



**LIABILITY AND REDRESS:  
PROPOSALS TOWARDS A SUPPLEMENTARY PROTOCOL**  
(Final Version, May 31<sup>th</sup>, 2010)

**Executive Summary**

This document brings an analysis of the proposals that aim at constructing the Supplementary Protocol on Liability and Redress in the case of damages resulting from transboundary movements of living modified organisms (LMOs) in the context of the Cartagena Protocol on Biosafety, based on the report of the 2<sup>nd</sup> Meeting of the Group of Friends of the Co-Chairs, occurred in Putrajaya, Malaysia, from 8<sup>th</sup> to 12<sup>th</sup> of February, 2010, (UNEP/CBD/BS/GF-L&R/2/3) and in the Notification SCBD/BS/WDY/ps/71342, presented by the Executive Secretariat of the Convention on Biological Diversity on the 6<sup>th</sup> of April, 2010.

The analysis still considers the proposal presented on the 24<sup>th</sup> of April, by the Co-Chairs on the guidelines for civil liability as well as the document prepared by the Secretariat about the concept of imminent threat of damage (UNEP/CBD/BS/GF-L&R/3/INF/2 – *The Concept of Imminent Threat of Damage and its Legal and Technical Implications*).

The Brazilian agricultural sector understands that the negotiations of the Article 27 of the Cartagena Protocol advanced towards a decision on the 5<sup>th</sup> Meeting of the Parties that will take place in Nagoya, in October 2010. But it is necessary to define central issues, such as operator, imminent threat of damage, insurances and financial guarantees, among others, if the aim is to achieve the implementation of the Supplementary Protocol by the Parties and the accomplishment of its goals.

The analysis of the Annex I (*Supplementary Protocol on [Liability and Redress for] damage resulting from transboundary movements of living modified organisms to the Cartagena Protocol on Biosafety*) brings favorable and opposite arguments of the discussion as well as propositions of the operational texts for sensitive themes in order to provide objectivity and to make the Supplementary Protocol operational.

The arguments and proposals presented here will be revised after the 3<sup>rd</sup> Meeting of the Group of the Friends of the Co-Chairs that will occur in Kuala Lumpur, in June, addressing the new proposals towards COP-MOP5.

## Appendix I

### *Draft decision BS-V/--*

#### ***International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms***

[[*Welcoming*][*Noting*] the private-sector initiative to provide for a contractual compensation mechanism concerning recourse in the event of damage to biological diversity caused by living modified organisms,]

#### **FAVORABLE ARGUMENTS**

1. Considering that the focus of Supplementary Protocol is to allow Parties to deal with damages caused by LMOs subject to transboundary movements to the use and conservation of the biodiversity, it is relevant to take into account effective means of compensation that can achieve the restoration of significant damages. The fact that the Parties discuss supplementary means of redress shows the importance of analyzing the initiative of the private sector. Furthermore, the African, Asian and Latin-American countries seem favorable to this idea, suggesting that such mechanism can be formally debated and even recognized in the context of the Supplementary Protocol.

#### *Annex I*

#### **[SUPPLEMENTARY PROTOCOL ON [LIABILITY AND REDRESS FOR] DAMAGE RESULTING FROM TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS TO THE CARTAGENA PROTOCOL ON BIOSAFETY]**

*The Parties to this Supplementary Protocol,  
Being Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, hereinafter referred to as “the Protocol”,  
Recalling Article 27 of the Protocol,  
Have agreed as follows:*

#### **Article 1**

[The objective of this Supplementary Protocol is to contribute to ensuring that prompt, adequate and effective response measures are taken in the event of damage or imminent threat of damage to the conservation and sustainable use of biological diversity resulting from living modified organisms that finds its origin in transboundary movements.]

FAVORABLE ARGUMENTS	OPPOSITE ARGUMENTS
<p>1. It is essential to limit the scope of the Supplementary Protocol to damages to the sustainable use and conservation of biological diversity.</p>	<p>1. Imminent threat of damage is a vague and inappropriate concept due to the following reasons: a) damage in the context of the Supplementary Protocol must be serious, measurable and significant; b) the LMOs are not inherently dangerous and, by that, cannot be treated as potential causes of damages; c) the LMOs subject to transboundary movements must be approved by the Parties, what presupposes the risk analysis in each case in the terms of the Article 15 and the Annex III of the Cartagena Protocol; d) if the Protocol aims at restore adverse, significant and measurable damages, it must not treat the concept of damage based on the threat, risk or any other forms of what can be considered damage;</p> <p>2. Any mention to imminent threat of damage must necessarily be understood as an exception (proposal of operation text in the Article 2(d)).</p>

