

## Chapter 31

### Liability and redress for damage arising from genetically modified organisms: Law and policy options for developing countries

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#### *1. Introduction*

##### *1.1. Background*

The Cartagena Protocol on Biosafety was finally concluded in the year 2000 after a failed first attempt. The negotiations were intense and rancorous. The advanced developed countries led by the United States – together with a very small number of developing countries – stood in stark opposition to the rest of the developing world. Amidst these negotiations it was not possible to complete the negotiations on two highly contentious and divisive issues: one was the documentation to accompany exports of genetically modified (GM) commodities intended for direct use for food, feed and processing;<sup>1</sup> the other was liability and redress if genetically modified organisms (GMOs) or living modified organisms (LMOs) moved across boundaries were to cause damage to the environment or to human health in the receiving country.

The Protocol, by its Article 27, provides for a process to be initiated for the elaboration of international rules and procedures for liability and redress. The first Meeting of the Parties established this process in February 2004 in Kuala Lumpur by Decision BS-1/8. An Open-ended Ad Hoc Working Group of Legal and Technical Experts was set up with clear Terms of Reference. The Working Group is to complete its work in 2007. Work has started in earnest and many – often conflicting proposals – have been collected under useful headings as a basis for negotiating the rules and procedures of a potential international liability and redress regime.

This chapter looks at the considerations developing countries may wish to take into account in deciding upon the nature of the regime, its key features and elements.

##### *1.2. Overall approach*

Law quintessentially captures policy that decision makers consider important. Behind each theory for adopting a position on an issue there is always a policy choice. The policy is based upon, and derived from, values and interests that a particular society wishes to advance: to protect certain activities, to afford justice to victims, or a trade-off of interests. These are then articulated into a specific law. It follows, then, that the first task of a decision maker is to identify the policy that the law should encapsulate.

What then is the policy in relation to a liability and redress regime for GMOs in the context of the Cartagena Protocol on Biosafety? First, the overall goal of the Protocol and the interest it advances must be reflected in the regime. Secondly, the purpose of the regime in relation to the specific activity must be clearly identified. What happens when there is damage which can be linked causally to a GMO or activity in relation to it? How is liability to be established? Who is to be held liable? What kind of damage is recoverable and how is that damage to be assessed? What defences are acceptable?

These questions must be addressed in the context of the nature of the harm and damage that accompanies the advancement of science and technology – in this case modern biotechnology and

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<sup>1</sup>The issue on documentation was finally resolved by a decision taken at the recently concluded 3rd Meeting of the Parties of the Protocol in February 2006 in Brazil.

its products. All this has to be placed within the overall goal of a justice system: *ubi jus ibi remedium* – where there is a grievance there is a remedy. What is the consequence of leaving a victim without a remedy? Can the victim prove his or her claim – given the complexities involved and the existing legal modes of proof, both substantive and procedural?

## 2. Overall goal of the Cartagena Protocol on Biosafety

### 2.1. Balancing competing interests

A crucial consideration in setting up a liability regime, and that underlies much of the ongoing negotiations, is the need to maintain a balance between, on the one hand, the protection of the public and the environment, and, on the other hand, the public and industry interest not to stifle innovation or drive away investors in biotechnology, or trade in products of biotechnology. These interests are reflected in the Convention on Biological Diversity (CBD), the parent convention of the Cartagena Protocol on Biosafety. Article 16(1) emphasises making available biotechnology that will enhance the conservation and sustainable use of biodiversity – an acknowledgment of the potential of biotechnology to promote human well-being, particularly in meeting critical needs for food, agriculture and health care.<sup>2</sup> The biosafety aspects are made clear by two articles in the CBD:

- Article 8(g) – which requires Parties to take national measures to ensure safety in respect of harm by LMOs to the environment that could adversely affect the conservation and sustainable use of biodiversity as well as human health
- Article 19(3) – which requires Parties to put in place an internationally binding instrument for biosafety.

It was this latter provision that set the stage for the final promulgation of the Cartagena Protocol. The Protocol, as finalized and adopted, is seen as a significant step forward in providing ‘an international regulatory framework to reconcile the respective needs of trade and environmental protection’ with respect to the biotechnology industry.<sup>3</sup> This means that research, development and trade in biotechnological products must be undertaken in conditions that do not compromise the safety of the environment and human health. The preamble to the Protocol makes this clear: ‘Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.’

### 2.2. Precautionary approach

The central paradigm of the Protocol is the precautionary approach in addressing safety issues. The precautionary approach allows States to take regulatory measures even if there is no certainty of the harm occurring. This is made necessary by the nature of the technology, which is relatively new. There is still considerable uncertainty surrounding these issues as well as the timeline for harm to manifest. Leading insurance companies attest to this fact and are reluctant – if not refusing – to provide cover. Part of the reason is that the potential for harm to be caused by GMOs may be great. A single remote incident may cause harm of an immense magnitude.

### 2.3. Liability and redress only applies when damage from GMOs results

In working out a liability and redress regime, it is as important to keep the objective clear. The issue of liability will only arise when there has been damage caused by GMOs. It must be established – in fact and in law – that the harm is directly attributed to the GMO (in particular its

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<sup>2</sup>Secretariat of the CBD, Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes, Montreal, 2000, Introduction, p. 1. Also CPB, preamble paragraph 6.

<sup>3</sup>See footnote ii.

properties, their reproduction or modification) or the activity in relation to it. Further, it must be established that there is a person who can be identified as being responsible. Only then will the issue of compensating for the harm done arise.

