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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

concerning the supplementary protection certificate for medicinal products

(Codified version)

(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 Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [3] has been substantially amended several times [4]. In the interests of clarity and rationality the said Regulation should be codified.

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

(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.

(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.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(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.

(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.

(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 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

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[1] OJ C 77, 31.3.2009, p. 42.

[2] Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 6 April 2009.

[3] OJ L 182, 2.7.1992, p. 1.

[4] See Annex I.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should 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.

(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,

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 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;

(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 Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use [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 medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2] or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [3] 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 and at the date of that application:

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

(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;

(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.

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.

[1] OJ L 378, 27.12.2006, p. 1.

[2] OJ L 311, 28.11.2001, p. 67.

[3] OJ L 311, 28.11.2001, p. 1.

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.

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.

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;

(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;

(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;

(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 authorisation to place the product on the market as referred to in point (b), proof of possession of 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.

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.

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.

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.

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

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;

(f) where applicable, an indication that the application includes an application for an extension of the duration.

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.

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.

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

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).

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.

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.

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.

4. Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national 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.

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 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.

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

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.

Article 17

Notification of lapse or invalidity

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

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).

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.

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 the national 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 20

Additional provisions relating to the enlargement of the Community

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

(a) 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 was lodged within six months from 1 January 2007;

(b) 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;

(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 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;

(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 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;

(e) 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;

(f) 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 was 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 after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 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 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;

(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 after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;

(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 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;

(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 in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;

(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 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.

Article 21

Transitional provisions

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.

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.

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.

Article 22

Repeal

Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, 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 20th day following 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 Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

ANNEX I

REPEALED REGULATION WITH LIST OF ITS SUCCESSIVE AMENDMENTS

(referred to in Article 22)

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
—	Recital 1
Recital 1	Recital 2
Recital 2	Recital 3
Recital 3	Recital 4
Recital 4	Recital 5
Recital 5	Recital 6
Recital 6	Recital 7
Recital 7	Recital 8
Recital 8	Recital 9
Recital 9	Recital 10
Recital 10	—
Recital 11	—
Recital 12	—
Recital 13	Recital 11
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3, introductory wording
Article 3, point (a)	Article 3, point (a)
Article 3, point (b), first sentence	Article 3, point (b)
Article 3, point (b), second sentence	—
Article 3, points (c) and (d)	Article 3, points (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 wording	Article 20, introductory wording
Article 19a, point (a), points (i) and (ii)	Article 20, point (b), introductory wording, points (i) and (ii)

Regulation (EEC) No 1768/92	This Regulation
Article 19a, point (b)	Article 20, point (c)
Article 19a, point (c)	Article 20, point (d)
Article 19a, point (d)	Article 20, point (e)
Article 19a, point (e)	Article 20, point (f)
Article 19a, point (f)	Article 20, point (g)
Article 19a, point (g)	Article 20, point (h)
Article 19a, point (h)	Article 20, point (i)
Article 19a, point (i)	Article 20, point (k)
Article 19a, point (j)	Article 20, point (l)
Article 19a, point (k)	Article 20, point (a)
Article 19a, point (l)	Article 20, point (j)
Article 20	Article 21
Article 21	—
Article 22	Article 13(4)
—	Article 22
Article 23	Article 23
—	Annex I
—	Annex II

REGULATION (EC) No 470/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council

(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 37 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the procedure referred to in Article 251 of the Treaty [2],

Whereas:

(1) As a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicinal products in foodstuffs at ever lower levels.

(2) In order to protect public health, maximum residue limits should be established in accordance with generally recognised principles of safety assessment, taking into account toxicological risks, environmental contamination, as well as the microbiological and pharmacological effects of residues. Account should also be taken of other scientific assessments of the safety of substances concerned which may have been undertaken by international organisations or scientific bodies established within the Community.

(3) This Regulation directly concerns public health and is relevant to the functioning of the internal market in products of animal origin included in Annex I to the Treaty. It is therefore necessary to establish maximum residue limits for pharmacologically active substances in respect of various foodstuffs of animal origin, including meat, fish, milk, eggs and honey.

(4) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [3] introduced Community procedures to evaluate the safety of residues of pharmacologically active substances in accordance with human food safety requirements. A pharmacologically active substance may be used in food-producing animals only if evaluated favourably. Maximum residue limits are established for such substances where they are considered necessary for the protection of human health.

(5) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products [4] provides that veterinary medicinal products may be authorised or used in food-producing animals only if pharmacologically active substances contained therein have been assessed as safe according to Regulation (EEC) No 2377/90. Moreover that Directive contains rules concerning the documentation of use, re-designation (off label use), prescription and distribution of veterinary medicinal products intended for use in food-producing animals.

(6) In the light of the European Parliament's resolution of 3 May 2001 [5] on the availability of veterinary medicinal products, the Commission's public consultation undertaken in 2004 and its assessment of the experience gained, it has proved necessary to modify the procedures for setting maximum residue limits while maintaining the overall system for setting such limits.

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[1] OJ C 10, 15.1.2008, p. 51.

[2] Opinion of the European Parliament of 17 June 2008 (not yet published in the Official Journal), Council Common Position of 18 December 2008 (OJ C 33 E, 10.2.2009, p. 30) and Position of the European Parliament of 2 April 2009 (not yet published in the Official Journal).

[3] OJ L 224, 18.8.1990, p. 1.

[4] OJ L 311, 28.11.2001, p. 1.

[5] OJ C 27 E, 31.1.2002, p. 80.

(7) Maximum residue limits are the points of reference for the establishment, in accordance with Directive 2001/82/EC, of withdrawal periods in marketing authorisations for veterinary medicinal products to be used in food-producing animals as well as for the control of residues in food of animal origin in the Member States and at border inspection posts.

(8) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of β-agonists [1] prohibits the use of certain substances for specific purposes in food-producing animals. This Regulation should apply without prejudice to any Community legislation prohibiting the use in food-producing animals of certain substances having a hormonal action.

(9) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [2] lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to legislation on maximum residue limits.

(10) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [3] lays down the framework for food legislation at Community level and provides for definitions in that area. It is appropriate that those definitions apply for the purposes of legislation on maximum residue limits.

(11) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [4] lays down general rules for the control of food in the Community and provides for definitions in that area. It is appropriate that those rules and definitions apply for the purposes of legislation on maximum residue limits. Priority should be given to the detection of the illegal use of substances and part of the samples should be selected according to a risk-based approach.

(12) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [5] entrusts the European Medicines Agency (the Agency) with the task of advising on the maximum residue limits for veterinary medicinal products which may be accepted in food of animal origin.

