

COMMON POSITION (EC) No 30/95

adopted by the Council on 27 November 1995

with a view to adopting Regulation (EC) No .../95 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products

(95/C 353/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF
THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure referred to in Article 189b of the Treaty ⁽³⁾,

- (1) Whereas research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices;
- (2) Whereas plant protection research contributes to the continuing improvement in crop production;
- (3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;
- (4) Whereas, by its very nature, the competitiveness of the plant protection sector calls for protection to innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ⁽⁴⁾;
- (5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization

to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

- (6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector;
- (7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;
- (8) Whereas, in its resolution of 1 February 1993 ⁽⁵⁾ on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission, which stressed the interdependence of economic growth and environmental quality; whereas improving protection of the environment means maintaining the economic competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;
- (9) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws heading to further disparities which would be likely to create obstacles to the free movement of plant protection products within the Community and thus directly affect the establishment and the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the EC Treaty;
- (10) Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a plant protection product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

⁽¹⁾ OJ No C 390, 31. 12. 1994, p. 21.

⁽²⁾ OJ No C 155, 21. 6. 1995, p. 14.

⁽³⁾ Opinion of the European Parliament of 15 June 1995 (OJ No C 166, 3. 7. 1995, p. 89), common position of the Council of 27 November 1995 (not yet published in the Official Journal) and decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 182, 2. 7. 1992, p. 1.

⁽⁵⁾ OJ No C 138, 17. 5. 1993, p. 1.

- (11) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;
- (12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;
- (13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;
- (14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;
- (15) Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the agricultural and environment protection policies pursued at both national and Community level;
- (16) Whereas only action at Community level can be effective in attaining the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products,
- (a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
 - (b) influence the life processes of plants, other than as a nutrient (e.g. plant-growth regulators);
 - (c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
 - (d) destroy undesirable plants; or
 - (e) destroy parts of plants, check or prevent undesirable growth of plants;
2. 'Substances': chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;
 3. 'Active substances': substances or micro-organisms including viruses, having general or specific action:
 - (a) against harmful organisms; or
 - (b) on plants, parts of plants or plant products;
 4. 'Preparations': mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;
 5. 'Plants': live plants and live parts of plants, including fresh fruit and seeds;
 6. 'Plant products': products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 5;
 7. 'Harmful organisms': pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;
 8. 'Product': the active substance as defined in point 3 or combination of active substances of a plant protection product;
 9. 'Basic patent': a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
 10. 'Certificate': the supplementary protection certificate.

HAVE ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'Plant protection products': active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

*Article 2***Scope**

Any product 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 authorization procedure as laid down in Article 4 of Directive 91/414/EEC ⁽¹⁾, or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

*Article 3***Conditions for obtaining a certificate**

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.

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 this product may be issued to each of these holders.

*Article 4***Subject-matter of protection**

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

⁽¹⁾ OJ No L 230, 19. 8. 1991, p. 1. Directive as last amended by Directive 95/36/EC (OJ No L 172, 22. 7. 1992, p. 8).

*Article 5***Effects of the certificate**

Subject to Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

*Article 6***Entitlement to the certificate**

The certificate shall be granted to the holder of the basic patent or his successor in title.

*Article 7***Application for a certificate**

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3 (1) (b) to place the product on the market as a plant protection product was granted.

2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

*Article 8***Content of the application for a certificate**

1. The application for a certificate shall contain:

- (a) a request for the grant of a certificate, stating in particular:
 - (i) the name and address of the applicant;
 - (ii) if he has appointed a representative, the name and address of the representative;
 - (iii) the number of the basic patent and the title of the invention;
 - (iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 (1) (b) and, if this authorization is not the first authorization to place the product on the market in the Community, the number and date of that authorization;
- (b) a copy of the authorization to place the product on the market, as referred to in Article 3 (1) (b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I (points 1-7) or B.I (points 1-7) of Annex II to Directive 91/414/EEC or in equivalent

national laws of the Member State in which the application was lodged;

- (c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official gazette or, failing such publication, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.

2. Member States may provide that a fee is payable upon application for a certificate.

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the organization referred to in Article 3 (1) (b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:

- (a) the name and address of the applicant;
- (b) the number of the basic patent;
- (c) the title of the invention;
- (d) the number and date of the authorization to place the product on the market, referred to in Article 3 (1) (b), and the product identified in that authorization;
- (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

Article 10

Grant of the certificate or rejection of the application

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

2. The authority referred to in Article 9 (1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9 (1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9 (1) is to grant certificates without verifying that the conditions laid down in Article 3 (1) (c) and (d) are met.

Article 11

Publication

1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the following information:

- (a) the name and address of the holder of the certificate;
- (b) the number of the basic patent;
- (c) the title of the invention;
- (d) the number and date of the authorization to place the product on the market referred to in Article 3 (1) (b) and the product identified in that authorization;
- (e) where relevant, the number and date of the first authorization to place the product on the market in the Community;
- (f) the duration of the certificate.