#### 2.4. Scenarios of harm

Harm from GMOs could result from any one of the situations described in the following. The harm could be to the environment, biodiversity, the ecosystem, and to species of flora and fauna, or it could be to human health. The harm could also be physical and/or socio-economic. The following is a non-exhaustive list of the potential harm that may be caused by a GMO:

1. GMOs from one field could cross over to the fields of other farmers and contaminate their non-GM crops. As a result, the farmers either would not be able to sell their crops or suffer a loss in income because of a reduced demand. This would be essentially economic loss.
2. GM bacteria in the soil may cause soil infertility. This could cause widespread damage to farmers and result in loss of livelihood.
3. GMOs can potentially affect the environment adversely through effects on non-target organisms, ecosystems and biodiversity. There may be displacement of conventional crops by a small number of GM crops or contamination of native or wild relatives. This could threaten biodiversity. It could also be particularly damaging to crops in centres of origin.<sup>4</sup>
4. Biodiversity could be destroyed if there is an impact on the ecosystem through the introduction of GMOs. For example, if vast tracts of natural forest are interspersed with non-flowering insect-resistant GM trees, animal life could be adversely affected. The richness and abundance of insects may also be destroyed.<sup>5</sup>
5. Human health may be impaired through the consumption of a GMO food product which causes allergic or toxic reactions.<sup>6</sup>
6. There may be long-term negative impacts on human health from small amounts of DNA in GM foods surviving in the gastrointestinal tract.
7. GM virus-resistant crops may create new, more virulent or widely spread viruses.<sup>7</sup>
8. GMOs using antibiotic resistant marker genes could cause antibiotic resistance in human gut bacteria or soil bacteria.

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<sup>4</sup>Simonetta Zarrilli, 'International Trade in GMOs and Multilateral Negotiations: A new dilemma for developing countries', in Francesco Francioni (ed), *Environment, Human Rights and International Trade*, 2001, p. 43.

<sup>5</sup>Based on Monsanto's plans in New Zealand to create a plantation of these trees to harvest wood: Nathan Batalion, 50 harmful Effects of GMO Foods, [www.satori-5.co.uk/word\\_articles/misc/50\\_harmful\\_effects\\_gm\\_foods.html](http://www.satori-5.co.uk/word_articles/misc/50_harmful_effects_gm_foods.html)

<sup>6</sup>WHO has identified potential impacts of transgenic crops to human health: WHO Report, *Modern Food Biotechnology, Human Health and Development: an evidence-based study*, 23 June 2005, at [www.who.int/foodsafety/publications/biotech/biotech\\_en.pdf](http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf)

<sup>7</sup>Union of Concerned Scientists, *Risks of Genetic Engineering*, [www.ucsusa.org/food\\_and\\_environment/biotechnology/page.cfm?pageID=346-](http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=346-)

### 3. Considering the key elements

#### 3.1. Establishing liability: What standard to adopt?

In this part I consider how liability is established when harm results. This section presents the factors taken into account – in law and fact.

How liability is established depends on the standard of liability imposed. There are two possible standards: fault-based liability and strict liability.

##### 3.1.1. Fault-based liability

This means that liability will only exist if fault is established. In common law jurisdictions, one has to prove three elements to establish fault:

- I. duty of care – that is, one has to identify a wrongdoer who owes the victim a duty of care
- II. breach of that duty
- III. damage resulting from the breach.

#### a. Proving the elements

##### i. The duty of care

This requires the identification of a wrongdoer. Sometimes it may be quite easy to identify the person responsible for the damage. This is not always the case, especially if the harm could be attributable to a large number of players. The identification of a person to be liable under the common law turns on a number of factors, such as

- the foreseeability of the harm
- the proximity of the relationship between the parties
- considerations of fairness and reasonableness<sup>8</sup>
- policy considerations to deny or limit liability.<sup>9</sup>

How easily is the duty of care established when we apply the fault-based standard of liability? It may often be difficult to identify a particular entity or person as responsible when applying these factors in a case of harm from a GMO. This is especially so in cases where GMOs spread beyond the intended receiving environment. For example, if a farmer buys and grows GMO seed, and this contaminates the fields of a neighbour, is he the wrongdoer?<sup>10</sup> In the Canadian Supreme Court decision in *Monsanto Canada v Percy Schmeiser*, a farmer who contended that his field was contaminated by GMOs was held liable for patent infringement. Would he be liable if fields in the vicinity were then contaminated by the GMOs from his field? If a liability regime were to hold him responsible, would this discourage farmers from buying and growing GM seeds and plants? In any case, how is proximity determined? What if there is an indeterminate class of people who are harmed by the activity? In the Australian High Court decision of *Perre v Apand Pty Ltd.*,<sup>11</sup> owners and growers of potatoes were held to be owed a duty of care by a farmer who had introduced bacterial wilt to other farms. This case did not involve GM crops. However, it suggests that a duty of care may be imposed with regard to an indeterminate class of people who can show harm. In this case, there was a law that banned the import of potatoes grown within 20 km of land affected by bacterial wilt, and hence the plaintiffs could not sell their potatoes. In the

<sup>8</sup>Caparo Industriels Plc v Dickman [1990] 2 AC 605, 628 (HL).

<sup>9</sup>Anns v London Borough of Merton [1978] AC 728, 751 (HL); South Pacific Manufacturing Co Ltd v NZ Security Consultants Ltd [1992] 2 NZLR 282, 294 (CA).

<sup>10</sup>[2001] FCT 256, High Court; [2003] 2 FC 165, Supreme Court

<sup>11</sup>There were actually seven judgments: [1999] HCA 36; (1999) 165 ALR 606 at [http://www.austlii.edu.au/au/cases/cth/high\\_ct/1999/36.html](http://www.austlii.edu.au/au/cases/cth/high_ct/1999/36.html)

absence of such a law, it is uncertain whether the court would have reached the same decision. Will courts elsewhere arrive at this decision?

Because of the application of multifarious factors in establishing who owes a duty of care, and to whom, the outcome is unpredictable. This means that it may not always be easy to establish this first element in a fault-based system of liability.

*ii. Breach of the duty of care*

The plaintiff must then prove that the defendant failed to exercise reasonable care. The standard of care is judged objectively – that of a reasonable person. The breach could be in relation to the creation of the GMO construct (in product liability parlance – the design defect), the testing of the GMO, the commercial manufacturing of the GMO (the manufacturing defect) or the marketing of the GMO (the marketing defect). The conduct of the defendant will be scrutinized. It is based on the factual circumstances of each case.

There are also other established bases on which courts in common law jurisdictions have acted in deciding a breach of the duty of care. These include: the probability of the risk, gravity of the danger, social utility of the activity, and the burden or difficulty in taking preventive measures. There are thus various bases on which a duty of care will be held not to have been breached. So, even if there is damage, a balancing of all these factors may mean that there is no liability. Compliance with statutory requirements may also be an important factor to suggest that the standard of care has not been violated. Additionally, the standard required of a producer of the GMO may be based on the state of the scientific and technical knowledge then existing. Standards under the law of negligence are also expected to require reasonable, and not absolute, safety. Some level of damage is thus accepted. In design and manufacturing of products, the manufacturer/producer is not an insurer in the sense that he is liable for all damage caused by the product. Thus, liability for negligence may be avoided for the making of low-quality products. If this can be extrapolated to the actual reproduction techniques involved in the production of GMOs, then again liability can be avoided.