(13) Maximum residue limits should be set for pharmacologically active substances used or intended to be used in veterinary medicinal products placed on the market in the Community.

(14) It appears from the public consultation and from the fact that only a small number of veterinary medicinal products for food-producing animals have been authorised in recent years that Regulation (EEC) No 2377/90 has resulted in such medicinal products being less readily available.

(15) In order to ensure animal health and welfare, it is necessary that veterinary medicinal products are available to treat specific disease conditions. Furthermore, the lack of availability of appropriate veterinary medicinal products for a specific treatment for a specific species may contribute to the misuse or illegal use of substances.

(16) The system established by Regulation (EEC) No 2377/90 should therefore be modified with a view to increasing the availability of veterinary medicinal products for food-producing animals. In order to serve that objective, provision should be made for the systematic consideration by the Agency of the use of a maximum residue limit established for one species or foodstuff for another species or another foodstuff. In this respect, the adequacy of the safety factors already inherent in the system should be taken into account in order to ensure that food safety and animal welfare are not compromised.

(17) It is recognised that, in certain cases, scientific risk assessments alone cannot provide all the information on which risk management decisions should be based and that other factors relevant to the matter under consideration should legitimately be taken into account, including the technological aspects of food production and the feasibility of controls. The Agency should therefore provide an opinion consisting of a scientific risk assessment and risk management recommendations on residues of pharmacologically active substances.

(18) Detailed rules on the format and content of applications for the establishment of maximum residue limits and on methodological principles of risk assessment and of risk management recommendations are necessary for the smooth functioning of the whole framework of maximum residue limits.

[1] OJ L 125, 23.5.1996, p. 3.
[2] OJ L 37, 13.2.1993, p. 1.
[3] OJ L 31, 1.2.2002, p. 1.
[4] OJ L 165, 30.4.2004, p. 1;. corrected by OJ L 191, 28.5.2004, p. 1.
[5] OJ L 136, 30.4.2004, p. 1.

(19) Besides veterinary medicinal products, other products which are not subject to specific legislation on residues, such as biocidal products, are used in animal husbandry. These biocidal products are defined in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1]. Furthermore, veterinary medicinal products not having a marketing authorisation in the Community may be authorised in countries outside the Community. That may be because in other regions different diseases or target species are more prevalent or because companies have chosen not to market a product in the Community. The fact that a product is not authorised in the Community does not necessarily indicate that its use is unsafe. For the pharmacologically active substances of such products, the Commission should be enabled to set a maximum residue limit for food, following an opinion by the Agency, in accordance with the principles set for pharmacologically active substances intended for use in veterinary medicinal products. It is also necessary to amend Regulation (EC) No 726/2004 to include, within the tasks of the Agency, advising on the maximum levels of residues of active substances in biocidal products.

(20) Under the system established by Directive 98/8/EC, operators having placed or seeking to place biocidal products on the market are obliged to pay charges for the evaluations carried out pursuant to different procedures associated with that Directive. This Regulation provides that the Agency is to carry out evaluations related to the establishment of the maximum residue limit for pharmacologically active substances intended to be used in biocidal products. As a consequence, this Regulation should clarify how those evaluations are financed, in order to take due account of fees already collected for evaluations carried out, or to be carried out, under that Directive.

(21) The Community contributes, in the context of the Codex Alimentarius, to the development of international standards on maximum residue limits, while ensuring that the high level of protection of human health maintained in the Community is not reduced. The Community should therefore take over without a further risk assessment those Codex Alimentarius maximum residue limits it has supported in the relevant Codex Alimentarius Commission meetings. Consistency between international standards and Community legislation on residue limits in food will thereby be further enhanced.

(22) Foodstuffs are subject to controls on residues of pharmacologically active substances in accordance with Regulation (EC) No 882/2004. Even if residue limits are not set for such substances pursuant to this Regulation, residues of such substances might occur due to environmental contamination or the occurrence of a natural metabolite in the animal. Laboratory methods are capable of finding such residues at ever lower levels. Such residues have caused different control practices in Member States.

(23) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries [2] requires that each consignment imported from a third country is subject to veterinary controls, and Commission Decision 2005/34/EC [3] lays down harmonised standards for the testing for certain residues in products of animal origin imported from third countries. It is appropriate to extend the provisions of Decision 2005/34/EC to all products of animal origin placed on the Community market.

(24) A number of pharmacologically active substances are prohibited or currently not authorised under Regulation (EC) No 2377/90, Directive 96/22/EC or Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [4]. The residues of pharmacologically active substances in products of animal origin arising, in particular, from illegal use or from environmental contamination should be carefully controlled and monitored in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products [5], regardless of the origin of the product.

(25) It is appropriate for the Community to provide for procedures to set reference points for action at concentrations of the residues for which laboratory analysis is technically feasible in order to facilitate intra-Community trade and imports, without undermining a high level of protection of human health in the Community. However, the setting of reference points for action should in no way serve as a pretext for condoning the illegal use of prohibited or non-authorised substances to treat food-producing animals. Therefore, any residues of those substances in food of animal origin should be considered undesirable.

(26) It is also appropriate for the Community to establish a harmonised approach for situations where Member States find evidence of a recurrent problem, since such a finding could suggest a pattern of misuse of a particular substance or a disregard for guarantees provided

[1] OJ L 123, 24.4.1998, p. 1.

[2] OJ L 24, 30.1.1998, p. 9.
[3] OJ L 16, 20.1.2005, p. 61.
[4] OJ L 268, 18.10.2003, p. 29.
[5] OJ L 125, 23.5.1996, p. 10.

by third countries concerning the production of food intended for import into the Community. Member States should notify the Commission of recurring problems, and appropriate follow-up measures should be taken.

(27) The current legislation on maximum residue limits should be simplified by placing together in one single Commission regulation all decisions classifying pharmacologically active substances as regards residues.

(28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(29) In particular, the Commission should be empowered to adopt methodological principles for the risk assessment and risk management recommendations regarding the establishment of maximum residue limits, rules on the conditions for extrapolation, measures setting reference points for action, including measures reviewing those reference points, as well as methodological principles and scientific methods for the establishment of reference points for action. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(30) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures setting reference points for action and measures reviewing those reference points.

(31) Since the objectives of this Regulation, namely the protection of human and animal health and ensuring the availability of appropriate veterinary medicinal products, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of this Regulation, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(32) In the interests of clarity, it is therefore necessary to replace Regulation (EEC) No 2377/90 with a new regulation.