**Article 2**

1. The terms used in Article 2 of the Convention and Article 3 of the Protocol shall apply to this Supplementary Protocol.
2. In addition, for the purposes of this Supplementary Protocol:
  - (a) “Conference of the Parties serving as the meeting of the Parties to the Protocol” means the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety;
  - (b) “Convention” means the Convention on Biological Diversity;
  - (c) “Damage” means an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that:
    - (i) Is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines recognized by a competent national authority that takes into account any other human induced variation and natural variation; and
    - (ii) Is significant as set out in paragraph 3 below;

### FAVORABLE ARGUMENTS

1. The scope of the damage in the context of the Cartagena Protocol is based on the need to protect the resources of the biological diversity of supposedly adverse effects caused by the LMOs subjected to transboundary movements. This is the mandate present in the Articles 1 and 4 of the Protocol, and that must guide its implementation;
2. The mensuration and verification of an adverse effect are essential to scientifically determine alterations in the biodiversity in order to characterize any damage as significant. By the fact that the existence of transboundary movements is necessary, the work of the national competent authorities or regional authorities will be essential to address and acquire essential data on the local biodiversity and, if necessary, can be extremely useful in this verification;
3. Possible damage to human health must arise from a previous damage of a LMO to the use and conservation of the biological diversity, and must be significant and scientifically measurable.

[(d) “Imminent threat of damage” is an occurrence or occurrences determined, on the basis of best available scientific and other relevant information, to be likely to result in damage if not addressed in a timely manner;]

### OPPOSITE ARGUMENTS

1. The expression “imminent threat of damage” treats the concept of damage in abstract, and assumes that the LMOs are dangerous *per se*, which is not scientifically valid. It jeopardizes the elaboration of the Supplementary Protocol that must allow the adoption of effective measures to address concrete cases of damage;
2. The fact the Co-Chairs have required to the Secretariat a concept-paper about imminent threat of damage and its technical and legal implications points to the relevance of an in-depth analysis of the need of the Supplementary Protocol to accept the imminent threat of damage; to achieve inputs of the International Plant Protection Convention (IPPC) can be very useful considering that the decision must be science-based;
3. The concept-paper (UNEP/CBD/BS/GF-L&R/3/INF/2) considers the concept of imminent threat of damage in the different environmental treaties as the need to prevent and/or mitigate the possible damages, what demands the occurrence of previous damage cases, characterized as adverse damages to biodiversity related to a specific LMO (analysis case by case);
4. Imminent threat of damage can only be accepted as an exception, and since significant cases of damage caused by specific LMOs are characterized and reported in the terms of Article 3 of the Supplementary Protocol that can give rise to threats of new damages and, for this reason, require preventive actions;
5. The Parties are obliged to report cases of adverse damages in the context of the Supplementary Protocol as a way to allow preventive

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actions to avoid damages to the use and the conservation of the biodiversity;

6. If imminent threat of damage is adopted as a concept, it is important to assure that it may deal with use for different purposes and illegal use of LMOs.

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**Proposition of concept of IMMEDIATE THREAT OF DAMAGE**

*“Imminent threat of damage” is an occurrence or occurrences determined, on the basis of best available scientific and other relevant information, to be likely to result in damage to the conservation and use of the biological diversity if not addressed in a timely manner; In order to enable preventive measures aiming to avoid possible damages and to prevent commercial disruptions, Parties must inform the BCH effective cases of damages in the context of the Supplementary Protocol that lead to serious and adverse effects, and the BCH must establish a record with examples of damages caused by such specific LMOs.*

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[(e) “Incident” means any occurrence or series of occurrences, [originating [in][from] a transboundary movement of LMOs][having the same origin] that causes damage[ or creates [a grave and] an imminent threat of causing damage];]

**OPPOSITE ARGUMENTS**

1. The term incident is not appropriate to treat serious and measurable damages to biodiversity. Incident can represent an event without relevance, what is not in the scope of damage and the need to characterize a damage as significant;
  2. It is essential to adopt a definition of damage consistent with the objectives of the Cartagena Protocol, avoiding the need to use the word incident, that must be applied as a last resort;
  3. If the Parties agree to maintain the concept of incident, it is understood they shall characterize an event that causes a damage in the context of the Supplementary Protocol; for this reason, it is not possible to accept the expression imminent threat of damage because is not related to concrete cases.
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**Proposition of the concept of INCIDENT**

“Incident” means any occurrence or series of occurrences, originating from a transboundary movement of LMOs that causes a significant damage to the conservation and sustainable use of biological diversity.

