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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	WP Innovation in Agriculture – Meeting of 5-6 October 2023 – Item 1: Presentation on biotechnology patents in plant breeding

Following the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 5-6 October 2023, delegations will find in annex the presentation given by the Commission on the above subject.

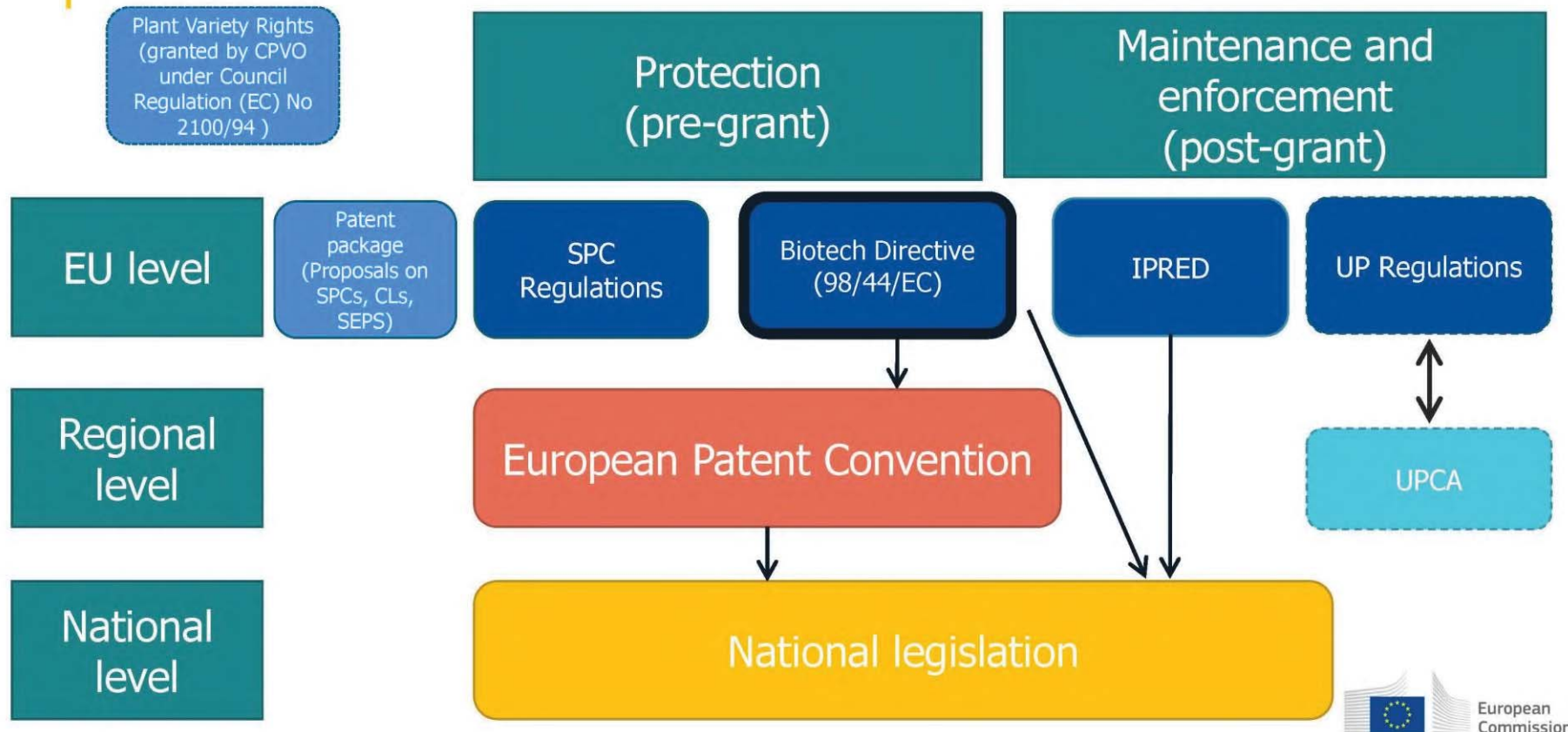


New Genomic Techniques IP implications

European Commission, DG GROW, IP unit (C4)

1

Background: Patent law in the EU



NGTs: Patenting vs placing on the market

EU Biotech Directive

- Harmonisation of the patenting conditions for biotechnological inventions
- Transposed into national law of EU Member States, reflected in the EPC

Patent protection

- The holder can prohibit others from exploiting an invention (for a limited period)
- Patent protection does not authorise the holder to use or commercialise the invention

Patenting vs marketing

- Patent protection for an NGT plant does not affect its status under regulatory law
- Regulatory status of an NGT plant does not affect its status under patent law

Regulatory framework for biotech products

- EU GMO legislation
- EU pharmaceutical legislation for biopharmaceuticals

Proposed NGT legislation

- Conditions for the placing on the market of plants produced by certain NGTs
- Regulatory equivalence of certain NGT plants to conventionally-bred plants