(33) A transitional period should be provided for in order to allow the Commission to prepare and adopt a regulation incorporating the pharmacologically active substances and their classification regarding maximum residue limits as laid down in Annexes I to IV to Regulation (EEC) No 2377/90, as well as certain implementing provisions for that new regulation,

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. For the purposes of ensuring food safety, this Regulation lays down rules and procedures in order to establish:

(a) the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin (maximum residue limit);

(b) the level of a residue of a pharmacologically active substance established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation (reference point for action).

2. This Regulation shall not apply:

(a) to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity, used in immunological veterinary medicinal products;

(b) to substances falling within the scope of Regulation (EEC) No 315/93.

3. This Regulation shall apply without prejudice to Community legislation prohibiting the use in food-producing animals of certain substances having a hormonal or thyrostatic action and of beta-agonists, as provided for by Directive 96/22/EC.

Article 2

Definitions

In addition to the definitions laid down in Article 1 of Directive 2001/82/EC, Article 2 of Regulation (EC) No 882/2004 and Articles 2 and 3 of Regulation (EC) No 178/2002, the following definitions shall apply for the purposes of this Regulation:

[1] OJ L 184, 17.7.1999, p. 23.

(a) 'residues of pharmacologically active substances' means all pharmacologically active substances, expressed in mg/kg or µg/kg on a fresh weight basis, whether active substances, excipients or degradation products, and their metabolites which remain in food obtained from animals;

(b) 'food-producing animals' means animals bred, raised, kept, slaughtered or harvested for the purposes of producing food.

TITLE II

MAXIMUM RESIDUE LIMITS

CHAPTER I

Risk assessment and risk management

Section 1

Pharmacologically active substances intended for use in veterinary medicinal products in the Community

Article 3

Application for an opinion of the Agency

Except in cases where the Codex Alimentarius procedure referred to in Article 14(3) of this Regulation applies, any pharmacologically active substance intended for use in the Community in veterinary medicinal products which are to be administered to food-producing animals shall be subject to an opinion of the European Medicines Agency (the Agency) established by Article 55 of Regulation (EC) No 726/2004 on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use (the Committee) established by Article 30 of that Regulation.

To that end, the applicant for a marketing authorisation for a veterinary medicinal product in which such a substance is used, a person intending to apply for such a marketing authorisation or, where appropriate, the holder of such a marketing authorisation, shall submit an application to the Agency.

Article 4

Opinion of the Agency

1. The opinion of the Agency shall consist of a scientific risk assessment and risk management recommendations.

2. The scientific risk assessment and the risk management recommendations shall aim to ensure a high level of human health protection, whilst also ensuring that human health, animal health and animal welfare are not negatively affected by the lack of availability of appropriate veterinary medicinal products. The opinion shall take account of any relevant scientific findings of the European Food Safety Authority (EFSA) established by Article 22 of Regulation (EC) No 178/2002.

Article 5

Extrapolation

With a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing animals, the Agency, while ensuring a high level of protection of human health, shall, when carrying out scientific risk assessments and when drawing up risk management recommendations, consider using maximum residue limits established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or maximum residue limits established for a pharmacologically active substance in one or more species for other species.

Article 6

Scientific risk assessment

1. The scientific risk assessment shall consider the metabolism and depletion of pharmacologically active substances in relevant animal species, the type of residues and the amount thereof, that may be ingested by human beings over a lifetime without an appreciable health risk expressed in terms of acceptable daily intake (ADI). Alternative approaches to ADI may be used, if they have been laid down by the Commission as provided for in Article 13(2).

2. The scientific risk assessment shall concern the following:

(a) the type and amount of residue considered not to present a safety concern for human health;

(b) the risk of toxicological, pharmacological or microbiological effects in human beings;

(c) residues that occur in food of plant origin or that come from the environment.

3. If the metabolism and depletion of the substance cannot be assessed, the scientific risk assessment may take into account monitoring data or exposure data.

Article 7

Risk management recommendations

The risk management recommendations shall be based on the scientific risk assessment performed in accordance with Article 6 and shall consist of an assessment of the following:

(a) the availability of alternative substances for the treatment of the relevant species or the necessity of the substance evaluated in order to avoid unnecessary suffering for animals or to ensure the safety of those treating them;

(b) other legitimate factors, such as the technological aspects of food and feed production, the feasibility of controls, conditions of use and application of the substances in veterinary medicinal products, good practice in the use of veterinary medicinal and biocidal products and the likelihood of misuse or illegal use;

(c) whether or not a maximum residue limit or a provisional maximum residue limit should be established for a pharmacologically active substance in veterinary medicinal products, the level of that maximum residue limit and, where appropriate, any conditions or restrictions for the use of the substance concerned;

(d) whether the data provided are not sufficient to allow a safe limit to be identified, or whether a final conclusion concerning human health with regard to residues of a substance cannot be established given the lack of scientific information. In either case, no maximum residue limit may be recommended.

Article 8

Applications and procedures

1. The application referred to in Article 3 shall comply with the format and content laid down by the Commission as provided for in Article 13(1) and shall be accompanied by the fee payable to the Agency.

2. The Agency shall ensure that the opinion of the Committee is given within 210 days of receipt of a valid application in accordance with Article 3 and paragraph 1 of this Article. This time limit shall be suspended where the Agency requests the submission of supplementary information on the given substance within a specific time period, and shall remain suspended until such time as the requested supplementary information has been provided.

3. The Agency shall forward the opinion referred to in Article 4 to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the Agency that he wishes to request a re-examination of the opinion. In that case the applicant shall submit the detailed grounds for his request to the Agency within 60 days of receipt of the opinion.

Within 60 days of receipt of the applicant's grounds for a re-examination request, the Committee shall consider whether its opinion should be revised and adopt the final opinion. The reasons for the conclusion reached on the request shall be annexed to the final opinion.

4. Within 15 days of the adoption of the final opinion, the Agency shall forward it to the Commission and the applicant, stating the grounds for its conclusions.

Section 2

Other pharmacologically active substances for which an opinion of the Agency may be requested

Article 9

Opinion of the Agency requested by the Commission or a Member State

1. The Commission or a Member State may submit to the Agency a request for an opinion on maximum residue limits in either of the following circumstances:

(a) where the substance in question is authorised for use in a veterinary medicinal product in a third country and no application for the establishment of a maximum residue limit for that substance in respect of the foodstuff or species concerned has been submitted pursuant to Article 3;

(b) where the substance in question is included in a medicinal product intended to be used pursuant to Article 11 of Directive 2001/82/EC and no application for the establishment of a maximum residue limit for that substance in respect of the foodstuff or species concerned has been submitted pursuant to Article 3 of this Regulation.

