



EUROPEAN COMMISSION

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Proposal for a

COUNCIL DECISION

**on the conclusion of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability
and Redress to the Cartagena Protocol on Biosafety**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The Convention on Biological Diversity (CBD), which entered into force on 29 December 1993, is today's main international instrument for addressing biodiversity issues. The three objectives pursued by the Convention are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.

Biosafety, one of the issues addressed by the Convention, concerns the need to protect human health and the environment from the potential adverse effects of the products of modern biotechnology.

The Conference of the Parties to the Convention on Biological Diversity (COP), at its second meeting, held in November 1995 pursuant to Article 19, paragraph 3 of the CBD, established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, specifically focusing on transboundary movement of any living modified organism. The Working Group held six meetings between July 1996 and February 1999.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted on 29 January 2000 as a supplementary agreement to the CBD and entered into force on 11 September 2003. This international treaty provides a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, or pose risks to human health.

Article 27 of the Cartagena Protocol mandated the Conference of the Parties serving as the Meeting of the Parties (COP/MOP) to establish at its first meeting a formal process with respect to the appropriate elaboration of international rules and procedures on liability and redress for damage resulting from transboundary movements of LMOs, with a view to endeavour to conclude this work within 4 years (i.e. by 2008).

During COP/MOP1, held in Kuala Lumpur from 23 to 27 February 2004, an Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Cartagena Protocol on Biosafety was established to analyse issues, elaborate options, and propose international rules and procedures on the subject.

In May 2008, the COP/MOP4, held in Bonn, achieved a political breakthrough in the negotiations, although it did not finalise the drafting of the agreed results. Therefore, the Parties agreed to work on the completion of a legally binding instrument at COP/MOP5 in Nagoya, Japan in October 2010, as well as to develop guidelines on civil liability. This legally binding instrument, largely inspired by the EU Environmental Liability Directive (ELD)¹, would allow national authorities to act on behalf of the collective good and ask operators for remedial measures in case of damage to biodiversity from LMOs, a novelty particularly in many developing countries.

¹ Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage

Final negotiations on the legally binding instrument and on the civil liability guidelines took place in a "Friends of the Co-Chairs" (FoC) group involving 26 of 157 Parties to the Cartagena Protocol, as well as advisors from other Parties. The EU had two seats at the negotiating table. The Commission acted as the EU negotiator for the legally binding instrument on the basis of a formal authorisation adopted by the Council in June 2007 and extended in time after COP/MOP4. The negotiating directives were refined various times and instructed the Commission to ensure that the results of the negotiation are consistent with relevant Union legislation and with the basic principles of Member States' law on liability and redress, and that it could be implemented in the EU without introducing or amending substantive rules on civil liability.

On 15 October 2010, as a result of final negotiations in Nagoya, the plenary of COP/MOP5 successfully adopted an international agreement, known as the "Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety"².

The COP/MOP5 decision adopting the Nagoya-Kuala Lumpur Supplementary Protocol calls upon the Parties to the CBD to sign the Protocol at the earliest opportunity and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, as soon as possible.

On 20 December 2010, the Council welcomed the adoption of the Nagoya-Kuala Lumpur Protocol³ and on 11 May 2011 the European Union signed the Supplementary Protocol.

In the European Union, the provisions of the Cartagena Protocol on Biosafety are covered by the European legislation on Biosafety which is maintaining as a central cornerstone the precautionary principle. The liability provisions of the Nagoya-Kuala Lumpur Supplementary Protocol are covered by the Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004, on environmental liability with regard to the prevention and remedying of environmental damage, which establishes a framework based on the "polluter pays" principle, according to which the polluter pays when environmental damage occurs. After the Directive entered into force on 30 April 2004, three years were given to the EU Member States (MS) to transpose the Directive in domestic law. By July 2010, the last MS finalised its transposition. The ELD was already amended twice through Directive 2006/21/EC on the management of waste from extractive industries and through Directive 2009/31/EC on the geological storage of carbon dioxide and amending several directives.