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(f) “Operator” [in relation to response measures] means any person in [direct or indirect] [operational] control of [the activity at the time of the incident causing damage resulting from the transboundary movement of living modified organisms][the living modified organism at the time that the condition giving rise to the damage arose] [and could include, as appropriate and as determined by domestic law, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier];

FAVORABLE ARGUMENTS	OPPOSITE ARGUMENTS
<p>1. The responsibility for a significant damage caused by a specific LMO depends on a concrete case that can characterize damage to the use and conservation of the biological diversity in the terms of the Article 4 of the Cartagena Protocol. For this matter, the operator will be the one that gives cause to a damage by the inappropriate and illegal use of a LMO, by the manipulation regardless the indicated proceedings by the developer of the technology or by the fact that the adverse effects to the biodiversity not known by the time of the commercial release or for tests occurred (considering in this case, the provisions in the Annex III.4 of the Cartagena Protocol on the lack of scientific evidences);</p> <p>3. The Article 20 of the Brazilian Biosafety Law determines the accountability, what could involve everyone cited in the last bracket.</p>	<p>1. [Operational] is not a necessary word in the concept of operator. The direct or indirect control of an activity is sufficient to link an individual to a LMO in a specific moment and activity.</p> <p>2. The concept of operator cannot be exclusionary; it is mandatory to consider an analysis case by case, and the casual link among the damage, the LMO in question, and the one that was directly or indirectly in power according to the Article 6 of the Supplementary Protocol.</p>

**Proposal for OPERATOR**

“Operator” in relation to response measures means any person that has the direct and indirect control of a LMO or a product containing viable LMOs that after being subject to a transboundary movement caused an adverse damage in light of Article 2 (c) that needs to be redressed. The operator could include, as appropriate, as determined by domestic law and after an investigatory process, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier;

- (g) “Protocol” means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
- (h) “Response measures” means reasonable actions, in the event of damage [or imminent threat of damage], to:
  - (i) Avoid, minimize, contain or mitigate damage[, or take the necessary preventive measures in case of imminent threat of damage], as appropriate;
  - (ii) Restore biological diversity through actions to be undertaken in the following order of preference:
    - a. Restoration of biological diversity to the condition that existed before the damage occurred, or its nearest equivalent; and where the competent authority determines this is not possible,

- b. Restoration by, *inter alia*, replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location.

**OPPOSITE ARGUMENTS**

1. Imminent threat of damage can only be accepted as an exception, in the terms of the proposal made in the Article 2 (d).

3. A “significant” adverse effect is to be determined on the basis of factors, such as:
- (a) The long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time;
  - (b) The extent of the qualitative or quantitative changes that adversely affect the components of biological diversity;
  - (c) The reduction of the ability of components of biological diversity to provide goods and services;
  - (d) The extent of any adverse effects on human health in the context of the Protocol.

**Article 3**

1. This Supplementary Protocol applies to damage to the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. This Supplementary Protocol applies to damage resulting from transport, transit, handling and use of living modified organisms [and products thereof] provided that these [living modified organisms][activities] find their origin in a transboundary movement. The living modified organisms referred to are those:
- (a) Intended for direct use as food or feed, or for processing;
  - (b) Destined for contained use;
  - (c) Intended for intentional introduction into the environment.

FAVORABLE ARGUMENTS	OPPOSITE ARGUMENTS
1. The Article 3.2 is appropriate since it does not deal with products thereof.	1. In the Article 3.1, is it important to substitute risks to human health for damages to human health. Despite the fact that the Cartagena

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Protocol deal with risks, the negotiation of the Article 27 demands that the damages must be significant, serious and measurable. The Parties already debated the importance in substitute the word risks (abstract) for damages (real) when dealing with human health; this will allow a higher consistence and predictability to the Supplementary Protocol;

2. *Products thereof*: products thereof derived from LMOs have no relation to the concept of living organism from the Articles 3 (h) and (g) of the Cartagena Protocol, and it derails the inclusion of products thereof in he Supplementary Protocol;

