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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.6.2008
COM(2008) 369 final

2008/0126 (COD)

Proposal for a

**REGULATION (EC) No .../... OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL**

of [...]

concerning the supplementary protection certificate for medicinal products

(Codified version)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen, thus giving him new opportunities and the chance to make use of the specific rights it gives him.

This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

For this reason a codification of rules that have frequently been amended is also essential if Community law is to be clear and transparent.

2. On 1 April 1987 the Commission therefore decided¹ to instruct its staff that all legislative acts should be codified after no more than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the Community rules are clear and readily understandable.
3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this² stressing the importance of codification as it offers certainty as to the law applicable to a given matter at a given time.

Codification must be undertaken in full compliance with the normal Community legislative procedure.

Given that no changes of substance may be made to the instruments affected by codification, the European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

4. The purpose of this proposal is to undertake a codification of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.³ The new Regulation will supersede the various acts incorporated into it;⁴ this proposal fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

¹ COM(87) 868 PV.

² See Annex 3 to Part A of the Conclusions.

³ Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

⁴ Annex I to this proposal.

5. The codification proposal was drawn up on the basis of a preliminary consolidation, in all official languages, of Regulation (EEC) No 1768/92 and the instruments amending it, carried out by the Office for Official Publications of the European Communities, by means of a data-processing system. Where the Articles have been given new numbers, the correlation between the old and the new numbers is shown in a table set out in Annex II to the codified Regulation.

↓ 1768/92 (adapted)

2008/0126 (COD)

Proposal for a

REGULATION (EC) No .../... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of [...]

concerning the supplementary protection certificate for medicinal products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the procedure laid down in Article 251 of the Treaty²,

Whereas:

↓

- (1) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products³ has been substantially amended several times⁴. In the interests of clarity and rationality the said Regulation should be codified.

↓ 1768/92 Recital 1

- (2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ L 182, 2.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ L 378, 27.12.2006, p. 1).

⁴ See Annex I.

↓ 1768/92 Recital 2

- (3) Medicinal 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.
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↓ 1768/92 Recital 3 (adapted)

- (4) At the moment , the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.
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↓ 1768/92 Recital 4

- (5) This situation leads to a lack of protection which penalises pharmaceutical research.
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↓ 1768/92 Recital 5 (adapted)

- (6) There exists the risk of research centres situated in the Member States relocating to countries that offer greater protection.
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↓ 1768/92 Recital 6 (adapted)

- (7) 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 medicinal products within the Community and thus directly affect the functioning of the internal market.
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↓ 1768/92 Recital 7 (adapted)

- (8) Therefore, the provision 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 medicinal product for which marketing authorisation has been granted is necessary. A Regulation is therefore the most appropriate legal instrument.
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↓ 1768/92 Recital 8 (adapted)

- (9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. 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 medicinal product in question first obtains authorisation to be placed on the market in the Community.

↓ 1768/92 Recital 9

- (10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.
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↓ 1768/92 Recital 13

- (11) Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,
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↓ 1768/92 (adapted)

HAVE ADOPTED THIS REGULATION:

Article 1

Definitions

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

- (a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- (b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;
- (c) ‘basic patent’ means a patent which protects a product as defined in point (b) as such, 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;
- (d) ‘certificate’ means the supplementary protection certificate;
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↓ 1901/2006 Art. 52, pt. 1)
(adapted)

- (e) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and of Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁵.
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⁵ OJ L 378, 27.12.2006, p. 1.

↓ 1768/92

Article 2

Scope

↓ 1768/92 (adapted)

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council ⁶ or Directive 2001/82/EC of the European Parliament and of the Council ⁷ may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

↓ 1768/92

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 and at the date of that application:

(a) the product is protected by a basic patent in force;

↓ 1768/92 (adapted)

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC , as appropriate;

↓ 1768/92

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

⁶ OJ L 311 , 28.11.2001 , p. 67 .

