Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0128(COD)	Awaiting Council's 1st reading position
Supplementary protection certificate for plant protection products. Recast Subject 3.10.09.02 Plant health legislation 3.50.16 Industrial property, European patent, Community patent, design and pattern Legislative priorities Joint Declaration 2023-24		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	JURI Legal Affairs		19/07/2023
		S&D WÖLKEN Tiemo	
		Shadow rapporteur	
		epp ZARZALEJOS Javier	
		renew europe. VÁZQUEZ LÁZARA Adrián	
		MAUREL Emmanuel	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	AGRI Agriculture and Rural Development		23/05/2023
		epp LINS Norbert	
	Committee for opinion on the recast technique	Rapporteur for opinion	Appointed
	JURI Legal Affairs		01/01/2023
		epp ADAMOWICZ Magdalena	
Council of the European Union			
European Commission	Commission DG	Commissioner	

European Economic and Social Committee	Internal Market, Industry, Entrepreneurship and SMEs BRETON Thierry

Key events

27/04/2023	Legislative proposal published	COM(2023)0223	Summary
11/09/2023	Committee referral announced in Parliament, 1st reading		
24/01/2024	Vote in committee, 1st reading		
01/02/2024	Committee report tabled for plenary, 1st reading	A9-0023/2024	Summary
27/02/2024	Debate in Parliament		
28/02/2024	Results of vote in Parliament		
28/02/2024	Decision by Parliament, 1st reading	T9-0098/2024	Summary

Technical information

Procedure reference	2023/0128(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 110
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	JURI/9/11947

Documentation gateway

Legislative proposal		COM(2023)0223	27/04/2023	EC	Summary
Document attached to the procedure		SWD(2023)0117	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0118	27/04/2023	EC	
Document attached to the procedure		SWD(2023)0119	27/04/2023	EC	
Document attached to the procedure		N9-0084/2023 OJ C 000 14.11.2023, p. 0000	21/06/2023	EDPS	
Specific opinion	AGRI	PE750.123	29/06/2023	EP	
Economic and Social Committee: opinion, report		CES2306/2023	20/09/2023	ESC	
Committee draft report		PE753.705	16/10/2023	EP	
Specific opinion	JURI	PE755.998	06/11/2023	EP	
Amendments tabled in committee		PE756.104	13/11/2023	EP	
Committee report tabled for plenary, 1st		A9-0023/2024	01/02/2024	EP	Summary

reading/single reading					
Text adopted by Parliament, 1st reading/single reading		T9-0098/2024	28/02/2024	EP	Summary

Supplementary protection certificate for plant protection products. Recast

PURPOSE: to simplify the EUs supplementary protection certificates (SPC) system as regards national SPCs for plant protection products and improve its transparency and efficiency.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: a supplementary protection certificate (SPC) is an intellectual property right that extends the term of a patent (up to five years) for a human or veterinary pharmaceutical or plant protection product that has been authorised by regulatory authorities, thereby encouraging innovation and promoting growth and employment in these sectors.

However, SPC protection is only available at national level. As a result, the current system suffers from fragmentation, leading to complex and costly procedures and legal uncertainty.

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

The Commissions intellectual property action plan of November 2020, which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EUs intellectual property system.

Research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices. Plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Union if they are covered by favourable rules that provide for sufficient protection to encourage such research.

This proposal is part of the EU patent package announced in 2023 which, besides the revision, modernisation and introduction of a system for unitary SPCs, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products, a unitary certificate for plant protection products and a unitary certificate for medicinal products.

CONTENT: this proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection certificate for plant protection products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

The SPC reform introduces a centralised examination procedure, implemented by the EU Intellectual Property Office (EUIPO), in close cooperation with the EU's national intellectual property (IP) offices. Under this scheme, a single application will be subject to a single examination process which, if positive, will result in the grant of a unitary SPC and of national SPCs in further Member States.

While that examination would be conducted by a centralised authority, the actual granting of SPCs would be done by the respective national offices of the designated Member States, based on a positive opinion from the central examination authority. The opinion of the central examination authority would be binding upon the national offices of the designated Member States.

