Position paper

New techniques of genetic modification, ITPGRFA and the Cartagena Protocol: potential incompatibility and impact on farmers rights and the seed systems

The EU's new regulatory framework for new techniques of genetic modification, also named "genomic" (NGTs), adopted in June 2026, creates a specific regulatory category for so-called Category 1 NGT plants. These plants are considered equivalent to conventionally bred plants under EU law and are therefore excluded from the EU's GMO regulatory framework. Category 2 NGT plants, by contrast, remain subject to risk assessment, authorisation, traceability and labelling requirements similarly to other GMOs.

This distinction raises important questions under the Cartagena Protocol on Biosafety. The Protocol defines a Living Modified Organism (LMO) according to the process through which an organism acquires a novel combination of genetic material, rather than according to whether it is classified as a GMO under the domestic legislation of a particular Party. The Protocol applies to the transboundary movement of LMOs.

Article 18 establishes specific requirements for the identification and documentation of LMOs subject to transboundary movement. Depending on their intended use, **accompanying documentation must identify the LMO and provide information concerning its identity, relevant traits or characteristics and, where applicable, unique identification**. COP-MOP (the Governing Body of the Cartagena Protocol on biosecurity) decisions have subsequently established practical arrangements for identification, including **the use of unique identifiers** for transgenic plants. A unique identifier is typically **a 9-digit alphanumeric code assigned to a specific transformation event**, allowing precise identification in documentation and product labelling. The Executive Secretary of the Convention on Biological Diversity was requested to maintain **a register of these unique identification codes** within the so-called Biosafety Clearing-House to harmonize data usage globally.

The EU framework creates a potential regulatory gap. For plants and products obtained through Category 1 NGT, GMO-specific traceability requirements do not apply on the grounds that the claimed genetic trait would not be distinguishable from genetic traits that could be obtained through conventional breeding techniques. This semantic trick allows to completely disregard the many other unclaimed genetic modifications (whether intentional or not), which are all signatures of the use of NGTs and make it possible to establish a unique identification of these "new" GMOs. Although the Regulation establishes a public database, identification numbers for documental traceability, and labelling requirements for plant reproductive material, **these measures are not necessarily equivalent to the analytical identification and documentation requirements established under Article 18 of the Cartagena Protocol** for LMOs subject to transboundary movement.

Implication for biosafety

Impacts can vastly exceed the European Union. Seeds and agricultural products move internationally through complex supply chains, and Parties to the Cartagena Protocol may receive products originating in or transiting through jurisdictions applying different regulatory classifications. If organisms falling within the Protocol's definition of LMOs are not identified and documented as such, importing **Parties may face difficulties in exercising their rights and fulfilling their obligations under the Protocol**, including risk assessment, risk management, withdrawal of products that are proved to be harmful for health and environment, prevention of illegal or unintentional transboundary movements, and implementation of national biosafety legislation. The Protocol itself demands the capacity to detect and identify LMOs as an important element of effective implementation.

Implication for farmers' rights and the implementation of the ITPGRFA

The issue has implications for farmers' seed systems and Farmers' Rights, since the introduction of NGT seeds or products, which will be likely covered by patents, without adequate identification and traceability could make it more difficult for farmers and public authorities to know whether genetic resources entering seed systems, ecosystems and food systems have been genetically modified and to exercise choices, as well as controls and management of risks that can arise from its use. This might also have serious impacts on the right of farmers to save, exchange and sell peasant or farm-saved seeds, as well as for gene banks operations. In the event of genetic contamination involving patented GMO traits, or the use of non-GMO peasant or traditional seeds containing a trait identical to that of one of these patented "new" GMOs, farmers, processors and distributors would be unable to protect themselves against being found liable for patent infringement. In case a gene banks is part of the ITPGRFA Multilateral System (MLS), the import and uncontrolled circulation of untraced LMOs can lead to patented traits

corresponding to genetic traits of seeds already present in the MLS ending up restricting the facilitated access to the original resources. This would lead to a de facto violation of the article 12.3d of the Treaty, prohibiting the patenting of PGRFA in the MLS, their genetic parts and components, as it will be impossible to prove the resource wasn't originally obtained from a gene bank. In the absence of unique identifiers of plants obtained through the patented invention, the scope of these patents will extend also to plants containing the genetic part of component identical to the one claimed by the patent, without them being obtained from the patented invention nor its reproduction. Since no third-party control is applied to exchanges of PGRFA between users after the first access to a gene bank of the MLS, a patent can be claimed by someone on a trait originally obtained from one of these gene banks by someone else. The current extensive use of the Digital Sequence Information (DSI), synthetic biology, artificial intelligence and New Genomic Techniques makes the operation even easier. With millions of sequence data already available for free download and use on open access databases, the capacity of the International Treaty to ensure compliance with rules governing the MLS are nullified. The result is that either the producers of plants obtained with NGTs are forced to give their products a unique identifier, or the free circulation of these LMOs can generate unwanted violations of the Cartagena Protocol by its Contracting Parties.

Proposed action

Governments that are Parties to the Cartagena Protocol and/or the ITPGRFA should request a formal examination of the compatibility of the EU regulatory framework with the Protocol and the Treaty. The most immediate mechanism available is the **Cartagena Protocol's compliance procedure** established under Article 34 and Decision BS-I/7.

Under this mechanism, a Party that is affected or likely to be affected may submit, through the Secretariat, a compliance submission concerning another Party. The Compliance Committee can examine the submission and adopt measures aimed at promoting compliance, including recommendations to the COP-MOP.

Accordingly, Parties that consider themselves affected or likely to be affected by the EU framework should consider submitting a case to the Compliance Committee of the Cartagena Protocol, requesting **clarification of whether the treatment of Category 1 NGT plants susceptible of transboundary movements is consistent with the EU's obligations under relevant provisions of the Protocol**.

Contracting Parties should also raise the issue within the COP-MOP, to open a discussion on the application of the Protocol's identification and documentation requirements to organisms produced through NGTs.

Where a formal dispute between Parties concerning the interpretation or application of the Protocol cannot be resolved through negotiation or mediation, **Article 27 of the Convention of Biological Diversity provides for dispute settlement**, including arbitration or submission to the International Court of Justice where the relevant Parties have accepted those mechanisms. If the Parties have not accepted the same compulsory mechanism, conciliation is provided for.

The IPC calls on all Contracting Parties to the Cartagena Protocol to raise the issue of compliance between the EU regulation on certain New Genomic Techniques and the protocol requirements for LMOs.