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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 unitary supplementary protection certificate for plant protection products - 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 39 amendments (amendments 1 to 39) to the proposal.

In addition, the EPP group tabled three amendments (amendments 40 to 42).

II. VOTE

When it voted on 28 February 2024, the plenary of the European Parliament adopted amendments 1 to 39 to the proposal for a Regulation. No other amendments were 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.

P9_TA(2024)0096

Unitary supplementary protection certificate for plant protection products

European Parliament legislative resolution of 28 February 2024 on the proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products (COM(2023)0221 – C9-0152/2023 – 2023/0126(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0221),
 - having regard to Article 294(2) and Article 118, first paragraph, of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0152/2023),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the letter from the Committee on Agriculture and Rural Development,
 - having regard to the report of the Committee on Legal Affairs (A9-0020/2024),
1. Adopts its position at first reading hereinafter set out;
 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 2 a (new)

Text proposed by the Commission

Amendment

(2a) That situation leads to a lack of protection which penalises plant protection research and the competitiveness of the sector.

Amendment 2
Proposal for a regulation
Recital 17

Text proposed by the Commission

Amendment

(17) One of the conditions for the grant of a certificate should be that the product should be 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.

(17) One of the conditions for the grant of a certificate should be that the product should be 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 **and drawings** of the patent, **on the basis of that person's general knowledge in the relevant field and of 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 of its 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 3
Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) 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.

Amendment

(18) 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 4
Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) The examination of an application for a unitary 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 procedure, in particular as regards qualification and conflicts of interest.

Amendment

(25) The examination of an application for a unitary 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 procedure, in particular as regards qualification and conflicts of interest.

Amendment 5
Proposal for a regulation
Recital 28

Text proposed by the Commission

(28) After the completion of the examination of a unitary certificate application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

Amendment

(28) After the completion of the examination of a unitary certificate application, and after the time limits for appeal and opposition have expired, or, the case being, 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.

Amendment 6
Proposal for a regulation
Recital 29

Text proposed by the Commission

(29) 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 the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

Amendment

(29) ***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 the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

Amendment 7
Proposal for a regulation
Recital 30

Text proposed by the Commission

(30) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment

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

Amendment 8
Proposal for a regulation
Article 2 – paragraph 1 – point 13 a (new)

Text proposed by the Commission

Amendment

(13a) ‘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 9
Proposal for a regulation
Article 3 – paragraph 1 – point b

Text proposed by the Commission

(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;

Amendment

(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 ***in at least one of the Member States in which that basic patent has unitary effect;***

Amendment 10
Proposal for a regulation
Article 3 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending for a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.

Amendment

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending for a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable. ***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 11
Proposal for a regulation
Article 9 – 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 12
Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

If the application for a unitary certificate complies with Article 11(1), the Office shall publish the application in the Register.

Amendment

If the application for a unitary certificate complies with Article 11(1), the Office shall publish the application in the Register ***without undue delay.***

Amendment 13
Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. The Office shall assess the application on the basis of all the conditions in **Article 3(1)**, for all Member States in which the basic patent has unitary effect.

Amendment

1. The Office shall assess the application on the basis of all the conditions in **Article 3** for all Member States in which the basic patent has unitary effect.

Amendment 14
Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

2. Where the application for a unitary certificate and the product to which it relates comply with **Article 3(1)** for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Amendment

2. Where the application for a unitary certificate and the product to which it relates comply with **Articles 3 and 6(2)** for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant **and publish it in the Register without undue delay**.

Amendment 15
Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

3. Where the application for a unitary certificate and the product to which it relates does not comply with **Article 3(1)** in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Amendment

3. Where the application for a unitary certificate and the product to which it relates does not comply with **Articles 3 and 6(2)** in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant **and publish it in the Register without undue delay**.