*iii. Damage*

The damage that is caused must have been reasonably foreseeable. Otherwise it is not recoverable and said to be too remote. Again, even if damage is caused by the GMO, the plaintiff is not compensated for his loss or injury if the defendant can prove that he did not foresee the damage. Neither the precise extent nor the precise manner of the infliction of the damage needs to be foreseeable.

*b. Burden of proof in fault-based liability*

In a fault-based liability system, the burden is on the person harmed to provide the evidence of the facts that will prove each element. Only then will negligence be established. The burden of proving that the damage from a GMO is the result of the breach of the defendant's duty may be onerous, given the complex and technical nature of the subject. The task is made more difficult and expensive if a relatively small plaintiff is pitted against a large GMO producer.

To establish his case, the victim must know quite completely the whole process in the production of the GMO, the circumstances of its creation, its testing, and distribution – matters which may be exclusively within the knowledge of the producer. Some parts of the process may even be the subject of trade secrets. There are procedural rules in most common law jurisdictions to assist access to some of this information. All the same, the task is formidable, may involve complex procedural manoeuvres and could involve huge costs.

*c. Difficulties posed by long time lag*

The difficulty of establishing liability is increased if there is a long time lag between the introduction of the GMO and the damage; this is an expected scenario. The number of people involved in handling, or using the product may also exacerbate the difficulty. It may make identification of the wrongdoer difficult too. If there is a time limitation for bringing the action, by the time the correct person is found, it may simply be too late. Alternatively, the correct party may have disappeared from the scene. Sometimes, if there could plausibly be more than one cause of the injury, the plaintiff may have to eliminate the role of the other causes.<sup>12</sup>

Critics of the fault-based system – especially for new and complex technologies – often claim that:

- there is arbitrariness and uncertainty of the end result – victims of the damage may go uncompensated
- the system is not cost effective<sup>13</sup>
- there is delay in obtaining compensation.

### 3.1.2. Strict liability

The alternative to fault-based liability is strict liability. Under such a regime, there is no need to show fault in order for liability to be imposed. To succeed, the victim needs only to prove the damage (the defect in the GMO, if any), and the causal link between the damage and the GMO. The conduct of the wrongdoer is irrelevant – unlike in the fault-based system. The crucial feature is the GMO and the activity in relation to it.

#### *a. Strict liability not exclusively for dangerous goods*

A strict liability standard is more commonly applied to dangerous or hazardous goods or activities, though not exclusively. For example, most jurisdictions – initiated originally by the United States – impose strict liability for any damage arising from defective consumer products. For instance, while the product itself – for example, a baby teat, or the activity in relation to it – a baby sucking on it – is not dangerous, strict liability can be imposed for a number of reasons.

#### *b. Policy choice and practical considerations: Better consumer protection, profiteer to bear loss, raising safety standards, easier for victims to obtain remedy*

Such a liability standard is said to overcome the problems inherent in contractual and negligence remedies – that have been highlighted earlier – and therefore gives better protection to consumers.<sup>14</sup> It is a matter of policy choice and other practical considerations. The United Kingdom's Pearson Commission justified the imposition of strict liability on the basis that the producer who profits from the product should accept its losses; that he was best placed to arrange for insurance and redistribute the loss; that strict liability would raise safety standards; and that all consumers should have the same protection as a consumer-purchaser.<sup>15</sup> In the United Kingdom, the introduction of strict liability was justified by cogent policy reasons and supported by considerable practical considerations – the key one of which was to make it easier for victims of harm caused by defective products to prove their cases as they no longer had to prove fault by the manufacturer.

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<sup>12</sup>Evans v Triplex Safety Glass Co [1936] 1 All ER 283.

<sup>13</sup>For the UK: The Pearson Commission Report stated that in its estimation the cost of administering the tort system was roughly double the benefits of the compensation: para 83. The Civil Justice Review made a similar finding.

<sup>14</sup>UK: The Law Commission and the Scottish Law Commission, Liability for Defective Products, HMSO Cmnd 6831. The Royal Commission Report on Civil Liability and Compensation for Personal Injury (1978) Vol. 1, HMSO Cmnd 7054. The former Commissions dealt with defective products and compensation for personal injury, damage to property or any other loss. The Royal Commission was not confined to defective products but limited to compensation for personal injury. It was chaired by Lord Pearson and its report is usually referred to as the Pearson Report.

<sup>15</sup>The Pearson Report, paras 1227–1236; and the Law Commissions Report, paras 38–42.

Even if liability is to be restricted to dangerous products or activities, these are judged on the basis of the incidence or the probability of occurrence and the magnitude of the harm. Hence, if the incidence is remote but the magnitude of the harm great – the Chernobyl disaster is a typical example – this would still constitute a dangerous activity for which, generally, the strict liability standard is imposed. The Swiss Reinsurance firm Swiss Re states that the issue is not whether genetic engineering is in fact dangerous, but how dangerous it is actually considered to be.<sup>16</sup> It noted that, as a new technology, ‘there are no means for comparison, hopes and fears are boundless and potential uses and supposed damages are initially unquantifiable’. It also noted that the lack of knowledge of the probability of the risk rather than the size of such risk made for difficulty in obtaining insurance for GMOs.<sup>17</sup>

*c. Precautionary Principle and strict liability*

It has also been suggested that, on the basis of the Precautionary Principle – the overarching and operating principle in the Cartagena Protocol on Biosafety – strict liability should be the standard because of the current uncertainties as to the magnitude of the potential damages and the extent to which they may occur over a long timeline.<sup>18</sup>

The precautionary approach or principle allows regulatory measures to be taken even where there is scientific uncertainty of the potential risks associated with particular uses of biotechnology. Indeed, the very necessity of adopting the Protocol stemmed precisely from the need for Parties to take precautionary measures.<sup>19</sup> The inclusion of the precautionary approach in the preamble and the objective (Article 1) of the Protocol suggests that the Protocol is itself an embodiment of the principle, aimed at ‘ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs’. The precondition to triggering the implementation of precautionary measures is ‘potential adverse effects’ as stated in Articles 10(6) and 11(8) of the Protocol. There are no objective and qualitative thresholds, which means that each Party can determine what threshold level it deems appropriate.

