



THE NAGOYA – KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS TO THE CARTAGENA PROTOCOL ON BIOSAFETY

An Introductory Note in Preparation for Signature and Ratification

I. BACKGROUND

- 1. Liability and redress for damage resulting from the transboundary movements of living modified organisms was one of the most controversial issues during the negotiations of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Some were in favour of rules on liability and redress being developed and included in the Protocol while others were opposed to the idea of having any such provision in the Protocol. Some argued that even if there was consensus to have substantive rules on liability and redress in the Protocol, there was not enough time to elaborate such rules, which were believed to be highly complex and sensitive to several Governments. As the negotiations on the Protocol entered the final phase, negotiators realized that there was a lack of both consensus and sufficient time to deal with any contents of possible rules on liability and redress. It was, therefore, finally accepted to continue the debate in a more deliberate manner after the adoption and entry into force of the Protocol.1/
- 2. Accordingly, the Biosafety Protocol was adopted in January 2000. It contains a provision committing the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP, the governing body of the Protocol) to adopt, at its first meeting, a process for the elaboration of liability and redress rules. That commitment was reflected in Article 27 of the Protocol which states as follows:

"The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of ongoing processes in international law on these matters, and shall endeavour to complete this process within four years."

3. The Intergovernmental Committee on the Cartagena Protocol on Biosafety, an interim arrangement established following the adoption of the Protocol to oversee preparations for the entry into force of the Protocol, carried out extensive work on a number of items, including liability and redress in the context of Article 27 of the Protocol. The Biosafety Protocol entered into force on 11 September 2003. Soon after, in February 2004, the first meeting of the COP-MOP was held. The meeting decided to establish, on the basis of the work and recommendations of the Intergovernmental Committee, an Openended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress to carry out the process pursuant to Article 27 of the Protocol.2/

^{2/} Decision BS-I/8, First meeting of the COP-MOP





<u>1</u>/ For a complete record of the negotiations please visit the Secretariat's web page at this link: http://bch.cbd.int/protocol/cpb art27 info.shtml.

- 4. The Working Group met five times between 2005 and 2008. The result of the five meetings of the Working Group supplemented by the work of a small group that met just before COP-MOP 4 was submitted to the fourth meeting of the Parties. Negotiations also continued in a contact group setting during COP-MOP 4. All these deliberations advanced the negotiations well. Nevertheless, they were not sufficient to resolve all the outstanding issues and to lead the process to finalization in 2008. Consequently, COP-MOP 4 adopted a decision3/ in which Parties agreed to establish a Group of the Friends of the Co-Chairs of the former Working Group to continue the negotiations.
- 5. The Group of Friends of the Co-Chairs met four times between 2008 and 2010. It finally agreed to the text of the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety and submitted its report, including the text and a draft decision on 11 October 2010 for the consideration and adoption of the fifth meeting of the COP-MOP in Nagoya, Japan. The Supplementary Protocol was adopted on 15 October 2010. The decision that adopted the Supplementary Protocol, i.e. decision BS-V/11, calls upon Parties to the Biosafety Protocol to sign the Supplementary Protocol at their earliest opportunity from 7 March 2011 to 6 March 2012. Parties to the Biosafety Protocol are also called upon to deposit their instruments of ratification, acceptance or approval or instruments of accession, as appropriate, as soon as possible.
- 6. The present note is intended to provide some basic information about the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress with a view to facilitating signature, ratification, acceptance, approval or accession to the Supplementary Protocol by States and regional economic integration organizations that are Parties to the Cartagena Protocol on Biosafety.

II. WHAT IS THE NAGOYA – KUALA LUMPUR SUPPLEMENTARY PROTOCOL?

- 7. The Nagoya Kuala Lumpur Supplementary Protocol is a treaty intended to supplement the Cartagena Protocol on Biosafety. Its adoption marks the completion of the negotiations that started in earnest in 1996 at the first meeting of the Open-ended Ad Hoc Working Group on Biosafety, an intergovernmental working group mandated by the second meeting of the Conference of the Parties to the Convention on Biological Diversity to negotiate a biosafety protocol.
- 8. A number of countries believed, from the outset of the negotiations on a biosafety protocol, that there was a need to establish liability and redress rules that specifically apply to living modified organisms or to activities involving such organisms. It was argued that there must be an obligation to take responsibility and to provide redress in the event risks associated with living modified organisms materialize and damage occurs. In that regard, Article 27 of the Biosafety Protocol took the first step, i.e. recognizing that damage could result from the transboundary movements of living modified organisms and, therefore, a multilateral process to discuss the matter was necessary. The subsequent negotiation process was, therefore, focused on issues such as the definition of damage, the attribution of responsibility to a person or persons for that damage and the kind of response measures that need to be taken to redress the damage or to prevent it, and what the nature of the instrument resulting from the negotiations should be. The Supplementary Protocol is a response to and fulfilment of Article 27 of the Biosafety Protocol.
- 9. The Supplementary Protocol seems also to be inspired, as stated in its preamble, by Principle 13 of the 1992 Rio Declaration on Environment and Development which appeals to States to "cooperate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control".
- 10. The objective of the Supplementary Protocol as stated in its Article 1 is to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health by providing international rules and procedures in the field of liability and redress relating to living modified organisms.

