A DEVELOPING COUNTRY PERSPECTIVE ON LIABILITY AND REDRESS FOR GM CROPS

A Position Paper

Intended for Use at the Fourth Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol (COP-MOP 4)

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Introduction

The transboundary nature of the production of and trade in Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) for the purpose of the Cartagena Protocol on Biosafety requires a comprehensive international regime complemented by an effective national legal regime. The two are necessary to address the risks inherent in the many potential damage scenarios, the difficulties inherent in obtaining compensation and redress for LMOs, the current gaps in national and international law and the mandate from the international community to develop such rules set out in the Cartagena Protocol on Biosafety. Article 27 of the Biosafety Protocol mandates the establishment of a Liability and Redress regime, which addresses the following:

- Both liability and redress;
- Ensure that the risks to the environment, human health and the socio- economic effects of damage resulting from the transboundary movement of LMOs are addressed;
- Create a consistent level of responsibility and predictability for LMO exporters;
- Provide assurance and confidence for developing countries when considering the import and use of biotechnology;
- Ensure that the victims have the right to recourse for damage suffered due to biotechnology;
- Promote the prevention of damage to the environment by internalizing the cost to operators of LMOs and implementing the 'Polluter-Pays' principle; and
- Ensure that preventive measures and response, remediation and restoration measures are taken for damage to the environment or biodiversity.

The agenda of the Protocol will be revisited in May 2008 at the Fourth Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP 4) in Bonn, Germany. Liability and Redress constitute one of main substantive issues on its agenda. The broad issues related to liability and redress, as were first outlined in Article 27 of the Protocol, are definition of damage, valuation of damage to biodiversity, threshold of damage, causation, channelling of liability, roles of Parties of import and export of the Protocol, standard of liability, insurance, standing/right to bring claims etc.

The following provides the context, existing opinions, and Gene Campaign's position for some of the outstanding issues related to Liability and Redress, the resolution of which is of crucial importance to developing countries:

Specific Liability Regime for GEOs

A national legal regime concerning Genetically Engineered Organisms (GEOs) should not be developed in a vacuum, but should benefit from the experience gained within existing legal frameworks for environmental liability. Though significant lessons can be learnt from the liability frameworks in the environment field, the introduction of GEOs

into the environment raises a number of complex legal questions which a general liability regime is not equipped to address.

Genetic engineering is a radical technology, in which genes are spliced from one organism and inserted into another. Although genetic modification has been a part of evolution within species, genetic engineering is significantly different from what takes place in nature in that it breaks down the species barrier and creates novel combinations of genes.

The risks posed by GEOs are, therefore, of a novel kind. Genetically engineered organisms are living organisms and therefore, capable of self-replicating. Once released into the environment, they are capable of multiplying and spreading through the ecosystem. They can transfer the foreign genes that are engineered into the other organisms, which can reproduce and spread modified genes further, thereby resulting in a kind of genetic pollution. Thus, it is impossible to recall a genetically engineered organism once it is introduced into the environment.

Moreover, there is evidence that random splicing of novel genes into the plants can produce unpredictable effects on the recipient plant. For example, introduction of a novel gene has radically changed the starch metabolism of the potato.

Unlike the chemical field, the results appear very late in biology. It is not easy to predict the long-term consequences of gene transfer into wild species. It is also possible that the true impact becomes clear only after several years of full scale commercial growing.

The arguments advanced by the industry that there is no evidence of any unique hazard because of the novel gene construct fall short of the truth. Reports and articles[1] reveal that only about 1% of the genetic transfer yields the desired result in comparison to 99% normal offspring from natural sexual breeding. The incorporation of foreign DNA alters the organism in constantly unpredictable ways. In plant transformation, many independent transgenic lines have to be screened before a line stably expressing a single copy of the transgene is isolated. Most, if not all commercially approved transgenic lines are genetically unstable and non-uniform. The majority of the transgenic animals that are born alive die at an early stage of life. In some cases the transformed genes do not pass onto the next generation, as the gene construct was not stably incorporated into the genes of the animal. Even where the gene construct was successfully incorporated, the subsequent breeding may raise problems. Thus, the claim that no liability is required as there is no evidence of damage displays a lack of understanding and a substantial measure of carelessness.

Considering the fact that introduction of GMOs into the environment raises novel issues, Gene Campaign advocates the creation and adoption of a liability regime which can cover the specific aspects and potential for harm of modern biotechnology.

Gene Campaign recognises the need for a liability regime specifically tailored to address the issues raised by cell technology that intervene in cell architecture, genetic composition and balance and that can create radical new proteins and compounds with unpredictable, possibly harmful effects on life forms. Given the sheer newness of the technology, Gene Campaign advocates that:

- A GEO specific liability regime must be based on the precautionary principle, where liability can be imposed on the basis of possible effects of introduction of GE products for which strict scientific proof is not yet available.
- Also, a liability regime needs to be context- specific; taking into account the ground realities in a country like India.

