



Council of the European Union
General Secretariat

**Interinstitutional files:
2023/0226 (COD)**

Brussels, 03 December 2023

WK 15958/2023 REV 1

LIMITE

**AGRI
AGRILEG
ENV
CODEC
PI**

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Counsellors/Attachés (Agri - Genetic Resources and Innovation in Agriculture)
N° prev. doc.:	ST 15205/2/23 REV 2; WK 15958/23 INIT
N° Cion doc.:	ST 11592 2023 INIT + ADD 1
Subject:	Regulation on new genomic techniques (NGT) - Room document on a study on the impact of patenting

Delegations will find in annex a room document on a study on the impact of patenting, put forward by the Presidency.

Room document

[...]

(46a) Directive 98/44/EC on the legal protection of biotechnological inventions sets out principles regarding the patentability of biological material including plants. The EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products which are obtained by means of essentially biological processes. It is important to ensure that farmers and breeders have access to techniques and material, to promote the diversity of plant reproductive material, such as seeds, at affordable prices, and to safeguard breeding and cultivation of unpatented crops for both conventional and organic production systems, while also strongly supporting innovation in plant breeding by preserving investment incentives. The Commission should assess, as part of a broader market analysis, the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. This assessment should consider that targeted mutagenesis and cisgenesis rely on the breeders' gene pool and therefore can result in plants with modifications equivalent to those that can be obtained by conventional breeding methods (category 1 NGT plants). The Commission should report on its findings and measures required to follow up as soon as possible and not later than [31 December 2026].

[...]

Article 30 bis

Study on the impact of patenting practices

The Commission shall conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry.

The Commission shall report on its findings and measures required to follow up the study not later than [31 December 2026].

[...]