⁷ OJ L 311 , 28.11.2001 , p. 1.

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 authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

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.

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 authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.
2. Notwithstanding paragraph 1, where the authorisation 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.

↓ 1901/2006 Art. 52, pt. 2 (adapted)

3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.
4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.
5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

↓ 1768/92

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 authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

↓ 1768/92 (adapted)

- (b) a copy of the authorisation 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 authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC .

↓ 1768/92

- (c) if the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication.

↓ 1901/2006 Art. 52, pt. (3)(a)

- d) where the application for a certificate includes a request for an extension of the duration:
- (i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

- (ii) where necessary, in addition to the copy of the authorisations to place the product on the market as referred to in point (b), proof that it has authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.
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↓ 1901/2006 Art. 52, pt. (3)(b)

2. Where an application for a certificate is pending, an application for an extended duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1(d) of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1(d) and a copy of the certificate already granted.

↓ 1901/2006 Art. 52, pt. (3)(c)

4 Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

↓ 1768/92

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 authorisation 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.

↓ 1901/2006 Art. 52, pt. (4)(a)

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

↓ 1768/92

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 authorisation to place the product on the market, referred to in Article 3(b), and the product identified in that authorisation;

- (e) where relevant, the number and date of the first authorisation to place the product on the market in the Community;
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↓ 1901/2006 Art. 52, pt. (4)(b)

- (f) where applicable, an indication that the application includes an application for an extension of the duration.
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↓ 1901/2006 Art. 52, pt. (4)(c)

3. Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an indication of the application for an extended duration of the certificate.

↓ 1768/92 (adapted)

Article 10

Grant of the certificate or rejection of the application ☒ for a certificate ☒

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(c) and (d) are met.
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↓ 1901/2006 Art. 52, pt. (5)

6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.

↓ 1768/92

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 authorisation to place the product on the market referred to in Article 3(b) and the product identified in that authorisation;
- (e) where relevant, the number and date of the first authorisation 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).

↓ 1901/2006 Art. 52, pt. (6)

3. Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected.

↓ 1768/92 (adapted)

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 authorisation 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.

↓ 1901/2006 Art. 52, pt. (7)

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

↓ 1768/92 (adapted)

4. Where a certificate is granted for a product protected by a patent which, before the 2 January 1993, has had its term extended or for which such extension was applied for, under national patent law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

↓ 1768/92

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;
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↓ 1768/92 (adapted)

- (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 authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC . The authority referred to in Article 9(1) of this Regulation may decide on the lapse of the certificate either of its own motion or at the request of a third party.

↓ 1768/92 (adapted)

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.

↓ 1901/2006 Art. 52, pt. (8)

Article 16

Revocation of an extension of the duration

1. The extension of the duration may be revoked if it was granted contrary to the provisions of Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration to the body responsible under national law for the revocation of the corresponding basic patent.

↓ 1768/92
→₁ 1901/2006 Art. 52, pt. (9)(a)

Article 17

Notification of lapse or invalidity

→₁ 1. ← 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).

↓ 1901/2006 Art. 52, pt. (9)(b)
(adapted)

2. If the extension of the duration is revoked in accordance with Article 16, notification thereof shall be published by the authority referred to in Article 9(1).

↓ 1901/2006 Art. 52, pt. (10)

Article 18

Appeals

The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(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.

↓ 1768/92

Article 19

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.

↓ 2003 Act of Accession Art. 20
and Annex II pt. 4.C.II.1.(a),
p. 342 (adapted)

Article 20

Additional provisions relating to the enlargement of the Community

Without prejudice to the other provisions of this Regulation, the following provisions shall apply:

↓ 2003 Act of Accession Art. 20
and Annex II, pt. 4.C.II.1.(a),
p. 342 (adapted)

- (a) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:
- (i) in the Czech Republic, after 10 November 1999, may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;
- (ii) in the Community, not earlier than six months prior to 1 May 2004, may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;
- (b) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;
- (c) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;
- (d) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004 .
- (e) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate is lodged within six months from 1 May 2004 .
- (f) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate is lodged within six months from 1 May 2004 .

