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PREFACE

The countries of the Western Hemisphere account for nearly half the nations of the world that have adopted agro-biotechnology, a fact that is reflected in recent statistics. The adoption of agro-biotechnology translates into the production of GMOs for food, animal feed and processing. However, the transboundary trade in these biotechnology products has raised concerns about the environment and food safety, particularly as regards public health. In response to these concerns, international agreements such as the Cartagena Protocol on Biosafety (CPB) have developed a number of articles, to which some countries have become parties while others have signed but not ratified these. There are also a number of countries that are not parties to the Protocol.

One of the Protocol articles that address the abovementioned concerns is Article 27 on liability and redress, which is being actively discussed by the working groups at the level of the CPB Secretariat.

In view of this, and in anticipation of the active role that the countries of the American Hemisphere must assume, the IICA Biotechnology and Biosafety Program, in the context of its general objectives, together with USDA, Agriculture Canada, Brazil and the Biotechnology Industry Organization (BIO), organized and implemented a hemispheric meeting to analyze and discuss the scope and implications of Article 27 on liability and redress. This meeting took place in Fortaleza, Brazil on March 20 and 21, 2007, and was attended by 30 delegates from 13 countries (Argentina, Barbados, Brazil, Chile, Colombia, Ecuador, Guatemala, Mexico, Paraguay, Peru, Dominican Republic, Uruguay and Venezuela).

As part of the Program, IICA previously sponsored the preparation of a working document on liability and redress to consider the different legal aspects of implementation and the discussions associated with this issue. The document was prepared by Dr. Katharina Kummer, based on terms of reference agreed upon and provided by IICA. This paper served as a working document during the meeting and was greatly enriched by the content of other presentations offered as part of the meeting program, which examined the possible impacts that the implementation of Article 27 might have on legislation, trade, research, insurance and other aspects.

Alter the meeting, the countries conducted a thorough review of the document and sent their observations and comments to IICA, which incorporated them into the final version of the document on Liability and Redress, presented here.

This document is now being circulated to all the Member States of IICA for its respective use and analysis in preparation for the next meeting on liability and redress, which will take place in Montreal, Canada in October 2007.

The Biotechnology and Biosafety Program wishes to express its acknowledgement and thanks to Dr. Kummer for her outstanding work in managing to turn such a complex issue into an accessible working document. It also wishes to thank all the delegates who attended the meeting in Fortaleza for their contributions, as well as the countries that sent their comments and suggestions to help complete this document.

The Program hopes that this document will facilitate discussions at the national level, bringing together the different actors associated with the aforementioned Article 27.

Area of Biotechnology and Biosafety
Directorate of Technical Leadership and Knowledge Management
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EXECUTIVE SUMMARY

In February 2007, the Working Group charged with the elaboration of a process to draft international rules and procedures for liability and redress under the Cartagena Protocol identified four options to be considered in the preparation of a future instrument: (1) State responsibility, (2) State liability, (3) civil liability and (4) and a system of administrative liability. This was an important step forward in a process that is expected to lead to a Decision by COP/MOP 4 regarding the possible inception of negotiations on a legal instrument.

An important next step is for the negotiating States to form their own opinions on the four options on the table. This should enable the Working Group at its next session to choose the option or options to be developed further, as a recommendation to COP/MOP4. In this sense, the Working Group is expected to move from outlining possibilities to a negotiating mode.

In order to be able to make an informed choice from among the options on the table, it is necessary to understand exactly what each option would entail and, on this basis, to assess possible consequences of each option. Given that liability is a complex area of the law, this could be quite a challenge, particularly for those who are not lawyers. The purpose of this discussion paper is to assist countries in this process. It constitutes a working document prepared under the auspices of IICA to facilitate discussions among its member countries.

Part I of the discussion paper provides an introduction to liability, its possible forms, and the levels at which it operates, as well as its key concepts. Since the document is addressed to a non-specialist audience, this presentation has purposely been worded in a non-legal, easy to understand way. This will inevitably imply a certain lack of legal precision. Part II first addresses the possible implications of each of the four options on a variety of national interests. Subsequently, it attempts to make an assessment of the costs, benefits and prospects of each possible option.

For easier reading, issues that could be further discussed are highlighted in red, examples are highlighted in green, and points that are considered to be of particular importance are highlighted in gray. The Annex contains a list of questions that could form the basis of discussion about the options on the table.

The explanations on the forms, levels and key concepts of liability in Part I should guide the reader through the maze of possibilities that have been tabled by the Working Group on Liability and Redress, which can be fairly impenetrable for the non-specialist. Part II should assist the reader in forming an opinion on some of the most critical questions that will need to be answered in order to make an informed choice from

amongst the options under consideration. These include the following: Is the concept of damage underlying the "traditional" forms of liability (State responsibility, State liability and civil liability) really adjusted to meeting concerns about possible impacts of LMOs? What is the ulterior purpose of a future instrument on liability – to encourage or to discourage the development and use and of LMOs? If a binding legal instrument on liability is adopted, what are its likely prospects for entering into force and becoming fully operational?

PART I: AN INTRODUCTION TO LIABILITY

1. Liability as a legal construct

1.1. What is liability?

Liability is a legal construct featuring specific elements and concepts defined by the law, which are explained in the following sections. In this sense, it differs from the everyday usage of the expression "to hold someone liable", which can refer to fairly vague notions such as making them pay, or considering them responsible. Liability in the legal sense is the obligation of a legal entity (e.g. a person, a company, a State) to provide compensation for damage caused by an action for which that legal entity is responsible. Liability arises if all of the following conditions are true:

- The action is in contravention of the legal rules;
- Damage has been caused;
- There is a causal link between action and damage;
- Responsibility for the damage can be attributed to the legal entity.

Example

A, driving his car, jumps a traffic light and hits B, a pedestrian correctly crossing the road. B sustains injuries that require hospital treatment. In this case, A is liable: Jumping traffic lights is against traffic laws; B has sustained injuries as well as financial damage (hospital treatment, loss of income due to inability to work); there is a direct causal link between jumping a traffic light and hitting someone; A is considered at fault, and responsibility is thus attributed to him.

These central elements are explained in Section 2 below.

1.2. Fundamental distinctions

It is important to make a clear distinction between the following concepts:

- · State responsibility and State liability
- Civil (or private) liability
- Administrative liability

State responsibility/liability essentially corresponds to the sphere of international law, while civil liability is a principle of the national or internal private law of countries and so-called administrative liability is a *sui generis* concept of internal public law. This distinction is fundamental since each legal system is governed by different principles that should be taken into consideration when assessing the feasibility and scope of each option. It is not the same to refer to a precept of international law, a system that possesses unique characteristics, as to a definition of internal law which will be limited by the specific characteristics of each country's legal system.

