropriate liability and redress regime: first, the effects of LMOs are still largely unknown so that any liability regime would be speculative at best. By contrast, a statutory liability regime is unlikely to anticipate all the possible harmful effects that might be generated by the manufacture and utilisation of LMOs. Second, LMOs may be dangerous and therefore a need for precaution arises.

In applying these tests, the courts should be guided by the provisions of relevant international instruments, including the Cartagena Protocol, which constitutes an expression of "reasonable expectations" of the international community. For instance, the statement of the precautionary principle follows from an international recognition of the need for and legitimacy of applying precaution in a situation of scientific uncertainty about the potential risks associated with particular uses of biotechnology. Whether or not there is a duty of care situation will depend on the level of compliance with the Protocol, e.g., whether there was exporter notification or risk assessment.

Corruption would no doubt compound the case, but the level of liability will depend on the extent to which one complied with requirements of the Protocol. Local courts need therefore not wait for their governments to domesticate international treaties. Where appropriate, they should treat treaties as expressions of the reasonable expectations of the people within their jurisdiction. Indeed some national constitutions such as the South African one mandate national courts to seek guidance from relevant international treaties.

d) Drawbacks of negligence principles

The concept of negligence presents a difficulty in enforcing liability and redress for biotechnology activities because of the *locus standi* requirements and the time limits. On the one hand, the plaintiff has to prove that the defendant, over and above the general public, owed him a duty of care. On the other hand, being a tort, an action accruing from it must statutorily be filed within 3 years from the date of occurrence. The requirement of foreseeability was also identified as one of the major issues that make the concept of negligence inappropriate while attaching liability and redress to activities involving GMOs. This is associated with lack of knowledge and therefore foreseeability.

For the common law negligence principles to provide an effective liability and redress regime for biotechnology activities, there needs to be training courses organised for policy makers, judges and the general public about the nature and potential adverse effects of LMOs.

2. Rule in Rylands vs Fletcher

This rule applies to anything brought on land in the course of its non-natural use, that is likely to do mischief on escape. Damage and escape need not be reasonably foreseeable. This concept was found to be weak because it contemplates natural users of land thus limiting its application to industrial and pollution activity on land. It also alienates damage caused by GMOs since GMOs by their nature are not "things" on land. In case the concept is to be utilised in apportioning and attaching liability, then it will only be used in instances where there was a deliberate act of introducing GMOs on land. Overall, it offers weak protection to litigants.

3. Nuisance

It was defined as an act or omission, which is an interference with, disturbance of or annoyance of a person in enjoyment or exercise of a right belonging to him as a member of the public, his ownership/occupation or enjoyment of his land, easement or profit or other use connected with land. This tort was found to be weak and inappropriate since it is only utilised when the damage extends to a neighbour or interferes with their comfortable enjoyment of land.

B. Disadvantages of Common Law in GMO Liability and Redress

As outlined above, the common law may offer a suitable liability and redress regime but it has a number of limitations. First, the common law's conception of rights is quite narrow. A broader conception of rights will thus be necessary if the law of torts is to provide an effective liability and redress regime for the use of LMOs. It is encouraging that courts throughout the Commonwealth have over the years relaxed their *locus standi* requirements. But there is still a need to retrain judges so that they may see beyond common law rights. Class actions would be a good way to go but there is limited experience where the loss or damage is by impairment or to the environment.

The common law works best where there is a good flow of information. Unfortunately, the international intellectual property regime has restricted it. For example, the protection of processes through patents limits the flow of technical information about biotechnology products. As a result, the amount of information available to operators, regulators, courts and the general public is not sufficient. In the context of the tort of negligence, this makes it difficult for courts to effectively apply the tests of foreseeability and reasonableness. Additionally, common law systems require effective law reporting. Unfortunately, law reporting has not been given the appropriate attention in developing countries, such as Kenya and Uganda.

In conclusion, while there is need to adopt new technology crucial for development especially in modernisation of agriculture, it is imperative to have a system in place to assess and manage risks present in biotechnology. In this regard, East African states should participate in the Cartagena Protocol discussions on liability and redress.

V. STATUTORY APPROACH TO LIABILITY AND REDRESS IN KENYA, UGANDA AND SWITZERLAND

In this section we will look at the approaches that Kenya, Uganda and Switzerland have taken to the liability issue. The Swiss example is interesting since it represents the only country that currently has a specific law on liability for biotechnology.

