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COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 24 January 2019

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: COM(2019) 13 final - ANNEX

Subject: ANNEX to the REPORT FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL on the Regulation EU/511/2014 of the
European Parliament and of the Council of 16 April 2014 on compliance
measures for users from the Nagoya Protocole on Access to Genetic
Resources and the Fair and Equitable Sharing of Benefits Arising from
their Utilization in the Union

Delegations will find attached document COM(2019) 13 final - ANNEX.

Encl.: COM(2019) 13 final - ANNEX



Brussels, 24.1.2019
COM(2019) 13 final

ANNEX

ANNEX

to the

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Regulation EU/511/2014 of the European Parliament and of the Council of 16 April 2014
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 Utilization
in the Union**

Annex

Background information to the Report under Art. 16(1) of Regulation (EU) 511/2014

International obligations deriving from the Nagoya Protocol

The Nagoya Protocol is an international agreement adopted in October 2010¹ to implement the third objective of the Convention on Biological Diversity,² namely the fair and equitable sharing of benefits arising from utilisation of genetic resources. The benefits are expected to be directed and hence contribute to the first and second objectives of the CBD, namely conservation of biological diversity and sustainable use of its components.

The Protocol establishes a common framework of principles and measures on access to genetic resources and the sharing of benefits deriving upon their utilization (commonly referred to as ABS). The Nagoya Protocol encompasses three types of measures: access, benefit-sharing and compliance measures. All Parties to the Protocol may establish access measures in the exercise of their sovereign rights over genetic resources while mindful of the Protocol's requirements for such measures (clarity, transparency, fair and non-arbitrary procedures for access etc.). Access measures should set conditions on how to obtain Prior Informed Consent (PIC) from a provider country and how to establish Mutually Agreed Terms (MAT) to share the benefits between the provider and the user of genetic resources. The second type of measures, namely benefit-sharing, is covered by contractual agreements (mutually agreed terms) and subject to contractual law. The third type of measures deal with the establishment of compliance measures, which is an obligation under the Protocol. Each Party needs to take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilised within its jurisdiction have been accessed in accordance with PIC and that MAT have been established, as required by the domestic ABS legislation of the provider country. To support compliance, Parties need to take appropriate measures to monitor the utilisation of genetic resources. In this context the Parties are required to establish checkpoints to collect relevant information related to PIC and MAT. This information is transferred to the ABS Clearing House (ABSCH)³ and also to the provider country. The ABSCH is an IT platform where Parties put all relevant legislative, administrative and policy measures; such as access laws, permits issued by the country (transferred into internationally recognised certificate of compliance), information concerning monitoring of the utilisation of genetic resources (transferred then into checkpoint communiqués), information concerning competent national authorities etc.. The ABSCH allows to share relevant information between all actors involved.

¹ The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity was adopted on 29 October 2010 in Nagoya, Japan by the tenth meeting of the Conference of the Parties to the CBD and entered into force on 12 October 2014, <http://www.cbd.int/abs/>.

² UN Convention on Biological Diversity, adopted in 1992 in Nairobi and opened for signature at the Rio Earth Summit (5 June 1992). Council Decision of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity gives the European Union's approval to the CBD; OJ L 309 of 13/12/1993, p.1 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31993D0626>.

³ Article 14 of the Protocol.