Likewise, this point becomes especially important when settling a dispute given that, if countries were finally to opt for a conflict resolution mechanism before national courts, with the possible recognition and enforcement of decisions or judgments made outside that State, the issue of characterizations (1) and the application of national or international law could lead to different rulings or results depending on which law is applied.

(a) State responsibility and State liability

The terms "State responsibility" and "State liability" denote the liability of a State for damage suffered by another State, a liability that is governed by international law. State responsibility arises if a State has acted in contravention of international law, whereas State liability arises even if the State has acted in accordance with its international obligations.

From the point of view of international law, it is more appropriate to affirm that a dispute arising between two States may be resolved through direct negotiation, conciliation, arbitration or legal settlement, among other mechanisms. Nevertheless, all conflict resolution mechanisms, even adjudicatory ones such as arbitration or recourse to an international court, are always established on a voluntary basis.

In fact, in many cases, the damage is not caused by the organs of the State but by an individual or company within that State. Likewise, it is often a private entity in the "victim" State that suffers the damage. Nevertheless, the legal relationship is between the State where the damage originated, and the State where the damage was sustained. Private entities have no role in the matter.



¹ The term "characterization" is used to express the definition or content assigned to each term in the national legislation.

In fact, a regime that addresses acts not prohibited may provide that the State that has caused the damage has responsibility or liability. An example of this may be found in the rules contemplated in the Convention on International Liability for Damage Caused by Space Objects (1971).

For its part, international law establishes that all internationally wrongful acts by a State generate international liability. An internationally wrongful act must be attributable to a State and must constitute a breach of an international obligation of that State. If these elements are substantiated, international law requires the State responsible to provide comprehensive reparation (2) for the damage caused, without making reference to responsibility or liability.

In this regard, the International Law Commission of the United Nations stipulates that for a State to be held liable for a wrongful act the following elements must exist: an international obligation that is breached, and conduct attributable to the State –either an action or omission- contrary to international obligations.

(b) Civil liability

Civil liability is the liability of a private entity (for example, a person or a company) for damage sustained by another private entity. An institution of the State (for example, a national or local government) may be a party in a civil liability case 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 this case, it will be a party on the same footing as a private entity.

Civil liability is governed by internal or national law, and claims are brought before a national court by the private entity that suffered the damage. Virtually every country in the world has national legislation on civil liability.





Person B (Suffering damage)

(c) Administrative liability

This approach has only recently entered the discussions within the framework of the Cartagena Protocol. Like civil liability, an administrative liability system operates at the national level. It gives a national authority the competence to directly address operators responsible for activities that pose a threat to the environment. The competent authority may request the operator to provide information on imminent threats to the environment, to take preventive action,

² Comprehensive reparation for damage caused by an internationally unlawful act may take the form of restitution, compensation or satisfaction. These remedies may be applied singly or in combination.

or to take remedial action if damage has already occurred. Hence, contrary to the other forms of liability, an administrative system allows intervention even before damage has occurred. In certain circumstances, the competent authority may take the necessary measures itself and reclaim the costs from the operator. An administrative system also provides access to justice for private entities who are not satisfied with the way in which the authority has exercised its competence in a specific case.

2. Key concepts of liability

The following overview is designed to provide a basic understanding of the concepts of liability. This is in itself a difficult undertaking because:

- The concepts are defined and applied differently in state liability, civil liability and administrative liability.
- National legislation on civil liability varies considerably from country to country. In particular, there is a marked difference between civil law and common law systems.

The concepts can therefore only be described in general terms to the extent that they constitute a common denominator between the different systems.

2.1. Substantive concepts

(a) Damage

The purpose of legal rules on liability is to ensure restitution or monetary compensation in the event of a measurable negative impact on a good or interest. Accordingly, in legal terms, an impact is considered damage only if it is

- (1) concrete and quantifiable,
- (2) attributable to a specific legal entity, and
- (3) recognized as damage by the applicable law (for example as being the result of unlawful conduct).

Impacts that do not feature all these characteristics are not considered damage in the legal sense.

Modern civil liability legislation distinguishes between traditional types of damage (death, personal injury including negative impacts on health, and damage to property or to economic interests, such as loss of income) and damage to the environment, which includes damage to biological diversity. Whereas traditional damage has always been part of the law, damage to the environment is a relatively new concept, some aspects of which remain to be clarified. Some countries have adopted specific legislation on civil liability for damage to the environment.

A key problem with regard to damage to the environment is how to measure negative impacts in a way that makes quantification and monetization possible. Some national legal systems establish a baseline against which to measure an impact, which is based on relevant science and environmental economics. If a baseline is used, only quantifiable impacts of a certain magnitude will be considered damage. Another approach is to define damage to the

environment as the costs of reasonable measures of reinstatement and/or prevention. Under this approach, if an ecosystem is harmed, the damage awarded will be the cost of measures necessary to restore the ecosystem to its former State, and/or the cost of measures to prevent the ecosystem from deteriorating further.

(b) Standard of liability (fault-based and strict liability)

Fault-based and strict liabilities are two different standards of liability.

Fault-based liability applies if the damage was caused through a willful or negligent act (fault) of the liable entity. Fault is determined on the basis of whether or not the entity to which the damage is attributed observed the prescribed duty of care in carrying out the activity. This must normally be proven by the entity bringing a claim (the claimant). Strict liability, on the other hand, applies regardless of whether or not the entity to which the damage is attributed is at fault, i.e. whether or not the duty of care was observed. The claimant is only required to prove the damage and the causal link, but not a failure to observe the duty of care.

Strict liability is generally advantageous for the claimant, as fault can be difficult to establish. It imposes an extra burden on legal entities that may be held liable for a given damage. In other words, strict liability gives the potential victim an advantage over the potentially liable entity. This is considered justified where the potentially liable entity has created a risk above what is generally accepted. In many national legal systems, strict liability therefore applies only to activities generally recognized as hazardous, whereas fault-based liability applies to all other activities.

(c) Scope

The term "scope" refers to what exactly is covered by a legal instrument. In the context of liability for damage caused in a transboundary context, the following key questions will generally have to be answered when defining the scope:

- Which substances are covered? For example, only LMOs as such, or also products of LMOs?
- Which transactions, or parts of transactions, are covered? For example, the entire transport from the point of loading in the territory of the exporting State to the point of unloading in the territory of the importing State -, or the part of the transport starting from the point of exit from the exporting State, or only from the point of entry into the importing State?

