Council of the European Union

Brussels, 26 March 2026
(OR. en)

7727/26

LIMITE

PI 42

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Interinstitutional Files:
2023/0126 (COD)
2023/0127 (COD)
2023/0128 (COD)
2023/0130 (COD)

NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	7319/26
Subject:	Supplementary Protection Certificates (SPCs) – Discussion paper

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (19.05.2026)

I. Introduction

Following the exchange of views held during the Working Party meetings on 21 January, 18 February and 18 March 2026 on the legal basis of the unitary SPC proposals, the Cyprus Presidency has continued to explore possible avenues to facilitate progress on this matter.

During the Working Party meeting on 18 March, the Presidency presented to Member States two possible solutions: **Solution A** (Unitary SPC based on Article 118 TFEU) and **Solution B** (Single SPC based on Article 114 TFEU). While most Member States maintained scrutiny reservations, there was a strong support to continue discussing and further elaborating Solution A, as it preserves the concept of a Unitary SPC based on Article 118 TFEU, whereas Solution B, which is based on Article 114 TFEU, attracted only limited support. In that context, Member States reiterated the need for a solution that ensures legal certainty, reduces fragmentation, and enhances the competitiveness of the Single Market, while remaining aligned with the current EU priorities.

The Presidency acknowledges the importance of finding an approach that fulfils the objectives of the SPC package reform. Taking into account the reactions of Member States on the proposed Solutions, the Presidency, in collaboration with the Commission, has further developed Solution A. Solution B has not been developed further at this stage, but it is not discarded. We may revisit Solution B if it turns out that other options do not receive the necessary support.

DELETED concerns could potentially be addressed through careful drafting. In light of the above, the Presidency has revised Solution A.

Delegations are invited to review and share their views on the revised Solution A set out below.

II. Solution A *(revised)*

It is recalled that Solution A (proposed in doc. 7319/26) **DELETED**, and which draws inspiration from the concept established in the Unitary Patent Regulation, in particular Article 18(2).

In response to several Member States underlining the importance of maintaining a genuinely unitary SPC, Solution A seeks to preserve the underlying philosophy of establishing a unitary SPC based on Article 118 TFEU.

The central idea of this approach is that the Unitary SPC Regulation should apply uniformly across the Union, both in its wording and legal structure, while the factual territorial scope of the SPC protection is linked to the jurisdictional framework of the Unified Patent Court (UPC). **DELETED**

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Main changes in the revised Solution A:

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The drafting suggestions in the revised Solution A are presented in the context of the proposal for a Regulation on medicinal products. With the necessary adjustments, these amendments could also be applied to the proposal for a Regulation on plant protection products and aligned with the SPC recast proposals.

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Summarising the core elements of Solution A:

- Preserves the idea/philosophy of a Unitary SPC Regulation based on Article 118 TFEU;

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Drafting suggestions for solution A (changes compared to the previous version of Solution A as set out in doc. 7319/26 are highlighted in grey-shade)***:***

New recital:

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Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(…)

(5) 'basic patent' means a ~~unitary~~ **European** patent **with unitary effect** which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder ~~for the purpose of the procedure for grant of~~ **in an application for** a unitary certificate **or in a combined application (in accordance with Article 32)**;

(…)

Article 3
Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the ~~Office~~ **central office (tbc)** on the basis of a basic patent if~~, in each of the Member States in which that basic patent has unitary effect~~, at the date of the application, all of the following conditions are fulfilled:

   (a) the product is protected by that basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;

(c) the product has not already been the subject of a certificate, nor of a unitary certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

(…)

Article 5
Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States ~~in which the basic patent has unitary effect~~.

2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States ~~in which the basic patent has unitary effect~~. The unitary certificate may only be ~~limited,~~ transferred or revoked, or lapse, in respect of all Member States.

Article 7
The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety~~, in each Member State in which the basic patent has unitary effect,~~ in accordance with the national law applicable to the basic patent as an object of property.

Article 55
Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(New) Article XX
Reporting on national measures

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Article 56
Evaluation

By xxxxxx [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation. **DELETED**

Article 57

Entry into force and application

1. This Regulation shall enter into force on XXX [OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union].

2. It shall apply from xxxxx [OP please insert first day of the ~~12th~~ **24th** month after the date of entry into force] **DELETED**

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