3. To be admitted by the Cartagena Protocol or by any mechanism or decision in its context, it is necessary that a product thereof originated from a LMO to be biological viable and able to transfer or replicate genetic material; in this sense, when the Annex III.5 of the Cartagena Protocol treats of products thereof, it mentions that they are products originally processed from LMOs that contains new detectable combinations of replicable genetic material obtained from biotechnology;

4. The soybean meal originated from a LMO cannot transfer or replicate genetic material, and although it is a product thereof, it cannot be considered a LMO; a cheese that contains a genetically modified enzyme able to transfer its genetic material is a product that contains a LMO, and for this reason, it must be considered in the context of the Supplementary Protocol;

5. If the expression products thereof are really adopted, it is going to be in prejudice of the objectives of the Cartagena Protocol and the Article 27 itself;

6. The expression *products containing viable LMOs* is appropriate in the specific case of accepting products thereof able to transfer or replicate genetic material: the characterization of the LMO is essential;

7. In the case of the adoption of some expression to define products

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thereof originated from LMOs that are able to transfer or replicate genetic material, it is essential that the Article 2 of the Supplementary Protocol adopt a very clear definition about it.

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**Proposal of the concept of PRODUCTS CONTAINING VIABLE LMOS**

Products containing viable LMOs are products derived from a novel combination of genetic material obtained through the use of modern biotechnology that is viable and that has the ability to transfer or replicate its modified genetic material. The product can be directly obtained from an LMO, or can have an LMO in its components since the ability to transfer or replicate its genetic material is maintained.

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3. With respect to intentional transboundary movements, this Supplementary Protocol applies to damage resulting from any authorized use of the living modified organisms [and products thereof] referred to in paragraph 2.
4. This Supplementary Protocol also applies to damage resulting from unintentional transboundary movements as referred to in Article 17 of the Protocol as well as damage resulting from illegal transboundary movements as referred to in Article 25 of the Protocol.

**Article 4 (adopted)**

1. This Supplementary Protocol applies to damage that occurred in areas within the limits of the national jurisdiction of Parties resulting from activities as referred to in Article 3.
2. Parties may use criteria set out in their domestic law to address damage that occurs within the limits of their national jurisdiction.
3. Domestic law implementing this Supplementary Protocol shall also apply to damage resulting from the transboundary movements of living modified organisms from non-Parties.

**Article 5 (adopted)**

This Supplementary Protocol applies to damage resulting from a transboundary movement of living modified organisms that started after the entry into force of this Supplementary Protocol for the Party into whose jurisdiction the transboundary movement was made.

**Article 6 (adopted)**

A causal link shall be established between the damage and the activity in question in accordance with domestic law.

**Article 7**

1. A Party shall[, consistent with international obligations,] provide for response measures consistent with the provisions outlined below and shall implement them in accordance with its domestic law.

2. Parties shall require the operator, in the event of damage [or imminent threat of damage], subject to any requirements of the competent authority, to:
  - (a) Immediately inform the competent authority;
  - (b) Evaluate the damage [or imminent threat of damage]; and
  - (c) Take appropriate response measures.
3. The competent authority shall:
  - (a) Identify the operator which has caused the damage [or the imminent threat of damage];
  - (b) Evaluate the damage and determine which response measures should be taken by the operator.

FAVORABLE ARGUMENTS	OPPOSITE ARGUMENTS
1. To adopt response measures towards a supposed damage must be the focus of the Supplementary Protocol.	<p>1. (b) <i>Evaluate the damage [or imminent threat of damage]</i>: damage in the context of the Supplementary Protocol must be serious and measurable, what is essential to permit its characterization as from a specific LMO; thus it is not correct to talk about an evaluation of a threat of damage;</p> <p>2. Imminent threat of damage must be considered an exception and, in this case, it must give rise to response measures if there are known examples of damages caused by specific LMOs that lead to preventive actions aiming at avoiding new damages. The proposal of the text to the Article 2 must be considered based on this.</p>

4. The competent authority may implement appropriate response measures including in particular when the operator has failed to do so.
5. The competent authority has the right to recover from the operator the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures. Parties may provide, in their domestic law, for other situations in which the operator may not be required to bear the costs and expenses.

