



2023/0126(COD)

13.10.2023

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DRAFT REPORT

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))

Committee on Legal Affairs

Rapporteur: Tiemo Wölken

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ***■*** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT 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 (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 (A9-0000/2023),
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 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 and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment 2

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.

Or. en

Amendment 3

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);

Or. en

Amendment 4

Proposal for a regulation

Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The applicant shall be responsible for the accuracy of the information and documentation submitted in relation to its application.

Or. en

Amendment 5

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 Article 3(1) **and Article 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.

Or. en

Amendment 6

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 Article 3(1) **and Article 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.

Or. en

Amendment 7

Proposal for a regulation Article 15 – paragraph 6

Text proposed by the Commission

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

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.

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.

Or. en

Amendment 8

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.

Or. en

Amendment 9

Proposal for a regulation

Article 15 – paragraph 10

Text proposed by the Commission

Amendment

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

10. The Office shall issue a decision **including a detailed reasoning for its decision** on the opposition within 6 months, unless the complexity of the case requires a longer period.

Or. en

Amendment 10

Proposal for a regulation

Article 15 – paragraph 11

Text proposed by the Commission

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

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.

notify the opponent of its decision and the Office shall mention this in the Register.

Or. en

Amendment 11

Proposal for a regulation

Article 16 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Once a competent national authority is appointed by the Office as a participating office, it shall appoint its designated examiners based on relevant expertise and whether they have sufficient experience for the centralised examination procedure.

Or. en

Amendment 12

Proposal for a regulation

Article 17 – 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;***

Or. en

Amendment 13

Proposal for a regulation

Article 17 – 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 set out in Article 10(5) of Regulation [COM(2023) 223].

(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) 223].

Or. en

Amendment 14

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

No later than three months 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:

Or. en

Amendment 15

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.

Or. en

Amendment 16

Proposal for a regulation

Article 21 – 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***;

Or. en

Amendment 17

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 supporting evidence for those grounds,*** shall be filed within 4 months of the date of notification of the decision.

Or. en

Amendment 18

**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.

Or. en

Amendment 19

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

Text proposed by the Commission

Amendment

4a. The rules set out in Article 166(9) of Regulation (EU) 2017/1001 shall be respected.

Or. en

Amendment 20

**Proposal for a regulation
Article 30 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

The applicant shall be responsible for the accuracy of the information and documentation submitted in respect of its application.

Or. en

Amendment 21

Proposal for a regulation

Article 33 – paragraph 1 – point k

Text proposed by the Commission

Amendment

(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;

(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;

Or. en

Amendment 22

Proposal for a regulation

Article 33 – paragraph 1 – point l

Text proposed by the Commission

Amendment

(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;

(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;

Or. en

Amendment 23

Proposal for a regulation

Article 40 – paragraph 3

Text proposed by the Commission

Amendment

3. If the Office or the relevant panel considers it necessary for a party, witness

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.

or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summonsed it shall be verified 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.

Or. en

Amendment 24

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 ... [OP, 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 to the Council. In its report, the Commission shall evaluate and assess whether the creation of a central authorisation procedure for plant protection products under the European Food Safety Authority is appropriate and also whether it is efficient and necessary.***

Or. en