2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the information listed in Article 9 (2).

Article 12

Annual fees

Member States may require that the certificate be subject to the payment of annual fees.

*Article 13***Duration of the certificate**

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.
2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.
3. For the purposes of calculating the duration of the certificate, account is taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product.

*Article 14***Expiry of the certificate**

The certificate shall lapse:

- (a) at the end of the period provided for in Article 13;
- (b) if the certificate-holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 12 is not paid in time;
- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place it on the market in accordance with Article 4 of Directive 91/414/EEC or equivalent provisions of national law. The authority referred to in Article 9 (1) may decide on the lapse of the certificate either on its own initiative or at the request of a third party.

*Article 15***Invalidity of the certificate**

1. The certificate shall be invalid if:
 - (a) it was granted contrary to the provisions of Article 3;
 - (b) the basic patent has lapsed before its lawful term expires;
 - (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.

*Article 16***Notification of lapse or invalidity**

If the certificate lapses in accordance with Article 14 (b), (c) or (d) or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9 (1).

*Article 17***Appeals**

1. The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.
2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.

*Article 18***Procedure**

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Regulation (EEC) No 1768/92, shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation.
2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

TRANSITIONAL PROVISIONS*Article 19*

1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic

patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.

2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.

Article 20

In those Member States whose national law did not, on 1 January 1990, provide for the patentability of plant protection products, this Regulation shall apply from 2 January 1998.

Article 19 shall not apply in those Member States.

FINAL PROVISION

Article 21

Entry into force

This Regulation shall enter into force six months after its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at . . .

For the European Parliament
The President

For the Council
The President

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 12 December 1994 the Commission submitted a proposal, based on Article 100a of the Treaty, concerning the creation of a supplementary protection certificate for plant protection products ⁽¹⁾.
2. The European Parliament delivered its first-reading opinion on 15 June 1995 ⁽²⁾. Further to that opinion, the Commission submitted an amended proposal for a Regulation ⁽³⁾ on 6 October 1995.

The Economic and Social Committee delivered its opinion on 27 April 1995 ⁽⁴⁾.

3. The Council adopted its common position, in accordance with Article 189b of the Treaty, on 27 November 1995.

II. OBJECTIVE

4. The purpose of the proposal is to enact at Community level a measure harmonizing the length of protection of plant protection products, while remedying the erosion of the length of patent protection for such products, by establishing a new national industrial property right (the 'supplementary protection certificate') to take effect at the end of the lawful term of the relevant patent for a period of up to five years, with the same effects as the patent.

III. ANALYSIS OF THE COMMON POSITION

General comments

5. The Council approves the proposal. The amended Commission proposal took on board all the amendments put forward by the European Parliament, with a few drafting changes, and made a number of amendments at the Council's instigation, for the sake of greater clarity in a number of provisions. The Council has included all of both sets of amendments in its common position.

Amendments put forward by the European Parliament

6. Amendments 1 and 2

The Commission included these amendments in its amended proposal in unchanged form (first and third recitals). The Council has included them in its common position.

7. Amendment 3

The Commission included this amendment in its amended proposal (fourth recital), with the replacement in French of the word *semblable* by *équivalente* ('the same' in English). In its common position, the Council has followed the wording used by the Commission in French, finding 'equivalent' more appropriate than the terms used in some language versions of the amendment put forward by the European Parliament.

⁽¹⁾ OJ No C 390, 31. 12. 1994, p. 21.

⁽²⁾ OJ No C 166, 3. 7. 1995, p. 89.

⁽³⁾ Not yet published in the Official Journal.

⁽⁴⁾ OJ No C 155, 21. 6. 1995, p. 14.

8. *Amendment 4*

The Commission included in its amended proposal this new recital put forward by the European Parliament (seventh recital), with a change in wording. The Council has included the recital in its common position in the wording proposed by the Commission. The Council shares the Commission's view that the objective mentioned in the recital is not the only true purpose of the supplementary protection certificate, there being others stated in other recitals.

Amendments at the Council's instigation

9. *Twelfth, 13th and 14th recitals*

In its amended proposal, the Commission added new 13th and 14th recitals to specify the extent of the protection provided by the certificate; that specification obviates the need for the last part of the ninth recital in the original proposal (corresponding to the 12th recital in the amended proposal). The Council has included in its common position the 12th, 13th and 14th recitals as contained in the amended proposal.

Lest the inclusion of those recitals in this Regulation and the omission of corresponding recitals in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ⁽¹⁾ give rise to differing interpretations of the two Regulations ⁽²⁾, the Council and the Commission plan to enter the following statement in the Council minutes when the Regulation is finally adopted and to make it available to the public:

'The Council and the Commission consider that the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4 and 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.'