Primary Civil Liability with Residual State Liability

States setting up a liability and redress regime need to consider whether to opt for a state liability regime or a civil (or private) liability regime or a combination of both.

The concept of state liability denotes the liability of a state for damage suffered by another state. It is based on the premise that every state is responsible for the actions of its nationals and that every state has the function of protecting the interests of its nationals. Thus, here, the legal relationship is between the state where the damage originated and the state where damage was sustained. The concept of state liability in the environmental field is not well developed. The 1972 Convention on International Liability for Damage Caused by Space Objects is the only example of an international treaty on state liability, which addresses damage caused in one state by space objects launched in another state.[2]

On the other hand, civil liability refers to the liability of a private entity (an individual, agency or company) for damage suffered by another private entity, where claims are brought before a national court by the private entity that suffered the damage. It is possible for a government authority to be the claimant or the defendant if it is in the same factual position as a private entity. For example, if it is the owner of a property that was damaged or the operator of a facility that caused the damage. In the latter case, the state or state owned institution producing GE products could be made liable.

Gene Campaign advocates:

- A regime providing for primary civil liability of private parties and residual liability of the state, in recognition of the duty of care owed by both.

- A liability regime equipped to address situations where-
    1. Stipulated conditions not complied with- party being held liable.
    2. Loss or damage occurs despite compliance with precautions- liability of both technology provider as well as regulatory agencies.

Damages- Functional and Geographical Scope

Owing to the specificities associated with GEOs, the uncertainties concerning the magnitude of possible damages to the environment, human and animal health and the extent to which they may occur over a long period of time, the term 'damage' needs to be given the widest interpretation. This need also arises from the fact that unlike other damages to the environment which could be rectified, it is not possible to 'recall' a genetically engineered organism once it is introduced into the environment. It is also not possible to predict its impact on the environment and the wide ecosystem and biosphere.

A liability and redress regime should be able to address the question of damages to areas which are not the object of real property rights, such as common/ community lands and the community should have the statutory right to seek reparation for the damage caused which may have consequences for their traditional livelihoods, economy, socio- cultural life, indigenous knowledge systems and their applications etc. To address this, apart from damage in areas under national sovereignty, the regime should also cover damage in areas beyond any national jurisdiction- that is, common lands. The precautionary principle needs also to be applied to the introduction of GEOs in the high seas.

Jurisdiction over actions under such a regime should lie with the courts of the country where the damage took place as well as in the courts of the country where the defendant has his habitual residence or his principal place of business. In this context, some elements could be borrowed from the Alien Torts Claim Act of the United States adopted way back in 1789. Under this Act, an alien can initiate a civil action in the American courts for a tort committed in violation of the law of nations or a treaty of the United States anywhere in the world.

Gene Campaign advocates:

- With regard to functional scope, 'damage' should be given the broadest possible interpretation, including damage resulting from the transport, transit, handling and/or use of LMOs and products resulting from transboundary movements of LMOs and products, including unintentional and illegal transboundary movements and in the case of preventive measures, damage threatened to be so caused.

- With regard to geographical scope, it should extend to damage in Parties (to the Biosafety Protocol), non- Parties and areas beyond national jurisdiction, irrespective of whether the transboundary movement has its origin in a Party or non-Party.

- A legal framework is necessary which enables an aggrieved party to sue for damages not only where the damage occurs but also in the country where the defendant habitually resides or has his place of business.

Definition and Valuation of Damage

Because of the peculiar nature of LMOs/GEOs and the limited knowledge and experience with such products, many countries have felt the need for focused attention in defining, valuing and classification of such damage. As such, the issue of defining damage has been accorded top priority by the Ad Hoc Group. According to Cullet[3], the definition for damages in the context of GEOs needs to be inclusive of damages to the environment, to human health, to property and to socio-economic interests. Environmental damage is central to a liability and redress regime for GEOs, given that the Biosafety Protocol is an environmental law treaty. However, while defining environmental damage and damage to biodiversity, the specific context of biotechnology needs to be kept in mind. As recognized in Article 26 of the Protocol, socio- economic aspects constitute an important concern of Member States and in fact some of the main impacts of the introduction of GEOs in agriculture may turn out to be the socio- economic aspects related to livelihood concerns. These impacts need to be recognized in a comprehensive definition of damages in the context of GEOs. Similarly, risks to human and animal health which also fall within the scope of the Protocol need to be considered as a number of GEOs end up directly or indirectly in the food and feed chain.

Closely related to the definition of damage, is the issue of valuation of damage. Where damage is not directly linked to property rights or where damage cannot be easily measures in financial terms such as in the case of loss of biodiversity, compensation cannot be conceived only in monetary terms. Where no direct economic loss is registered, the restoration of the environment is one solution. In case where damage is irreversible,

other solutions must be devised, for example, creation of a similar environment in a different location or a criminal sanction. The Lugano Convention is noteworthy with regard to the definition of damage. It includes impairment of the environment not just limited to the costs of measures of reinstatement actually to be undertaken, but also the costs of preventive measures and any loss or damage caused by preventive measures.