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Decision BS-IV/12, Fourth meeting of the COP-MOP

- 11. The Supplementary Protocol defines "damage" as an adverse effect on the conservation and sustainable use of biological diversity that is measurable and significant.4/ It also provides for an indicative list of factors that should be used to determine the significance of an adverse effect5/. Once the threshold of significant damage has been met, the need for response measures arises. The Supplementary Protocol is the first multilateral environmental agreement to define 'damage to biodiversity'. Traditional damage, which is common in third-party civil liability instruments, and which includes personal injury, loss or damage to property or economic interests, is not covered by the Supplementary Protocol.
- 12. The Supplementary Protocol is the second liability instrument to be concluded in the context of a multilateral environmental agreement following the 1999 Protocol on Liability and Compensation to the Basel Convention on the Transboundary Movement of Hazardous Wastes (the "Basel Protocol"). The Basel Protocol adopts a civil liability approach, in particular in its definition of damage. It covers traditional damage due to an incident occurring during a transboundary movement of hazardous wastes and other wastes and their disposal. It envisages compensation for such damage, including the recovery of costs of preventive and reinstatement measures in the event of environmental damage. It enters into force if ratified or acceded to by twenty Parties to the Convention. However, only ten instruments of ratification or accession have been deposited so far.
- 13. The Nagoya Kuala Lumpur Supplementary Protocol has adopted an administrative approach for addressing damage resulting from living modified organisms. The elements of the administrative approach are specified in Article 5 of the Supplementary Protocol. Article 5 deals with how, when and who should take response measures in the event of damage or sufficient likelihood of damage resulting from living modified organisms that find their origin in a transboundary movement. This provision, together with the definitions of 'damage' and 'response measures', is believed to be the core of the Supplementary Protocol.
- 14. In 2002, the Secretariat of the Convention on Biological Diversity, which is also the Secretariat for the Cartagena Protocol on Biosafety, had conducted a review of national measures relevant to liability and redress involving living modified organisms. 6/ The findings indicated that a number of national legal systems operate through both civil liability and administrative mechanisms. Under civil liability systems, some countries have enacted specific laws to provide a basis for claiming compensation for environmental damage suffered in which activities involving living modified organisms are thought to be included. In the case of administrative mechanisms, a typical characteristic was the use of licensing or authorization to administer the implementation of laws. 7/ Where damage occurred, these mechanisms typically provided for measures by public authorities to require the license- or permit-holders to take actions or the authority itself to take measures to prevent further damage and restore the environment.

III. WHY NAME THE SUPPLEMENTARY PROTOCOL AFTER TWO CITIES, NAGOYA AND KUALA LUMPUR?

15. It is common practice to name treaties after their place of adoption. The Supplementary Protocol was adopted in Nagoya, Japan following the final and critical negotiations. It was also noted, however, that Kuala Lumpur, Malaysia, has a special place in the history of the Supplementary Protocol. Kuala Lumpur was the city where the initial mandate for the negotiations on liability and redress under Article 27 of the Protocol was adopted on 27 February 2004 by the first meeting of the COP-MOP, and it hosted the last two negotiation sessions preceding Nagoya. Parties considered these events as crucial and, therefore, decided to acknowledge the places where these events took place by attaching the names of the two cities to the Supplementary Protocol.

^{4/} Paragraph 2, Article 2 of the Supplementary Protocol.

^{5/} Paragraph 3, Article 2

^{6/} See document UNEP/CBD/ICCP/3/3, available at the Secretariat's website:

http://www.cbd.int/doc/meetings/bs/iccp-03/official/iccp-03-03-en.pdf.

^{7/} *Ibid*, paragraph 7.