In the circumstances of point (b) of the first subparagraph, where minor species or minor uses are concerned, the request may be submitted to the Agency by an interested party or organisation.

Articles 4 to 7 shall apply.

A request for an opinion referred to in the first subparagraph of this paragraph shall comply with the format and content requirements laid down by the Commission pursuant to Article 13(1).

2. The Agency shall ensure that the opinion of the Committee is given within 210 days of receipt of the request by the Commission, a Member State or an interested party or organisation. This time limit shall be suspended if the Agency requests the submission of supplementary information on the given substance within a specific time period and until such time as the requested supplementary information has been provided.

3. Within 15 days of the adoption of the final opinion, the Agency shall forward it to the Commission and, as applicable, to the Member State or the interested party or organisation which made the request, stating the grounds for its conclusions.

Article 10

Pharmacologically active substances contained in biocidal products used in animal husbandry

1. For the purposes of Article 10(2)(ii) of Directive 98/8/EC, for pharmacologically active substances intended to be used in a biocidal product used in animal husbandry, the maximum residue limit shall be established:

(a) following the procedure referred to in Article 9 of this Regulation for:

(i) active substances/product type combinations included in the 10-year programme of work referred to in Article 16(2) of Directive 98/8/EC;

(ii) active substances/product type combinations to be included in Annexes I, IA or IB to Directive 98/8/EC for which a dossier has been accepted by the competent authority as referred to in Article 11(1)(b) of that Directive before 6 July 2009;

(b) following the procedure referred to in Article 8 of this Regulation and on the basis of an application submitted in accordance with Article 3 of this Regulation for all other active substances/product type combinations to be included in Annexes I, IA or IB to Directive 98/8/EC for which the establishment of a maximum residue limit is deemed necessary by the Member States or the Commission.

2. The Commission shall classify the pharmacologically active substances referred to in paragraph 1 in accordance with Article 14. For the purposes of classification, a regulation as referred to in Article 17(1) shall be adopted by the Commission.

However, any specific provisions relating to the conditions of use of the substances classified in accordance with the first subparagraph of this paragraph shall be laid down pursuant to Article 10(2) of Directive 98/8/EC.

3. The costs of evaluations carried out by the Agency following a request made in accordance with paragraph 1(a) of this Article shall be covered by the budget of the Agency as referred to in Article 67 of Regulation (EC) No 726/2004. However, this shall not apply to the evaluation costs of a rapporteur designated, in accordance with Article 62(1) of that Regulation, for the establishment of a maximum residue limit where that rapporteur has been appointed by a Member State that has already received a fee for that evaluation on the basis of Article 25 of Directive 98/8/EC.

The amount of the fees for evaluations carried out by the Agency and the rapporteur following an application made in accordance with paragraph 1(b) of this Article shall be established in accordance with Article 70 of Regulation (EC) No 726/2004. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products [1] shall apply.

Section 3

Common provisions

Article 11

Review of an opinion

Where the Commission, the applicant under Article 3 or a Member State, as a result of new information, considers that a review of an opinion is necessary in order to protect human or animal health, it may request the Agency to issue a new opinion on the substances in question.

Where a maximum residue limit has been established in accordance with this Regulation for specific foodstuffs or species, Articles 3 and 9 shall apply for the establishment of a maximum residue limit for that substance for other foodstuffs or species.

The request referred to in the first subparagraph shall be accompanied by information explaining the issue to be addressed. Article 8(2) to (4) or Article 9(2) and (3), as appropriate, shall apply to the new opinion.

Article 12

Publication of opinions

The Agency shall publish the opinions referred to in Articles 4, 9 and 11 after deleting any information of a commercially confidential nature.

[1] OJ L 35, 15.2.1995, p. 1.

Article 13

Implementing measures

1. In accordance with the regulatory procedure referred to in Article 25(2), the Commission shall, in consultation with the Agency, adopt measures regarding the form and content of the applications and requests referred to in Articles 3 and 9.

2. The Commission shall, in consultation with the Agency, Member States and interested parties, adopt measures regarding:

(a) the methodological principles for the risk assessment and risk management recommendations referred to in Articles 6 and 7, including technical requirements in accordance with internationally agreed standards;

(b) rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or a maximum residue limit established for a pharmacologically active substance in one or more species for other species, as referred to in Article 5. Those rules shall specify how and under what circumstances scientific data on residues in a particular foodstuff or in a species or more species may be used for setting a maximum residue limit in other foodstuffs, or other species.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

CHAPTER II

Classification

Article 14

Classification of pharmacologically active substances

1. The Commission shall classify the pharmacologically active substances subject to an opinion of the Agency on the maximum residue limit in accordance with Article 4, 9 or 11, as appropriate.

2. The classification shall include a list of pharmacologically active substances and the therapeutic classes to which they belong. The classification shall also establish, in relation to each such substance, and, where appropriate, specific foodstuffs or species, one of the following:

(a) a maximum residue limit;

(b) a provisional maximum residue limit;

(c) the absence of the need to establish a maximum residue limit;

(d) a prohibition on the administration of a substance.

3. A maximum residue limit shall be laid down where it appears necessary for the protection of human health:

(a) pursuant to an opinion of the Agency in accordance with Article 4, 9 or 11, as appropriate; or

(b) pursuant to a decision of the Codex Alimentarius Commission, without objection from the Community Delegation, in favour of a maximum residue limit for a pharmacologically active substance intended for use in a veterinary medicinal product, provided that the scientific data taken into consideration have been made available to the Community Delegation prior to the decision of the Codex Alimentarius Commission. In this case, an additional assessment by the Agency shall not be required.

4. A provisional maximum residue limit may be established in cases where scientific data are incomplete, provided that there are no grounds for supposing that residues of that substance at the level proposed constitute a hazard to human health.

The provisional maximum residue limit shall apply for a defined period of time, which shall not exceed five years. That period may be extended once for a period not exceeding two years where it is demonstrated that such an extension would allow completion of scientific studies in progress.

5. No maximum residue limit shall be established where, pursuant to an opinion in accordance with Article 4, 9 or 11, as appropriate, it is not necessary for the protection of human health.

6. The administration of a substance to food-producing animals shall be prohibited, pursuant to an opinion in accordance with Article 4, 9 or 11, as appropriate, in either of the following circumstances:

(a) where any presence of a pharmacologically active substance or residues thereof in foods of animal origin may constitute a hazard to human health;

(b) where no final conclusion concerning the effect on human health of residues of a substance can be drawn.

7. Where it appears necessary for the protection of human health, the classification shall include conditions and restrictions for the use or application of a pharmacologically active substance used in veterinary medicinal products which is subject to a maximum residue limit, or for which no maximum residue limit has been set.