In the case of genetic engineering, the definition of damage needs to determine whether plaintiffs must wait for actual damage to become visible or whether an evidence of unintended gene introgression is sufficient.

Gene Campaign advocates:

- Definition of damage to include:

  (a) Damage to human health including:

    (i) Loss of life or personal injury or disease together with medical costs including costs of diagnosis and treatment and associated costs;

    (ii) Impairment of health;

    (iii) Loss of income;

    (iv) Public health measures;

  (b) Damage to or impaired use of or loss of property;

  (c) Loss of income /directly/indirectly/derived from an economic interest in any use of the environment/ biological diversity, incurred as result of impairment of the environment/biological diversity/ taking into account savings and costs;

  (d) Loss of income, loss of or damage to cultural, social and spiritual values, loss of or reduction of food security and livelihood, damage to agricultural biodiversity, loss of competitiveness or other economic loss or other loss or damage to indigenous or local communities.

  (e) Damage to the environment and biological diversity, including:

    (i) The costs of reasonable measures of reinstatement or remediation of the impaired environment/biological diversity, /where possible/, measured by the costs of measures actually taken or to be undertaken, including introduction of original components;

    (ii) Where reinstatement or remediation to the original state is not possible, the value of the impairment of the environment, taking

(iii) The costs of response measures, including any loss or damage caused by such measures;

(iv) The costs of preventive measures, including any loss or damage caused by such measures

(v) The costs of any interim measures; and

(vi) Any other damage to or impairment of the environment, taking into account any impact on the environment.

- Unlike other damages, in the field of biology, damage may not be immediately visible and evidence of harm can surface many years after. In such cases, absolute proof of damage should not be limited to what is immediately apparent but should be anticipated from the occurrence of a primary event. In the case of transgenics, their detection in unintended organisms and locations should be regarded as constituting damage.

Liability of Non- Parties

Article 24 of the Cartagena Protocol on Biosafety provides that transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. It also states that the Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

Gene Campaign advocates:

- National rules on liability and redress should cover damage resulting from the transboundary movements of LMOs from non-Parties, in accordance with Article 24 of the Cartagena Protocol and COP/MOP decisions BS-I/11 and III/6.

Channelling of Liability

A number of persons are involved in the handling, transport and use of LMOs. In the event of damage, the applicable legal rules determine which of these persons are liable. National and international civil liability rules use different ways to attribute liability. Options include:

- Channelling liability for the entire transaction to one particular operator in the chain; for example, the producer, or the person arranging the transboundary movement;

- Channelling liability to each operator for the particular stage of the transaction for which he or she is responsible;
- Holding all persons involved in the transaction jointly and severally liable; this means that the victim will be able to bring a claim against any or all of them for the entire damage.[4]

The notion of channelling comes into play when the standard of liability is not fault based. In those instances, liability is normally channeled in accordance with the 'Polluter-Pays' principle. According to the submission of the European Union[5], all activities must internalize all the costs, and the industries and activities connected with the use of LMOs are not an exception to such a principle. Accordingly, it has been submitted that the primary liability for damage resulting from the transboundary movement of LMOs should rest with person or persons responsible for the carrying out of an action related to the transboundary movement of LMOs that may be directly or indirectly at the origin of the damage.

While the 'Polluter Pays' principle should prevail, the State, under whose jurisdiction or control activities involving LMOs are carried out, cannot escape inclusion in the liability. Principle 21 of the Stockholm Declaration and Principle 2 of the Rio Declaration both recognise the general duty of States for transboundary harm. This obligation means that States must take measures to prevent the occurrence of transboundary environmental harm and where harm does occur, to redress the consequent damage. Even if private individuals cause the environmental injury in their personal capacity, States still have the obligation to prevent the harm by taking appropriate measures by exercising due diligence to prevent private individuals from causing environmental harm.

One issue being debated in this context is channelling the liability to the person who is in the best position to prevent damage or one who is most financially liquid. Another issue is whether liability should be channelled to a single person or multiple persons. While it has been admitted that the channelling to multiple persons will result in the need for multiple coverage for liabilities arising out of a single accident, require a bigger share of the capacity of the relevant securities market and hence, increase the costs of covering such liabilities, nevertheless, channelling to multiple persons enhance the options for claimants to recover damage.

