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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for plant protection products (recast) - Outcome of the European Parliament's first reading (Strasbourg, 26 to 29 February 2024)

I. INTRODUCTION

The rapporteur, Tiemo WÖLKEN (S&D, DE), presented a report on the above proposal for a Regulation on behalf of the Committee on Legal Affairs (JURI) which contained 33 amendments (amendments 1 to 33) to the proposal.

In addition, the EPP group tabled one amendment (amendment 34).

II. VOTE

When it voted on 28 February 2024, the plenary of the European Parliament adopted amendments 1 to 33 to the proposal for a Regulation. No other amendment was adopted.

The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto.

ANNEX

(28.2.2024)

P9_TA(2024)0098

Supplementary protection certificate for plant protection products (recast)

European Parliament legislative resolution of 28 February 2024 on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) (COM(2023)0223 – C9-0149/2023 – 2023/0128(COD))

(Ordinary legislative procedure – recast)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0223),

– having regard to Article 294(2) and Article 114(1) Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0149/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 September 2023[1],

– having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts[2],

– having regard to Rules 110 and 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Agriculture and Rural Development,

– having regard to the report of the Committee on Legal Affairs (A9-0023/2024),

[1] OJ C, C/2023/865, 08.12.2023, ELI: http://data.europa.eu/eli/C/2023/865/oj.
[2] OJ C 77, 28.3.2002, p. 1.

A. whereas, 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 and whereas, 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;

1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1
Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art ***by*** the description of the patent on ***its*** filing date. This should not necessarily require that the active substance of the product be explicitly identified in the claims**.** Or, in the event of a preparation, this should not necessarily require that each ***of its*** active substances be explicitly identified in the claims, provided that each ***of them*** is specifically identifiable in the light of all the information disclosed by that patent.	(11) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art ***in light of*** the description of the patent on ***the basis of that person's general knowledge in the relevant field and on the prior art at the*** filing date ***or priority date of the basic patent***. This should not necessarily require that the active substance of the product be explicitly identified in the claims or, in the event of a preparation, this should not necessarily require that each active substances be explicitly identified in the claims, provided that each ***active substance*** is specifically identifiable in the light of all the information disclosed by that patent ***on the basis of the prior art at the filing date or priority date of the basic patent***.

Amendment 2
Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, ***either alone or in combination with one or more additional active ingredients,*** whether for the same application or for a different one.	(12) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, or complexes, equivalent to the product from a phytosanitary perspective, should not have already been the subject of a prior certificate, whether for the same application or for a different one.

Amendment 3
Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.	(32) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates ***and related patent*** matters, located today at national offices only. To ensure an optimal quality of the examination, ***the Office and the competent national authorities should make sure that designated examiners have the relevant expertise and sufficient experience in the assessment of supplementary protection certificates. Additional*** suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.

Amendment 4
Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.	(40) ***To safeguard procedural rights and ensure a complete system of remedies,*** where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.

Amendment 5
Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.	(41) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their ***relevant expertise, independence and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment 6
Proposal for a regulation
Article 2 – paragraph 1 – point 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) 'economically linked' means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder.

Amendment 7
Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. 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 .	2. 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. ***The same principle shall 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.***

Amendment 8
Proposal for a regulation
Article 8 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) where applicable, the consent of the third party referred to in Article 6(2) of this Regulation;

Amendment 9
Proposal for a regulation
Article 15 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the certificate was granted contrary to Article 3;	(a) the certificate was granted contrary to Articles 3 ***and 6***;

Amendment 10
Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the centralised application for a certificate and the product to which it relates comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.	2. Where the centralised application for a certificate and the product to which it relates comply with Articles 3(1) ***and 6(2)*** in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

Amendment 11
Proposal for a regulation
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.	3. Where the centralised application for a certificate and the product to which it relates does not comply with Articles 3(1) ***and 6(2)*** in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.

Amendment 12
Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.	2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 ***or 6*** are not fulfilled for one or more of the designated Member States.

Amendment 13
Proposal for a regulation
Article 26 – paragraph 4 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) any evidence the opponent relies on in support of the opposition.

Amendment 14
Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission	*Amendment*
6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate ***this to*** opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.	6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall 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 referred to in paragraph 1.

Amendment 15
Proposal for a regulation
Article 26 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. In cases where several oppositions have been filed against an examination opinion, the Office shall deal with the oppositions jointly and issue one single decision in respect of all oppositions filed.

Amendment 16
Proposal for a regulation
Article 26 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.	9. The Office shall 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.

Amendment 17
Proposal for a regulation
Article 26 – paragraph 10

Text proposed by the Commission	*Amendment*
10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.	10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and ***notify the opponent of its decision,*** and the Office shall mention this in the Register.

Amendment 18
Proposal for a regulation
Article 26 – paragraph 11

Text proposed by the Commission	*Amendment*
11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall mention this in the Register.	11. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, ***notify the opponent of its decision*** and the Office shall mention this in the Register.

Amendment 19
Proposal for a regulation
Article 26 – paragraph 12 a (new)

Text proposed by the Commission	*Amendment*
	12a. Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Amendment 20
Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. 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 in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications.	1. 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 in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications***, on the basis of their relevant expertise and their experience in the field***.

Amendment 21
Proposal for a regulation
Article 28 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) ***geographical balance amongst the participating offices***;	(a) ***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***;

Amendment 22
Proposal for a regulation
Article 28 – paragraph 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) where possible, geographical balance amongst the participating offices;

Amendment 23
Proposal for a regulation
Article 28 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) ***no more*** than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).	(c) ***that there is*** than one examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

Amendment 24
Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal shall be filed within ***4*** months of the date of notification of the decision.	3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement setting out the grounds of appeal, including the evidence supporting these grounds, shall be filed within ***three*** months of the date of notification of the decision. ***Any reply to the statement of grounds of appeal shall be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office shall, where applicable, fix a date for oral proceedings within three months following 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.***

Amendment 25
Proposal for a regulation
Article 29 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Office shall inform the applicant of its decision without undue delay.

Amendment 26
Proposal for a regulation
Article 29 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards ***may*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.	5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards ***shall*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

Amendment 27
Proposal for a regulation
Article 30 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.	4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166(5) of Regulation (EU) 2017/1001. ***When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters shall be taken into account.***

Amendment 28
Proposal for a regulation
Article 30 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Article 166(9) of Regulation (EU) 2017/1001 shall apply to the Boards of Appeal in matters regarding centralised applications for certificates.

Amendment 29
Proposal for a regulation
Article 34 – paragraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) the date and ***a summary of*** the examination opinion in respect of each of the designated Member States;	(j) the date and the examination opinion in respect of each of the designated Member States;

Amendment 30
Proposal for a regulation
Article 34 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion;	(l) where applicable, the filing of an opposition, ***its status*** and its outcome, including where applicable a summary of the revised examination opinion;

Amendment 31
Proposal for a regulation
Article 34 – paragraph 1 – point m

Text proposed by the Commission	*Amendment*
(m) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;	(m) where applicable, the filing of an appeal, ***its status*** and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

Amendment 32
Proposal for a regulation
Article 44 – paragraph 3

Text proposed by the Commission	*Amendment*
3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.	3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summonsed, the Office or the relevant panel, as applicable, shall be verify that that expert is free of any conflict of interest.*** The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

Amendment 33
Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
By [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall carry out an evaluation of the application of Chapter III.	By … [OJ: please insert: five years after the date of application], and every five years thereafter, the Commission shall carry out an evaluation of the application of Chapter III ***and present a report on the main findings to the European Parliament and to the Council***.