FAVORABLE ARGUMENTS
1. To the extent the Supplementary Protocol aims at creating the foundations in order to allow the Parties to implement regulations concerning liability and redress for damages caused by LMOs to the use and conservation of biodiversity, the role of the Competent National

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Authorities as the ones to determine the actions to be taken by the operators, the appropriate response measures and how the evaluation and mensuration process will take place in effective cases of damage will be essential;

2. The role of the Brazilian Biosafety Law and the Competent National Authorities before the Cartagena Protocol must be the basis for the implementation of the Supplementary Protocol.

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6. Decisions of the competent authority requiring the operator to take response measures should be reasoned. Such decisions should be notified to the operator. Domestic law shall provide for remedies, including the opportunity for an administrative or judicial review of such decisions. The competent authority shall, in accordance with domestic law, also inform the operator of the available remedies. Recourse to such remedies shall not impede the competent authority from taking response measures in appropriate circumstances, unless otherwise provided by domestic law.

7. In implementing this Article and with a view to defining the specific response measures to be required or taken by the competent authority, Parties may, as appropriate, assess whether response measures are already addressed by their domestic law on civil liability.

**Article 8 (adopted)**

1. Parties may provide, in their domestic law, for the following exemptions:

- (a) Act of God or *force majeure*;
- (b) Act of war or civil unrest.

2. Parties may provide, in their domestic law, for any other exemptions or mitigations as they may deem fit.

**Article 9 (adopted)**

This Supplementary Protocol shall not limit or restrict any right of recourse or indemnity that an operator may have against any other person.

**Article 10 (adopted)**

Parties may provide, in their domestic law, for relative and/or absolute time limits including for actions related to response measures and the commencement of the period to which a time limit applies.

**Article 11 (adopted)**

Parties may provide, in their domestic law, for financial limits for the recovery of costs and expenses related to response measures.

## **Article 12**

1. [Parties may[, consistent with international [law][obligations],] require the operator to establish and maintain, during the period of any applicable time limit, financial security, including through self-insurance.]
2. [Parties are urged to take measures to encourage the development of financial security instruments and markets by the appropriate economic and financial operators, including financial mechanisms in case of insolvency, with the aim of enabling operators to use financial guarantees to cover their responsibilities under domestic law implementing this Supplementary Protocol.]

### **OPPOSITE ARGUMENTS**

1. The Article 12 cannot be accepted for the following reasons:

- a) To the extent the Article 15 of the Cartagena Protocol requires a risk analysis for LMOs subjected to transboundary movements and the Parties that usually approve them demands accuracy processes of risk analysis, the Supplementary Protocol should not charge insurance or financial guarantees to prevent or enable the restoration of possible damages;
  - b) By the fact there is no clear evidence on the LMO damages to the biodiversity, and, in principle, a non-LMO could also cause damages, it is discriminatory to create insurances only to LMOs, what would increase the costs of countless products around the world, even though this is not necessary to accomplish the goals of the Cartagena Protocol and the Supplementary Protocol;
  - c) There is no way to establish an insurance or other financial guarantee against possible damages if there is no concrete examples to enable how to measure possible prejudices or impacts; this creates more uncertainties on the costs of those guarantees, what would have to be done by any operator, what makes this obligation hard to be implemented and really expensive;
2. The Article 12.2 is also not acceptable by the fact it can result in trade restrictions and high costs in the trade relations with specific countries, even though this is not relevant and necessary to avoid LMO damages to the biodiversity.

## **Article 13**

1. Parties shall provide, in their domestic law, for rules and procedures that address damage resulting from transboundary movements of living modified organisms. To implement this obligation, Parties shall provide for response measures in accordance with this Supplementary Protocol and may, as appropriate:
  - (a) Apply their existing domestic laws, including where applicable general rules and procedures on civil liability;
  - (b) Apply or develop civil liability rules and procedures specifically for this purpose; or
  - (c) Apply or develop a combination of both.
- [2. Parties [should][shall][may] assess whether their domestic law provides for adequate rules and procedures on civil liability for material or personal damage incidental to the damage as defined in Article 2, paragraph 2 (c), and consider:

- (a) Applying their existing domestic laws, including where applicable general rules and procedures on civil liability;
- (b) Applying or developing civil liability rules and procedures specifically for this purpose; or
- (c) Applying or developing a combination of both.]<sup>1</sup>

3. When developing rules and procedures as referred to in subparagraphs (b) or (c) of paragraph[s] 1 [or 2] above, Parties [should][shall][may], as appropriate, address, *inter alia*, the following elements:

- (a) Damage;
- (b) Standard of liability including strict or fault-based liability;
- (c) Channelling of liability, where appropriate;
- (d) Right to bring claims.