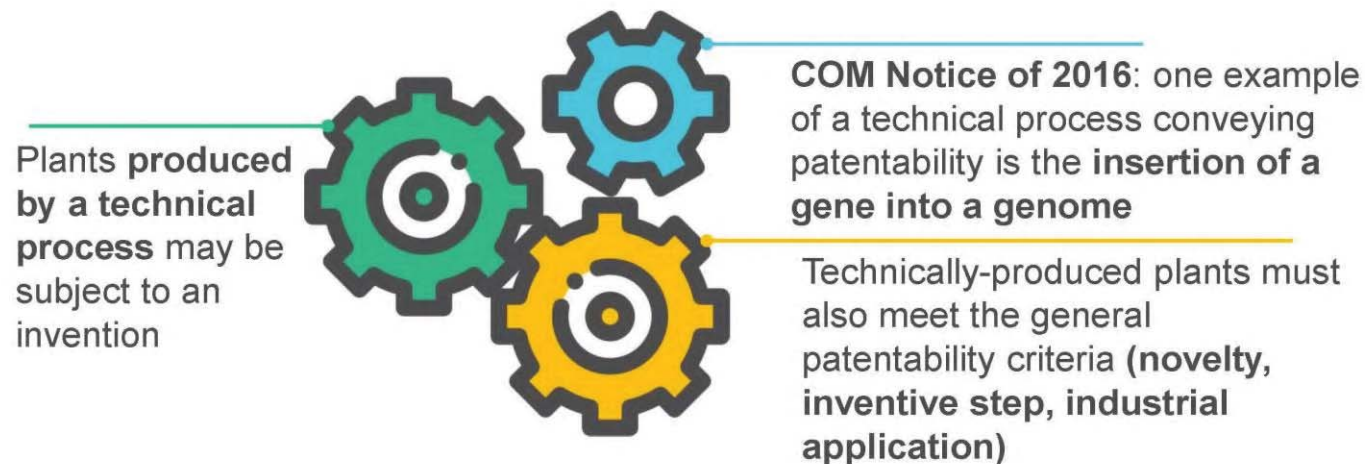


Biotech Directive: Background

- Key objective: Harmonised EU legal framework to protect biotech inventions needed to attract investments and encourage innovation in this field
- Overall picture: 56 Recitals and 18 Articles
 - **Patentability of biological material and exceptions (Art. 3-6)**
 - Scope of protection (Art. 8-11)
 - Non-exclusive compulsory licensing (Art. 12)
 - Deposit of biological material (Art. 13)
 - Final provisions (Art. 14-18)
- Main provisions of the Biotech Directive taken over in the EPC Rules



Biotech Directive: Patenting of plants (Art.3)



Biotech Directive: Exceptions (Art. 4)

Plant and animal varieties (inventions concerning plants and animals not technically confined to a particular variety are patentable)



Essentially biological processes (EBP) to produce plants and animals + **COM Notice from 2016** confirming that the Biotech Directive is to be interpreted in a way that **prohibits the patenting of plants and animals produced by EBP**

Exclusion of plants produced by EBP implemented in EPO practice:

- If a technical feature is obtainable both by technical process or EBP, **excluded subject-matter is to be disclaimed**

Patentability of NGT plants

NGT plants are produced by a technical process and thus may be patented (if they also meet the strict general patentability criteria)

Patents on NGT plants do not protect identical plants obtained by natural processes (cf. EPO disclaimer solution), nor plants that are in the public domain already

Scope of protection (Art. 8-9 Biotech Directive) of NGT patents ultimately a matter for national jurisdictions/UPC; issue of proof in case of disputes

Patented NGT material: access and transparency

- Identifying the IP status of breeding material and securing access to such IP may be challenging to certain market players in the plant sector
- Patent legislation includes tools facilitating research and access
 - Breeders' exemption (UPCA)
 - Research exemption (UPCA)
 - Farmer's privilege (Biotech Directive)
 - Compulsory cross-licensing (Biotech Directive)
- Private initiatives have been developed to improve transparency and facilitate access (e.g. the Agricultural Crop Licensing Platform (ACLP))



Next steps concerning NGTs and IP

- Commission's Communication of 5 July 2023:
 - *The Commission will 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 genetic material and techniques and on availability of seeds to farmers as well as the overall competitiveness of the EU biotech industry.** The Commission will report on its findings by 2026. It will identify possible challenges in the sector and serve as basis to decide on any possible follow-up actions.*
- Preparatory work for the assessment underway, links with wider political context (SOTEU)
- Evidence- based approach to identify issues and the possible follow-up measures, if any
- Input from all stakeholders and Member States will be important
- Updates to the Member States in the Commission's IP expert group / CWP on IP