Gene Campaign advocates:

- Application of 'Polluter Pays' principle (with the technology provider coming under the definition of 'polluter').
- Liability to be channelled jointly or severally to the following persons, except in the case of agriculture or forestry:
    - The developer
    - The producer
    - The notifier
    - The exporter
    - The importer
    - The owner of the installation
    - The carrier
    - The supplier, provided he knows the nature of the LMOs and the risks associated thereto
    - The provider of the technology
    - The governmental agencies that deal with the LMOs e.g. customs etc.
    - The operator
- The definition of operator to include
    - Any person who has the operational control;
    - Any person who is in the best position to control the risks and prevent the damage;
    - Any person who operates the activity from which the LMOs are discharged;
    - Any person who does not comply with the provisions implementing the Biosafety Protocol;
    - Any entity who has the responsibility to put in place the provisions for implementing the Protocol;
    - Any person to whom intentional, reckless or negligent acts or omissions can be attributed.
- There should be a provision expressly exempting end- users; it should ensure that no liability is channelled to end-users such as farmers and consumers.
- In case of agriculture and forestry, when harm is caused by bringing LMOs into the market for use as aids to agriculture or forestry, the following operators shall be responsible:
    - The producer who first placed these organisms on the market;
    - In case of imported LMOs, the producer who first placed them in the market abroad and the importer are jointly and severally liable.
    - The owner of a company or installation that imports such organisms is jointly and severally liable with the producer; and
    - The persons who have handled such organisms improperly or have otherwise contributed to the worsening of the harm (here also, end users should be expressly exempted from liability). .

- When LMOs are released unintentionally during transport, the transporter should be responsible for taking immediate measures, but the owner or the sender will pay the cost of measures taken.
- The states are often involved in promoting biotechnological innovations. Thus, state liability should apply for the acts that are not prohibited by international law.
- The Residual state liability shall apply in the cases where it is either impossible to identify the perpetrator who had caused damage or where all other options had been exhausted. Also, in cases where the financial securities of the primary liable person are not sufficient to cover liabilities.

Limitations on Patent Liability

An important question which states need to address, while drawing up a framework for liability and redress, is the question of patent liability. Patent liability is relevant in the context of the debate for two broad reasons.[6] First, while there is no recognized legal connection between the granting of a patent on a GEO and the biosafety procedures leading to its commercialization, the link exists in practice and needs to be recognized. Second, while the liability of persons illegally using a patented invention has generally been separate from biosafety considerations, this is, for instance, not the case in the context of GE seeds where there is a potential clash of liabilities between the liability of the entity commericalising the seed and the liability of the farmers found in possession of GE seeds without having purchased it from a licensed dealer.

Since most GEOs are protected by patent or other intellectual property rights, the case of Monsanto v P. Schmeiser[7] deserves special attention in the context of patent liability arising from contamination (as opposed to breach of contact between the farmer and the patent holder). In this case, Percy Schmeiser was held liable by the Canadian Supreme Court for having acquired the patented GE canola involuntarily. In other words, the simple presence of the GE seed on his land without his knowledge or consent was found to be an infringement of Monsanto's patent.

The Schmeiser case highlights the need for liability regimes to address the relationship between intellectual property rights and property rights such as land rights as well as the relationship with other rights such as the fundamental right to food. Indeed, if the Schmeiser precedent were to be adopted in other jurisdictions, it would have far reaching consequences for farmers the world over, as well as to issues related to land management generally. For instance, a land user will be both responsible for the unwanted intrusion on the land and for the damage that occurred as a result of the unwanted intrusion/contamination against the will of the land user.

In the Indian agricultural setting, there is a high likelihood of contamination of non- GE crops by GE crops, which put the Indian farmer in a very vulnerable position. Here, individual plots of agricultural land are not separated by fence, but are simply demarcated with the help of heaped ploughed soil. Thus, Gene Campaign advocates the introduction of specific legal provisions and rights to farmers, which would protect them against innocent infringement. Also, the international regime must set minimum standards to deal squarely with the limits of patent protection.

Gene Campaign advocates:

- The farmer should have legal protection against unauthorized transgression or trespass by an unwanted alien crop/ gene.

- In a situation where owing to contamination, the farmer has saved seeds of the GE crop, the Farmer's Right to save, replant or sell seeds cannot be made subject to any claim by the GE crop owner.

- The scope of the provision for innocent infringement under the Protection of Plant Varieties and Farmers' Rights Act, 2001 require to be extended. Under this provision, farmers are guarded against legal actions arising from the infringement of rights granted under the Act.

- No liability should be attached for unintentional damages caused by a farmer who has chosen to grow GE crops. A farmer's decision to grow GE crops cannot be attributed to an intention to cause damage and it is unlikely that he would even have the knowledge of any such possible damage.

Standards for Liability

International as well as national legal regimes generally provide for three standards of liability, which are:

- Fault-based liability, which requires that the damage be caused through a wilful or negligent act of the liable person. Fault is determined on the basis of whether or not the person to whom the damage is attributed observed the prescribed duty of care in carrying out the activity.
- Strict liability, which applies regardless of whether or not the person to whom the damage is attributed is at fault. The claimant is only required to prove the damage and the causal link, but not a failure to observe the duty of care. This means *prima facie* liability, but the actor can avail of a limited set of defenses such as Act of God, act of war or civil unrest, and intervention by third parties.

- Absolute liability- This standard of liability only requires the establishment of a causal link between an act or omission and the damage, and does not allow for defences.