Article 15

Accelerated procedure for an opinion of the Agency

1. In specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the Commission, any person who has submitted an application for an opinion pursuant to Article 3 or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products.

2. The format and content of the application referred to in paragraph 1 of this Article shall be laid down by the Commission pursuant to Article 13(1).

3. By way of derogation from the time limits laid down in Article 8(2) and Article 9(2), the Agency shall ensure that the opinion of the Committee is given within 120 days of receipt of the application.

Article 16

Administration of substances to food-producing animals

1. Only pharmacologically active substances which are classified in accordance with Article 14(2)(a), (b) or (c) may be administered to food-producing animals within the Community, provided that such administration is in accordance with Directive 2001/82/EC.

2. Paragraph 1 shall not apply in the case of clinical trials which are accepted by the competent authorities following notification or authorisation in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

Article 17

Procedure

1. For the purposes of the classification provided for in Article 14, the Commission shall prepare a draft regulation within 30 days of receipt of an opinion of the Agency as referred to in Article 4, 9 or 11, as appropriate. The Commission shall also prepare a draft regulation within 30 days of receipt of the decision of the Codex Alimentarius Commission, without objection from the Community Delegation, in favour of the establishment of a maximum residue limit as referred to in Article 14(3).

Where the opinion of the Agency is required and the draft regulation is not in accordance with this opinion, the Commission shall provide a detailed explanation of the reasons for the divergence.

2. The regulation referred to in paragraph 1 of this Article shall be adopted by the Commission in accordance with, and within 30 days of the end of, the regulatory procedure referred to in Article 25(2).

3. In the case of an accelerated procedure as referred to in Article 15, the Commission shall adopt the regulation referred to in paragraph 1 of this Article in accordance with, and within 15 days of the end of, the regulatory procedure referred to in Article 25(2).

TITLE III

REFERENCE POINTS FOR ACTION

Article 18

Establishment and review

When it is deemed necessary in order to ensure the functioning of controls of food of animal origin imported or placed on the market in accordance with Regulation (EC) No 882/2004, the Commission may establish reference points for action for residues from pharmacologically active substances which are not subject to a classification in accordance with Article 14(2)(a), (b) or (c).

The reference points for action shall be reviewed regularly in the light of new scientific data relating to food safety, the outcome of the investigations and analytical tests referred to in Article 24 and technological progress.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 26(4).

Article 19

Methods for establishing reference points for action

1. The reference points for action to be established pursuant to Article 18 shall be based on the content of an analyte in a sample, which can be detected and confirmed by official control laboratories designated in accordance with Regulation (EC) No 882/2004 with an analytical method validated in accordance with Community requirements. The reference point for action should take into account the lowest residue concentration which can be quantified with an analytical method validated in accordance with Community requirements. The Commission shall be advised on the performance of analytical methods by the relevant Community reference laboratory.

2. Without prejudice to the second subparagraph of Article 29(1) of Regulation (EC) No 178/2002, the Commission shall, where appropriate, submit a request to EFSA for a risk assessment as to whether the reference points for action are adequate to protect human health. In those cases, EFSA shall ensure that the opinion is given to the Commission within 210 days of receipt of the request.

3. The principles of risk assessment shall be applied in order to guarantee a high level of protection of health. The risk assessment shall be based on methodological principles as well as scientific methods to be adopted by the Commission in consultation with EFSA.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3).

Article 20

Community contribution to the support measures for reference points for action

If the application of this Title requires the Community to finance measures in support of the establishment and functioning of reference points for action, Article 66(1)(c) of Regulation (EC) No 882/2004 shall apply.

TITLE IV

MISCELLANEOUS PROVISIONS

Article 21

Analytical methods

The Agency shall consult Community reference laboratories for laboratory analysis of residues designated by the Commission in accordance with Regulation (EC) No 882/2004 on appropriate analytical methods for detecting residues of pharmacologically active substances for which maximum residue limits have been determined in accordance with Article 14 of this Regulation. For the purposes of harmonised controls, the Agency shall provide information regarding those methods to the Community reference laboratories and national reference laboratories designated in accordance with Regulation (EC) No 882/2004.

Article 22

Circulation of foodstuffs

Member States may not prohibit or impede the import or the placing on the market of food of animal origin on grounds related to maximum residue limits or reference points for action where this Regulation and its implementing measures have been complied with.

Article 23

Placing on the market

Food of animal origin containing residues of a pharmacologically active substance:

(a) classified in accordance with Article 14(2)(a), (b) or (c) at a level exceeding the maximum residue limit established pursuant to this Regulation; or

(b) not classified in accordance with Article 14(2)(a), (b) or (c), except where a reference point for action has been set for that substance pursuant to this Regulation and the level of residues does not equal or exceed that reference point for action;

shall be considered not to comply with Community legislation.

Detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated under Article 11 of Directive 2001/82/EC shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 26(2) of this Regulation.

Article 24

Action in case of confirmed presence of a prohibited or non-authorised substance

1. Where the results of analytical tests are below the reference points for action, the competent authority shall carry out the investigations provided for by Directive 96/23/EC to determine whether there has been illegal administration of a prohibited or non-authorised pharmacologically active substance and, where relevant, shall apply the penalty provided for.

2. Where the results of those investigations or analytical tests on products of the same origin show a recurrent pattern indicating a potential problem, the competent authority shall retain a record of the findings and inform the Commission and the other Member States in the Standing Committee on the Food Chain and Animal Health referred to in Article 26.

3. Where appropriate, the Commission shall submit proposals, and in the case of products of third country origin, bring the matter to the attention of the competent authority of the country or countries concerned requesting clarification as to the recurrent presence of residues.

4. Detailed rules on the application of this Article shall be adopted. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3).

TITLE V

FINAL PROVISIONS

Article 25

Standing Committee on Veterinary Medicinal Products

1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 26

Standing Committee on the Food Chain and Animal Health

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1),(2),(4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 27

Classification of pharmacologically active substances under Regulation (EEC) No 2377/90

1. By 4 September 2009, the Commission shall adopt, in accordance with the regulatory procedure referred to in Article 25(2), a regulation incorporating the pharmacologically active substances and their classification regarding maximum residues limits as laid down in Annexes I to IV to Regulation (EEC) No 2377/90 without any modification.

2. For any substance referred to in paragraph 1 for which a maximum residue limit has been established under Regulation (EEC) No 2377/90, the Commission or a Member State may also submit to the Agency a request for an opinion on extrapolation to other species or tissues in accordance with Article 5.

