

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

2012/0278(COD) - 16/04/2014 - Final act

PURPOSE: to promote the fair and equitable sharing of the benefits arising from the utilisation of genetic resources in accordance with the Nagoya Protocol.

LEGISLATIVE ACT: Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

CONTENT: the Regulation establishes **rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources**, in accordance with the provisions of the Nagoya Protocol. Its implementation should contribute to the conservation of biological diversity and the sustainable use of its components, in accordance with the provisions of the Convention on Biological Diversity.

The Nagoya Protocol, attached to the Convention on Biological Diversity, is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Protocol further elaborates upon the general rules of the Convention on access to genetic resources and sharing of monetary and non-monetary benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources ('access and benefit-sharing'). In accordance with Council Decision 2014/283/EU, the Nagoya Protocol was approved on behalf of the Union.

Scope: the Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources within the scope of the Convention, which are accessed after the entry into force of the Nagoya Protocol for the Union. Traditional knowledge includes knowledge, innovations and practices, of indigenous and local communities embodying traditional lifestyles, relevant for the conservation and sustainable use of biological diversity.

Rules to be respected by users: the Regulation stipulates that all users of genetic resources and traditional knowledge associated with genetic resources should exercise **due diligence** to ascertain whether genetic resources and traditional knowledge associated with genetic resources have been accessed in accordance with applicable legal or regulatory requirements and to ensure that **benefits are fairly and equitably shared upon mutually agreed terms**.

In that context, competent authorities should accept **internationally-recognised certificates of compliance** as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein.

Competent authorities: each Member State shall designate one or more competent authorities to be responsible for the application of this Regulation. The competent authorities shall carry out **checks** to verify whether users comply with their obligations. In doing so, they should consider that the implementation of a **recognised best practice** for access and benefit sharing by a user reduces that user's risk of non-compliance. The competent authorities shall keep, for at least five years, records of the **checks**.

The Commission shall make public, including via the internet, a **list of the competent authorities of the Member States**. In addition, it shall establish a **register of collections of genetic resources** within the Union which is internet-based and easily accessible to users.

Complementary measures: the Regulation provides that the Commission and the Member States will be required, among others:

- promote and encourage **information, awareness-raising and training activities** to help stakeholders and interested parties to understand their obligations;
- encourage the development of **sectoral codes of conduct, model contractual clauses, guidelines and best practices**, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises;
- promote the development and use of **cost-effective communication tools** in support of monitoring and tracking the utilisation of genetic resources;
- encourage users to direct benefits from the utilisation of genetic resources **towards the conservation of biological diversity**.

Representatives of the Member States and other interested parties in issues related to the implementation of this Regulation shall meet in a **consultation forum**.

Reports and review: in principle, the Member States shall submit to the Commission a report on the application of this Regulation by 11 June 2017 and every five years thereafter. Not later than one year after the time-limit for submission of reports, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation. Every 10 years after its first report the Commission shall review the functioning and effectiveness of this Regulation in achieving the objectives of the Nagoya Protocol.

ENTRY INTO FORCE: 09.06.2014.