Thus, the rules of both strict and absolute liability make the defendant liable for accidental harm caused, without any intention and negligence on his part. The rationale behind these higher standards of liability is that the activities coming within their fold are those entailing extraordinary risk to others, either in the seriousness or the frequency of the harm threatened.

The rule of strict liability, as laid down in Rylands v Fletcher[8], provides for three conditions for its application. Firstly, the defendant should have brought or collected on his land some dangerous thing, that is, a thing likely to do mischief if it escapes. The liability exists whether the land is or not owned by the defendant. The second condition for the rule to apply is that the thing causing the damage must escape to the area outside the occupation and control of the defendant. And thirdly, there must be non- natural use of the land, with the concept of non- natural use being flexible. This rule of strict liability for damage may best be summed up in the words of Blackburn, J.: "The rule of law is that the person who, for his own purpose, brings on his land and collects and keeps there anything likely to do mischief if it escapes, must keep it at his own risk; and if he does not do so is prima facie answerable for all the damage which is the natural consequence of its escape". As already mentioned, this rule allows for some exceptions or defences.

In most national legal regimes, strict liability for environmental damage applies to activities generally recognized as hazardous with high potential of causing severe damage to the environment and human health, such as marine transport of crude oil, transport and management of toxic chemicals and wastes, and nuclear activities. There is a growing respectable scientific concern that GMOs are intrinsically hazardous. Even if the incidence of any harm occurring may be low, the magnitude of the harm, once it takes place, could be incredibly great, with long term and short term impacts on other crops and species, ecosystems, human and animal health and socio- economic effects. The potential costs arising out of harm caused by genetically engineered organisms in a worst case scenario, could easily run into millions. The movement of these GEOs, through trade, to parts of the world with knowledge that these countries lack the capacity to assess the technology and its products adequately and put in place measures to deal with them safely, makes the transboundary activity ultra hazardous as well[9]. Also going by the conditions laid down in Rylands v Fletcher, damage due to GEOs fulfils these requisites, in the sense that GMOs are dangerous things likely to do mischief on escape, and the damage escapes to the area outside the control of the defendant. Also, use of GEOs could be broadly interpreted as non- natural use of the land.

The majority of nations that have implemented GEO liability legislation have recognized the pitfalls of a fault- based system. Reports submitted on national laws[10] show that, to a large extent, the basic standard to apply to LMO-related activities is strict liability, where liability is engaged regardless of fault. In the Danish Act on Environmental Damage, all the activities identified in the list of the Act are subject to strict liability. The German Genetic Engineering Act focuses on the sheer risk posed by LMOs whether or not the person responsible for the genetic engineering operation is at fault. Section 23 of the Norwegian Act lays down strict liability "for damages regardless of any fault on his part

when the activity causes damage, inconvenience or loss by deliberate release or emission of LMOs into the environment".

It has been pointed out that a strict liability regime should be implemented when the need to protect the public and provide effective compensation outweights the need to establish the moral culpability of the defendant.[11] It has been recognized that with the rapidly changing nature of biotechnology, it is difficult to define a socially optimal duty of care and assess when that duty has been breached. When a strict liability system is in place, the search for a socially optimal duty is unnecessary. A strict liability system is especially appropriate in a situation where a party derives an economic benefit from the risk it creates (which is the case with trade in GEOs).

Similarly submissions[12] have been made in favour of a strict liability regime for GEOs because it is unfair to expect that resource poor farmers who plant Bt cotton for instance, and who suffer some sort of damage, should have to prove the causal connection between the act of planting genetically engineered cotton and the resultant damage that has arisen from such planting. It is believed that the interest of the public is best served by a strict liability approach.

The Space Objects Liability Convention imposes strict or absolute liability. Three reasons have been advanced to justify the imposition of strict or absolute liability in the context of the Space Objects Convention, which resonates well with the challenges posed by GEOs. First, scientific causation is difficult to establish given the nature of the technology and its relative short history. Second, there is secrecy attached to the space exploration programmes. Accessing information to establish fault would be unusually difficult. Third, the person who benefits from the activity should bear the cost.

In recognition of the intrinsically hazardous nature of GEOs, Gene Campaign supports the adoption of a strict liability regime for damage. In addition to strict liability, Gene Campaign believes in the need for adopting absolute liability zero tolerance legislation for contamination in centers of origin and genetic diversity.

The Cartagena Protocol points out that centers of origin and genetic diversity of crops are of crucial importance to the future security of humankind (Preamble, 141). The Protocol signals the need for special care in the conservation of such locations and the need to be particularly sensitive to the potential effects of LMOs on such centers. The Indian region is one of the world's eight centres of crop plant origin and diversity. At least 166 food/crop species and 320 wild relatives of crops have originated here. Gene flow and contamination in these centres of origin and genetic diversity could lead to irrepressible loss of traditional plant varieties and agricultural diversity, having grave consequences for food security. Hence, there is need for imposition of absolute liability without exceptions in these regions.