In the context of a liability instrument, the concept of scope is essential to define which issues or acts will be affected by the regime, and also to determine the type of conduct expected from those States that become parties and from the private entities involved.

For example, depending on the scope allotted to Article 27, this could cover liability and redress for damage resulting from transboundary movements, but the movement from the port to a point within a State could be excluded, since this movement would take place within a same territory, in other words, it

would be an intrastate movement. Nevertheless, such damage would be addressed by the national liability regime.

(d) Causation

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 entity responsible for the harmful action be held liable. This is one of the basic requirements for both fault-based and strict liability to be attributed to a legal entity.

The requirement of a causal link between an activity and specific damage means that legal entities can be held liable only for damage that is clearly the result of their actions. Without this built-in protection, anyone could be held liable for something only very remotely connected with his or her actions.

In different legal systems, causation is defined in different ways. A common approach is for the law to require two things: (1) that the damage has in fact been caused by the action or omission, i.e. that there is a chain of events starting with the action or omission of a person, and ending with damage sustained by someone else (sometimes referred to as "actual causation" or "cause-in-fact") and (2) that the action or omission is recognized by the law as a cause of the damage (sometimes referred to as "legal causation" or "cause-in-law"). Only if both requirements are met will the person considered responsible for the action or omission be held liable.

In this sense it should be noted that the attribution of liability is also subject to the action or omission producing a reasonable probability of a wrongful conduct or act occurring.

It is important for the regime to be comprehensive and provide guidance, in an efficient and effective manner, and under parameters of reasonability and proportionality, particularly if cases involving the reasonability of a State's actions are to be analyzed (assessed on the basis of its legal obligations, the means for satisfying these and the characteristics of each situation).

Example

A seed company sells LMO cottonseeds to a farmer. The resulting cotton harvest is processed by a successive chain of manufacturers, resulting in the production of cotton socks. A local store then sells a pair of these socks to a purchaser, who slips on the stairs while wearing these socks and breaks a leg. In this case, there is actual causation between the action of the seed company (sale of the seeds to the farmer) and the damage (injury to the purchaser of the socks): if the seed company had not sold the seeds, the purchaser of the socks would not have broken his leg. However, the damage sustained by the purchaser of the socks is so remotely connected with the action of selling the seeds that it was not reasonably possible for the seed company to foresee it. The requirement of legal causation is therefore not met, and the seed company is not liable for the injury to the purchaser of the socks.

(e) Channeling of liability

Most transboundary transactions involve a chain of operators who have control of the substance or activity at different stages. These may include the person who makes the arrangements for the export of the substance, the owner of the industrial installation from which the substance is exported, the owner of the vessel or vehicle transporting the substance, the person who physically loads, transports or releases the substance, and the person who takes charge of the substance at the point of destination.

To ensure clarity and predictability for both the potential victims and the potentially liable persons, legal systems use different ways to attribute liability. The options include the following:

- Channeling liability for the entire transboundary movement to one particular operator in the chain (for example, the producer, or the person arranging the transboundary movement);
- Channeling liability to each operator for the particular stage of the transaction of which he or she is in charge;
- 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.

It is important that liability is attributed to clearly identifiable actors who have some degree of control over the activity. This makes it possible for potential victims to know whom to address. It also allows a legal entity engaging in a particular activity to assess whether or not he or she might be liable for damage resulting from that activity. Whichever solution is chosen, liability is always assigned to one or more persons who are involved in a transaction in a significant way and have a high degree of actual control over it (and often also an economic interest in it).

A company will be liable for the actions of its employees. Most legal systems provide that the liable entity may have recourse to others who contributed to the damage. This means that they can recover from such entities all or part of the compensation that they have to pay to the victims.

(f) Exemptions

If damage occurs due to an event that was beyond the control of the potentially liable entity and could not have been foreseen, it would not be appropriate to hold that entity liable. Therefore, most national civil liability regimes provide that, in such circumstances, the entity is exempted from liability. This can be put forward as a defense in court. Many legal systems differentiate between total exemption from liability when the event beyond the control of the defendant is the sole cause of the damage, and reduction of compensation when it is only a partial cause.

Exemptions or limitation of liability may be invoked in any type of regime, not just in civil liability proceedings.

Events that are beyond the control or influence of anyone, and can therefore be used as a defense in civil liability proceedings if they were the cause of the damage, typically include the following:

• Armed conflict, civil war, insurrection, and similar events

- Natural phenomena of an exceptional, inevitable, unforeseeable and irresistible character (also referred to as Acts of God or force majeure), for example: hurricanes or tornados, massive landslides, avalanches, and floods
- Acts or omissions of a third party
- Acts or omissions of the person who suffered the damage.

2.2. Procedural concepts

(a) The burden of proof

"Burden of proof" denotes the principle in procedural law that determines which of the legal entities involved in a court case must submit proof of the facts that substantiate a claim. Although there are limited exceptions in some national legal systems, the burden of proof as a general rule is attributed to the claimant.

In other words, the burden of proof is the principle that determines which party in a legal process has the obligation to prove an allegation or a claim. The burden of proof always falls upon the claimant (the person who alleges a fact must prove it), save if the law determines otherwise. Therefore, it is understood that any legal entity alleging the liability of another must prove that the requirements are met in order to attribute such liability. However, this may be inverted through the approval of a legal rule in consideration of assessments of an ontological nature.

In view of the foregoing, it is normally up to the claimant to prove that liability arises. This includes submitting proof that the claimant has sustained damage and that there is a causal link (proof of both actual and legal causation) between the action of the defendant and the damage. In matters of civil liability, if liability is fault-based, the claimant must also prove that the defendant has breached the duty of care through intentional act or omission. The same applies to the claimant State under State responsibility.

(b) Standing to bring a claim

Legal entities wishing to bring a claim must demonstrate that they have an interest as recognized by the applicable law. Under civil liability, a private actor (e.g. a person or company) who can demonstrate an interest may bring a case before a national court. Most legal systems recognize an interest if the claimant has been directly and materially impacted by the alleged damage. Under State liability, only States can bring a case before the International Court of Justice or an international arbitration institution, provided they can demonstrate an interest.

Public interest groups do not normally have standing to bring a liability case. Under State liability, this is because they are not States. Under civil liability, they are not considered to have a concrete interest unless the damage affects them in a material way. This would be the case, for example, if the claim concerns damage to land owned and managed as a protected area by a non-governmental organization.