FAVORABLE ARGUMENTS	OPPOSITE ARGUMENTS
<p>1. The Supplementary Protocol must be the basis for the Parties to adopt regulations that aims at addressing possible damages to LMOs to the use and conservation of the biological diversity.</p>	<p>1. In the Articles 13.2 and 13.3, the Supplementary Protocol cannot be mandatory when treats of proceedings on civil liability; the Parties agreed in the MOP 4 (2008) to negotiate a mechanism of L&amp;R focused on a binding decision based on an administrative approach, and this decision defines the mandate of the Supplementary Protocol that cannot demand obligations in the context of civil liability;</p> <p>2. To encourage the Parties to adopt measures concerning civil liability is possible, what avoids the use of the words [should] or [shall] as in the Articles 12.2 and 12.3;</p> <p>3. The Brazilian Biosafety Law must serve as a parameter for the implementation of the Cartagena Protocol and the Supplementary Protocol.</p>

**Article 14 (adopted)**

The Conference of the Parties serving as the meeting of the Parties to the Protocol shall undertake a review of the effectiveness of this Supplementary Protocol five years after its entry into force and every five years thereafter, provided information requiring such a review has been made available by Parties. The review shall be undertaken in the context of the assessment and review of the Protocol as specified in

<sup>1</sup> The African Group reserves the right to re-visit the wording of this paragraph.

Article 35 of the Protocol, unless otherwise decided by the Parties to this Supplementary Protocol. The first review shall include a review of the effectiveness of Article 13.

**Article 15 (adopted)**

This Supplementary Protocol shall not affect the rights and obligations of States under the rules of general international law with respect to the responsibility of States for internationally wrongful acts.

**Article 16 (adopted)**

1. Subject to paragraph 2 of Article 32 of the Convention, the Conference of the Parties serving as the meeting of the Parties to the Protocol shall serve as the meeting of the Parties to this Supplementary Protocol.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol shall keep under regular review the implementation of this Supplementary Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Supplementary Protocol and, *mutatis mutandis*, the functions assigned to it by paragraphs 4 (a) and (f) of Article 29 of the Protocol.

**Article 17 (adopted)**

The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Supplementary Protocol.

**Article 18 (adopted)**

1. This Supplementary Protocol shall supplement the Protocol and shall neither modify nor amend the Protocol.

2. Nothing in this Supplementary Protocol shall derogate from the rights and obligations of the Parties to this Supplementary Protocol under the Convention and the Protocol.

3. Except as otherwise provided in this Supplementary Protocol, the provisions of the Convention and the Protocol shall apply to this Supplementary Protocol.

**Article 19**

This Supplementary Protocol shall be open for signature at [...] by Parties to the Protocol from [...] to [...], and at the United Nations Headquarters in New York from [...] to [...].

**Article 20 (adopted)**

1. This Supplementary Protocol shall enter into force on the ninetieth day after the date of deposit of the fortieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Protocol.
2. This Supplementary Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves it or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval, or accession, or the date on which the Protocol enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

#### **Article 21**

[No reservations may be made to this Supplementary Protocol.]

#### **Article 22 (adopted)**

1. At any time after two years from the date on which this Supplementary Protocol has entered into force for a Party, that Party may withdraw from this Supplementary Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.
3. Any Party which withdraws from the Protocol in accordance with Article 39 of the Protocol shall be considered as also having withdrawn from this Supplementary Protocol.

#### **Article 23 (adopted)**

The original of this Supplementary Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Supplementary Protocol.

DONE at [...] on this [...] day of [...] two thousand and [...].

**DRAFT GUIDELINES ON CIVIL LIABILITY AND REDRESS IN THE FIELD OF DAMAGE RESULTING FROM TRANSBOUNDARY MOVEMENTS OF  
LIVING MODIFIED ORGANISMS  
(Co-chairs draft Guidelines circulated on April 24<sup>th</sup>, 2010)**

The following analysis considers that the guidelines on civil liability must incentive the Parties to effectively implement regulations aiming to address cases of damages to the use and conservation of the biological diversity, the main goal of the Cartagena Protocol.

Proposal of Co-Chairs

**Guideline 1**

Objective

The objective of these Guidelines is to provide guidance to Parties regarding domestic rules and procedures on civil liability for damage resulting from transboundary movements of living modified organisms, taking also into account risks to human health.