The rule of absolute liability was evolved in the Indian legal system in M.C. Mehta v Union of India[13] by the Supreme Court of India, in preference to the rule of strict liability laid down in Rylands v Fletcher. It expressly declared that the new rule was not subject to any of the exceptions under the rule in Rylands v Fletcher. The Court observed that " this rule (Rylands v Fletcher evolved in the 19th century at a time when all these developments of science and technology had not taken place…We have to evolve new

principles and lay down new norms which would adequately deal with the new problems which arise in a highly industrialized economy". The Apex Court laid down a new "no-fault" absolute liability standard which provided that where an enterprise is engaged in a hazardous or inherently dangerous activity and harm results to anyone on account of an accident in the operation, the enterprise is strictly and absolutely liable to compensate all those who are affected by the accident. Such liability is not subject to any of the exceptions which operate vis-à-vis the tortuous principle of strict liability. Such an enterprise owes an absolute and non- delegable duty to the community to ensure that no harm results to anyone and if any harm results, the enterprise must be absolutely liable to compensate for such harm.

Gene Campaign advocates:

(i) A no- fault, strict liability regime for any undesirable geneflow or geneflow to untargeted species, because of the current uncertainties concerning the magnitude of the possible damages and the extent to which they may occur over a long period of time.

(ii) Imposition of absolute standard of liability with no exceptions in case of any kind of geneflow, no matter even 0.01%, in centres of origin and genetic diversity.

Exemptions from Liability

The concept of liability is based on the notion that a person or entity that has control over an activity is responsible for damage caused by that activity. This applies to both fault-based and strict liability. The law recognizes some defences, which a defendant is allowed to take in civil liability proceedings. By proving certain events that are beyond the control or influence of anyone, the defendant may avoid his liability. However, no such defences can be pleaded in the case of absolute liability.

Liability and redress regimes differ according to the number and the scope of the defences allowed. The main defences allowed generally include the following:

- Natural phenomenon of exceptional, inevitable, unforeseeable and irresistible character (also referred to as Acts of God or *force majeure*);
- Armed conflict, civil war, insurrection and similar events;
- Act or omission of a third person.

Other defenses that can be found in international and national liability and redress regimes or drafts of such regimes include:

- Compliance with a compulsory measure imposed by a public authority;
- Permission of an activity by means of a generally applicable law or in a specific authorization issued to the operator;
- The state-of-the-art defence for activities that were not considered harmful according to the state of scientific and technical knowledge at the time they were carried out.

Gene Campaign advocates:

- No exemption in case of absolute liability, which is the standard for contamination in centres of origin.
- In case of strict liability, the exemptions should be:
  (a) Act of God/ *force majeure*
  (b) Act of war or civil unrest
  (c) Intervention by a third party (including intentional wrongful acts or omissions of the third party)
  (d) Compliance with compulsory measures imposed by a competent national authority
  (e) Permission of an activity by means of an applicable law or a specific authorization issued to the operator
  (f) The 'state-of-the-art' in relation to activities that were not considered harmful according to the state of scientific and technical knowledge at the time they were carried out.
- However, in cases d, e, and f, the discharge shall be partial and the state shall take the residual liability.
- In case the damage occurs due to third party intervention, the third party should be held liable.

Causation and Burden of Proof

Causation, also referred to as the 'causal link', is the link that the law establishes between an event, action or omission and specific damage: only if causation is demonstrated will the person responsible for the action be held liable for the damage. This is one of the basic requirements for liability- whether fault- based, strict or absolute, to be attributed to a person or to another legal entity.

In law, the defendant is held liable for the wrongful act only if it is the proximate, direct or immediate cause of injury (*causa causans*) and not merely a *causa sine qua non* (cause without any other cause). The court employs the test of reasonable foresight or probability, as per which if the consequences of a wrongful act could have been foreseen by a reasonable man, they are not too remote. There is also the test of directness, according to which a person is liable for all the direct consequences of his wrongful act, whether he could have foreseen them or not; because consequences which directly follow a wrongful act are not too remote.

It would be difficult to apply the generally followed legal tests to establish causation in the context of GEOs /LMOs, because of the complexities of their interactions with the receiving environment and the possible timescales involved. The question of causality is one which has been widely discussed in the context of environmental damage. Various questions regarding the difficulties which can surface concerning the identification of the

link between the source of the contamination of the environment and the felt impacts have been debated. The problem first surfaced in the context of the environmental contamination by sources which are either distant in space or time from the impacts. Examples include the case of damage caused in a radiological emergency which can take years or decades to become apparent, and the case of long- range air pollution where the source may be hundreds of miles away from the impact and may also be in a different country.

These issues are quite similar in the case of genetically engineered organisms also, where source may be distant in space or time from the impact. Then again, in case of GEOs, damage may be too diffused to be traceable, although having the potential to be significant, long term or wide spread. The existing tests would fail to establish causation in a case, where for instance, the increase in usage of herbicide in a GM Herbicide Tolerant crop damages the crop in the neighbouring field. In such a case, shall the damage be attributed to the GM nature of the crop or the activity of over usage of herbicide associated with such farming.

