



COMMISSION OF THE EUROPEAN COMMUNITIES

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Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)

concerning the creation of a supplementary protection certificate
for plant protection products

(presented by the Commission pursuant to Article 189 a (2)
of the EC-Treaty)

EXPLANATORY MEMORANDUM

GENERAL PRESENTATION

In December 1994 the Commission presented to Parliament and to the Council a proposal for a Regulation concerning the creation of a supplementary protection certificate for plant protection products.¹

The Economic and Social Committee adopted its opinion on 27 April 1995.²

Parliament discussed the proposal in detail in its various committees and during its plenary session in June 1995.³

The purpose of the amended proposal is to take account of these opinions and to clarify, where necessary, the wording of a number of provisions. In particular, the amended proposal allows for the amendments to Directive 91/414/EEC, made after the Commission had presented its proposal.

Parliament examined the economic conditions in which the plant protection industry operates within the Community and set out the specific characteristics of this sector in relation to its objectives and in view of its international competitors.

The Commission is willing to accept the four amendments adopted by Parliament, all of which aim to clarify the economic and legal conditions under which the plant protection sector in the Community operates.

¹ OJ No C 390, 31.12.1994, p. 21.

² OJ No C

³ OJ No C

EXAMINATION OF THE RECITALS

RECITAL NO 1

The purpose of this new recital, which adopts in full Amendment 1 adopted by Parliament, is to make clear that plant protection research contributes to improvements in production and procurement of good-quality food.

RECITAL NO 3

This recital has been amended to include the full text of Amendment 2 adopted by Parliament. It states that plant protection products will continue to be developed if there is adequate protection in the Community to encourage research.

RECITAL NO 4

This new recital, which adopts almost the same wording as Amendment 3 adopted by Parliament, states that the plant protection sector is in a situation similar to that of the pharmaceuticals industry when an equivalent measure to restore the effective duration of patent protection was proposed and adopted.⁴

RECITAL NO 7

This new recital, which adopts almost the same wording as Amendment 4 adopted by Parliament, states that one of the proposal's objectives is to place European industry on the same competitive footing as its international competitors.

RECITALS NOS 13 AND 14

These two new recitals set out the scope of protection conferred by the supplementary certificate and clarify the links between the basic patent covering a plant protection product and the supplementary certificate for the same product. They also state the conditions under which a supplementary certificate may be obtained for the derivatives of a plant protection product already covered by a supplementary certificate.

⁴ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products; OJ No L 182, 2.7.1992, p. 1.

EXPLANATION OF THE PROVISIONS

ARTICLE 2

The slightly revised wording takes account of any problems that could arise in the Member States which were not able to transpose Directive 91/414/EEC concerning the placing of plant protection products on the market by the required deadline, and in the new Member States which have transitional periods in which to transpose Community directives.

ARTICLE 3 (2)

This new paragraph states that, as a rule, the holder of a number of patents for the same plant protection product may not be granted a number of certificates for that product, and sets out the specific circumstances (where two or more applications are pending) in which two or more certificates may be issued for the same product.

ARTICLE 8 (1)

Since the Commission presented its proposal, Directive 91/414/EEC concerning the placing of plant protection products on the market has been amended by Directive 94/37/EEC of 22 July 1994. Annex II to Directive 91/414/EEC has also been amended. The new wording of Article 8(1)(b) takes account of this amendment.

In addition, the new Article 8(c)(1) allows for the situation in Member States in which the authorization to place plant protection products on the market is not published in an Official Journal or another official publication. In those Member States, the application for a certificate must be accompanied by any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.

ARTICLE 13 (3)

This new paragraph takes account of the special features of the authorization procedure for placing plant protection products on the market. For the purposes of calculating the duration of the supplementary protection certificate, provisional authorization is taken into account only if it is subsequently followed by a definitive authorization concerning the same product. This provision applies equally to the system under Directive 91/414/EEC and, where appropriate, to equivalent provisions of national law.

ARTICLE 18

There has been a Community Regulation concerning the creation of a supplementary protection certificate for medicinal products since 1992; under that Regulation, a number of Member States have adopted special procedural provisions concerning the issue of those supplementary certificates. The amendment to Article 18 allows the Member States which already have special provisions for supplementary protection certificates for medicinal products to apply them, *mutatis mutandis*, to supplementary protection certificates for plant protection products.

ARTICLE 20

This new Article takes account of the specific situation of Member States which have recently introduced into national law the principle of patentability of plant protection products. Under Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, it was decided that the Member States whose laws introduced the patentability of pharmaceutical products only very recently would be able to implement the Regulation five years later than the other Member States. This deferral means that an application for a supplementary protection certificate for a medicinal product will be acceptable in the Member States concerned only from 2 January 1998. Under this Regulation, account should be taken of the similar situation existing in a number of Member States with regard to the patentability of plant protection products; for those Member States, the date of application of this Regulation should coincide with that of Regulation No 1768/92 for medicinal products.

ARTICLE 21

This amendment takes account of the situation in Member States in which the national parliament must adopt implementing rules for this Regulation (statutory regulations allowing taxes to be levied, etc.) and which need time to do so. In order to allow for this difficulty, the Article states that the Regulation is to enter into force six months after its publication in the Official Journal of the European Communities.