3. Levels of civil liability legislation

3.1. National legislation on civil liability

Most if not all countries of the world have in place legislation on civil liability. If damage has occurred in a purely national context (for example, if it was caused by a person within State A and sustained by another person in State A), it will be subject to the applicable law of that State, and the courts of that State will adjudicate the claim. In this scenario, there is no need for an international regime. If there is a transboundary dimension (for example, if the damage was caused by a person in State A and suffered by a person in State B), the rules of private international law of the State where the action is brought will determine which national law is applicable, and which State's courts will adjudicate the claim.

3.2. International civil liability treaties

(a) The role of civil liability treaties

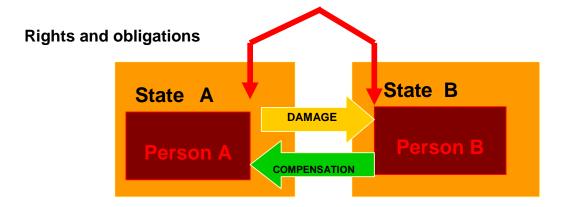
As noted above, in the event of transboundary damage, the victims may need to bring a claim in a foreign country. This can be very complex due to the difference in legal rules and procedures from country to country. The purpose of international civil liability treaties is to facilitate cross-border litigation by:

- Establishing uniform provisions for key issues of civil liability
- Establishing uniform procedures
- Providing for mutual recognition of judgments

These treaties create direct obligations for States, inasmuch as they must incorporate the provisions of such agreements into their national legal system. Thus, as soon as these obligations are incorporated into the legal system of each country, they become applicable to private entities.

In concrete terms, the treaty provisions will directly apply to any damage that comes within the ambit of the treaty. If parties have differing national liability rules in place, these will be "overruled" by the provisions of the treaty. Therefore, a State that becomes a party to a treaty will most likely adapt its national legislation to the provisions of that treaty.

International Treaty



Civil liability treaties have been adopted in areas where transboundary damage is particularly likely to occur.

These apply to transactions that are considered especially hazardous, such as:

- Transport of crude oil by sea
- Operation of nuclear installations
- Management of hazardous substances and wastes

(b) Substantive issues covered by civil liability treaties

International liability treaties only address key issues where a uniform approach is considered especially important. All other issues are governed by the national law of the country where the case is brought. Key issues addressed by civil liability treaties are:

- Types of damage covered (traditional / environmental): Existing international civil liability treaties cover both traditional and environmental damage. Damage to the environment is usually defined as the costs of reasonable measures of reinstatement, and of reasonable measures of prevention.
- Scope: Existing treaties applicable to transboundary movements of potentially hazardous substances generally specify the types of substances that are covered, and the points in a transaction at which liability begins and ends. Given that only parties to the treaties have rights and obligations under the provisions of a treaty, damage caused or sustained in a non-party is excluded.
- Standard of liability (fault-based or strict): Existing treaties are limited to specific types
 of hazardous activities, for which they establish strict liability. Such treaties exist in the
 domains that have recognized high potential for causing severe damage to the
 environment and to human health. Under some international civil liability treaties, only the
 operator in control of the hazardous substance or activity at the time of the incident is
 strictly liable, whereas fault-based liability applies to any other person who contributed to
 the damage.

- Channeling of liability: Existing treaties define the person or persons to whom responsibility for a given transaction can be attributed. Different options were chosen under different treaties (one operator is liable for the entire transaction; each operator is liable for the stages of the transaction of which he/she is in charge; or joint and several liability applies).
- Financial limitation of liability and compulsory insurance: Many existing treaties
 provide for an upper financial limit per event for which a person may be held liable. As a
 complement to this, the treaties oblige potentially liable operators to take out insurance or
 provide other types of financial guarantee, for a defined minimum amount. This provision
 is intended to ensure that compensation can be provided in the event of damage.
- Exemptions: Existing civil liability treaties generally provide for exemptions for damage
 caused by armed conflict and similar events; Act of God (force majeure); and acts or
 omissions of a third person or of the person who suffered the damage.

(c) International compensation fund

As a complement to a civil liability regime, it is possible to establish an international fund, receiving compulsory contributions from operators for the purpose of providing compensation to victims of damage caused by those operators. The fund provides compensation to the extent that this cannot be obtained under the provisions of the civil liability treaty (for example, if the financial limit of liability per event is exceeded, or if the liable operator cannot be identified). In the environmental field, one such compensation fund is already in operation, namely the International Oil Pollution Compensation Fund (IOPC Fund), established as part of the civil liability treaty for marine pollution by crude oil transported by sea.

An international fund may serve to complement any type of liability regime, not only a civil liability regime. The contributions, moreover, may be obligatory or voluntary, on the one hand, and of public, private or mixed origin on the other. The combination of any of these may give rise to different systems.

It should be borne in mind that the establishment of a compensation fund is not a simple and practical solution to the problem of ensuring compensation for damage. First, a compensation fund is not an alternative but a complement to a liability treaty: such a treaty must be in place if the compensation fund is to be of any value. Second, a legal instrument establishing the fund must be negotiated to address a number of substantive and procedural issues, such as the definition of damage and financial limitations for compensation per incident. This is likely to create similar controversies to those encountered in negotiating a liability treaty. Third, a compensation fund is normally an international body with its own institutional infrastructure. Its operation therefore requires considerable resources.

3.3. The interplay between national and international civil liability legislation

Since an international civil liability treaty addresses only specific key issues, leaving all others to be governed by national legislation, it does not replace the need for national legislation and a functioning judicial system at the national level. On the contrary, a country will not be able to fully meet its

obligations under a civil liability treaty if it does not have national civil liability legislation and judicial institutions in place.

- Civil liability treaties do not establish international courts or tribunals. Each party to the
 treaty must adjudicate in international claims brought before its courts. It must therefore
 have national legislation governing all substantive issues not addressed under the treaty.
- Each party to the treaty will have to enforce judgments passed by the courts of other
 parties on a transboundary issue that concerns it. In order to be able to do this, a country
 must have functioning judicial institutions in place.

PART II: LIABILITY AND BIOSAFETY

1. Liability discussions under the Biodiversity Convention and the Biosafety Protocol

1.1. Biodiversity Convention

Under Article 14 of the Convention, a process has been initiated to develop possible rules on liability for damage caused to biological diversity from any source. For this purpose, a Group of Legal Experts on Liability and Redress was established; however, this process has stagnated mainly due to financial constraints. At the Eighth Meeting of the Conference of Parties, held in March 2006, no decisions were taken on substantive actions in this regard.