- (g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to ☒ 1 May 2004 ☒ may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than ☒ 1 May 2004 ☒;
- (h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate is lodged within six months starting no later than ☒ 1 May 2004 ☒;
- (i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to ☒ 1 May 2004 ☒ may be granted a certificate, provided that the application for a certificate is lodged within six months ☒ from 1 May 2004 ☒, including in cases where the period provided for in Article 7(1) has expired;
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↓ Act of Accession of 2003
Art. 20 and Annex II, pt.
4.C.II.1.(a), p. 342

- (j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date;
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↓ 2005 Act of Accession Art. 16
and Annex III, pt 1 II.1(a)
(adapted)

- (k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate is lodged within six months ☒ from 1 January 2007 ☒;
- (l) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than ☒ 1 January 2007 ☒.

↓ 1768/92 (adapted) → ₁ 2003 Act of Accession Art. 20 and Annex II, pt. 4.C.II.1(b) p. 342

Article 21

⊗ Transitory provisions ⊗

→₁ 1. ← This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before ⊗ 2 January 1993 ⊗ or to applications for a certificate filed in accordance with that legislation before ⊗ 2 July 1992 ⊗.

↓ 1994 Act of Accession Art. 29 and Annex I, XI.F.I(c) p. 233 (adapted)

With regard to Austria, Finland and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before . ⊗ 1 January 1995 ⊗

↓ 2005 Act of Accession Art. 16 and Annex III, pt.1 II.1(b) (adapted)

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to ⊗ 1 May 2004 and the national legislation of Romania prior to 1 January 2007 ⊗.

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Article 22

Repeal

Regulation (EEC) No 1768/92 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 23

Entry into force

This Regulation shall enter into force ☒ on the twentieth day following that of ☒ its publication in the *Official Journal of the European ☒ Union ☒* .

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

Done at Brussels, [...]

For the European Parliament
The President
[...]

For the Council
The President
[...]



ANNEX I

Repealed Regulation with list of its successive amendments

Council Regulation (EEC) No 1768/92
(OJ L 182, 2.7.1992, p. 1)

Annex I, point XI.F.I, of the 1994 Act of Accession
(OJ C 241, 29.8.1994, p. 233)

Annex II, point 4.C.II, of the 2003 Act of Accession
(OJ L 236, 23.9.2003, p. 342)

Annex III, point 1.II, of the 2005 Act of Accession
(OJ L 157, 21.6.2005, p. 56)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council
(OJ L 378, 27.12.2006, p. 1) Only Article 52

ANNEX II

CORRELATION TABLE

Regulation (EEC) No 1768/92	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3, introductory words	Article 3, introductory words
Article 3(a)	Article 3(a)
Article 3(b), first sentence	Article 3(b)
Article 3(b), second sentence	—
Article 3(c) and (d)	Article 3(c) and (d)
Articles 4 to 7	Articles 4 to 7
Article 8(1)	Article 8(1)
Article 8(1a)	Article 8(2)
Article 8(1b)	Article 8(3)
Article 8(2)	Article 8(4)
Articles 9 to 12	Articles 9 to 12
Article 13(1), (2) and (3)	Article 13(1), (2) and (3)
Articles 14 and 15	Articles 14 and 15
Article 15a	Article 16
Articles 16, 17 and 18	Articles 17, 18 and 19
Article 19	—
Article 19a, introductory words, point (a)(i) and (ii)	Article 20, introductory words, point (a) introductory words, and points (i) and (ii)
Article 19a(b) to (l)	Article 20(b) to (l)
Article 20	Article 21
Article 21	—
Article 22	Article 13(4)

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Article 23

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Article 22

Article 23

Annex I

Annex II