Any protocol to the Convention on Biological Diversity, pursuant to Article 34 thereof, is open for ratification, acceptance or approval by Member States and by regional economic integration organisations. In accordance with Article 34, paragraph 3, of the Convention, regional economic integration organisations must declare the extent of their competence with respect to the matters governed by the relevant protocol. To fulfill this obligation, the Commission has prepared the Declaration annexed to the present proposal.

² http://bch.cbd.int/protocol/NKL_text.shtml

³ See Council Conclusions "Convention on Biological Diversity: outcome of and follow-up to the Nagoya Conference (11-29 October 2010)" of 20 December 2010, paragraph 2.

In accordance with the advisory opinion of the Court of Justice⁴, the Decision on the conclusion should be based on Article 192 (1) TFEU, in conjunction with Article 218(6)(a) TFEU (.

In view of the above the Commission proposes that the Council authorizes the President to designate the person(s) empowered to deposit the instrument of approval of the Nagoya-Kuala Lumpur Supplementary Protocol on behalf of the Union and to confer on them the necessary powers thereto.

⁴ ECJ Opinion 2/2000, 6 December 2001.

Proposal for a

COUNCIL DECISION

on the conclusion of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192, in conjunction with Article 218(6) (a) thereof,

Having regard to the proposal from the European Commission,⁵

Having regard to the consent of the European Parliament,⁶

Whereas:

- (1) Article 27 of the Cartagena Protocol on Biosafety bound the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP/MOP) to initiate a process with respect to the elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms.
- (2) In June 2007, the Council adopted a Decision authorising the Commission to participate in the liability and redress negotiations on behalf of the Union as regards matters falling within Union competence, in accordance with certain negotiating directives. That authorisation was extended in October 2008 to cover the final stages of the negotiations.
- (3) On 11 October 2010, during the fifth Conference of the Parties serving as the Meeting of the Parties to the Protocol in Nagoya, Japan, the EU unanimously supported the final compromise reached on the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, following consideration that it was within the limits of the agreed EU positions and negotiating directives addressed to the Commission.
- (4) On 15 October 2010, the final plenary of COP/MOP5 successfully adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

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- (5) On 20 December 2010, the Council welcomed the adoption of the Nagoya-Kuala Lumpur Supplementary Protocol.
- (6) In accordance with Council Decision of 6 May 2011⁷, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was signed by the Union on 11 May 2011, subject to its conclusion at a later date.
- (7) According to Article 34 of the Convention on Biological Diversity, any protocol to that Convention is subject to ratification, acceptance or approval by States and by regional economic integration organisations.
- (8) The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety contributes to the achievement of the objectives of the environmental policy of the Union. It is therefore appropriate that this Protocol be concluded on behalf of the Union as soon as possible.
- (9) The agreement should be approved on behalf of the European Union.

HAS ADOPTED THIS DECISION:

Article 1

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council shall designate the person empowered to proceed, on behalf of the European Union, to the deposit of the instrument of approval provided for in Article 18 of the Agreement, in order to express the consent of the European Union to be bound by the Agreement. The deposit of the instrument of approval shall take place simultaneously with those of the Member States. At the same time, the designated person shall deposit the declaration set out in the Annex to this Decision, in accordance with Article 34(3) of the Convention on Biological Diversity.

Article 3

This Decision shall be published in the Official Journal of the European Union.

Done at Brussels,

*For the Council
The President*

⁷ Decision not yet published

ANNEX

DECLARATION BY THE EUROPEAN UNION IN ACCORDANCE WITH ARTICLE 34 (PARAGRAPH 3) OF THE CONVENTION ON BIOLOGICAL DIVERSITY

"The European Union declares that, in accordance with the Treaty on the Functioning of the European Union, and in particular Article 191 thereof, it is competent for entering into international agreements, and for implementing the obligations resulting therefrom, which contribute to the pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment;*
- protecting human health;*
- prudent and rational utilisation of natural resources;*
- promoting measures at international level to deal with regional or worldwide environmental problems, including climate change.*

Moreover, the European Union adopts measures at European Union level in the area of judicial cooperation in civil matters for the proper functioning of its internal market

The European Union declares that it has already adopted legal instruments, binding on its Member States, covering all matters governed by this Protocol.