**Guideline 2**

Use of Terms

1. The terms used in Article 2 of the Convention, Article 3 of the Protocol and Article 2 of the Supplementary Protocol apply to these Guidelines except as otherwise defined in paragraph 2 below.
2. In addition, for the purposes of these Guidelines:
  - (a) "Damage" means;
    - (i) Loss of life or personal injury [incidental to damage to the conservation and sustainable use of biological diversity];
    - (ii) Loss of or damage to property [incidental to damage to the conservation and sustainable use of biological diversity];
    - (iii) Pure economic loss;
    - (iv) Costs of response measures;
    - (v) Damage to the conservation and sustainable use of biological diversity not redressed under the Supplementary Protocol.

## OPPOSITE ARGUMENTS

1. The definition of damage in the Supplementary Protocol, appointed in the Article 2 (c) follows the scope of the Cartagena Protocol to seek to prevent damages to the use and conservation of the biological diversity, taking into account damages to the human health and to determine that these damages must be significant, serious and measurable. The adoption of guidelines on civil liability cannot broaden this scope as cited in the items 2(a) (i) (ii) and (iii) above;
2. To create *guidelines* that help Parties to adopt L&R regimes is very important to foster the implementation of the Cartagena Protocol, but this does not mean that these guidelines must exceed the predicted goals of the Protocol that has been extensively negotiated and discussed by the Parties.

(b) “Damage to the conservation and sustainable use of biological diversity” means damage as defined in Article 2, paragraph 2(c), of the Supplementary Protocol;

(c) “Pure economic loss” means loss of income, unaccompanied by personal injury or damage to property, directly deriving from an economic interest in any use of components of biological diversity and incurred as a result of damage to the conservation and sustainable use of biological diversity;

(d) “Supplementary Protocol” means [Supplementary Protocol on [Liability and Redress for] Damage Resulting from Transboundary Movements of Living Modified Organisms to the Cartagena Protocol on Biosafety].

### Guideline 3

#### Scope

1. These Guidelines apply to damage resulting from transport, transit, handling and use of living modified organisms [and products thereof] provided that these [living modified organisms][activities] find their origin in a transboundary movement. The living modified organisms referred to are those:

- (a) Intended for direct use as food or feed, or for processing;
- (b) Destined for contained use;
- (c) Intended for intentional introduction into the environment.

2. With respect to intentional transboundary movements, these Guidelines apply to damage resulting from any authorized use of the living modified organisms [and products thereof] referred to in paragraph 1 above.

3. These Guidelines also apply to damage resulting from unintentional transboundary movements as referred to in Article 17 of the Protocol as well as damage resulting from illegal transboundary movements as referred to in Article 25 of the Protocol.

#### OPPOSITE ARGUMENTS

1. To include products thereof in the scope of the guidelines on civil liability means to extrapolate the limits of the Cartagena Protocol since the LMO must have the ability to transfer or replicate its genetic material. Processed products or products thereof that are not able to transfer or replicate genetic material cannot affect the biological diversity and cannot be considered in the scope of any instrument adopted in the Cartagena Protocol;

2. The appropriate expression to embrace products that are able to transfer or replicate genetic material is "products that contains viable LMOs". A table made with a genetically modified tree cannot transfer or replicate its genetic material, unless this type of wood have not been processed and have sprouts; the table is a product thereof that cannot transfer or replicate genetic material in question and, for this reason, cannot be accepted in the context of the Protocol. However, a genetically modified enzymes or bacteria used to produce dairy products or beverages that have the ability to transfer or replicate genetic material must be considered in the context of the Protocol and the Supplementary Protocol. There are various examples that would need to be accessed, and this analysis must be taken into account in order to enable an accurate way to address LMOs in the context of the Cartagena Protocol and its decisions;

3. When the Annex III.4 of the Cartagena Protocol refers to products thereof, it refers expressly to products thereof originated from LMOs that contains new detectable combinations of replicable genetic material obtained from biotechnology; this reinforces that the ability to transfer and/or replicate genetic material is an essential requirement for the context of the Supplementary Protocol.

#### Guideline 4

##### Liability

1. The standard of liability should be strict where the damage has been caused by a living modified organism that a risk assessment has identified as hazardous.
2. In cases where the standard of liability is strict, liability should be channelled to the operator.
3. In cases where the standard of liability is strict and two or more operators have caused the damage, their liability should be joint and several.
4. In cases where the standard of liability is strict, the right of recourse or indemnity that an operator may have against another person should not be limited or restricted.