Article 17 shall apply.

Article 28

Reporting

1. By 6 July 2014, the Commission shall submit a report to the European Parliament and to the Council.

2. The report shall, in particular, review the experience gained from the application of this Regulation, including experience with substances classified under this Regulation which have a multiple use.

3. The report shall, if appropriate, be accompanied by relevant proposals.

Article 29

Repeal

Regulation (EEC) No 2377/90 is hereby repealed.

Annexes I to IV to the repealed Regulation shall continue to apply until the entry into force of the regulation referred to in Article 27(1) of this Regulation, and Annex V to the repealed Regulation shall continue to apply until the entry into force of the measures referred to in Article 13(1) of this Regulation.

References to the repealed Regulation shall be construed as references to this Regulation or, as appropriate, to the regulation referred to in Article 27(1) of this Regulation.

Article 30

Amendments to Directive 2001/82/EC

Directive 2001/82/EC is hereby amended as follows:

1. Article 10(3) shall be replaced by the following:

'3. By way of derogation from Article 11, the Commission shall establish a list of substances:

— which are essential for the treatment of equidae, or

— which bring added clinical benefit compared to other treatment options available for equidae,

and for which the withdrawal period shall not be less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

2. in Article 11(2), the third subparagraph shall be replaced by the following:

'The Commission may modify these withdrawal periods or establish other withdrawal periods. In so doing, the Commission may differentiate between foodstuffs, species, routes of administration and annexes to Regulation (EEC) No 2377/90. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).'.

Article 31

Amendment to Regulation (EC) No 726/2004

Article 57(1)(g) of Regulation (EC) No 726/2004 shall be replaced by the following:

'(g) advising on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (*).

(*) OJ L 152, 16.6.2009, p. 11'.

Article 32

Entry into force

This Regulation shall enter into force on the 20th day following 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 Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

REGULATION (EC) No 471/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

on Community statistics relating to external trade with non-member countries and repealing Council Regulation (EC) No 1172/95

(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 285(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Central Bank [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) The statistical information on Member States' trade flows with non-member countries is of essential importance for the Community's economic and trade policies and for analysing market developments for individual goods. The transparency of the statistical system should be improved to enable it to react to the changing administrative environment and to satisfy new user requirements. Council Regulation (EC) No 1172/95 of 22 May 1995 on the statistics relating to the trading of goods by the Community and its Member States with non-member countries [3] should therefore be replaced by a new Regulation in conformity with the requirements set out in Article 285(2) of the Treaty.

(2) External trade statistics are based on data obtained from customs declarations, as provided for in Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [4] (hereinafter referred to as the Customs Code). Progress in European integration and the resulting changes in customs clearance, including single authorisations for the use of the simplified declaration or the local clearance procedure, as well as centralised clearance, which will emanate from the current process of modernisation of the Customs Code as laid down in Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code) [5] (hereinafter referred to as the Modernised Customs Code) warrant a number of changes. In particular, they make it necessary to adjust the way external trade statistics are compiled, to reconsider the concept of the importing or exporting Member State, and to define more precisely the data source for compiling Community statistics.

(3) Simplifications of customs formalities and controls under the Modernised Customs Code can lead to customs declarations not being available. In order to keep the compilation of external trade statistics complete, measures should be adopted which ensure that those economic operators who benefit from the simplification provide statistical data.

(4) Decision No 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on a paperless environment for customs and trade [6] will set up an electronic customs system for the exchange of data contained in customs declarations. In order to record the physical trade flow of goods between Member States and non-member countries and to ensure that data on imports and exports is available in the Member State concerned, arrangements between customs and statistical authorities are necessary and should be specified. This includes rules on the exchange of data between Member States' administrations. This data exchange system should benefit as far as possible from the infrastructure established by the customs authorities.

(5) In order to allocate Community exports and imports to a given Member State, it is necessary to compile data on the 'Member State of destination', for imports, and the 'Member State of actual export', for exports. In the medium term, those Member States should become the importing and the exporting Member State for external trade statistics purposes.

(6) For the purposes of this Regulation, goods for external trade purposes should be classified in accordance with the Combined Nomenclature established by Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [7] (hereinafter referred to as the Combined Nomenclature).

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[1] OJ C 70, 15.3.2008, p. 1.
[2] Opinion of the European Parliament of 23 September 2008 (not yet published in the Official Journal), Council Common Position of 16 February 2009 (OJ C 75 E, 31.3.2009, p. 58) and Position of the European Parliament of 2 April 2009 (not yet published in the Official Journal).
[3] OJ L 118, 25.5.1995, p. 10.
[4] OJ L 302, 19.10.1992, p. 1.
[5] OJ L 145, 4.6.2008, p. 1.
[6] OJ L 23, 26.1.2008, p. 21.
[7] OJ L 256, 7.9.1987, p. 1.

(7) To meet the needs of the European Central Bank and of the Commission for information on the share of the euro in international trade in goods, the invoicing currency of exports and imports should be reported at an aggregated level.

(8) For the purposes of trade negotiations and internal market management, the Commission should be provided with detailed information on the preferential treatment of goods imported into the Community.

(9) External trade statistics provide data for the compilation of balance of payments and national accounts. The characteristics which make it possible to adapt them to balance of payments purposes should become part of the mandatory and standard data set.

(10) Member States' statistics on customs warehouses and free zones are not the subject of harmonised provisions. However, the compilation for national purposes of these statistics remains optional.

(11) Member States should provide Eurostat with annual aggregated data on trade broken down by business characteristics, one of the uses of which is to facilitate the analysis of how European companies operate in the context of globalisation. The link between business and trade statistics is established by merging data on the importer and the exporter available on the customs declaration with data requested by Regulation (EC) No 177/2008 of the European Parliament and of the Council of 20 February 2008 establishing a common framework for business registers for statistical purposes [1].

(12) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics [2] provides a reference framework for the provisions laid down in this Regulation. However, the very detailed level of information on trade in goods requires specific confidentiality rules if these statistics are to be relevant.

(13) The transmission of data subject to statistical confidentiality is governed by the rules set out in Regulation (EC) No 223/2009 and in Council Regulation (Euratom, EEC) No 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities [3]. Measures which are taken in accordance with those Regulations ensure the physical and logical protection of confidential data and ensure that no unlawful disclosure and non-statistical use occur when Community statistics are produced and disseminated.

(14) In the production and dissemination of Community statistics under this Regulation, the national and Community statistical authorities should take account of the principles set out in the European Statistics Code of Practice, which was adopted by the Statistical Programme Committee on 24 February 2005 and appended to the Recommendation of the Commission of 25 May 2005 on the independence, integrity and accountability of the national and Community statistical authorities.