1.2. Biosafety Protocol

(a) History and current status of the negotiations

Following heated debates on liability during the negotiations on the Cartagena Protocol, Article 27 was adopted as a so-called enabling provision, i.e. as a legal basis for further discussion under the Protocol. It provides for adoption of a process for elaborating international rules and procedures on liability for damages caused by LMOs, taking into account ongoing processes in international law on these matters. Article 27 requires the COP/MOP to initiate this process at its first meeting, and to endeavor to complete it within a period of four years.

Accordingly, the Working Group on Liability and Redress was established at the first meeting of COP/MOP in May 2004 to elaborate the process for developing international liability rules. The deadline for the completion of the process is May 2008, when the 4th COP/MOP will be held in Bonn.

As of March 2007, the Working Group had held three meetings and two further meetings are expected to take place prior to COP/MOP 4. Based on the work of the Working Group, the COP/MOP is expected to establish a negotiation group to elaborate a possible future legal instrument(s) on liability and redress.

(b) Options on the table

Given that Article 27 does not prescribe the elaboration of a particular form of international rules and procedures, one of the first tasks is to determine which form would be most appropriate. At the three meetings held to date, the Working Group discussed possible approaches as well as elements of the future rules. At the third meeting held in February 2007, it prepared a blueprint for a COP/MOP Decision, which contains four possible approaches to the elaboration of rules and procedures on liability and redress for damage caused by transboundary movements of LMOs. For each approach, different options have been identified, with the understanding that no specific choice was being made at this time. The blueprint will be considered further at the next meeting of the Working Group, with the idea that the delegations will have clarified their positions regarding their choice of options by that time.

Approaches considered by the Working Group

- 1. State responsibility: The Working Group envisaged a reference to existing rules of international law on the responsibility of a State for damage caused to another State through breach of an international obligation.
- **2. State liability:** In the case of liability of a State, even in the event that it has not breached international obligations, the Working Group identified the options of developing binding or non-binding international rules, or of not developing rules in this field.
- **3. Civil liability**: As described above, civil liability applies to damage caused by a private entity to another private entity; the entity that sustained the damage can claim compensation before a national court. The Working Group identified the options of developing binding or non-binding rules, or a combination of both, or of not developing rules in this field. Facilitating transboundary civil liability litigation through private international law is also a possibility.
- 4. Administrative system: As described above, an administrative system at the national level allows a competent authority to require an operator to take preventive or remedial measures in respect to damage to the environment, and provides access to justice for persons or groups who are not satisfied with the way in which the authority has acted in a specific case. The Working Group considered the development of binding or non-binding international rules for establishing an administrative system, or international guidelines for developing national rules, or a combination of both. Another option is not to address this issue.

With regard to approaches 2, 3 and 4, the options include the development of binding and non-binding international rules. The difference can be described as follows:

Types of instruments considered by the Working Group

- 1. Binding international rules: Binding international rules impose rights and obligations on States. They normally take the form of a treaty, or an amendment or annex to an existing treaty.
- **2. Non-binding international rules**: This type of rules is of a recommendatory nature, designed to assist States in addressing the issue in question at the national level. A form commonly used in international treaties is that of guidelines.

(c) Alternative conflict resolution as a complementary tool?

Under Approaches No. 3 (civil liability) and 4 (administrative system), the possibility of using alternative conflict resolution methods in addition to the future instrument has also been discussed. Such methods also allow for settlement of a dispute without resorting to national or international court systems. There are numerous specialized institutions in different parts of the world that provide international conflict management and dispute resolution services; some of these also provide support services to parties engaged in a dispute.

Alternative conflict resolution methods include:

- 1. Arbitration: Based on a mutual agreement by the parties in a dispute, an arbitral tribunal is appointed, constituted by an equal number of members chosen by each party and a neutral president elected by the tribunal. After hearing the case, the tribunal renders a decision that is binding on the parties and cannot be appealed. Rules on arbitration have been elaborated by a number of international bodies, including the UN Commission on International Trade Law (UNCITRAL), the Permanent Court of Arbitration (PCA) as well as the institutions that provide international arbitration services, mentioned above. Rulings issued by arbitral tribunals can be enforced in all countries that are parties to the 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards, i.e. most countries of the world.
- 2. Conciliation: As in arbitration, this procedure involves the appointment of a neutral person or body, by common decision of the parties to the dispute. Unlike an arbitral tribunal, a conciliation body, after hearing the case, does not render a decision binding on the parties to the dispute, but offers possible solutions to the conflict. The parties can choose whether or not to accept these recommendations. The rulings of a conciliation body do not represent an adjudication of the legal issues. Also, the conciliation rulings do not need to be within the confines of the legal rules governing the issue that would be applied in formal litigation, but can be (and often are) based on what is acceptable to the parties to the dispute.
- **3.** *Mediation:* Mediation is a process through which a neutral mediator assists the parties in resolving their conflict in a way that is acceptable to both. Unlike in arbitration and conciliation, the mediator does not address the substance of the dispute, but uses specific tools and methods that enable the parties themselves to devise a solution. As in conciliation, this solution must not necessarily be within the confines of the legal rules that would be applied in formal litigation. Participation in the process is voluntary, and each party can decide to end the process at any time. The outcome is an agreement concluded by both parties, by which they agree to be bound.

2. Potential impacts of the options on national interests

In order to make an informed choice from among the options on the table, it is important to fully understand the concepts underlying each option, and to be able to assess, as far as possible, the implications at the practical level. This section therefore examines the implications of each option on the following central domains:

- Public research
- Agricultural and industrial development
- International trade
- Food safety

- Environmental protection
- Public perception (concerns of civil society)

2.1. State responsibility

As described above, State responsibility is governed mainly by a set of rules of customary international law. These are unwritten rules that are usually very general, and are not specifically adapted to complex technical fields such as biotechnology. Under the approach identified by the Working Group, no new rules on State responsibility would be developed, but instead reference would be made to the existing rules. Since the majority of these belong to the realm of Common Law, they apply in any event, regardless of whether or not such a reference is made.

2.2. State liability

State liability is a concept that has been subject to ample discussion in the past decades, but has yet to gain recognition among States as well as in the academic world. If a decision were taken to formulate international rules in this field, a State could be held liable by another State for damage caused by LMOs, even where there has been no breach of international law (unlike State responsibility, which only arises if the State has acted in contravention of international law). In concrete terms, a State could be required to provide compensation for all damage that originated under its jurisdiction or control, even if the State authorities acted in accordance with their international obligations. Depending on how the key concepts described above would be addressed in the instrument to be developed, this could generate a flood of international claims before the International Court of Justice or international arbitration tribunals.