How are ‘potential adverse effects’ established so that a decision based on the Precautionary Principle can be taken? This requires a decision to be taken as follows.<sup>20</sup>

First, identify the potentially negative effects of the LMO. This requires scientific research. Second, carry out a risk assessment. This is based on existing knowledge and available information providing the views of scientists on: reliability of the assessment, remaining uncertainties, and topics for further discussion. Where it is not possible to complete a comprehensive assessment of risk, there should be an evaluation of available scientific information.

Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen

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<sup>16</sup><http://www.swissre.com/INTERNET/pwswpspr.nsf>

<sup>17</sup>Thomas Epprecht, ‘Biotechnology Risk Perception in Liability Insurance’, accessible at <http://www.cid.harvard.edu/cidbiotech/comments/comments86.htm>. See also Duncan Currie, ‘Liability for Damage for Genetic Modification: the scope and limit of common law remedies in the GM context’, 2004, at pp. 31-32.

<sup>18</sup>See for example, Philippe Cullet, ‘Liability and Redress in Biotechnology: towards a development of rules at the national and international levels’, COP/MOP 1 Biosafety Protocol, Background Paper, Feb 2004, International Environmental Law Research Centre, Geneva, <http://www.ielrc.org/content/w0401.pdf>

<sup>19</sup>Laurence Graff, ‘The Precautionary Principle’, in *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* Bail C, Falkner R and Marquand H (eds), Earthscan, 2002, p. 410 at p. 412.

<sup>20</sup>Based on Markus Gehring and Marie-Claire Segger, ‘Precaution in Trade Law: The Precautionary Principle and its Implications for the WTO’, Research Paper.

- the measurements made
- the samples drawn
- the models used
- the causal relationship employed.

It may also arise from controversy concerning existing data or lack of some data, and may relate to quantitative or qualitative elements of the analysis.

Scientific evaluators take these into account in their research methods. Further, risk managers are aware of these uncertainty factors when they adopt measures to manage risk. However, in some situations, for example where there is insufficient, inconclusive or imprecise data, it is not possible to apply these cautionary aspects in practice. It becomes impossible to determine the risk in question with sufficient certainty. It is clear, then, that the Precautionary Principle is not directly triggered by the existence of potential harm, but specifically addresses situations where this harm is scientifically uncertain. Not just any degree of uncertainty prompts the application of the principle. It is only triggered when the degree of harm is approximately proportionate based on a rough balancing of different considerations.

In these situations, then, the decision maker is entitled to take a decision he deems necessary to deal with the LMO. The absence of scientific consensus is no basis for inaction. Even a minority scientific view – if credible and reputable – can be the basis of the action, as made clear by Item 4 of Annex III to the Protocol.<sup>21</sup>

Fault-based liability – as discussed earlier – requires proof, not only of damage resulting from the product but also that the damage was caused by the manufacturer failing in his duty to take reasonable care. In contrast, the focus for strict liability is on the actual performance and condition of the product, not on the manufacturer's care. The application of the Precautionary Principle also dispenses with the need for establishing the duty of care of the manufacturer. Hence, the Precautionary Principle and strict liability go hand in hand.

*d. Shifting the burden of proof – mechanism for implementing the precautionary approach*

Reversing the burden of proof facilitates the proof of liability, as discussed earlier. When the burden of proof to establish safety is reversed, the manufacturer must show that the product is safe. This is, in fact, a mechanism for the implementation of the precautionary approach. The mandatory requirement of prior approval before certain products can be put on the market – drugs, pesticides, food additives – is a clear reflection of countries applying the precautionary approach. The risk assessment provisions in the Protocol require the manufacturer or developer of the LMO to show that his product is safe for releasing into the environment. The producer bears the burden of showing that the product is safe. Both these facets taken together suggest that the strict – not the fault-based – liability standard is appropriate where the Precautionary Principle is the basis for decision making.

In the *EC-Asbestos Dispute*, the WTO's Appellate Body applied the two facets of the Precautionary Principle without referring to it directly. First, it was applied by confirming the right of Members to determine the level of health they deemed appropriate. By this, the burden of proof shifts to the proponent of the potentially harmful activity. The Appellate Body also held that a risk may be evaluated either in quantitative or qualitative terms, and that countries could take into account minority scientific opinion that is qualified and respected. In its words:

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<sup>21</sup>Supported by the WTO Appellate Body in *The EC- Asbestos Dispute*: For a contrary view, see Laurence Graff, cited earlier, at p. 418.



(A) Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.<sup>22</sup>

#### 4. Countries adopting strict liability in relation to GMOs

##### 4.1. National regimes

###### 4.1.1. Norway: Gene Technology Act, Act 38 of 2 April 1993

The person responsible for an activity pursuant to the Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of GMOs into the environment: Section 23.

###### 4.1.2. Switzerland: Law on Genetic Engineering, 2003

Anyone who is responsible for obtaining authorization and labelling and who deals with GMOs under contained conditions or releases such organisms for experimental purposes or illegally places them on the market, is liable for any damage due to the modification of the genotype arising out of these dealings: Article 30(1).

Also, if damage is caused by any other legally marketed GMO due to the modification of the genotype, the person responsible for obtaining authorization shall be liable if the organism is defective: Article 30(4).

###### 4.1.3. Austria: Gene Technology Act (510 of 1994), amended in 1998 and 2002

The Act imposes strict liability on any party releasing GMOs for harm to health, property or the environment.

###### 4.1.4. Germany: the Gene Technology Act 1990<sup>23</sup>

Liability is strict.<sup>24</sup>

###### 4.1.5. New Zealand: Hazardous Substances and New Organisms Act 1996<sup>25</sup>

In 2003 New Zealand introduced legislation to establish a strict liability regime for victims of harm caused by activities in breach of the regulatory regime for new organisms, including GMOs.<sup>26</sup>

##### 4.2. *Supra-national liability regimes*

###### 4.2.1. Council of Europe Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment – the Lugano Convention

This Convention is commonly referred to as the Lugano Convention. It is a pan-European convention and is not yet in force. The Convention provides for strict liability of operators of activities dangerous to the environment.<sup>27</sup> It covers the production, culturing, handling, storage, use, destruction, disposal, release, or any other operation dealing with one or more GMOs which as a result of the properties of the organism, the genetic modification or the conditions under

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<sup>22</sup>At p. 64.