(15) Specific provisions should be formulated to remain in force until such time as changes in customs legislation result in additional data on the customs declaration and until Community legislation requires the electronic exchange of customs data.

(16) Since the objective of this Regulation, namely establishing the common framework for the systematic production of Community external trade statistics, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(17) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [4].

(18) In particular, the Commission should be empowered to adapt the list of customs procedures or customs-approved treatment or use which determine an export or import for external trade statistics; to adopt different or specific rules for goods or movements which, for methodological reasons, call for specific provisions; to adapt the list of goods and movements excluded from external trade statistics; to specify the data sources other than the customs declaration for records on imports and exports of specific goods or movements; to specify the statistical data, including the codes to be used; to establish

[1] OJ L 61, 5.3.2008, p. 6.
[2] OJ L 87, 31.3.2009, p. 164.
[3] OJ L 151, 15.6.1990, p. 1.
[4] OJ L 184, 17.7.1999, p. 23.

requirements for data related to specific goods or movements; to establish requirements on the compilation of statistics; to specify the characteristics of samples; to establish the reporting period and the level of aggregation for partner countries, goods and currencies; and also to adapt the deadline for transmitting statistics, content, coverage and revision conditions for statistics already transmitted; and to establish the deadline for transmitting statistics on trade by business characteristics and statistics on trade broken down by invoicing currency. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes a common framework for the systematic production of Community statistics relating to trade in goods with non-member countries (hereinafter referred to as external trade statistics).

Article 2

Definitions

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

(a) 'goods' means all movable property, including electricity;

(b) 'statistical territory of the Community' means the 'customs territory of the Community' as defined in the Customs Code with the addition of the Island of Heligoland in the territory of the Federal Republic of Germany;

(c) 'national statistical authorities' means the national statistical institutes and other bodies responsible in each Member State for producing external trade statistics;

(d) 'customs authorities' means the 'customs authorities' as defined in the Customs Code;

(e) 'customs declaration' means the 'customs declaration' as defined in the Customs Code;

(f) 'decision by customs' means any official act by customs authorities relating to accepted customs declarations and having legal effect on one or more persons.

Article 3

Scope

1. External trade statistics shall record imports and exports of goods.

An export shall be recorded by Member States in the event that goods leave the statistical territory of the Community in accordance with one of the following customs procedures or customs-approved treatment or use, laid down in the Customs Code:

(a) exportation;

(b) outward processing;

(c) re-exportation following either inward processing or processing under customs control.

An import shall be recorded by Member States in the event that goods enter the statistical territory of the Community in accordance with one of the following customs procedures laid down in the Customs Code:

(a) release for free circulation;

(b) inward processing;

(c) processing under customs control.

2. The measures designed to amend non-essential elements of this Regulation relating to the adaptation of the list of customs procedures or customs-approved treatment or use referred to in paragraph 1 in order to take into account changes in the Customs Code or provisions deriving from international conventions, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

3. For methodological reasons, certain goods or movements call for specific provisions. This concerns industrial plants, vessels and aircraft, sea products, goods delivered to vessels and aircraft, staggered consignments, military goods, goods to or from offshore installations, spacecraft, electricity and gas and waste products (hereinafter referred to as specific goods or movements).

The measures designed to amend non-essential elements of this Regulation, inter alia by supplementing it, relating to specific goods and movements and to different or specific provisions applicable to them, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

4. For methodological reasons, certain goods or movements shall be excluded from external trade statistics. This concerns monetary gold and means of payment which are legal tender; goods the intended use of which is diplomatic or similar nature; movements of goods between the importing and exporting Member State and their national armed forces stationed abroad as well as certain goods acquired and disposed of by foreign armed forces; particular goods which are not the subject of a commercial transaction; movements of satellite launchers before their launching; goods for and after repair; goods for or following temporary use; goods used as carriers of customised information and downloaded information; and goods declared orally to customs authorities which either are of a commercial nature, provided that their value does not exceed the statistical threshold of EUR 1 000 in value or 1 000 kg in net mass, or are of a non-commercial nature.

The measures designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, relating to the exclusion of goods or movements from external trade statistics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

Article 4

Data source

1. The data source for records on the imports and exports of goods referred to in Article 3(1) shall be the customs declaration, including possible amendments or changes to statistical data resulting from decisions by customs pertaining to it.

2. Where the further simplification of customs formalities and controls pursuant to Article 116 of the Modernised Customs Code results in records on the imports and exports of goods not being available at customs authorities, the economic operator to whom the simplification was granted shall provide the statistical data defined in Article 5 of this Regulation.

3. Member States may continue to use other data sources for the compilation of their national statistics until the date of implementation of a mechanism for mutual data exchange by electronic means referred to in Article 7(2).

4. For specific goods or movements as referred to in Article 3(3), data sources other than the customs declaration can be used.

5. The measures designed to amend non-essential elements of this Regulation, inter alia by supplementing it, relating to the data collection according to paragraphs 2 and 4 of this Article, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3). These measures shall take the utmost account of the necessity to set up an efficient system which would minimise the administrative burden on economic operators and administrations.

Article 5

Statistical data

1. Member States shall obtain the following set of data from records on imports and exports referred to in Article 3(1):

(a) the trade flow (import, export);

(b) the monthly reference period;

(c) the statistical value of the goods at the national border of the importing or exporting Member States;

(d) the quantity expressed in net mass and in a supplementary unit if indicated on the customs declaration;

(e) the trader, being the importer/consignee on import and the exporter/consignor on export;

(f) the importing or exporting Member State, being the Member State where the customs declaration is lodged, if indicated on the customs declaration:

  (i) on import, the Member State of destination;

  (ii) on export, the Member State of actual export;

(g) the partner countries, that is:

  (i) on import, the country of origin and the country of consignment/dispatch;

  (ii) on export, the country of last known destination;

(h) the goods according to the Combined Nomenclature, being:

  (i) on import, the goods code of the TARIC subheading;

  (ii) on export, the goods code of the Combined Nomenclature subheading;

(i) the customs procedure code to be used for determining the statistical procedure;

(j) the nature of the transaction if indicated on the customs declaration;

(k) the preferential treatment on import where granted by customs authorities;

(l) the invoicing currency if indicated on the customs declaration;

(m) the mode of transport, detailing:

  (i) the mode of transport at the frontier;

  (ii) the internal mode of transport;

  (iii) the container.