The issue of State liability is a complex matter from the theoretical point of view, and is relatively new in the ambit of international law. The debate, which began at the end of the 1970s in the UN International Law Commission, has been superseded and is guided by real circumstances. Nowadays, reference is no longer made to a generic concept of liability for lawful acts and, in the sphere of ILC; the issue has been reduced to the regulation of very hazardous and highly polluting activities. Therefore, what was previously termed liability for lawful acts today may be defined as the mechanisms or instruments developed by International Law to compensate for damage produced by activities that are not prohibited under this regime, and where the parties involved have also taken all due precautions.

As regards the potential consequences of establishing a regime with these characteristics whereby states have liability, it is likely that these would be far more burdensome than the main one identified by the author i.e. the large number of claims that might be made in international courts. Indeed, by establishing the liability of States, countries would be dissuaded from ratifying any future instrument since they might find themselves obliged to respond for

damage caused, even in cases where all due care and precautions had been taken.

This matter should be carefully analyzed since it could have the opposite of the desired effect, deterring States from ratifying a treaty that would hold them responsible for actions or behavior that they could not have prevented, foreseen, controlled or avoided, but for which they would nevertheless be held liable.

2.3. Civil liability

As explained previously, civil liability is governed by the national legislation of each country. Basically, there are two possible interventions at the international level: the elaboration of non-binding guidelines designed to assist countries in developing national legislation, and the elaboration of a civil liability treaty providing unified rules on substantive and procedural aspects of liability.

A negative outcome of this type of liability relates to the harmonization problems generally encountered in establishing guidelines, since the definition of the essential elements of a future liability regime is left freely to the decision of the States.

It should also be noted that non-binding rules or guidelines, once adopted by the destination country of the exports, produce an extraterritorial effect for any country wishing to export to that country.

(a) Development of non-binding rules or guidelines

This may be considered a "soft" approach, under which countries are free to decide how to use or apply the guidelines. These will probably be used in a way that is consistent with their own national legal systems, in particular, with existing civil liability legislation. Countries that do not yet have liability legislation addressing environmental damage may use the guidelines to develop such legislation. The impacts this could have on the issues outlined above would to a large extent depend on the content of the guidelines, and the way in which countries use them. To the extent that the guidelines recommend specific action on the key concepts of liability, the consequences will be as described below, if a country decides to adhere to the recommendation in question.

(b) Development of a legally binding regime

As mentioned, this approach would mean the elaboration of binding rules on key aspects of liability in the form of a treaty. States that chose to become parties would be bound by this treaty (or amendment, or annex) in the sense that its provisions would apply to any civil liability litigation under its jurisdiction, in lieu of the existing national legal rules governing civil liability. Hence those States that would become parties to a future civil liability treaty

would need to adapt existing national liability legislation to the treaty's provisions.

→ Discouragement or prevention of LMO development and use?

Adopting an international treaty on civil liability always entails striking a balance between controlling perceived risks and allowing an essentially beneficial activity to proceed. Depending on which consideration is given more weight in the drafting, the treaty will be more or less "friendly" either to the promoters of the activity or to those who are concerned about the risks. If a civil liability treaty in the area of biosafety is adopted and enters into force, its impacts in States that choose to become parties will thus depend on the content of its provisions on the key issues explained above. If the content of the provisions is such that they will effectively discourage even render impossible the development and use of LMOs, this would be likely to have effects in all the domains listed above. Public research on biotechnology and the development or accommodation of a biotechnology industry would become difficult in countries that were parties to the treaty. Farmers would tend to avoid working with LMO crops. In addition, it is likely that international trade in LMOs would diminish significantly from and to parties to the future treaty. Depending on the viewpoint, these possible effects will be judged differently. Those concerned about the perceived risks of biotechnology are likely to consider such consequences to be desirable, and may even see discouragement of the use of biotechnology as the ultimate objective of a civil liability treaty. Those who regard biotechnology as important for achieving food safety, improving health care and promoting environmental protection (e.g. by reducing the need for pesticide use) will probably see the same consequences as undesirable, and will wish to avoid them.

A future treaty is likely to have the effect of discouraging the development and use of LMOs if it addresses the key issues of civil liability in a specific manner, as explained below.

- <u>Damage</u>: Impacts could be expected, particularly if the definition of damage covered impacts that the law does not currently recognize as damage (such as changes in social and cultural practices, and spiritual values). In order for liability provisions to address undesirable consequences of an activity without compromising the activity itself, the definition of damage must be clear, and also relatively narrow. Too broad a definition of damage, comprising every possible impact of an activity, will generally be prohibitive.
- Standard of liability: If the treaty provided for strict liability for all transactions involving LMOs, this would mean that anybody involved in such transactions could be held liable for damage regardless of whether or not they are at fault. This would make anybody handling LMOs (producers, farmers, research institutions, transporters, storage facilities) open to liability claims even if they took all proper care. This is likely to be prohibitive. In this context, it is worth noting that most existing civil liability treaties do impose strict liability. However, these treaties apply to substances and operations that are generally considered to pose a special risk to the environment, such as transport of crude oil by sea, and management of nuclear materials. With respect to LMOs, various international organizations and expert bodies have concluded that the process of genetic modification is not hazardous as such.

- <u>Channeling of liability</u>: If liability were attributed not only to a person or persons who are
 involved in a transaction in a significant way, and who have a high degree of actual
 control over it, but also to persons only remotely connected to the activity, this would
 entail considerable insecurity. The persons concerned would find it difficult to assess
 under which circumstances they could be held liable. This could make them reluctant to
 engage in relevant activities.
- Exemptions: If the treaty did not provide the generally accepted exemptions from liability where the damage was caused wholly or partly by an event outside the control of the potentially liable entity, this would again entail significant insecurity and discourage the development and use of biotechnology. Also, exemptions regarding acts in compliance with compulsory measures issued by a competent national authority and acts taken in accordance with permission of an activity by means of an applicable law or a specific authorization issued to the operator are appropriate in the specific context of the biosafety protocol.
- Scope: The most important questions here are probably which organisms or substances are covered (e.g. LMOs or also products containing LMOs), and which transactions are covered (e.g. only the international transfer of LMOs, or any transaction involving LMOs wherever it takes place). The broader the scope, the more likely the treaty will be to discourage development and use of LMOs, especially if the contents of other key provisions were as described above.
- Insurability of risks: If the treaty provided that potentially liable operators must take out insurance to cover possible risks, but established liability for risks that the insurance industry does not cover, operators would be unable to comply with the provisions of the treaty. In addition, the development and use of LMOs would probably no longer be financially viable.