<sup>23</sup>It came into effect on 20 June 1990. It has been altered by eight Acts, the last one on 22 June 2004.

<sup>24</sup>Anja Gerdung, 'Germany's Liability Law for GMO Cultivation', June 2006, Sustainability Council of NZ, at pp. 3-4.

<sup>25</sup>Amendments made to the Act: sections – 124A – 124I, www.legislation.govt.nz.

<sup>26</sup>Submission of NZ to the Working Group of Legal and Technical Experts on Liability and Redress in the context of the Biosafety Protocol on Biosafety, 2nd Meeting, Montreal, 20-24 Feb 2006, UNEP/CBD/BS/WG-L&R/2/INF/2\*, 12 Jan 2006, at p. 4.

<sup>27</sup>Article 6.

which the operation is exercised, present a significant risk for man, the environment or property.<sup>28</sup> Liability lies for damage caused by the activity as a result of incidents.<sup>29</sup> The term refers to sudden, continuous or a series of occurrences having the same origin. It must cause damage or create a grave and imminent threat of causing damage.<sup>30</sup> An emission as well as the dispersal of GMOs constitutes an incident.

#### 4.2.2. Biosafety legislation of the European Union (EU)

The EU has a comprehensive regulatory system governing the release and marketing of GMOs. Directive 2001/18<sup>31</sup> on the Deliberate Release into the Environment of GMOs sets out the law relating to the placing on the market of GMOs as or in products as well as other releases.

The Directive aims to address the issue of coexistence of, on the one hand, conventional and organic farming, and on the other, GM farming. It does this by setting out the appropriate risk assessment and authorization procedures for the marketing of GMOs for cultivation. Nonetheless, it recognizes the possible occurrence of gene flow. Accordingly, in 2003, the EC amended the Directive to enable member states to ‘take appropriate measures to prevent the adventitious presence of GMOs in other products’.<sup>32</sup> The EC was asked to develop Guidelines to allow for the coexistence of GM and non-GM farming. The Guidelines focus on such matters as separation distances and coordination between neighbouring farmers. The Guidelines make a passing reference to liability, advising member states to ascertain whether their existing national civil liability laws offer sufficient and equal opportunities to ensure coexistence. They also say that farmers, seed suppliers and other operators should be fully informed of the liability criteria that apply in their country in the case of damage caused by admixture.<sup>33</sup> This does not preclude, but paves the way for, the adoption of strict liability regimes.

#### 4.2.3. EU Liability Directives: Directive 85/374 as amended by Directive 1993/34

This Directive deals with product liability, which includes agricultural products. Product liability provides for strict liability of producers for defective products, that is, products that do not provide the safety that can be expected of them. This excludes recovery of contamination damage by coexistence farming, as such damage will usually be caused by cultivating GMOs that are fit for their purpose. Such damage may be avoided by cautious handling of the GMOs. Under product liability, a producer may be strictly liable for lack or insufficient instructions for handling. However, the instructions for handling are usually included in the authorization procedures. So again, coexistence damage is not covered. Additionally, liability under the Directive for property damage excludes property used commercially. This will effectively prevent recovery in virtually all cases.

#### 4.2.4. Countries opting for strict liability – based on the submissions to the Legal and Technical Experts Working Group on liability and redress<sup>34</sup>

The following countries have suggested strict liability in a liability and redress regime: Brazil, Egypt, the EU (with a limited number of defences and combined with a fault-based liability scheme), India, Liberia, Norway (possible combination with fault-based liability needs further

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<sup>28</sup>Articles 2(1)(b) and 6(1)(b).

<sup>29</sup>Article 6(1).

<sup>30</sup>Article 2(11).

<sup>31</sup>Of 12 March 2001. For placing on the market, the Directive is pre-empted by sectoral regulation, in particular placing on the market of transgenic food and feed: Regulation 1829/2003 and 1830/2003. Seeds must be authorized under both the Directive and the relevant sectoral directives and implementing national seed laws.

<sup>32</sup>By Article 43 of Regulation 1829/2003, introducing a new article 26a.

<sup>33</sup>Guidelines of 23 July 2003, Commission Recommendation 2003/556, recommendation point 2.1.9.

<sup>34</sup>Montreal, 18-20 October 2004, UNEP/CBD/BS/TEG – L&R/1/INF/1, 20 Sept 2004.

discussion), Palau, Slovenia, Sri Lanka, Switzerland, and Uganda. This represents 10 out of the 22 countries that responded in English. The EU represents a further 25 countries.

Further, in the ongoing negotiations on liability and redress, strict liability was the preference for the African Union – representing some 33 countries – as well as a large number of the 17 developing countries with the largest areas of diversity and known as the ‘Group of Megadiverse Countries’.

### 5. Defences to strict liability

Views vary on how a strict liability regime is to be implemented. Some provide for no defences or exemptions at all – more properly described then as an absolute liability regime; some allow limited defences; and some allow defences, which, critics say, undermine the reason for introducing strict liability.

The rationale for the defences is to strike a fair balance between the interest of the producer and that of the user. It is the *quid pro quo* – a sort of trade-off – for imposing strict liability.<sup>35</sup>

#### 5.1. Defence: ‘Development risk’ and ‘state of the art’

##### 5.1.1. Differentiating

The most controversial defence is the development risk – sometimes also referred to as the ‘state-of-the-art’ -- defence. There is, however, a clear difference between the two expressions. ‘State of the art’ connotes that the product was safe when judged against the prevailing safety standard at the time it was put into circulation. ‘Development risk’ describes situations in which the product is defective when put into circulation but the producer can seek to avoid liability relying on the defence that the defect was not reasonably discoverable given the then existing knowledge.<sup>36</sup>

##### 5.1.2. Arguments for and against including the ‘development risk’ defence

Policy makers will have to decide on whether to include this as a defence to strict liability. The prime reason will be for the one who profits to bear the responsibility and to ensure that the victim is not left uncompensated. Excluding this defence in the product liability laws of industrialized countries, such as the US and several European countries, in respect of pharmaceutical products has not stifled product innovation.<sup>37</sup> Indeed, it may even spur these companies to invest more actively in safety research.<sup>38</sup> Those who argue in favour of this defence say that it would discourage innovation and stifle research – especially in high technology development areas where there are likely to be unknown hazards and always subject to technological improvements – where producers have carried out reasonable research, testing, literature review, monitoring, and warning about their product.<sup>39</sup> The defendant bears the burden of proof to establish the defence. This may not necessarily tilt the balance in the victim’s favour. All the defendant needs to do is give some evidence of the lack of requisite knowledge. The victim must then disprove the assertion. The risk must be *absolutely* undiscoverable, that is, that the particular risk was absolutely unknown and undiscoverable at a given time. The issue in strict liability is whether the defect in the product could be scientifically and technically discoverable.