IV. WHAT IS THE CORE OBLIGATION OF A PARTY TO THE SUPPLEMENTARY PROTOCOL?

- 16. The focus of the Supplementary Protocol on Liability and Redress is to support Parties in their efforts to address damage to biological diversity resulting from living modified organisms by providing some essential elements that may be taken into account at the national level in developing or implementing legislative, administrative or judicial rules or procedures relevant to liability and redress. Parties are required to provide, in their domestic law, for rules and procedures that address damage.8/ This requirement does not necessarily entail the enactment of a new law. It can be fulfilled by applying existing domestic law.
- 17. The central obligation that a Party to the Supplementary Protocol assumes is to provide for response measures in the event of damage resulting from living modified organisms. 9/ In that regard, Parties to the Supplementary Protocol have to:
- (a) Require the appropriate operator, in the event of damage, to (i) immediately inform the competent authority; (ii) evaluate the damage; and (iii) take appropriate response measures.
- (b) Make sure that the competent authority (i) identifies the operator which has caused the damage; (ii) evaluates the damage; and (iii) determines which response measures should be taken by the operator and provides reasons for such determination.
- (c) Require the operator to take appropriate response measures where there is sufficient likelihood that damage will result if timely response measures are not taken.
- (d) Put in place a requirement whereby the competent authority itself may implement appropriate response measures, in particular in situations where the operator has failed to do so, subject to a right of recourse by the competent authority to recover, from the operator, costs and expenses incurred in relation to the implementation of the response measures.
- 18. "Operator" according to the Supplementary Protocol, means any person in direct or indirect control of the living modified organism. The determination of who the specific operator might be in any given circumstance is left to domestic law.10/
- 19. The Supplementary Protocol defines "response measures" as reasonable actions to (i) prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; and (ii) restore biological diversity. The operator or the competent authority, as the case may be, is also expected to undertake actions following a specified order of preference as part of the response measures for the restoration of biological diversity. 11/
- 20. Finally, it is appropriate to note that the response measures defined in the Supplementary Protocol are to be implemented in accordance with domestic law. 12/ This provision provides Parties with maximum flexibility in the implementation of their treaty obligation.

V. WHY SIGN AND RATIFY THE SUPPLEMENTARY PROTOCOL?

21. The conclusion of the Cartagena Protocol on Biosafety has been hailed as a significant step forward in providing an international regulatory framework that reconciles the respective needs of trade and environmental protection regarding a rapidly growing biotechnology industry. The conclusion of the Supplementary Protocol on Liability and Redress is equally significant because it puts in place the missing piece from the Protocol on Biosafety and makes it complete ten years after its adoption.

<u>8/</u> Paragraph 1 of Article 12 of the Supplementary Protocol.

^{9/} Article 5, paragraph 1 of Article 12 of the Supplementary Protocol.

^{10/} Paragraph 2(c) of Article 2 of the Supplementary Protocol.

^{11/} Paragraph 2(d) of Article 2 of the Supplementary Protocol.

<u>12/</u> Paragraph 8 of Article 5 of the Supplementary Protocol.

- 22. The Supplementary Protocol creates further confidence and an enabling environment for the environmentally sound application of modern biotechnology, making it possible to derive maximum benefit from the potential that the technology has to offer while, on the one hand, minimizing the possible risks to biodiversity and to human health and, on the other, adopting the necessary redress mechanisms in the event something goes wrong and biodiversity suffers damage. Signing and subsequently ratifying or acceding to the Supplementary Protocol would demonstrate yet another commitment to the conservation and sustainable use of biological diversity.
- 23. The entry into force of the Supplementary Protocol will also create an incentive to operators to do their best to ensure safety in the development and handling of living modified organisms. It is expected to be an important additional tool for Parties to fulfil their obligations under the Biosafety Protocol to "ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health"13/.
- 24. Furthermore, in adopting the Supplementary Protocol, the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol has recognized the need for complementary capacity building measures with a view to assisting developing countries to develop and/or implement their domestic laws that have relevance to the implementation of the Supplementary Protocol. The ratification and entry into force of the Supplementary Protocol would, therefore, present another opportunity for both developed and developing country Parties to the Cartagena Protocol on Biosafety to forge further cooperation in the building of capacities that are necessary to support the safe development and use of modern biotechnology.
- 25. Finally, as mentioned earlier, the Nagoya Kuala Lumpur Supplementary Protocol is different from the Basel Protocol in its approach. The latter is based on civil liability rules. The Supplementary Protocol's administrative approach appears to be aligned with national legal systems which use administrative mechanisms to address environmental damage. The Supplementary Protocol also provides that Parties may apply their existing domestic law, including general rules and procedures on civil liability, or apply or develop civil liability rules and procedures specific to damage resulting from living modified organisms. 14/ Many believe that the compromise of having a treaty on liability and redress for biodiversity damage based on an administrative approach with a civil liability option at the national level provides sufficient flexibility and space to accommodate existing regulatory approaches. Such a flexible approach is in turn believed to facilitate expeditious signature and subsequent ratification and entry into force of the Supplementary Protocol.