Amended proposal for a
EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)
concerning the creation of a supplementary protection
certificate for plant protection products

(presented by the Commission under Article 189a(2) of the EC Treaty)

ORIGINAL PROPOSAL

AMENDED PROPOSAL

**THE EUROPEAN PARLIAMENT
AND THE COUNCIL OF THE
EUROPEAN UNION,**

Having regard to the Treaty establishing
the European Economic 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

**THE EUROPEAN PARLIAMENT
AND THE COUNCIL OF THE
EUROPEAN UNION,**

Unchanged

Having regard to the proposal from the
Commission,¹

Unchanged

(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;

¹ OJ No C

² OJ No C

¹ OJ No C 390, 31.12.1994, p. 21.

OJ No C

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- (1) Whereas plant protection research contributes to the continuing improvement in crop production;
- (2) Whereas plant protection products, especially those that are the result of long, costly research, will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;
- (3) 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 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;

- (2) Unchanged
- (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 the same protection to be afforded to innovation as that granted to medicinal products by Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products;
- (5) Unchanged

(4) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector;

(5) Whereas, in its Resolution of 1 February 1993³ 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 competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;

(6) Unchanged

(7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its American and Japanese counterparts;

(8) Unchanged

³ OJ No C 138, 17.5.1993, p. 1.

OJ No C 138, 17.5.1993, p. 1.

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(6) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading 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 Treaty establishing the European Community;

(7) 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;

(9) Unchanged

(10) Unchanged

(8) 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 fifteen years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;

(9) 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; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a plant protection product;

(11) Unchanged

(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 grants 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 grants the same protection;

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(10) 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 policies pursued both at national and Community level;

(11) 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;

**HAVE ADOPTED THIS
REGULATION:**

(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 product, provided that the derivatives are the subject of patents specifically covering them;

(15) Unchanged

(16) Unchanged

**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:
 - 1.1. 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;
 - 1.2. influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);
 - 1.3. preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
 - 1.4. destroy undesired plants; or
 - 1.5. destroy parts of plants, check or prevent undesired growth of plants;

**Article 1
Definitions**

Unchanged

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:
 - 3.1. against harmful organisms; or
 - 3.2. 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 at point 5;

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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 is defined at point 3 or combination of active substances of a plant protection product;
9. "basic patent": a patent which protects a product as defined at point 8 as such, a preparation as defined at 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.

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 Council Directive 91/414/EEC,⁴ 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 the entry into force of Directive 91/414/EEC for 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

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;

⁴ OJ No L 230, 19.8.1991, p. 1.

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 Council Directive 91/414/EEC,⁴ 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. Unchanged

⁴ OJ No L 230, 19.8.1991, p. 1.

- 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 a number of patents for the same product may not be granted a number of certificates for that product. However, where two or more applications are pending, two or more certificates may be issued for the same product to two or more holders of different patents for the same product.

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.

Unchanged

Article 5

Effects of the certificate

Subject to the provisions of 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.

Unchanged

Article 6

Entitlement to the certificate

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

Unchanged

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(b) to place the product on the market as a plant protection product was granted.

Article 4

Subject-matter of protection

Article 5

Effects of the certificate

Article 6

Entitlement to the certificate

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;

2. Unchanged

Article 8
Content of the application for a certificate

1. Unchanged
- a) Unchanged
 - i) Unchanged
 - ii) Unchanged
 - iii) Unchanged

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- iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(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(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 or B.I of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged;

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- 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 Official Journal or any other document including the information required.

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

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. Unchanged

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 authorization referred to in Article 3(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(b), and the product identified in that authorization;

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 authorization 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. Unchanged:
 - a) Unchanged
 - b) Unchanged
 - c) Unchanged
 - 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.

- c) Unchanged

Article 10
Grant of the certificate or rejection of the application

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.

- 1. Unchanged
- 2. Unchanged
- 3. Unchanged
- 4. Unchanged

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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(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(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.

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**

Unchanged

- a) unchanged
- b) unchanged
- c) unchanged
- 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) unchanged
- f) unchanged

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.

**Article 12
Annual fees**

Unchanged

**Article 13
Duration of the certificate**

1. Unchanged
2. Unchanged

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.

- 3. For the purposes of calculating the duration of the certificate, account is taken of a provisional first marketing authorization only if it is subsequently followed by a definitive authorization concerning the same product.

Article 14

Expiry of the certificate

Unchanged

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Article 15
Invalidity of the certificate

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 so 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.

Unchanged

Article 16
Notification of lapse or invalidity

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).

Unchanged

**Article 17
Appeals**

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.

**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 shall apply to the certificate, unless that law lays down special procedural provisions for certificates.
2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

**Article 17
Appeals**

Unchanged

**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 1768/92, shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation.
2. Unchanged

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TRANSITIONAL PROVISIONS

TRANSITIONAL PROVISIONS

Article 19

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.

Unchanged

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 20
Entry into force**

This Regulation shall enter into force three 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 Brussels,

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.

Unchanged

Done at Brussels,

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