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<sup>35</sup>This was the explanation for the EC Directive on Product Liability: Dept of Trade and Industry, Implementation of EC Directive on Product Liability: an explanatory and consultative note, 1985.

<sup>36</sup>Clark, A, Product Liability, 1989, p. 151.

<sup>37</sup>Bradgate & Savage, ‘The Consumer Protection Act (1987) NLJ 1049.

<sup>38</sup>US: Beshada v Johns-Manville Products Corp 90 NJ 191 447 A 2d 539 (1982) 206, 548.

<sup>39</sup>Hodges C, Product Liability: European Laws and Practice, 1993, 82-83.

### 5.1.3. The defence and the precautionary approach

A modified form of the defence to take into account the precautionary approach may be that the defendant needs to prove that he adopted the precautionary approach in considering the possible adverse effects of an LMO product.<sup>40</sup>

### 5.2. Defence: Compliance with legal requirements

This allows a defendant to plead in his defence that the defect is due to compliance of the product with mandatory regulations issued by the authorities. The defect must be the inevitable result of compliance. That is, that the product could not have been produced in accordance with the regulations without causing the product to be defective. The decisive factor is that the defendant had no choice because he had a legal obligation to comply. There must be a direct causal link between the defect and the compliance. For example, if the law requires that the product be made of a material resistant to, for example, fire, then the defence will only be available if the harm is directly and inevitably related to making it fire resistant. The defence may not be available if other harm is caused or if other factors contribute to the harm. Any such defence must take into account any discretion given to the producer in complying with the law, for example, if a minimum specification standard of compliance is imposed. If it is still impossible to produce a non-defective product, only then is the defence available. If it is clear that by using even the minimum standard the product would be rendered defective, then it could be argued that the producer should not go ahead to market the product. He would then, in any event, be liable in negligence even if he keeps within the legal limits of the statutory requirement.<sup>41</sup>

### 5.3. Defence: Limitation

#### 5.3.1. For bringing an action

It is quite common to impose time limits for initiating legal proceedings. Time runs from the date on which the cause of action accrued, usually the date the victim has knowledge of the facts:

- about the damage as would lead a reasonable person to consider it sufficiently serious to justify instituting an action for damages
- that the damage was wholly or partly attributable to the facts and circumstances alleged to constitute the defect
- the identity of the defendant.<sup>42</sup>

#### 5.3.2. Cut-off date

Some laws include, in addition, a cut-off date – referred to as a repose period – for bringing an action.

### 5.4. Other defences

Examples of other usual defences include the following: force majeure; intentional intervention by a third party; act of God; war and hostilities; compliance with a compulsory measure by a public authority.<sup>43</sup>

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<sup>40</sup>Kate Cook, 'Liability: No Liability, No Protocol', in Bail et al. at p. 384. also see White Paper etc.

<sup>41</sup>Albery and Budden v BP Oil Ltd and Anor The Times May 9 1980.

<sup>42</sup>Limitation Act 1980, s. 14(1A) enacted pursuant to Schedule 1 para 3, Consumer Protection Act (UK).

<sup>43</sup>The Lugano Convention makes an additional requirement: where the damage was caused 'by the pollution at tolerable levels under local relevant circumstances': Article 8.

## 6. Causation: establishing the causal link

### 6.1 Problems

Under fault-based liability laws, a causal link must be established between the breach of duty and the harm. This is usually the most onerous task in a negligence claim. The chain of causation may be disrupted even partially. In the drugs liability situation there may be multifarious causes for the harm caused, such as environmental or biological causes. Much the same problems will apply to harm caused by GMOs. The damage may take a long time to manifest, sometimes even decades. The source of the damage may also have travelled over long distances, even from outside the territorial jurisdiction of a country. Establishing the link may involve highly complicated and competing expert opinions. In common law countries, causation can only be established by proving that the act caused or made a material contribution to the damage. In a situation where there is uncertainty amongst scientific/professional opinion of the cause of the harm then it must be shown that it is the alleged cause and not any of the other causes that – more probably – caused the harm.<sup>44</sup> That is, the product made a material contribution to the damage.

In product liability cases, the problem can be complicated by the often lengthy chain of distribution and assembled products containing component parts manufactured by others. There may also be a large number of GM growers in the vicinity – any one or more of whose acts may have contaminated the non-GM farmer's fields. Alternatively, the seeds causing the contamination may have travelled from afar. Intervening acts of others, however, only break the chain if the subsequent conduct or knowledge of the danger is held to be the sole cause of the harm;<sup>45</sup> otherwise liability will be joint or concurrent amongst the parties at fault,<sup>46</sup> although the victim may have to sue many parties and end up paying the costs of those exonerated from the fault.

There have been attempts to overcome these problems. The first attempt is by relieving the affected consumer from having to prove fault. He need only prove that the *product* caused the harm, not the *producer*. Also, intermediate examination does not excuse liability of the manufacturer for defects existing at the time the product is put into circulation. Further, a large range of potential defendants who can be sued are identified<sup>47</sup> – saving the difficulty of having to identify and, perhaps needlessly, suing all potential wrongdoers. Also, the remedy is in addition to that obtainable under the common law.

These options may be considered by developing countries for inclusion in a liability and redress regime to overcome the difficulties associated with establishing causation under the common law.