VI. HOW TO SIGN AND RATIFY OR ACCEDE TO THE SUPPLEMENTARY PROTOCOL

26. States and regional economic integration organizations that are Parties to the Cartagena Protocol on Biosafety are eligible to become party to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

(a) Signature

- 27. The Nagoya Kuala Lumpur Supplementary Protocol remains open for signature from 7 March 2011 to 6 March 2012 at the United Nations Headquarters in New York. Parties to the Protocol on Biosafety are encouraged to sign the Supplementary Protocol on 7 March 2011 or as soon as possible thereafter.
- 28. Signature is an expression of goodwill towards the adoption of an international agreement without necessarily implying acceptance of any legal commitment to the provisions of the agreement. It, however, represents a commitment to refrain from acts that would defeat the object and purpose of the agreement.

^{13/} Paragraph 2 of Article 2 of the Cartagena Protocol on Biosafety.

^{14/} Article 12 of the Supplementary Protocol

Signature is also an indication of the signatory's intention to take steps to express its consent to be bound by the agreement at a later date. 15/

- 29. The Secretary-General, as depository, requires a valid instrument of full powers to sign a treaty. Accordingly, full powers need to be issued for the signature of the Supplementary Protocol. Full powers must:
 - (i) be signed by a head of State, head of Government or minister of foreign affairs;
 - (ii) indicate the title of the treaty, i.e. Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety; and
 - (iii) state the full name and title of the representative authorised to sign.
- 30. Such specific powers may not be needed in the case of some countries that have deposited general full powers with the Secretary-General authorising a specified representative to sign all treaties of a certain kind. A head of State, head of Government or minister for foreign affairs may sign a treaty without an instrument of full powers.

(b) Depositing instruments of ratification, acceptance, approval or accession

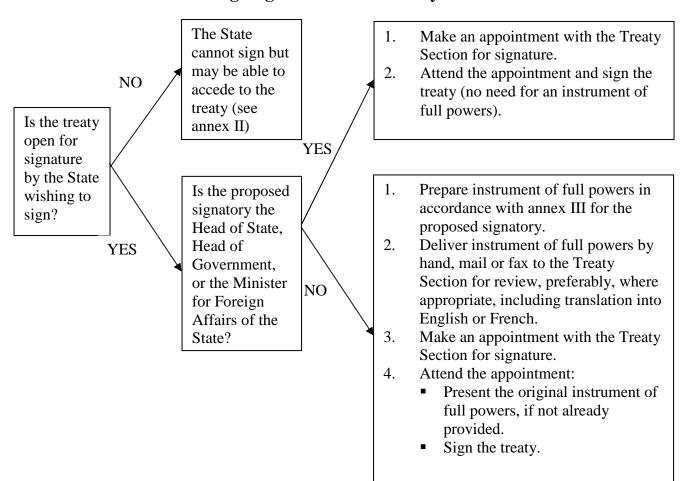
- 31. The States or regional economic integration organizations that sign the Supplementary Protocol before the closing date for signature may then proceed to take steps at the domestic level that would lead to depositing their instruments of ratification, acceptance or approval with the Secretary General.
- 32. Those Parties to the Protocol on Biosafety that may not be able to sign the Supplementary Protocol by 6 March 2012 but wish to become Parties may do so by acceding to it. Accession is different from the other procedures, namely ratification, acceptance and approval. Accession enables States to become Parties to an international agreement without having previously signed it. Nevertheless, ratification, acceptance, approval and accession have the same legal effect.
- 33. According to recognized international practice, instruments of ratification, acceptance, approval or accession are always a result of an act of a legislative organ or an executive decision of the head of State or Government to express the Government's consent to be bound by an international agreement. The relevant instruments are issued and signed either by a head of State or Government or by a minister for foreign affairs and represent an expression of explicit acceptance, at the international level, to be legally bound by the international agreement.
- 34. Like many other treaties, the entry into force of the Supplementary Protocol depends on the submission of instruments of ratification, acceptance, approval or accession by a specific minimum number of States. The Supplementary Protocol requires the deposit of such instruments from 40 Parties to the Cartagena Protocol on Biosafety for it to enter into force.
- 35. Annexes I and II, below, detail how to arrange with the Treaty Section of the United Nations in New York to: (i) sign a treaty; and (ii) ratify, accept, approve or accede to a treaty, while model instruments of: (i) full powers; (ii) ratification, acceptance and approval; and (iii) accession are attached as annexes III to V.16/

^{15/} Article 18 of the Vienna Convention on the Law of Treaties.