A solution for this problem lies in case law itself. In Scott v Shepherd[14], it was held that it is not necessary that the event which is immediately connected with the consequences is proximate and that farther from it is too remote.

Various countries have tried to overcome this difficulty in establishing causation in case of LMOs/GEOs by adopting the approach of reversal or reduction of the burden of proof in that causation is presumed until the defendant can demonstrate otherwise. The Austrian Law on Genetic Engineering as well as the German Genetic Engineering Act has adopted this approach. When the damage is caused by LMOs, it is presumed to have been caused by such properties of these organisms as a result of genetic engineering operations. Yet such presumption would be invalid if the damage is likely to have been caused by other properties of these organisms.

Gene Campaign advocates:

- Determination of causation in case of LMO related damage should not be subject to the usual standards adopted in law, as it is both difficult and different.

- Causation shall be presumed to have been caused by introduced/ modified traits of LMOs/ GEOs, unless proved to have been caused by some other properties of these organisms.

- Taking into account the specificities of GEOs, the burden of proof should be reversed from the plaintiff to the defendant (which the law holds ‘justified' in special circumstances.

Standing/ Right to Bring Claims

The subjects of the right to make claims are different for interstate claims based on international law, on the one hand, and claims based on civil liability, on the other. As for interstate claims based on international law, a State has the right to make claims on its own behalf that may include claims on behalf of its nationals and in special cases, on behalf of a group of States or the international community as a whole (Articles 42 to 48 of the 2001 ILC Articles on the Responsibility of States for Internationally Wrongful Acts).[15] As for claims based on civil liability, the right to make claims is governed by the applicable domestic law on procedural matters. Generally, in most legal systems, persons or other entities wishing to bring a claim must demonstrate that they have an interest as recognized by the applicable law. Usually, the interest of a party is recognized if the person or entity is directly and materially impacted by the alleged damage.

One issue which has been widely debated in the context of the GEO liability and redress debate is whether or not a non- governmental organisation (NGO) has the right to sue and seek remediation for natural resource damages. An NGO acting in the general interest (*actio popularis*) serves a fundamental civil purpose, fulfilling capacities for which the government is incapable. They are the vessels through which the affected parties' concerns are communicated.

Gene Campaign is in favour of the approach taken under the Basel Convention, where the person who may bring claims is not specified. By implication, the right to bring claims rests with any person who suffers damage; this would cover individuals, entities, the State itself under the provisions of the Protocol as well as under general rules of International law on State responsibility. Also, 'interest' of the affected party should be given a broad interpretation to include public interest or *actio popularis* as well, thus giving a right to non- governmental organisations.

Gene Campaign advocates:

1. An interested party is any person directly or indirectly affected by or engaging in the transboundary movement of GM organisms. A person advocating on behalf of those directly or indirectly affected, such as an NGO, is also an interested party.
2. Depending upon the type of damage, standing to bring claims should rest with the following
    (a) Traditional damage- affected person, dependents, or any other person acting on behalf or in the interest of that person;
    (b) Damage to biodiversity, environment, public health, health of animals- affected state, interested groups acting in vindication of common interest, interested groups acting in public interest;
    (c) Damage to human health- affected state, interested groups acting in vindication of common interest, interested groups acting in public interest;
    (d) Socio-economic damage- affected communities, injured person, interested groups acting in vindication of common interest, interested groups acting in public interest, state acting in interest of communities.

Limitation in Time

The limitation of liability in time is a common feature of liability and redress regimes to reduce the risk of liability of the person to whom liability has been channelled and to avoid legal proceedings where the evidence has become unreliable. Time limits are generally of two kinds: absolute time limit, within which an action may be brought and relative time limit, during which a victim should be allowed to bring a claim after the identification of the damage and the person liable.

In the case of damage caused by LMOs, the time limit should take into consideration the fact that the harmful effects may only manifest themselves after a long period. Damages due to the biological activity of LMOs, or due to the fact that the organisms themselves are living and may reproduce, may only appear after several generations from the (unintentional or intentional) release of the LMO. The Swiss Gene Technology Act provides for an absolute time limit of 30 years and a relative time limit of three years. Similar provisions exist in the Danish Act on Environmental damage, which includes two time- period limitations:

(i) Five years from the day of knowledge (or should have had knowledge) of the damage, the tort feasor, and his location;

(ii) A maximum of 30 years counted from the time of the act having caused the damage.

Gene Campaign advocates:

- Considering the difficulty in estimating the exact timeline of potential damages and the fact that long-term damages cannot be ruled out, an absolute time limit of 50 years (a period during which effects on two generations could be manifest).

- A relative time line of atleast 10 years, considering the fact that an affected party (for instance, a community or a farmer) in a developing country like India may be ill- equipped to institute a claim in a short time frame.

Financial Safeguard/ Insurance

An important issue under strict liability is the extent to which it should be possible for GEO developers to transfer their risks to others by means of liability insurance. The main argument in favour of insurance is that it ensures victims of actually receiving compensation, whereas, strict liability on its own could lead to situations in which the liable firm proves to have inadequate financial resources to meet the claim.