→ Public perception

An immediate effect of the adoption of a civil liability treaty might be to reassure those concerned about possible environmental and health effects of LMOs that their concerns are being addressed at the international level. Even a decision on the negotiation of a treaty by the COP/MOP might have this effect. This could be independent of the content of the treaty, and of the question whether it is likely to enter into force and become operational. Conversely, adoption of a civil liability treaty might foster greater concern and misperception about the possible effects of LMOs to the extent it suggest that a threat exists that has yet to be proven

2.4. Administrative system

Like civil liability, an administrative system is established at the national level. In some countries, systems of this nature already exist. The EU Directive on Environmental Liability is an example of an instrument on the establishment of administrative systems. Possible interventions at the international level include: the elaboration of binding international rules to regulate key aspects of these systems, which would be applicable in all countries bound by the rules, and the elaboration of guidelines to assist countries in establishing and managing their national administrative systems. The difference between the

two forms is essentially the same as under civil liability, explained in Section 2.3 above.

(a) Development of non-binding rules or guidelines

As under civil liability, this would be the "soft" approach, under which countries are free to decide how to use or apply the guidelines. They will probably make use of them in a way that is consistent with their national legal systems, especially taking into account the existing administrative systems that some countries may already have in place.

(b) Development of a legally binding regime

As with civil liability, it would be possible to design a legally binding instrument that would contain unified provisions on the key elements of an administrative system. As is the case with civil liability treaties, such an instrument would be binding on States that chose to become parties. The provisions of the instrument would be directly applied at the national level in each party. Consequently, existing national systems of the parties to the instrument would need to be adapted to the provisions of the instrument. The EU Directive may have a certain model function for this option.

→ Advantages over civil liability

The specific purpose of administrative systems is to address "new" forms of damage that transcend the traditional forms for which the concept of civil liability was developed. For this reason, this approach may be better suited than civil liability to deal with the specific aspects of damage to the environment, including such damage as could be caused by LMOs. In particular:

Similarly, the concept of an administrative system could be interesting if we consider that concerns are related, at least in part, to possible future impacts that are not known today, whereas civil liability is limited to damage already known.

3. Assessing the options: Practical considerations

- 3.1. The legal concept of damage in the context of LMOs
- → A question that deserves careful consideration is whether the legal concept of damage that underlies civil liability, State responsibility and State liability is appropriate in the context of LMOs.

As explained above, this concept was designed to address the concrete, measurable and quantifiable (in monetary terms) forms of damage that are traditionally addressed by liability rules. The difficulty of addressing damage to

biodiversity, and to the environment in general, is an indication that this concept may be too narrow. In the context of LMOs, possible impacts are hard to pin down, given that damage to human health or to the environment has yet to be determined. This issue mainly has to do with concerns about impacts as yet unknown that could emerge in the future, as well as concerns about possible non-measurable changes that could occur due to use of LMOs.

The following impacts of LMOs are not covered by the legal definition of damage, and thus would not come within the scope of an instrument on civil or State liability:

- Changes of an ethical, non-monetary nature that may result from LMO use (for example, changes in social or cultural behavior, or impacts on spiritual values). Such impacts are not quantifiable in monetary terms.
- Financial losses that are not due to negative properties of LMOs, but to other factors such
 as market forces or customer preferences (for example, loss of income for traditional
 farmers due to LMO crops that are more effective, or cheaper). Such losses are not
 recognized as damage by the law. Bringing a product onto the market that sells better
 and therefore causes losses to competitors- is not considered unlawful behavior.

Therefore, a major aim of a liability instrument could be to ensure preparedness to face the negative impacts that could become evident in the future, and in particular to prevent these from happening. This concern cannot be satisfactorily addressed through an instrument that relies exclusively on the concept of concrete, measurable and quantifiable damage that has already occurred.

3.2. Binding international rules: Prospects for entry into force

→ If the option of elaborating binding international rules is chosen, the likelihood of these becoming operational should be a crucial consideration. This applies regardless of the legal form of the instrument (a new treaty, or an amendment or annex to an existing treaty), and independently of whether the instrument provides international rules on civil liability, State liability or administrative liability.

For a State to be bound by a treaty, it must become a party to it through the process established by international law (ratification, accession). The treaty does not bind a State that does not become a party, and therefore has no effect. Likewise, a treaty only enters into force if and when a minimum number of States have become parties.

States are under no obligation to become parties to a treaty, even if they have participated in its negotiation and adoption (and even if they have promoted the treaty). Those States that are not satisfied with the outcome of the treaty negotiations, or consider the treaty's provisions too far removed from their own national legislation on liability, will probably not become parties. Thus, it appears reasonable to initiate negotiations on an international treaty only if there is widespread conviction of its need within the international community.

The negotiation process for a binding treaty tends to be more complex and lengthy than for a non-binding instrument. During treaty negotiations, the States tend to be more careful about what they agree to, bearing in mind that

the intention is for them to become parties and be bound by the resulting treaty, even though there is no obligation to do so.

Therefore, when selecting an option, it is important to bear in mind the real possibility of a lengthy and costly negotiating process resulting in a "dead letter agreement".

3.3. Costs, benefits and prospects of each option

(a) State responsibility

As explained previously, the option on the table is a reference to existing rules, which means that the costs and the benefits are likely to be minimal. In fact, it is unlikely to entail any change in the status quo: since State responsibility is mainly based on Common Law, the relevant rules already apply, but in the past States have been very reluctant to resort to this instrument in the environmental field. This attitude is unlikely to change.

(b) State liability

Developing rules on State liability is likely to be an onerous task. As explained above, if this option were chosen, the possible implications could be considerable, but precisely because of this, it seems very unlikely that the negotiating States will agree to this approach. Since experience shows that States are very reluctant to agree to State responsibility in an environmental context, they will be even more reluctant to agree to State liability. In addition, the concept of damage underlying State liability is perhaps insufficient to address the real concerns in this area. This option could therefore entail significant costs and few –if any – benefits.

(c) Civil liability

For this approach, the considerations concerning the concept of damage and the prospects of entry into force of binding international rules are especially relevant.

With respect to the option of elaborating a binding international treaty, it should be borne in mind that none of the treaties on civil liability for environmental damage that were adopted in the 1980s and 1990s have entered into force, since not enough States chose to become parties. Therefore, it is quite possible that a civil liability treaty for damage resulting from LMOs would meet the same fate and join the ranks of the other "dead letter" agreements in this field.

Surveys carried out by treaty secretariats have identified a number of reasons why countries did not ratify existing civil liability treaties. It is interesting to note that these cases were not limited to countries that were opposed to civil liability during the negotiation processes.

