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From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	8851/23 + ADD 1-4; 8869/23 + ADD 1-6
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for plant protection products Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 - *Optional consultation of the European Economic and Social Committee**

1. On 27 April 2023, the Commission submitted to the Council and the European Parliament the above-mentioned proposals[1]. The proposals aim at creating a unitary supplementary protection certificate for medicinal products on the one hand, and for plant protection products on the other.

2. Supplementary protection certificates (SPCs) are intellectual property rights that extend the 20-year term of patent protection for medicinal or plant protection products by up to 5 years. The purpose of SPCs is to offset the loss of effective patent protection due to the compulsory and often lengthy testing required in the EU for the regulatory marketing authorisation of these products.

* The sole purpose of this note is to decide on the consultation of another institution/body and not on the substance.

1 Doc. 8851/23 and doc. 8869/23.

3. The EU unitary patent entered into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner.

4. The above-mentioned proposals for unitary SPCs build on the unitary patent and are based on the first paragraph of Article 118 TFEU, which does not provide for an obligatory consultation of the Economic and Social Committee.

5. However, the two proposals are part of a package along with two other legislative proposals, namely the two 'recast' proposals revising the Regulations on *national* supplementary protection certificates for plant protection products[2] and medicinal products[3]. These latter two proposals are based on Article 114(1) TFEU, which does provide for a consultation of the Economic and Social Committee.

6. The overall aim of the package is to simplify the EU's SPC system, as well as to improve its transparency and efficiency. Considering the 'package-character' and the subject matter of the proposals, it would appear appropriate to consult the Economic and Social Committee also on the two proposals for *unitary* supplementary protection certificates.

7. The Permanent Representatives Committee is therefore invited to decide, under Article 304 TFEU and Article 19(7)(h) of the Council's Rules of Procedure, to consult the Economic and Social Committee on the above-mentioned proposals on unitary supplementary protection certificates for medicinal and for plant protection products, and to request the Committee to give its opinion as soon as possible.

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[2] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for plant protection products (recast) – doc. 8887/23.

[3] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for medicinal products (recast) – doc. 8894/23.