A. Kenya

Kenya ratified the Protocol in January 2000 and the Protocol came into force on 11 September, 2003.Under the Protocol process however the negotiations for an effective system of liability and redress with regard to GMOs and their derivatives is still a subject of debate. Other issues yet to be agreed on relate to labelling and traceability. The uncertainty regarding these issues seems to support strongly the precautionary approach in

- Regulating the transit of GMOs
- Restrictimg of GMOs to contained use in laboratories
- Subjecting all GMO for use in pharmaceuticals to Advance Informed Agreement(AIA)

Kenya supports the precautionary principle in its environmental protection and sustainable development policies. The principle in accordance with the Kenyan law is that:

> *Where there are threats of damage to the environment, whether serious or irreversible, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The need to protect human health and the environment from the possible adverse effects of products of modern biotechnology and the great potential that modern biotechnology has in the promotion of human-well being in food, agriculture and health care are the two sides of the same coin. Nobody is clear as of now how to address these two aspects of modern biotechnology. The confusion therefore must be addressed by all stakeholders so that the policy makers as well as the law makers will have a foot to stand on once they make their decision which, either way, could have far wider repercussions on the survival of the Nation.

The Protocol in its preamble recognises the limited capabilities of many countries, particularly developing ones, to cope with the nature and scale of known and potential risks associated with living modified organisms and for this reason the polluter pay principle comes in handy. The Kenyan law stipulates that the cost of cleaning up any element of the environment damaged by pollution, compensating victims of pollution, cost of beneficial uses lost as a result of an act of pollution and other costs that are connected with or incidental to the foregoing, is to be paid or borne by the person convicted of pollution under this act or any other applicable law. Pollution is defined as any direct or indirect alteration of the physical, thermal, chemical, biological, or radioactive properties of any part of the environment by discharging, emitting, or depositing wastes so as to affect any beneficial use adversely, to cause a condition which is hazardous or potentially hazardous to public health, safety or welfare, or to animals, birds, wildlife, fish or aquatic life, or to plants or to cause contravention of any condition, limitation, or restriction which is subject to a licence under this act.

The adverse effect of LMOs may not be considered as pollution in the strict application of the above definition but the concept is still applicable when it comes to the introduction of LMOs into the environment although meant for beneficial use but turning out to be harmful. The question is who pays for the consequences? The Kenyan law seems to favour the position that the producer or manufacturer of such LMOs pays and this may require ensuring in our laws that the manufacturer or exporter of such LMO has adequately underwritten the risk through insurance to cover any such eventualities.

Kenya's Standards Act expects certain high quality standards to be kept and when it comes to food such standards should ensure that what is put out for human consumption is not poisonous or dangerous to their health. If it is, then such information should be provided on the package so that a person may make a choice as to the risk they maybe taking. The developer of the LMO is liable to pay for damages caused by such LMOs. Further, the importer or the person who releases it for public use should be held liable to pay compensation.

As Kenya begins to think through a viable liability and redress system for biotechnology system, there is no doubt that her existing laws will inform her policy. In order to come up with a clear liability and redress regime she must ensure that the following are done:

- The precautionary principle measures are practically seen in a simple AIA process;
- Public participation supported by adequate information is strengthened;
- The polluter pays concept is enshrined in any agreements that are concluded; and
- Adequacy of insurance cover in case of reparation or compensation.

B. Uganda

While addressing liability and redress even under the common law, statutory provisions inevitably come in. Chapter 74 of Uganda's laws prescribes the time within which an action may be brought. This has a bearing on liability and redress in GMOs on seeking a synergy between the common law and statutory law. While common law concepts discussed hereinabove may be fundamental in determining liability and redress, actions are to be filed in compliance with the time bounds prescribed by the statute.

While filing claims, they must comply with the Civil Procedure in terms of demands of disclosure of cause of action, *locus standi* and breach of right. Under the Penal Code Cap. 106 there is no specific mention of GMOs. The code largely deals with criminal offences. Its failure to specifically mention or in any way attach sanctions to GMOs' activity makes it unsuitable as an avenue for the attainment of criminal liability and redress.

Other statutes that may be of use in liability and redress include:

- The Plant Protection Act 1964
- The Food and Drugs Act 1964
- The Uganda National Council for Science and Technology Statute 1990
- The National Agricultural Research Organisation Statute 1992
- The Biosafety Regulations.

C. Switzerland

Switzerland has developed a law to specifically deal with liability and redress in respect of GMOs. The law is christened the Federal Law relating to the Protection of the Environment. For liability to attach the following are essential ingredients that need to be established and proven:

- There has to be an aggrieved person
- There has to be damage
- Causation of damage must be established
- One has to be faulted.

