



## Legal/Policy Aspects ABNE Policy Brief No. 1



### Implementation of the Cartagena Protocol at the National Level – Legal Issues

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There are many legal issues that a country will encounter when it attempts to implement and comply with the Cartagena Protocol. This policy brief generally describes several of those legal issues including : liability and redress, socio-economic considerations, public participation, and transparency and confidentiality.

#### Liability and Redress

Liability is the obligation of a legal entity, such as a person, corporation, or government office, to provide compensation for damage caused by an action of that legal entity for which that legal entity is responsible for. Liability will arise when an action contravenes legal rules; damage has been caused; there is a causal link between the action and the damage; and responsibility for the action can be attributed to that legal entity.

Within the context of the Cartagena Protocol, liability and redress refers to whether there should be an international liability and redress system for any environmental damage caused by a transboundary movement of an LMO in the event of any environmental damage. Currently, there is a significant divide in ideologies between countries who favour a strict liability regime, and those who favour a liability and redress regime that takes cognizance of existing liability and regimes within the legal systems of member states.

If a country opts to develop a separate national liability and redress regime to deal specifically with living modified organisms, the specific challenges will be defining exactly what constitutes damage, determining an adequate timeline for ascertaining damages, and defining who should be liable for the determined damages. A country might also opt to use its existing liability and redress regime for environmental damage. This issue, however, will remain uncertain for countries until the debate on the International regime for the Cartagena Protocol is finalized.

#### Socio-economic Considerations

The Cartagena Protocol allows the possibility of including socio-economic considerations in biosafety regulatory approval processes for LMOs. Article 26 of the Protocol provides that Parties may take into account socioeconomic considerations in reaching a decision on import of LMOs, but only to the extent consistent with that country's other international obligations (These obligations could include any international agreements and treaties that a country is party to). The Protocol further limits what may be taken into account by describing socioeconomic considerations as those "arising from the impacts of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

By definition, socio-economic assessments are ex-ante—before-the fact procedures—for those products in the regulatory approval process. There may be some cases where some biosafety regulatory systems may require post-release monitoring and evaluation of socio-economic impacts, but this instance clearly falls under the realm of ex-post assessments, where there is a long and well-established literature and experience for assessments after environmental release.

The Protocol in itself does not define socio-economic considerations and the interpretation of this Article has been left to individual parties. If a country decides to include socio-economic considerations in its regulatory process, a clear definition on what issues will constitute socio-economic considerations and how they will be factored into the decision making process should be included in the law, regulations or guidelines.

#### Public Participation

Article 23 of the Cartagena Protocol encourages Parties to "promote and facilitate public awareness, education and participation in the safe transfer, handling and use of LMOs...". The Protocol further provides that the consultation with the public as part of decision-making is necessarily unique to each country's legal system and regulations. In addition, any public participation that is permitted in a country with respect to biosafety decision making should not differ in any material way from participation permitted in that country on other matters that may impact the conservation and sustainable use of biodiversity. The legal challenge will be to ensure that issues on public participation with regard to the implementation of the Cartagena Protocol will be treated in the same manner as any other public participation mechanism currently in use within a Country.

As the Cartagena Protocol does not give guidance on the public participation procedures to be used in the decision making process, it will be important that when engaging the public the level of education, the language of communication and the medium to be used should consider all the unique needs of each country.

### **Transparency and Confidentiality**

Article 21 of the Cartagena Protocol allows certain information provided by a notifier (applicant) to be treated as confidential. The Protocol provides that the name and address of the notifier; a general description of the living modified organism or organisms; a summary of the risk assessment; and any methods and plans for emergency response shall not be treated as confidential. This information is considered to be information that must be supplied in the public interest. The onus is on the notifier to specify the information it considered to be treated as confidential. However, not all information identified by the applicant as “confidential” qualifies to be treated as such. Countries need to provide clear guidelines on confidentiality in their laws and regulations since this issue is linked to transparency. Information that may have an adverse economic impact on the business of the developer should be kept confidential as this information may provide a competitor an unfair advantage. Trade secrets, the gene construct and the efficacy data are types of information considered as material to be treated as confidential. The location of field trials and the personal information of the applicant are also treated as confidential in most instances. Countries should strive to reach a balance on what information can be kept confidential and what should be availed to the public. The public needs to be educated on why some information will remain confidential as this is important in the decision making process.

Transparency is an integral part of a regulatory process as it ensures that the regulatory process within the country is clear to the applicant, the Government, regulators and the general public. Countries should therefore ensure that the regulatory process has legal rules that set forth the application process, including the information required on the application, the parties involved and the office responsible for the activities to be undertaken. Those regulations or guidelines should ensure that decisions are availed to both the applicant and the public. A mechanism of how the application and decision documents can be availed to all interested parties should also be initiated. The legal challenge will be the creation of balance between the competing interest of the applicant and the information to be availed to the public.

### **Conclusions**

The challenge for countries will be to ensure that the laws developed address issues that have not been clearly defined by the Cartagena Protocol yet are important in its implementation at the national level. Clear and concise rules will go a long way in ensuring that the objective of the Cartagena Protocol to ensure an adequate level of protection for transboundary activities involving LMOs.

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***This is the first of a series of policy briefs*** to be developed by the African Union/NEPAD - African Biosafety Network of Expertise (ABNE) addressing Legal/Policy aspects of modern biotechnology. ***This policy brief is targeted for regulators and decision makers.***

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