10. *Article 2*

The Council has included in its common position the change made in the amended Commission proposal, replacing 'before the entry into force of Directive 91/414/EEC for the Member State concerned' by 'before Directive 91/414/EEC was implemented by the Member State concerned'. This wording is intended to make allowance for the situation of those Member States which have been unable to transpose that Directive within the allotted time and also for the transitional period available to the new Member States for transposing Community Directives.

11. *Article 3 (2)*

In its amended proposal, the Commission proposed a new Article 3 (2) to make it clear that, while the same holder of a number of patents may not be granted more than one certificate for the same product, two or more certificates may be issued for the same product to holders of different patents under certain circumstances. The Council has included this new paragraph in its common position.

The statement referred to in the second paragraph in Article 9 also relates to this new paragraph.

⁽¹⁾ OJ No L 182, 2. 7. 1992, p. 1.

⁽²⁾ See also 11, 12 and 19 below.

12. *Article 8 (1) (c)*

The amended Commission proposal contains an amendment to Article 8 (1) (c), designed to make allowance for different practices in the Member States as regards the publication or otherwise of marketing authorizations and the evidence to be supplied of the issue of such authorizations, failing their publication. The Council has included this amendment in its common position.

The statement referred to in the second paragraph in Article 9 also relates to this amendment as compared with the corresponding provision of Regulation (EEC) No 1768/92.

13. *Article 13 (3)*

The Council has included in its common position the new Article 13 (3) contained in the amended Commission proposal. The amendment stipulates that, for the purposes of calculating the duration of the supplementary protection certificate, account is taken of the date of a provisional first marketing authorization, but only if it is followed by a definitive authorization concerning the same product; this may involve a provisional first organization issued under the procedure in Directive 91/414/EEC or a provisional first authorization issued under an equivalent provision of national law.

Since this aspect is specific to the procedure for the placing on the market of plant protection products, the amendment is not covered by the statement referred to in the second paragraph in Article 9.

14. *Article 18 (1)*

The Council has included in its common position an amendment proposed in Article 18 (1) of the amended Commission proposal. The amendment is designed to allow Member States to apply to certificates under this Regulation, *mutatis mutandis*, the procedural provisions they have adopted for certificates under Regulation (EEC) No 1768/92, which should enable them to streamline the national measures to be taken.

15. *Article 20*

The Council has included in its common position the new Article 20 contained in the amended Commission proposal. The new Article, corresponding to Article 21 of Regulation (EEC) No 1768/92, states that the Regulation is not to apply until 2 January 1998 (the same date as for Regulation (EEC) No 1768/92) in those Member States whose national law did not, on 1 January 1990 (the same date as for Regulation (EEC) No 1768/92), provide for a patentability of plant protection products. The Council considers that the reasons for which such a provision was included in Regulation (EEC) No 1768/92 also apply in the case of this Regulation.

16. *Article 21*

The Council has included the amendment proposed by the Commission to extend the period before entry into force of the Regulation from three to six months as from the date of its publication in the Official Journal. The Council considers that a period of three months would be insufficient for those Member States whose national parliaments have to adopt measures in implementation of the Regulation. Moreover, the six-month period matches that under Regulation (EEC) No 1768/92.

Technical adjustments17. *References to Article 3*

The inclusion of the new Article 3 (2) has given rise to adjustments in the numbering of several references to Article 3 (in Article 7 (1), Article 8 (1) (a) (iv) and (b), Article 9 (1) and (2) (d), Article 10 (5) and Article 11 (1) (d)).

18. *Article 8 (1) (b)*

The Council has included in its common position the adjustment proposed by the Commission in its amended proposal to Article 8 (1) (b), to take account of the amendment of Parts A.1 and B.1 of Annex II to Directive 91/414/EEC by Directive 94/37/EEC of 22 July 1994.

Amendment made by the Council19. *Article 17 (2)*

The Council has added a new Article 17 (2). Since the duration of the certificate depends on the date of the first marketing authorization in the Community as stated in the application for a certificate and since the authority referred to in Article 9 does not check whether that date is correct, the Council sees a need to stipulate that, should that date prove incorrect, the decision to grant the certificate is open to an appeal aimed at rectifying the duration of the certificate. As that decision is not covered by those referred to in paragraph 1 of the Article, it needs to be mentioned in a separate paragraph.

The statement referred to in the second paragraph in Article 9 also relates to this new paragraph.

The Commission has agreed to the new paragraph.

IV. CONCLUSIONS

20. The Council has accepted in substance all the amendments put forward by the European Parliament as well as all the amendments, basically by way of clarification, contained in the amended Commission proposal. It has also added a new paragraph to Article 17, which has been agreed to by the Commission.
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