**Guideline 5**

## Exemptions

Parties should consider the application of exemptions from liability, in particular:

- (a) Act of God or force majeure;
- (b) Act of war or civil unrest.

**OPPOSITE ARGUMENTS**

1. The exemptions provided in the Report of the second Group of Friends of the Co-Chairs meeting should be included in any Guidelines on Civil Liability. Parties must have all relevant options available to handle exemptions in their domestic regulations, as the following options: (a) Intervention by a third party; (b) A specific order imposed by a public authority on the operator and the implementation of such order caused the damage; (c) An activity expressly authorized by and fully in conformity with an authorization given under domestic law; and (d) An activity not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the activity was carried out.

**Guideline 6**

## Time Limits

Parties should consider the application of relative and/or absolute time limits, including the commencement of the period to which a time limit applies.

**Guideline 7**

## Financial Limits

Parties should consider the application of financial limits in cases where the standard of liability is strict.

**Guideline 8**

## Financial Security

1. [Parties may[, consistent with international [law][obligations],] require the operator to establish and maintain, during the period of any applicable time limit, financial security, including through self-insurance.]
2. [Parties are urged to take measures to encourage the development of financial security instruments and markets by the appropriate economic and financial operators, including financial mechanisms in case of insolvency, with the aim of enabling operators to use financial guarantees to cover their responsibilities.]

#### OPPOSITE ARGUMENTS

1. To require that different operators maintain insurances or financial guarantees during the time limit that the Parties can define, that would not be the same in different Parties, will create high and unnecessary costs to prevent possible damages in the context of the Supplementary Protocol;
2. Considering the concept of operator in Article 2(c) of the Supplementary Protocol, and that the characterization of who is the operator will depend on a concrete and significant damage caused by a LMO in the light of provisions in the Article 3, it creates the need that all possible operators have insurances even without knowing if the LMO in question could cause a damage in the terms of the Protocol, what is against the goals that originated the Cartagena Protocol;
3. The possibility that food and feed products suffer an increase of costs to assure that the redress of possible damages, that are not known and are not quantifiable is very feasible and dangerous;
4. To become possible to create insurances of this nature, it is necessary to be clear what damages are possible to occur and the estimation of the costs of redress; without these requirements, it is not possible to think about the establishment of an insurance or a financial guarantee.
5. Alternative means of redress must be seek by the Supplementary Protocol and by the Parties.

#### Guideline 9

##### Claims for Compensation

1. Any person or group of persons, including public authorities, should be entitled to claim compensation for loss of life or personal injury, loss of or damage to property and pure economic loss in consequence of the occurrence of damage resulting from the transboundary movement of living modified organisms in addition to, where appropriate, the reimbursement of the costs of response measures.
2. Parties may allow claims for compensation of damage to the conservation and sustainable use of biological diversity.

#### OPPOSITE ARGUMENTS

1. The goal of these Guidelines on Civil Liability and the Supplementary Protocol is to conduct the Parties to implement L&R rules to address possible damages of LMOs to the use and conservation of the biological diversity. When it occurs a damage, the involvement of the competent national authorities is extremely important;
2. The Brazilian Regulation, which determines the objective responsibility in cases of damages to the environment, the Federal Prosecution Service and the State Prosecution Service have the legitimacy to propose civil or criminal responsibility lawsuits for damages to the environment according to Article 14, (1), of the Law 6938/1981, which establishes the Environmental National Policy. Thus, it is not possible to accept the proposal expressed in the item (1), because besides of creating conflicts with the domestic legislation, it would allow unfounded questioning and demands about the effects allegedly harmful of biotechnology, involving products that are not able to multiple or transfer genetic material.

#### **Guideline 10**

##### Settlement of Claims

1. Parties should provide for civil law procedures to settle claims for compensation of damage.
2. Where agreed by both or all parties, claims for compensation of damage may be submitted to arbitration in accordance with the Permanent Court of Arbitration Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment.

#### **Guideline 11**

##### Access to Information

Any person or group of persons sustaining damage should be entitled to any information directly relevant to the presentation of a claim for compensation of damage from the operator or the competent authority in possession of such information, unless such disclosure is not permitted under Article 21 of the Protocol, is specifically prohibited by law or violates the legally protected interests of third parties.