Amendment 16
Proposal for a regulation
Article 15 – 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 17
Proposal for a regulation
Article 15 – 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 the reasoning for its decision to the*** opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

Amendment 18
Proposal for a regulation
Article 15 – paragraph 9 a (new)

Text proposed by the Commission

Amendment

9a. 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 19
Proposal for a regulation
Article 15 – paragraph 10

Text proposed by the Commission

10. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

Amendment

10. 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 20
Proposal for a regulation
Article 15 – paragraph 11

Text proposed by the Commission

11. 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.

Amendment

11. 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 21
Proposal for a regulation
Article 15 – 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 22
Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

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 applications for unitary certificates.

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 applications for unitary certificates ***based on relevant expertise and sufficient experience required for the centralised examination procedure.***

Amendment 23
Proposal for a regulation
Article 17 – paragraph 3 – point a

Text proposed by the Commission

(a) ***geographical balance amongst the participating offices;***

Amendment

(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 24
Proposal for a regulation
Article 17 – paragraph 3 – point a a (new)

Text proposed by the Commission

Amendment

(aa) where possible, geographical balance amongst the participating offices;

Amendment 25
Proposal for a regulation
Article 17 – paragraph 3 – point c

Text proposed by the Commission

(c) no **more than one** examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 223].

Amendment

(c) **that there is** no examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

Amendment 26
Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

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 shall take one of the following decisions:

Amendment

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 shall take one of the following decisions, **without undue delay**:

Amendment 27
Proposal for a regulation
Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Office shall inform the applicant of its decision without undue delay.

Amendment 28
Proposal for a regulation
Article 21 – paragraph 1 – point a

Text proposed by the Commission

(a) the certificate was granted contrary to **Article 3**;

Amendment

(a) the certificate was granted contrary to **Articles 3 and 6(2)**;

Amendment 29
Proposal for a regulation
Article 22 – paragraph 12

Text proposed by the Commission

12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, ***to the extent that it has been declared invalid.***

Amendment

12. ***To the extent that it has been declared invalid,*** the unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation.

Amendment 30
Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission

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.

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, ***including the evidence supporting those grounds,*** shall be filed within **3** 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 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.

Amendment 31
Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards *may* annul or alter the opinion.

Amendment

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards ***shall*** annul or alter the opinion.

Amendment 32
Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission

4. Members of the Boards of Appeal in matters regarding unitary certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.

Amendment

4. Members of the Boards of Appeal in matters regarding unitary 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 concerning applications for unitary certificates, due consideration shall be given to their previous experience in matters concerning supplementary protection certificates or patent law.

Amendment 33
Proposal for a regulation
Article 27 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Article 166(9) of Regulation (EU) 2017/1001 shall apply to Boards of Appeal in matters regarding unitary certificates.

Amendment 34
Proposal for a regulation
Article 32 – paragraph 1

Text proposed by the Commission

1. Communications addressed to the Office **may** be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications **may** be submitted electronically.

Amendment

1. Communications addressed to the Office **shall** be effected by electronic means. The Executive Director shall determine to what extent and under which technical conditions those communications **are to** be submitted electronically.

Amendment 35
Proposal for a regulation
Article 33 – paragraph 1 – point i

Text proposed by the Commission

(i) the date and **a summary of** the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

Amendment

(i) the date and the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

Amendment 36
Proposal for a regulation
Article 33 – paragraph 1 – point k

Text proposed by the Commission

(k) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

Amendment

(k) where applicable, the filing of an opposition, **its status** and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

Amendment 37
Proposal for a regulation
Article 33 – paragraph 1 – point 1

Text proposed by the Commission

(l) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

Amendment

(l) 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 38
Proposal for a regulation
Article 40 – paragraph 3

Text proposed by the Commission

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.

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. ***Where an expert is summonsed, the Office or the relevant panel, as the case may be, shall 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 39
Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission

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.

Amendment

By ... [OJ: please insert: five years after the date of application], and every five years thereafter, the Commission shall 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 shall assess the feasibility and benefits of establishing a central authorisation procedure for plant protection products under the European Food Safety Authority.***