Basic information

2023/0126(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Awaiting Council's 1st reading position
Unitary supplementary protection certificate for plant protection products **Subject** 3.10.09.02 Plant health legislation 3.50.15 Intellectual property, copyright 3.50.16 Industrial property, European patent, Community patent, design and pattern	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs	WÖLKEN Tiemo (S&D)	18/11/2024
	Shadow rapporteur ZARZALEJOS Javier (EPP) ZŁOTOWSKI Kosma (ECR) SAEIDI Arash (The Left)	

Former committee responsible	Former rapporteur	Appointed
JURI Legal Affairs	WÖLKEN Tiemo (S&D)	19/07/2023

Former committee for opinion	Former rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	LINS Norbert (EPP)	23/05/2023

Council of the European Union

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	BRETON Thierry

Key events

Date	Event	Reference	Summary
27/04/2023	Legislative proposal published	COM(2023)0221	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	A9-0020/2024	Summary
27/02/2024	Debate in Parliament		
28/02/2024	Decision by Parliament, 1st reading	T9-0096/2024	Summary
28/02/2024	Results of vote in Parliament		
13/11/2024	Committee referral announced in Parliament, 1st reading		

Technical information

Procedure reference	2023/0126(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 118-p1
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	JURI/9/11900

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Specific opinion	AGRI	PE750.122	29/06/2023	
Committee draft report		PE753.702	13/10/2023	
Amendments tabled in committee		PE756.100	13/11/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0020/2024	01/02/2024	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0096/2024	28/02/2024	Summary

European Commission

Document type	Reference	Date	Summary
	COM(2023)0221		

Legislative proposal		27/04/2023	Summary
Document attached to the procedure	SEC(2023)0172	27/04/2023	
Document attached to the procedure	SWD(2023)0117	27/04/2023	
Document attached to the procedure	SWD(2023)0118	27/04/2023	
Document attached to the procedure	SWD(2023)0119	27/04/2023	
Commission response to text adopted in plenary	SP(2024)270	08/07/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	N9-0084/2023 OJ C 000 14.11.2023, p. 0000	21/06/2023	
EESC	Economic and Social Committee: opinion, report	CES2306/2023	20/09/2023	

Additional information

Source	Document	Date
EP Research Service	Briefing	18/04/2024

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency

Name	Role	Committee	Date	Interest representatives
WÖLKEN Tiemo	Rapporteur	JURI	19/12/2023	CropLife Europe
WÖLKEN Tiemo	Rapporteur	JURI	19/12/2023	European Commission
WÖLKEN Tiemo	Rapporteur	JURI	06/10/2023	MEDICINES FOR EUROPE
WÖLKEN Tiemo	Rapporteur	JURI	15/09/2023	CropLife Europe
WÖLKEN Tiemo	Rapporteur	JURI	15/09/2023	European Commission - DG GROW
WÖLKEN Tiemo	Rapporteur	JURI	13/09/2023	Bundesverband der Pharmazeutischen Industrie e.V. Verband der Chemischen Industrie e.V. Verband der forschenden Pharma-Unternehmen

Unitary supplementary protection certificate for plant protection products

2023/0126(COD) - 28/02/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 406 votes to 192, with 9 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products.

As a reminder, the proposed regulation lays down rules on the unitary supplementary protection certificate for plant protection products protected by a European patent with unitary effect and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

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 unitary certificate

A unitary certificate should be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, 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 plant protection product has been granted in accordance with Regulation (EC) No 1107 /2009;

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

(d) the authorisation is the first authorisation to place the product on the market as a plan protection product.

Lodging of an application for a unitary certificate

The application for a unitary certificate should be lodged with the Office. If the application for a unitary certificate complies with the provisions of the Regulation, the Office should publish it in the register as soon as possible.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include any evidence the opponent relies on in support of the opposition.

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.

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.

If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it should reject the opposition and notify the opponent of its decision, and the Office should mention this in the Register.

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.

Grant of a unitary certificate or rejection of the application for a unitary certificate

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office should implement without undue delay the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

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

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 the case may be, should verify that that expert is free of any conflict of interest.

Evaluation

By five years after the date of application, and every five years thereafter, the Commission should evaluate the implementation of this Regulation and present a report on the main findings to the European Parliament and the Council. As part of that evaluation, the Commission should assess the feasibility and benefits of establishing a central authorisation procedure for plant protection products under the European Food Safety Authority.

Unitary supplementary protection certificate for plant protection products

2023/0126(COD) - 01/02/2024 - Committee report tabled for plenary, 1st reading/single reading

The Committee 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 unitary supplementary protection certificate for plant protection products.

As a reminder, the proposed regulation lays down rules on the unitary supplementary protection certificate for plant protection products protected by a European patent with unitary effect and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

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:

Conditions for obtaining a unitary certificate

A unitary certificate should be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, 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 plant protection product has been granted in accordance with Regulation (EC) No 1107 /2009;

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

(d) the authorisation is the first authorisation to place the product on the market as a plan protection product.

Lodging of an application for a unitary certificate

The application for a unitary certificate should be lodged with the Office. If the application for a unitary certificate complies with the provisions of the Regulation, the Office should publish it in the register as soon as possible.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include **any evidence** the opponent relies on in support of the opposition.

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.

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.

Grant of a unitary certificate or rejection of the application for a unitary certificate

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office should implement **without undue delay** the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

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 shall 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.

Communications to the Office

Communications addressed to the Office should be made by electronic means.

Evaluation

By five years after the date of application, and every five years thereafter, the Commission should evaluate the implementation of this Regulation and present a report on the main findings to the European Parliament and the Council. As part of that evaluation, the Commission should assess the feasibility and benefits of establishing a central authorisation procedure for plant protection products under the European Food Safety Authority.

Unitary supplementary protection certificate for plant protection products

2023/0126(COD) - 27/04/2023 - Legislative proposal

PURPOSE: to simplify the EU Supplementary Protection Certificate (SPC) system and improve its transparency and efficiency, by creating a unitary certificate for plant protection products.

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 Commission’s intellectual property action plan of November 2020, which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU’s intellectual property system.

Pharmaceutical research plays a decisive role in the continuing improvement in public health. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

There is a clear need to **complement the unitary patent ('European patent with unitary effect') with a unitary SPC**. The proposed creation of a unitary SPC will be fully compatible with the unitary patent system provided for in Regulation (EU) No 1257/2012 and the Unified Patent Court Agreement (UPCA). The unitary patent will enter into force on 1 June 2023, allowing a single patent covering all participating Member States in a unitary manner.

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 centralised procedure for the grant of national certificates for plant protection products, and a unitary certificate for medicinal products.

CONTENT: this proposal lays down rules on the **unitary supplementary protection certificate for plant protection products** protected by a European patent with unitary effect and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

The proposed SPC reform includes the creation of a **unitary SPC**, complementing the unitary patent that will enter into force on 1 June 2023. In the absence of a unitary SPC, a unitary patent could be extended only by means of national SPCs, i.e. in a non-unitary manner, leading to greater administrative burden and costs.

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.

The SPC centralised procedure can be used by any company, start-up, research organisation, innovator, etc. that holds a valid patent on a medicinal product or a plant protection product, and a corresponding marketing authorisation in the EU. Applicants will be able to file a '**combined application**' with a view to the grant of both a unitary SPC and national SPC for additional Member States not covered by the **unitary patent.** This application will be subject to a single examination which, if positive, will result in the grant of a unitary SPC (for those 17 Member States participating in the unitary patent system at the moment) and of national SPCs in further Member States.