It provides for strict liability and insurance cover and other financial guarantees. The main thrust of the statute is prevention of environmental damage. Compensation is also catered for under this statute. The insurance industry and financial sectors are fully involved. The statute covers the release of GMOs into the environment for trial purposes and for commercialisation. It seeks to channel liability to the producer and the GMO farmer. Right of recourse generally lies against those persons that inappropriately handle GMOs. In the case of contained use or trial release of GMOs causing damage, the permit holder is strictly liable. In the case of commercialised/marketed GMOs, the permit holder is strictly liable if the victim is a farmer or a consumer of

a product of a farmer. The time limitation within which one could bring a suit is thirty years for any loss or damage that may accrue. The statute's important elements are compensation for environmental loss, optional financial guarantees and the facilitation of the burden of proof.

VI. CONCLUSION AND THE WAY FORWARD

A. General Scope

In developing a liability and redress regime for biotechnology activities, there is need to distinguish between civil and penal liability. Patent liability should also be considered as a separate issue. Some of the issues to be considered here are: the obligation to provide for compensation for damage caused by activities which pose potential risks to persons property and the environment; liability for environmental contamination (Oil Pollution Convention, Trail smelter case, Basel Protocol); Liability for food chain contamination (under Swiss law covered by general principles of law and in Kenya the common law tort of negligence would apply); Liability for lawful commercialisation or release; The concept of strict liability (Rylands v. Fletcher); Liability for unlawful commercialisation or release; Penal liability; Civil liability as far as the liable person is solvent; Whether absolute liability would be appropriate; Liability for controlled or uncontrolled spread of transgenic organisms – strict liability; and patent Liability - Breach of Patent Law requires civil liability as one of the possible consequences.

These issues have to be considered within the purview of international instruments that the East African countries have ratified or are participating in such as: CBD, Cartagena Protocol Codex alimentarius, (Bases of global standards in food trade); WTO agreement on sanitary and phytosanitary measures; TRIPS; and joint efforts of FAO; WHO, UNEP to deal with health and environmental risks associated with biotechnology.

There is also need to look at the national instruments that are relevant. In Kenya, these include: Constitution: guarantees the right to life; EMCA: a right to clean and healthy environment, obligation to protect environment; Provides penal and civil sanctions for infringement. Standards Act; Regulations and guidelines for biosafety and biotechnology for Kenya (NCST) 1998; Draft Constitution Draft Biosafety Bill and the Draft Biotechnology and Biosafety Policy. In Uganda they include: The Constitution, 1995 which provides for the protection of the environment: of importance for the control of hazardous LMOs; The National Environmental Statute, an umbrella statute giving a framework with which sectoral laws are to conform: The Agricultural, Seed and Plant statute which offer protection, regulation and control of plant breeding and variety release, import, quality assurance of seeds and plant materials; the Plant Protection Act; The Uganda National Bureau of Standards Act; The Uganda National Council of science and technology statute; and the Uganda National Council of Science and Technology, Biosafety Regulations 1999.

B. Tenets of a Liability and Redress System for Biosafety

The following points arose from the debates and discussions in the workshop.

1. Relevance/ Limitations of Existing Liability Regimes

a) Common law

Relevant torts include: negligence, nuisance and the rule in Rylands v. Fletcher. The limitations of these include limited law reporting; the onerous evidentiary burdens which are not easy to discharge.

b) Statutory law

Relevant laws include framework environmental laws which embody such principles as the precautionary and polluter pays principles; right to clean & healthy environment and public participation. The limitations include liability for adverse effects of GMOs not envisaged in current laws on public health and food safety e.g., Kenya's Food and Drugs Act only covers liability for "fitness for human consumption". But GMOs may be fit for human consumption and still have adverse effects. Further, there are defects in our judicial systems and laws of civil procedure and cases may not be decided on merits and the evidentiary burden is not easy to discharge.

Causation is also difficult because isolating causal factors where there are multiple causes is not easy. There are inadequate human resources in terms of numbers and knowledge base. There are very few people to articulate issues in courts and to decide.

We can borrow from other systems such as the Swiss law but we need to adapt them to suit our socio-economic cultural and political circumstances.

c) State responsibility

Relevant international law includes the Trail Smelter arbitration for damage originating from outside a state's boundary. Customary international law principles on state responsibility are also relevant and specific treaties relating to specific issues. The limitations here include limited case law with few pertinent decisions; liability is only state-to-state and no redress is available for private actors.

d) Civil responsibility regimes in international law

Under the nuclear energy schemes, liability is absolute except in instances of war and natural disasters. Liability is exclusively channelled to the operator of the nuclear installation or ship. Limitations to liability may be placed on the amount payable and the duration. It is noteworthy that payments have prescribed limits supported by compulsory insurance or security held by the operator and guaranteed by the state.