### 6.2. National laws

#### 6.2.1. Austria: Law on Genetic Engineering

The Austrian law reverses the burden of proof. There is a presumption that the damage is caused by the characteristics of the LMO resulting from the genetic modification. The presumption is rebuttable by showing a likelihood that the damage is not due to the characteristics of the LMO resulting from the genetic modification (or in combination with other hazardous activities) of the

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<sup>44</sup>Wilsher v Essex Area Health Authority [1988] 1 All ER 871 (UK HL) explaining McGhee v National Coal Board [1973] 1 WLR 1 (UK HL) – which allowed a claim on the grounds that the defendant's negligence materially increased the risk of the plaintiff developing the injury on the state of the existing knowledge.

<sup>45</sup>Evans v Triplex Safety Glass Ltd [1936] 1 All ER 283; Taylor v Rover Co Ltd [1966] 2 All ER 181.

<sup>46</sup>Griffiths v Arch Engineering Co Ltd [1968] 3 All ER 217.

<sup>47</sup>See text: section 8.

LMO. This is to overcome the difficulty of establishing proof because of the complexities of the interaction of the LMO with the receiving environment and the possible timescales involved.

### 6.2.2. Germany: Gene Technology Act<sup>48</sup>

The Act provides for strict joint and several liability for both alternative and cumulative causation of damage by GMOs. If the GM material cannot be traced back to a particular farmer, all neighbours that *appear* to have (potentially) caused the transfer of GMO features are jointly and severally liable.<sup>49</sup> This eases the burden of proof if it is beyond doubt that a farmer in the given area is growing the type of GMO that has caused the harm.<sup>50</sup> There is criticism that there is no need to establish the chain of causation to establish fault, and that the claimant farmer can place the blame on any farmer in his region growing the offending type of GMO. Also the biotechnology industry and the German Research Foundation have criticized the fact that a GMO farmer can be held liable even if he has complied with good practice as outlined in the Act.<sup>51</sup> They propose that a GMO farmer be held liable only if he disregards the good practice. In all other cases the victim is to be compensated by a fund.<sup>52</sup>

## 7. Damage recoverable

### 7.1. Scope

The damage recoverable can be defined narrowly or broadly. There have been various proposals to the Working Group on Liability and Redress in the ongoing negotiations under the Cartagena Protocol on Biosafety. Industry's proposal confines the damage to the conservation and sustainable use of biodiversity. This is interpreted to mean an adverse and significant change resulting in the decrease in the variability among living organisms. Damage may be determined by reference to the causative event: directly attributable to the properties of the GMO, their reproduction or modification, and the transfer of genetic material from these organisms: see the Austrian law (Section 6.2.1).

Canada also suggests that under Article 27 of the Protocol, damage should be confined to damage to biological diversity; and human health damage should be that which arises from adverse effects on biological diversity.<sup>53</sup>

The EU categorizes the damage as:

- damage to the conservation and sustainable use of biodiversity
- traditional damage
- damage to human health.

Damage covered by the first bullet is as to the variability among living organisms from all sources – including diversity within species, between species and of ecosystems. The EU proposes that thresholds of damage be described either in non-determined qualitative adjectives, such as: 'significant'; or in quantitative terms. If the former, it will then be for a court to decide what constitutes 'significant' damage. If the latter, these should be based on baselines and

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<sup>48</sup>As amended: First Act Reforming Genetic Engineering Law – passed on 21 Dec 2004 and in force from 1 Feb 2005: Anja Gerdung, Germany's Liability Law, Sustainability Council of NZ, June 2006, at p. 8.

<sup>49</sup>If the separate and independent acts of two or more persons or corporations combine naturally and directly to produce a single indivisible injury, then the actors are joint tortfeasors, jointly and severally liable for the full amount of the plaintiff's damages: Restatement of Torts, US. A defendant held liable to pay the whole damage to a plaintiff may seek recourse against the other defendant(s) for the extent to which that other was liable.

<sup>50</sup>Anja Gerdung, at p. 10.

<sup>51</sup>Section 16b. Anja Gerdung, at p. 13.

<sup>52</sup>Anja Gerdung, at p. 13.

<sup>53</sup>At p. 11.

identified criteria.<sup>54</sup> Reinstatement should be an important remedy. It should be primary restoration, to the condition that existed before or the nearest equivalent (complementary remediation).<sup>55</sup>

*The Lugano Convention* states the following damage that has to be compensated for: personal injury, loss or damage to property, and, loss or damage by impairment of the environment including loss of profits from such impairment resulting from the properties of GMOs. Also recoverable: cost of preventive measures that have been taken after an incident has occurred to prevent or minimize loss or damage.<sup>56</sup> In the case of pure environmental damage, the costs of measures of reinstatement are recoverable. ‘Reinstatement’ refers to reasonable measures to restore or reinstate damaged or destroyed components of the environment, or to introduce, where reasonable, the equivalent of these components into the environment. A member country’s internal law is to determine who is entitled to take these measures.

## 8. Determining the wrongdoer

### 8.1. Who is liable?

One way out of the difficulties in identifying the wrongdoer in fault-based systems is to specify in the law the person to be held liable; or prescribe criteria to ascertain such a person or entity. Many jurisdictions opt to hold the person/entity, that either created the harm or who is in operational control, liable. Determining this would depend on the facts. If damage results from the inherent quality of the modification of the GMO, then it would be the person who produces or develops the GMO. It depends on the nature of the activity which causes the damage or the measures that need to be taken.<sup>57</sup>

Some also suggest as the wrongdoer, the person who obtains the approval for export or import of the GMO. In most cases, it will be the patent holder as commercialized GMOs are almost always protected by patents and approval is sought by the holder. It is suggested that this will solve the problem where GMOs spread beyond the specific environment into which they have been introduced, for example, as in the case of a farmer who buys and grows GMO seed which contaminates the fields of a neighbour.

#### 8.1.1. Person who causes the harm?

It is clear that it is generally accepted that the defendant should be the person who causes the harm. Yet who is such a person? The person or the entity can be identified by reference to its role or the activity that has a clear connection with the harm, such as for example, ‘producer’, ‘notifier’, ‘transporter’, ‘patent holder’.

#### 8.1.2. Where more than one person is liable: channelling liability, joint and several liability

What if there is more than one person who has caused the harm? For example, where the GMO itself, as well as the lack of instructions as to its use, or improper use cause the harm. Then it should be possible to channel liability to a chain of multiple persons. The concept of joint and several liability can be a useful solution especially where more than one person is potentially

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<sup>54</sup>At pp. 22-23.