- **1.** <u>Economic reasons</u>: Heavy financial burden for operators, especially for small and medium enterprises, due to high financial limits and/or impossibility of obtaining insurance coverage required by the treaty.
- **2.** <u>Legal reasons</u>: Incompatibility of the treaty provisions with the country's national legislation on civil liability.
- <u>3. Political reasons</u>: Low priority of the treaty on the national agenda, no need identified and/or opposition by national stakeholders, unwillingness to commit unless a minimum number of other countries do likewise.
- **4.** Reasons related to capacity (developing countries and countries in transition): Inadequacy of existing national legislation and judicial system, insufficient capacities for meeting relevant challenges, lack of awareness of the benefits and drawbacks of adhering to the treaty.

Against this background, it would appear that the costs of negotiating an international civil liability treaty might well outweigh the benefits.

The elaboration of non-binding guidelines might be more promising if these are specifically designed to assist countries in overcoming the capacity-related obstacles to the elaboration and implementation of national civil liability legislation. Nevertheless, the question of whether an approach focusing on the traditional legal concept of damage would be appropriate in the context of LMOs would remain, among many other questions.

(d) Administrative system

With regard to the possibility of elaborating an international treaty, the constraints outlined above will also need to be taken into consideration. The development of non-binding rules may therefore be seen as a more promising option.

→ Given that the concept of administrative liability appears better adjusted to the concrete concerns and situation in the context of LMOs, the inception of such systems by countries under the umbrella of international guidelines could be an effective and efficient way of addressing the problem.

(e) Alternative conflict resolution methods as a complement to a legal instrument

The advantages of alternative conflict resolution (arbitration, conciliation, mediation) are increasingly being recognized. In addition to being cheaper and more flexible than formal litigation procedures, they allow the parties to a dispute to remain in control of the process as well as the outcome. Unlike formal litigation procedures, alternative dispute resolution methods do not establish a strict division between State actors and private actors; thus they can also be used in a dispute between a State and a private entity (e.g. a company). The entities involved in a conflict are free to determine who is involved, what expertise is relevant, and the basis on which a solution is

sought. Another advantage is the possibility of choosing specialized arbitrators or conciliators who are more knowledgeable of the technical aspects of the issue under dispute than all-purpose judges.

- → In the event of an international dispute arising over risks or damage resulting from LMOs subject to transboundary movement, resorting to national civil liability rules or a national administrative system may not be adequate or sufficient due to the international dimension. In this case, using the services of an existing institution for alternative conflict resolution could provide an efficient and cost-effective solution.
- 3.4. What is the ulterior objective of a future instrument on liability and redress?

The agreed objective of a future instrument on liability and redress is to provide remediation of damage resulting from transboundary movements of LMOs [that might be caused by LMOs in an international context.] In conjunction with this, the prevention of damage before it occurs could also be seen as an objective, although there has been no agreement on this among participants.

→ Different negotiating States and other interested groups will have ulterior objectives, depending on their position on the more general debate on biosafety. In choosing the option most appropriate to address the issues on the table, it may be useful to take these into consideration.

Ulterior objective	Prospects for achieving it
Discouraging or preventing the development and use of biotechnology	This could be achieved through the adoption of binding civil liability rules designed in such a way as to dissuade potential operators from engaging in activities involving LMOs, essentially through creating a state of uncertainty about what they might be held liable for.
Ensuring that the development and use of biotechnology can proceed without undue restrictions	The best option for achieving this objective would be to elaborate rules that are non-binding in form, and are designed in such a way that they provide maximum legal certainty to operators.
Providing countries that do not have adequate national legislation or judicial institutions with an international system to ensure redress to individuals that have sustained damage	To achieve this objective, it would be most effective to develop guidance tools to assist countries in developing appropriate national instruments. An international civil liability treaty cannot replace the need for national legislation and functioning institutions.

CONCLUDING REMARKS

While the main objective of this paper is to assist readers in forming their own opinion rather than to point to one or other of the options on the table as the preferred solution, there are a few conclusions to be drawn from the above.

Having analyzed the options, a major question to be addressed in the context of the ongoing negotiations should be what precisely a future instrument on liability is expected to achieve. The driving force appears to be concern about as yet unknown impacts of LMOs that could appear in the future, and about possible non-measurable changes that could occur due to use of LMOs. State liability, State responsibility and civil liability focus on the remediation of concrete, measurable and quantifiable (in monetary terms) damage that has already occurred. Therefore, their suitability for dealing with future unknown impacts should be called into question. Administrative liability, developed to prevent and/or remedy "new" forms of impacts on the environment, could be a better option to address these concerns.

As regards the content of possible future rules on liability, another key question is that of the ulterior objective of a future instrument on liability. A future instrument on liability, especially if a legally binding form is chosen, can be designed in such a way that it will discourage the development and use of LMOs by creating a state of legal uncertainty that will likely be dissuasive. It can also be designed in such a way as to allow these activities to proceed by limiting intervention of the law to instances where there is a concrete risk.

When considering the option of binding international rules on liability, it should be borne in mind that such rules only enter into force if a minimum number of States become parties, and that no State is under any obligation to do so. The majority of existing treaties on civil liability, for example, have never entered into force. Hence, the real possibility of a lengthy and costly negotiating process resulting in a "dead letter agreement" should be taken into consideration when making a choice.

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Annex: Questions to be discussed in Fortaleza

Note: The issues that could usefully be discussed are highlighted in red in the document. These are listed below as specific questions (not necessarily in the same order in which they are presented in the document).

- 1. How useful is the concept of damage (as it underlies State liability, State responsibility and civil liability) for addressing concerns in the area of biosafety?
 - To what extent do the possible impacts of LMOs correspond to the legal concept of damage?
 - What are examples of actual damage caused by LMOs to biodiversity, to the environment in general and to public health, in particular as a result of transboundary movements?
- 2. What is the likelihood of a prospective binding legal instrument entering into force and becoming operational (also bearing in mind that existing civil liability treaties have become "dead letters")?
- 3. How does the administrative approach compare with in the context of prevention/reparation of prospective damage caused by LMOs?
- 4. What are the prospects of establishing informal conflict resolution mechanisms (arbitration, conciliation, mediation) as a complement to a legal instrument on civil liability or administrative systems?
- 5. What could or should be done under the Biosafety Protocol in the way of capacity building to help countries develop national measures for preventing damage to biodiversity that may be caused by LMOs?
- 6. Which is the best way to address public concerns regarding LMOs (regardless of whether or not real dangers exist)?
- 7. What is the ulterior objective of a future instrument, or what do participants consider that it should be? Which approaches are best suited to achieving this objective?