The Council of Europe Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment of 1993 aims at ensuring adequate compensation for damage resulting from activities dangerous to the environment (Art. 1). Dangerous activities are defined to include GMOs, which as a result of their properties pose a significant risk for man, the environment or property (Art.2).

Just like in state responsibility, limitations in this scheme include limited case law; limited development of principles relating to liability (and limited focus on environment); there is also an upsurge in emphasis of international environmental law on preventive measures.

2. Fault based/ strict/ absolute liability?

Fault Based: One must prove intention/ negligence of defendant;
Strict: No need to show intention/ negligence of defendant but it must be proved, for instance that the product was defective;
Absolute: Defendant has no defence open to them such as act of God defence for hazardous activities.

Strict liability was favoured above fault-based and strict. This was especially in the food regime practices where it is difficult to prove intention and negligence and there is need to ensure potential defendants take all due precautions. Further the liability should be joint and several to ensure that there is fair allocation of responsibility between defendants.

3. Definition of liability regime

The Liability regime should be comprehensive including: Civil; Penal; State liability – through joint and several liability. The state should be responsible for public actors. An international civil liability scheme should be established to cover activities of multinational corporations (MNCs). MNCs should contribute to the liability scheme.

4. Channelling of liability

There was no agreement on whether liability should be channelled to farmers. They however agreed that the seed producer, marketer/ trader and any entity not acting appropriately should be liable.

5. Type of compensation

Compensation should include financial/pecuniary aspects in the form of damages/fines and also restoration/reinstatement of the environment to the "best extent possible" as provided for in Kenya's Environment Management and Coordination Act.

6. Who should be compensated?

A distinction should be drawn between damage to humans where rights holders should be recompensed and damage to the environment where government agencies should use funds in the public interest. In instances where the government has sanctioned the activity, there are potential conflicts of interest and funds could be managed by a different agency of government.

7. Time limits

The time limits should be determined through a scientific approach. With regard to impacts on human health, physiological effects manifest themselves within five years generally and shorter time frames of about ten years should be adopted. For impacts on the environment/ecosystems, longer time frames of thirty years should be adopted.

8. Procedure to prosecute

A mixed system should be adopted with special technical courts and courts of first instance to hear evidence. Appeals should be addressed through the ordinary court process. Overall, there is need to educate scientists on how the legal process works especially with regard to the question of evidence in technical matters and the avoidance of frivolous law suits. There is also need to build capacity for public interest litigation in biosafety with the aim of protecting the interests of unorganized groups such as farmers and consumers against MNCs.

C. The Way Forward

Standard/product liability is relevant so long as there is evidence of proof of causation. The limits of standard and product liability are that one pays for causing damage. It is important to have standard liability in keeping with NES and EMCA position of polluter pays. However, Proving causation is a limitation and there is an information gap which makes it difficult to establish a rigorous nexus between damage and causation. There is need for scientific expertise in proving damage and judicial officers need to be trained to appreciate the technical and scientific concepts and terms.

In standard liability there are time limits of three years within which to bring an action. The costs of litigation are also high and access to accurate information may not readily avail information. The lack of resources can also hamper bringing in expert opinion.

With product liability, it attaches onto the final product and the point of use. If the product causes damage then the user may be liable if damage is caused by his use of the product and where the user acts against prescribed instructions on the manual of use. The manufacturer will be at fault if the product is defective and damage occurs because of that defect. Liability covers product not process, thus previous input is not held accountable. The time limitation of three years is still a handicap and there may be need to redefine the term manufacturer to make it applicable to GMOs. In case of a wrong usage of the GMO product, the user will be sued jointly and severally with the manufacturer. Lack of legal representation may lead to liability attaching to a user notwithstanding absence of causation.

The advantages of GMO specific liability is that one can tailor the regime for time limitation to the traceability of GMOs. It will also help to evaluate environmental damage and control the illegal introduction of GMOs. The disadvantage of GMO specific liability is that causation is hard to establish.

1. Role of scientific data in decision making.

Decision-making should be founded on specific data. Where there is divergence in scientific data, there are problems. Bio-ethics should also be used to inform the process and public awareness and cultural issues should also inform the process.

2. Role of insurance

The risk caused by GM is insurable and risk coverage should be done by way of policy plans. There should also be sensitisation of the public about the risk. On the issue of who is to take out the insurance cover, each entity in the GMO activity line has to take cover according to the magnitude of risk, with the manufacturer as the highest risk taker. Farmers who work with GMOs also need to take insurance cover, as well as consumers. The cover for consumers should however not be mandatory. The insurance premiums will be used to finance compensation and should be determined by actuarial scientists.