Considering the nature and scope of possible damage that may result from release of certain LMOs, Egypt[16] in its submissions before the Technical Group of Experts has pointed out that it will not be either fair or realistic to set a ceiling for the compensation. Thus, this would require establishing a system of compulsory insurance, rather than a voluntary fund, to cover such liability.

Compulsory insurance have been mandated by the Convention on Civil Liability for Oil Pollution Damage, 1969 and the Basel Protocol on Liability and Compensation Resulting from the Transboundary Movement of Hazardous Wastes and their Disposal. Elaborate rules exist under these international conventions for States to ensure that the person/s potentially liable take out the compulsory insurance and provide adequate evidence of the insurance or other cover.

In order to guarantee adequate compensation for victims of damage, some countries also require the operator to maintain compulsory insurance. In Australia, the Gene Technology Regulator may impose a license condition on a person dealing with a LMO requiring them to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing. Under the German Genetic Engineering Act, operators are obliged to provide for guarantee for any damage or injury that may be caused by genetic engineering operations. Similarly, the Swiss Gene Technology Act requires the proprietors to guarantee their liability through insurance or in another form.

In India, we have the Public Liability Insurance Act, 1991, which provides for mandatory insurance for the purpose of providing an immediate relief to the persons affected by accidents occurring while handling any hazardous substance. The Act covers every industry, public or private, which handles hazardous substances. The Act defines a 'hazardous substance' as one which, by reason of its chemical or physio- chemical properties or handling, is liable to cause harm to human beings, other living creatures, property or the environment. 'Handling' in relation to any hazardous substance, includes the manufacture, processing, treatment, packaging, storage, transportation, use, collection, destruction, conversion etc. of such hazardous substance. Thus, GEOs/LMOs may be construed as falling within the ambit of this Act, thus, requiring their handling to be compulsorily insured.

Many have suggested that compulsory insurance on its own is not sufficient, claiming that when a risk manifests itself as a loss, insurance can only pay indemnity in the form of money, and therefore, the only risks that qualify as insurable are those that are generally accepted, and about which there is consensus as to the value of a damaged entity and the way a loss can be compensated.[17] Crucially, if the liability instrument should demand compulsory insurance, this requirement will only bind the liable party, and the insurance company may still limit or decline to provide cover.

In the circumstances, it has been felt that issues of coverage of liability should go beyond merely requiring compulsory insurance by the identified liable person. Arguments have been advanced in favour of an international indemnification fund, established with contributions from the biotechnology industry, and other actors benefiting from the international commerce involving GEOs, as well as those countries that have approved activities (imports, exports, release) in relation to GEOs. However, since the contributions by the State come from public spending budgets, their contributions should only be used in circumstances where the liable person is unable to meet its obligations. An example can be taken from the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 (also referred to as the HNS Convention), which provides for the creation of an international indemnification fund.

Gene Campaign advocates:

1. Commercial insurance should be compulsory for all parties involved in the transboundary movement of genetically engineered organisms.

2. Creation of an international indemnification fund to secure compensation for damage that may be caused by LMOs/GEOs.

Access to Information/ Right to Know

A liability and redress regime for GEOs should expressly stipulate obligations, on the part of the liable persons, to provide the injured party with information about the characteristics and adverse effects of LMOs as well as steps involved in the genetic

engineering operations or a release. Both the Austrian Law on Genetic Engineering and the German Genetic Engineering Act contain such provisions, safeguarding the right to information of the injured party, subject to the rules of confidentiality.

In India, the Consumer Protection Act of 1986 guarantees to the consumer the right of informed choice, acknowledging that people must have the right to full knowledge about anything they consume. However, there exist serious bottlenecks in the implementation of this right in the case of GE products. In recognition of the right to information of consumers, farmers and others, Gene Campaign supports the incorporation of provisions in a liability and redress regime to achieve the same.

Gene Campaign advocates:

- Proper labeling, which confers the consumer the right of choice to accept or reject a product.
- Farmers opting to cultivate GE crops should be provided with full information about the possible effects by those responsible for introducing them.
- Traders, dealers etc. who stock or sell GE seeds must also be provided with complete information, so as to prevent contamination.
- Above all, specific legal provisions must be introduced to ensure public participation in the decision making process for the introduction of GE crops/ food.

In conclusion, Gene Campaign supports the development of an India- specific liability and redress regime, based on the above components, as well as the incorporation of these principles in an international regime. The precautionary principle should form the legal basis for addressing the uncertainities linked to this still relatively novel technology, whose dangers are yet to be proven. The adoption of a strong liability and redress regime, based on the precautionary principle and which adequately addresses existing regulatory gaps, would help India reconcile the aim of promoting biotechnology with the need to avoid adverse impacts on the environment. The interests of justice and equity demands that there exists a clear framework for compensation to the injured party should harm occur.

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