The core substantive features of the proposed centralised procedure i.e. the conditions for obtaining certificates, as well as their legal effect are the same as those of the existing SPC regime. This proposal introduces new procedural provisions as regards the centralised examination and is not intended to modify the scope nor the effect of the rights conferred by national SPCs currently granted according to Regulation (EC) No 1610/96.

The new rules, however, do not alter the competence of national IP Offices in granting national SPCs, following the binding opinion issued by the examination authority, run by the EUIPO. The reform of the national SPC regime does also not alter the eligibility criteria to obtain an SPC, which remain the ones currently foreseen in Article 3 in the existing legislation for both pharmaceutical products and plant protection products.

Supplementary protection certificate for plant protection products. Recast

The Commission on Legal Affairs adopted the report by Tiemo WÖLKEN (S&D, DE) on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast).

As a reminder, the proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection certificate for plant protection products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal. As regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Centralised procedure for certificates

It is stated that the Office should issue a decision on the opposition, including a detailed reasoning for that decision, within 6 months, unless the complexity of the case requires a longer period. Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed, that authority should designate one or more examiners to be involved in the examination of one or more applications for unitary certificates based on relevant expertise and sufficient experience required for the centralised examination procedure.

Examination panels

The assessments should be conducted by an examination panel including one member of the Office as well as two examiners from two different participating competent national authorities. When setting up an examination panel, the Office should ensure the following:

- relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, geographical balance amongst the participating offices.

Appeals

The report underlined the need to safeguard procedural rights and ensure a complete system of remedies.

In case of an appeal, a written statement setting out the grounds of appeal, including the evidence supporting those grounds, should be filed within 3 months of the date of notification of the decision. Any reply to the statement of grounds of appeal should be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office should, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the date of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

When appointing members of the Boards of Appeal in matters concerning applications for unitary certificates, due consideration should be given to their previous experience in matters concerning supplementary protection certificates or patent law

Taking of evidence

If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it should issue a summons to the person concerned to appear before it. Where an expert is summonsed, the Office or the relevant panel, as applicable, should verify that that expert is free of any conflict of interest.

Supplementary protection certificate for plant protection products. Recast

The European Parliament adopted by 523 votes to 26, with 69 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast).

As a reminder, the proposal for a recast of Regulation (EC) No 1610/96 lays down the rules on the supplementary protection certificate for plant protection products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal. As regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Conditions for obtaining a certificate

The proposal provides that the holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked.

According to Members, the same principle should apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.

Opposition

The opposition should include any evidence the opponent relies on in support of the opposition. If the opposition panel notes that the notice of opposition does not comply with the provisions of the Regulation, it should reject the opposition as inadmissible, and communicate its decision as well as its reasoning for that decision to the opponent, unless these deficiencies have been remedied before expiry of the opposition filing period.

In cases where several oppositions have been filed against an examination opinion, the Office should deal with the oppositions jointly and issue one single decision in respect of all oppositions filed.

It is stated that the Office should issue a decision on the opposition, including a detailed reasoning for that decision, within 6 months, unless the complexity of the case requires a longer period.

Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed, that authority should designate one or more examiners to be involved in the examination of one or more applications for unitary certificates based on relevant expertise and sufficient experience required for the centralised examination procedure.

Examination panels

The assessments should be conducted by an examination panel including one member of the Office as well as two examiners from two different participating competent national authorities. When setting up an examination panel, the Office should ensure the following:

- relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, geographical balance amongst the participating offices.

Appeals

Parliament underlined the need to safeguard procedural rights and ensure a complete system of remedies.

In case of an appeal, a written statement setting out the grounds of appeal, including the evidence supporting those grounds, should be filed within 3 months of the date of notification of the decision. Any reply to the statement of grounds of appeal should be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office should, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the date of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

When appointing members of the Boards of Appeal in matters concerning applications for unitary certificates, due consideration should be given to their previous experience in matters concerning supplementary protection certificates or patent law

Taking of evidence

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Report

By five years after the date of application, and every five years thereafter, the Commission should carry out an evaluation of the application of Chapter III (Centralised procedure for certificates) and present a report on the main findings to the European Parliament and to the Council.