For state actors, the state should be held liable for allowing activities adversely affecting the environment/human/animal/plant health. Courts should be involved in adjudicating claims. Insurance companies will also require state investigators in determining liability.

Government underwrites its researchers to be held responsible.

As an alternative to insurance, alternative financial guarantee options should also be explored. The government should provide these guarantees. Private-sector actors being the primary beneficiaries should take out mandatory insurance while in the case of public /private sector partnerships, guarantees should also be provided by way of an endowment fund.

3. Liability and consumer choice

The consumer has a right to choose. Lack of disclosure by the manufacturer to the consumer should occasion liability. Further, lack of information that will enable a consumer to make an informed choice should occasion liability whether there is damage or not.

4. What qualifies as GMO for liability and redress?

All GMOs and their derivatives should trigger liability and redress.

5. Role of diverse regulators in liability and redress

a) Kenya Bureau of Standards (KEBS)

- Develop standards for regulating and products;
- GMO product specifications;
- Codes of practice/guidelines for handling GMO processes; and
- Testing methods.

b) Kenya Plant Health Inspectorate Service (KEPHIS)

- Examining the safety of plants & plant products before entry, for purposes of preventing diseases & pests;
- KEPHIS should be held liable for allowing any harmful products especially disease & pest infected GMO; and
- They need to inspect & monitor GMO activity and should terminate license in case of risk. Failure should attract institutional responsibility.

c) National Council for Science & Technology (NCST)

- The National Biosafety Committee is a clearinghouse that handles and approves GMO work on the basis of sufficient data;
- Approval should be on the basis of GMO safety; and
- Institutional responsibility, thus liability, for permitting harmful GMOs.

d) National Environmental Management Authority (NEMA)

- After commercialisation NEMA needs to do an audit and provide data in case of damage, in collaboration with lead agencies and when persons seek redress; and
- NEMA should conduct inspections and monitoring; liability should result if they fail.

e) Department of Veterinary Services

- Handles animals and feeds of animal origin (bone meal, blood meal);
- Needs to take preventative measures against introduction of disease and pest infected GMO;
- Needs to continuously monitor & inspect the effect of the products;
- They offer data instances where claimants seek redress; and
- They take institutional responsibility for failure to conduct inspections & monitoring.

e) Pest Control Products Board

- Regulates, controls and registers pest control products in Kenya looking at appropriateness of usage;
- The GMO pesticide approved and registered that is harmful should occasion liability; and
- They should also provide data and technical information to claimants seeking redress.

f) Liability and redress in National Biosafety Frameworks

- NBF needs to capture clearly the need for liability and redress systems; and
- There is need for a specialized tribunal to adjudicate on GMO liability and redress issues.

Nairobi, 5 November 2003.

Annex: List of Participants

Migai AKECH
Email: migai@yahoo.com

Doris AKOL
Email: dorisakol@hotmail.com

Roselyn AMADI
Email: roselynamadi@hotmail.com

Juerg BALLY
Email: juerg.bally@ buwal.admin.ch

Lilian Anne CHEROTICH
Email: lilichero2001@yahoo.com

Philippe CULLET
Email: pcullet@ielrc.org

Edwin NGURE KAMERI
Email: kadugee@yahoo.com

Javason KAMUGISHA
Email: jkamugisha@muklaw.ac.ug

Patricia KAMERI MBOTE
Email: pkameri-mbote@ielrc.org

Joseph KIMARU KEERU
Email: jkeeru@kebs.org

Harrison MACHARIA KAMAU
Email: ncstnbo@insightkenya.com

Gladys NJERI MAINA
Email: kephis@nbnet.co.ke

Lois MURAGURI
Email: L.muraguri@cgiar.org

Francis NANG'AYO
Email: biotech@skyweb.co.ke

Elvin NYUKURI
Email: E.nyukuri@cgiar.org

Cecilia NZAU
Email: nzaucecilia@yahoo.com

Anne OBUYA
Email: Awino25@yahoo.com

Samuel J. OCHIENG
Email: cin@insightkenya.com

Prof. James OPIYO OCHANDA
Email: Jochanda@uonbi.ac.ke

Albert SIMIYU MURAMBI
Email: asimiyu@ielrc.org

Moses M. SHAHA
Email: moses.388ke@mail.com

For more information on the Workshop and the participants,
please visit the Workshop's website at

http://www.ielrc.org/activities/workshop_0309