<sup>55</sup>This could be for replacement of the loss by other components of the biodiversity at the same location or for the same use, or remedial action in relation to the same or other components at another location or for other type of use.

<sup>56</sup>Articles 2(7), (9), and 6(1).

<sup>57</sup>The EU proposes any one (or more) of the following: the developer, the producer, the notifier, the exporter, the importer, the carrier, and the supplier: UNEP/CBD/BS/WG-L&r/2/INF/1, and INF/2, 12 Jan 2006, second meeting, Montreal, 20-24 February 2006.

liable, and when it is unclear which person contributed to the damage and to what extent. The concept allows for an action to proceed against any one or more persons who caused or contributed to the damage – and recovery is sought against any one or more of them. The total pecuniary liability remains the same.

### 8.1.3. Additional tiers of liability

What if the damage cannot be entirely, or partially, redressed by the person to whom primary liability is channelled? Situations like this may arise in the following cases:

- The primary liable person cannot be identified
- The primary person escapes liability because of a defence
- Expiry of a time limit for bringing the action
- A financial limit has been reached
- The financial securities of the primary liable person are insufficient to cover liabilities
- The provision of interim relief is desired.

Then it may be desirable to consider providing for other parties who are involved to assume liability. In such a situation there could even be considered residual liability of the State.

## 8.2. National laws

### 8.2.1. Switzerland: Gene Technology Law

Switzerland's Section 30(2) provides:

*The person subject to authorization is solely liable* for damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted marketing of genetically modified organisms, that is the result of the modification of the genetic material.

### 8.2.2. Norway: Gene Technology Act

Under this Act, the liability is of the person responsible for the activity.<sup>58</sup> The activities that the Act covers are: contained use, and deliberate release – defined as any production and use of GMOs other than contained use. The 'person responsible for the activity' is defined as the person who produces or uses GMOs within the meaning of the Act. This could be a physical or legal person who operates the activity ('operator') from which the GMOs are discharged. In general, the person with the duty to provide information or to obtain approval under the Act may be subject to orders under the Act. This is said to be in line with the 'polluter pays' principle.

## 9. The form of the regime to be developed

Article 27 of the Cartagena Protocol on Biosafety does not prescribe the form of the regime to be adopted for the liability and redress regime. There are three possible forms that could be considered:

- A transnational regime
- A civil liability regime
- An international arbitral regime.
- The relative merits and demerits of each of these are considered.

### 9.1. An international arbitral regime

By using an arbitral regime, States can submit a dispute to an international arbitration body. The parties are States, not private actors. Parties can either establish a complete negotiated claims procedure which is detailed; or leave it simple and let most of the key issues and features be

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<sup>58</sup>Section 23, The Gene Technology Act (Act no. 38 of 2 April 1993).



established by the ad hoc tribunal to which the dispute is referred. The key procedural issues and features to be dealt with in respect of an international arbitral regime include:

- On jurisdiction: procedural rules for determining jurisdiction
- On applicable law or choice of law: may provide procedural rules for choice of law, as well as concrete legal standards to determine liability for all disputes
- On recognition and enforcement of judgments: may include provisions for the same, as well as require parties to ratify – if they are not already parties – the UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards.<sup>59</sup>

Two multilateral agreements use this arbitral regime for dispute settlement: the 1982 UN Convention on the Law of the Sea, and the 1972 Convention on International Liability for Damage caused by Space Objects. Issues of liability and redress are then referred to these tribunals.<sup>60</sup>

International arbitral bodies include: the Permanent Court of Arbitration, the International Court of Environmental Arbitration and Conciliation, and possibly the International Court of Justice.

### 9.2. A transnational regime

A transnational regime will facilitate private parties to bring claims to national courts. It will establish the process for parties to do so. It will rely on pre-existing national, and generally accepted international rules on private international law to instruct parties and courts in determining jurisdiction, choice of law and the recognition and enforcement of foreign judgments. There will be common procedures but no internationally recognized standards for determining jurisdictions; and no internationally accepted procedures to instruct courts on how to choose the applicable law. The court will do this by applying its own laws and procedures.

The difficulty is that different states and regions have differing and conflicting rules and principles. Some states may not even have these rules. Resolving such conflicts of law may be too onerous a task in any dispute.

### 9.3. A civil liability regime

A civil liability regime will – unlike the aforementioned two regimes – establish rules and substantive standards for the adjudication of disputes. Cases will still be brought to national courts. However, the national and the international legal standards for liability and redress will be harmonized. Thus, there will be established clear rules to determine jurisdiction, and there will be set internationally recognized legal standards on the applicable law. It will provide for the recognition and enforcement of judgments, as well as include provisions on access to justice and non-discrimination. Most multilateral environmental agreements that have addressed liability have opted for civil regimes. Examples include: the Paris and Vienna Conventions on nuclear liability; the 1992 Protocol amending the International Convention on Civil Liability for Oil Pollution Damage; the 1977 Convention on Civil Liability for Oil Pollution Damage resulting from Exploration for and Exploitation of Seabed Mineral Resources; the 1989 Convention on Civil Liability for Damage Caused by Road, Rail and Inland Navigation Vessels; the 1999 Basle Convention; and the 1996 International Convention on Liability and Compensation for Damage in connection with the Carriage of Hazardous and Noxious Substances by Sea.

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<sup>59</sup>Awards issued by arbitration bodies, subject to very limited exceptions, can be enforced easily in the courts of countries that have ratified the Convention. To date 137 countries have ratified it.

<sup>60</sup>The Space Objects Convention provides standards for the potential parties to a claim, the standard of liability, damage, compensation, applicable law, time limits, possible interim measures for large-scale danger and final binding agreement or recommendatory award.

*10. Conclusion*

The various options that may be considered by developing countries in designing their liability and redress regime have been discussed. The adoption of any particular option will have to balance the competing domestic interests. In some countries these interests have crystallized around the proponents of biotechnology (usually the ministries of trade and innovation) and those concerned with the environment and human health (ministries of natural resources and the environment and health). Ultimately, however, a liability and redress regime must serve the wider interest of justice, and assure a remedy for any damage caused by GMOs.