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SUMMARY LEGAL NOTE ON COMPLIANCE OF COMMISSION'S PROPOSAL ON NGTs WITH THE CARTAGENA PROTOCOL

The Cartagena Protocol on Biosafety is an additional protocol to the Convention on Biological Diversity. It is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

It was adopted on 29 January 2000 and entered into force on 11 September 2003. The Protocol seeks to protect biological diversity against the potential risks posed by living modified organisms resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory.

The UE has ratified the Protocol on June 25th, 2002.

1. Compatibility of EU Commission's Proposal with the Cartagena Protocol

Article 14 (1) of the Protocol provides that parties may agree on regional arrangements:

> "*Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements* ***do not result in a lower level of protection than that provided for by the Protocol.***"

As the NGT proposal is designed to apply within the EU, it can be construed as a regional arrangement.

However, according to the Protocol, an arrangement as such **shall not lead to a lower level of protection.**

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On this point, the Protocol provides for clear guarantees for importing States, which are absent in the Commission's proposal.

Thus, the Protocol (see annex III) establishes the content of the **risk assessment** required by article 15 of the Protocol. According to the Protocol, it shall be "*carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques*". More precisely, Annex III sets out a series of common requirements.

Concerning the EU Commission legislative Proposal, no risk assessment is required for Category 1 NGT plants. Some rough information has to be communicated in the verification file (Articles 6 and 7), but this information does not encompass a risk assessment of Category 1 NGT plants.

Doubtless regarding Cat 1 NGTs, the legislative Proposal leads to a lower level of protection.

Furthermore, article 18 of the Cartagena Protocol provides for **mandatory labelling** of living modified organisms:

> " *Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol,* ***clearly identifies them as living modified organisms****; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.*"

As the Proposal does not contain any labelling for Cat 1 NGTs (except for seeds, but not for products) it also inevitably leads to a lower level of protection.

Regarding Category 2 NGT plants, the Commission's Proposal lists various items of information that shall be communicated to the national competent authority (but further details are still to be defined *via* an implementing act (Article 27(c)). For Category 2 NGT plants, the required risk assessment might also constitute a lower level of protection.

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2. Execution of Commission's Proposal with regard to the obligations laid down in the Cartagena Protocol

Article 8 of the Cartagena Protocol requires exporter countries to address importing countries a formal mandatory notification before the transboundary movement of an LMO. Article 8 §1 is written as follow:

> "*The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.*"

Thus, this notification shall include various pieces of information listed in Annex I. Among the information that shall be provided, figures notably:

> "*the Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism*", as well as the "*previous and existing risk assessment report*".

This notification will lead the importing Party to make an informed decision of agreement or refusal for the introduction of LMOs within its territory, according to Article 10.

Also, article 15 foresees a risk assessment enabling the importing State to make a decision of agreement or not :

> "*1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health. 2.The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.(…)*"

Furthermore, as stated above, Article 18 provides for a mandatory labelling of LMOs for transboundary movements. More precisely, each State shall take appropriate measures to require that the documentation accompanying LMO that are intended for direct use as food or feed, or for processing, **clearly identifies** that the products in question "may contain" living

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modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information.

Also, for LMOs that are intended for intentional introduction into the environment of the importing State, and for any other LMOs within the scope of the Protocol, the documentation shall clearly identify them as LMOs ; specifying the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and containing a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

Recital (4) of the NGT proposal states that "*transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003*". Yet, Regulation (EC) No 1946/2003 lays down requirements coming from the Cartagena Protocol.

However, as the Commission's proposal does not provide for any risk assessment or any labelling for Cat 1 NGTs, these LMOs could not be legally imported by non-EU countries which are also Parties to the Cartagena Protocol.

Furthermore, these non-compliances with the Protocol would lead to further breaches for intermediate exporting countries, in the case where they would not be direct producers. Indeed, these countries would not be able to know if the product is an NGT / LMO, and thus would not be able to fulfil their own obligations under the Cartagena Protocol. For example, an exporter of a Cat 1 NGT product will not be able to notify a third country of export as required under the Protocol since, without any labelling, it will not be aware that the product falls under the Protocol's definition of LMO.

This situation may give rise, at the very least, to **disputes between contracting parties** under the Cartagena Protocol. According to article 27 of the Convention on Biological Diversity, disputes shall be settled through negotiation and conciliation.

However, such an outright violation of the Cartagena Protocol could also discredit the UE on the international scene and even have consequences on international trade.

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