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Subject: Annex to the Proposal for a Decision of the European Parliament and of the Council on the conclusion of the Nagoya-Kuala Lumpur Supplementary protocol on Liability and Redress to the Cartagena Protocol on Biosafety
Text of the Agreement
NAGOYA-KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Delegations will find attached Commission document COM(2012) 236 final.

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ANNEX

to the

Proposal for a Decision of the European Parliament and of the Council on the conclusion of the Nagoya-Kuala Lumpur Supplementary protocol on Liability and Redress to the Cartagena Protocol on Biosafety

Text of the Agreement

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

ANNEX

**to the
Proposal for a Decision of the European Parliament and of the Council on the
conclusion of the Nagoya-Kuala Lumpur Supplementary protocol on Liability and
Redress to the Cartagena Protocol on Biosafety**

**Text of the Agreement
NAGOYA-KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY
AND REDRESS 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”,

Taking into account Principle 13 of the Rio Declaration on Environment and Development,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Recognizing the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the Protocol,

Recalling Article 27 of the Protocol,

Have agreed as follows:

Article 1

Objective

The objective of this Supplementary Protocol 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.

Article 2

Use of terms

1. The terms used in Article 2 of the Convention on Biological Diversity, hereinafter referred to as “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 serving as the meeting of the Parties to the Protocol;
 - (b) “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 authority that takes into account any other human induced variation and natural variation; and
 - (ii) Is significant as set out in paragraph 3 below;
 - (c) “Operator” means any person in direct or indirect control of the living modified organism which could, as appropriate and as determined by domestic law, include, *inter alia*, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier;
 - (d) “Response measures” means reasonable actions to:
 - (i) Prevent, minimize, contain, mitigate, or otherwise avoid 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.
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

Scope

1. This Supplementary Protocol applies to damage resulting from living modified organisms which 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, this Supplementary Protocol applies to damage resulting from any authorized use of the living modified organisms referred to in paragraph 1 above.
3. 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.
4. 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.
5. This Supplementary Protocol applies to damage that occurred in areas within the limits of the national jurisdiction of Parties.
6. Parties may use criteria set out in their domestic law to address damage that occurs within the limits of their national jurisdiction.
7. Domestic law implementing this Supplementary Protocol shall also apply to damage resulting from transboundary movements of living modified organisms from non-Parties.

Article 4

Causation

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

Article 5

Response measures

1. Parties shall require the appropriate operator or operators, in the event of damage, subject to any requirements of the competent authority, to:
 - (a) Immediately inform the competent authority;
 - (b) Evaluate the damage; and
 - (c) Take appropriate response measures.
2. The competent authority shall:
 - (a) Identify the operator which has caused the damage;
 - (b) Evaluate the damage; and
 - (c) Determine which response measures should be taken by the operator.
3. Where relevant information, including available scientific information or information available in the Biosafety Clearing-House, indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, the operator shall be required to take appropriate response measures so as to avoid such damage.
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.
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 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.
8. Response measures shall be implemented in accordance with domestic law.

Article 6

Exemptions

1. Parties may provide, in their domestic law, for the following exemptions:
 - (a) Act of God or force majeure; and
 - (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 7

Time limits

Parties may provide, in their domestic law, for:

- (a) Relative and/or absolute time limits including for actions related to response measures; and
- (b) The commencement of the period to which a time limit applies.

Article 8

Financial limits

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

Article 9

Right of recourse

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

Financial security

1. Parties retain the right to provide, in their domestic law, for financial security.
2. Parties shall exercise the right referred to in paragraph 1 above in a manner consistent with their rights and obligations under international law, taking into account the final three preambular paragraphs of the Protocol.

3. The first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol after the entry into force of the Supplementary Protocol shall request the Secretariat to undertake a comprehensive study which shall address, *inter alia*:
 - (a) The modalities of financial security mechanisms;
 - (b) An assessment of the environmental, economic and social impacts of such mechanisms, in particular on developing countries; and
 - (c) An identification of the appropriate entities to provide financial security.

Article 11

Responsibility of States for internationally wrongful acts

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 12

Implementation and relation to civil liability

1. Parties shall provide, in their domestic law, for rules and procedures that address damage. 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 law, 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 shall, with the aim of providing adequate rules and procedures in their domestic law on civil liability for material or personal damage associated with the damage as defined in Article 2, paragraph 2 (b):
 - (a) Continue to apply their existing general law on civil liability;
 - (b) Develop and apply or continue to apply civil liability law specifically for that purpose; or
 - (c) Develop and apply or continue to apply a combination of both.
3. When developing civil liability law as referred to in subparagraphs (b) or (c) of paragraphs 1 or 2 above, Parties shall, 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.

Article 13

Assessment and review

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 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 Articles 10 and 12.

Article 14

Conference of the Parties serving as the meeting of the Parties to the Protocol

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 15

Secretariat

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

Article 16

Relationship with the Convention and the Protocol

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

2. This Supplementary Protocol shall not affect 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, *mutatis mutandis*, to this Supplementary Protocol.
4. Without prejudice to paragraph 3 above, this Supplementary Protocol shall not affect the rights and obligations of a Party under international law.

Article 17

Signature

This Supplementary Protocol shall be open for signature by Parties to the Protocol at the United Nations Headquarters in New York from 7 March 2011 to 6 March 2012.

Article 18

Entry into force

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 the deposit of the fortieth instrument as referred to in 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 on 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 19

Reservations

No reservations may be made to this Supplementary Protocol.

Article 20

Withdrawal

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 21

Authentic texts

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 Nagoya on this fifteenth day of October two thousand and ten.