 $[\]underline{16}$ / Treaty Handbook, prepared by the Treaty Section of the Office of Legal Affairs, United Nations, (2006 Reprint)

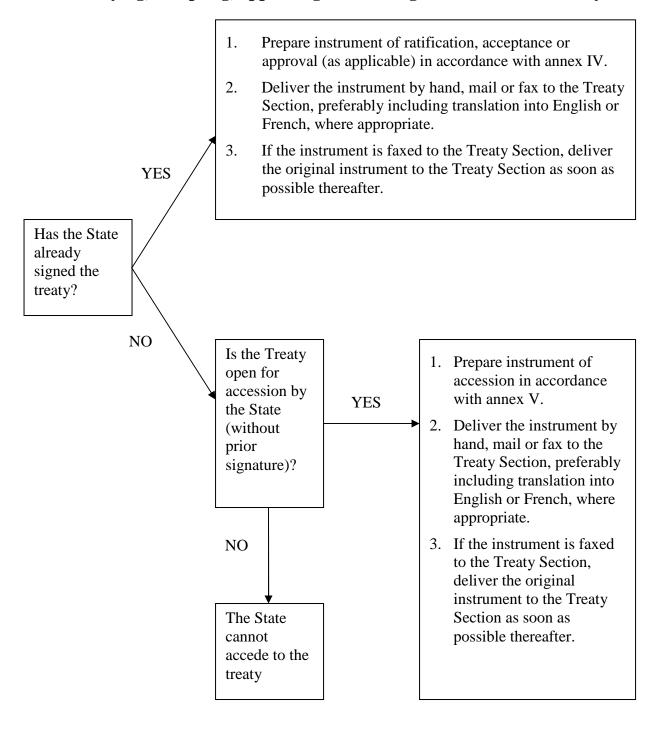
Annex I

Signing a multilateral treaty



Annex II

Ratifying, accepting, approving or acceding to a multilateral treaty



Annex III

MODEL INSTRUMENT OF FULL POWERS

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

FULL POWERS
I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs],
HEREBY AUTHORISE [name and title] to [sign *, ratify, denounce, effect the following declaration in respect of, etc.] the [title and date of treaty, convention, agreement, etc.] on behalf of the Government of [name of State].
Done at [place] on [date].
[Signature]

^{*} Subject to the provisions of the treaty, one of the following alternatives is to be chosen: [subject to ratification] or [without reservation as to ratification]. Reservations made upon signature must be authorised by the full powers granted to the signatory.

Annex IV

MODEL INSTRUMENT OF RATIFICATION, ACCEPTANCE OR APPROVAL

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

$[{\bf RATIFICATION\,/\,ACCEPTANCE\,/\,APPROVAL}]$

WHEREAS the [title of treaty, convention, agreement, etc.] was [concluded, adopted, opened for signature, etc.] at [place] on [date],

AND WHEREAS the said [treaty, convention, agreement, etc.] has been signed on behalf of the Government of [name of State] on [date],

NOW THEREFORE I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs] declare that the Government of [name of State], having considered the above mentioned [treaty, convention, agreement, etc.], [ratifies, accepts, approves] the same and undertakes faithfully to perform and carry out the stipulations therein contained.

IN WITNESS WHEREOF, I have signed this instrument of [ratification, acceptance, approval] at [place] on [date].

[Signature]

Annex V

MODEL INSTRUMENT OF ACCESSION

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

ACCESSION
WHEREAS the [title of treaty, convention, agreement, etc.] was [concluded, adopted, opened for signature, etc.] at [place] on [date],
NOW THEREFORE I , [name and title of the Head of State, Head of Government or Minister for Foreign Affairs] declare that the Government of [name of State], having considered the above mentioned [treaty, convention, agreement, etc.], accedes to the same and undertakes faithfully to perform and carry out the stipulations therein contained.
IN WITNESS WHEREOF, I have signed this instrument of accession at [place] on [date].
[Signature]