2. The measures designed to amend non-essential elements of this Regulation, by supplementing it, relating to further specification of the data referred to in paragraph 1 of this Article, including the codes to be used, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

3. Where not otherwise stated and without prejudice to customs legislation, the data shall be contained in the customs declaration.

4. For specific goods or movements as referred to in Article 3(3) and data provided in accordance with Article 4(2), limited sets of data may be required.

The measures designed to amend non-essential elements of this Regulation, by supplementing it, relating to these limited sets of data, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

Article 6

Compilation of external trade statistics

1. Member States shall compile for each monthly reference period statistics on imports and exports of goods expressed in value and quantity by:

(a) goods code;

(b) importing/exporting Member States;

(c) partner countries;

(d) statistical procedure;

(e) nature of the transaction;

(f) preferential treatment on import;

(g) mode of transport.

Implementing provisions for compiling the statistics may be determined by the Commission in accordance with the procedure referred to in Article 11(2).

2. Member States shall compile annual statistics on trade by business characteristics, namely the economic activity carried out by the enterprise according to the section or two-digit level of the common statistical classification of economic activities in the European Community (NACE) and size-class measured in terms of number of employees.

The statistics shall be compiled by linking data on business characteristics recorded according to Regulation (EC) No 177/2008 with the data recorded according to Article 5(1) of this Regulation on imports and exports. To this end, national customs authorities shall provide the relevant traders' identification number to national statistical authorities.

The measures designed to amend non-essential elements of this Regulation, by supplementing it, relating to the linking of the data and these statistics to be compiled, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

3. Every two years Member States shall compile statistics on trade broken down by invoicing currency.

Member States shall compile the statistics using a representative sample of records on imports and exports from customs declarations which contain the data on the invoicing currency. If the invoicing currency for exports is not available on the customs declaration, a survey shall be carried out to collect the required data.

The measures designed to amend non-essential elements of this Regulation, inter alia by supplementing it, relating to the characteristics of the sample, the reporting period and the level of aggregation for partner countries, goods and currencies, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

4. The compilation by Member States of additional statistics for national purposes may be determined where the data are available on the customs declaration.

5. Member States shall not be obliged to compile and transmit to the Commission (Eurostat) external trade statistics on statistical data which, according to the Customs Code or to national instructions, are not yet recorded nor can be straightforwardly deduced from other data on the customs declaration lodged at their customs authorities. The transmission of the following data is therefore optional for Member States:

(a) on import, the Member State of destination;

(b) on export, the Member State of actual export;

(c) the nature of the transaction.

Article 7

Data exchange

1. Without delay and at the latest during the month following the month the customs declarations were accepted or were subject to decisions by customs pertaining to them, national statistical authorities shall obtain from customs authorities the records on imports and exports based on the declarations which are lodged with those authorities.

The records shall contain at least those statistical data listed in Article 5 which are, according to the Customs Code or to national instructions, available on the customs declaration.

2. With effect from the date of implementation of a mechanism for mutual data exchange by electronic means, customs authorities shall ensure that records on imports and exports are transmitted to the national statistical authority of the Member State which is indicated on the record as:

(a) on import, the Member State of destination;

(b) on export, the Member State of actual export.

The mechanism for mutual data exchange shall be implemented at the latest when Title I, Chapter 2, Section 1 of the Modernised Customs Code is applicable.

3. Implementing provisions for determining the transmission referred to in paragraph 2 of this Article may be determined in accordance with the procedure referred to in Article 11(2).

Article 8

Transmission of external trade statistics to the Commission (Eurostat)

1. Member States shall transmit to the Commission (Eurostat) the statistics referred to in Article 6(1) no later than 40 days after the end of each monthly reference period.

Member States shall ensure that the statistics contain information on all imports and exports in the reference period in question, making adjustments where records are not available.

Member States shall transmit updated statistics when statistics already transmitted are subject to revisions.

Member States shall include in the results transmitted to the Commission (Eurostat) any statistical information which is confidential.

The measures designed to amend non-essential elements of this Regulation, inter alia by supplementing it, relating to the adaptation of the deadline for transmitting statistics, content, coverage and revision conditions for the statistics already transmitted, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

2. The measures designed to amend non-essential elements of this Regulation, by supplementing it, relating to the deadline for transmitting statistics on trade by business characteristics referred to in Article 6(2) and statistics on trade broken down by invoicing currency referred to in Article 6(3), shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(3).

3. Member States shall transmit the statistics in electronic form, in accordance with an interchange standard. The practical arrangements for the transmission of the results may be determined in accordance with the procedure referred to in Article 11(2).

Article 9

Quality assessment

1. For the purpose of this Regulation, the following quality criteria shall apply to the statistics to be transmitted:

(a) 'relevance', which refers to the degree to which statistics meet current and potential needs of the users;

(b) 'accuracy', which refers to the closeness of estimates to the unknown true values;

(c) 'timeliness', which refers to the period between the availability of the information and the event or phenomenon it describes;

(d) 'punctuality', which refers to the delay between the date of release of the data and the target date (the date by which the data should have been delivered);

(e) 'accessibility' and 'clarity', which refer to the conditions and modalities by which users can obtain, use and interpret data;

(f) 'comparability', which refers to the measurement of the impact of differences in applied statistical concepts, measurement tools and procedures when statistics are compared between geographical areas, sectoral domains or over time;

(g) 'coherence', which refers to the adequacy of the data to be reliably combined in different ways and for various uses.

2. Member States shall provide the Commission (Eurostat) with a report on the quality of the statistics transmitted every year.

3. In applying the quality criteria laid down in paragraph 1 of this Article to the statistics covered by this Regulation, the modalities and structure of the quality reports shall be defined in accordance with the procedure referred to in Article 11(2).

The Commission (Eurostat) shall assess the quality of the statistics transmitted.

Article 10

Dissemination of external trade statistics

1. At Community level, external trade statistics compiled in accordance with Article 6(1) and transmitted by the Member States shall be disseminated by the Commission (Eurostat) by the Combined Nomenclature subheading at least.

Only where an importer or exporter so requests shall the national authorities of a given Member State decide whether the external trade statistics of that Member State which may make it possible to identify that importer or exporter are to be disseminated or are to be amended in such a way that their dissemination does not prejudice statistical confidentiality.

2. Without prejudice to data dissemination at national level, detailed statistics by the TARIC subheading and preferences shall not be disseminated by the Commission (Eurostat) if their disclosure would undermine the protection of the public interest as regards the commercial and agricultural policies of the Community.

Article 11

Committee procedure

1. The Commission shall be assisted by the Committee on statistics relating to the trading of goods with non-member countries.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 12

Repeal

Regulation (EC) No 1172/95 shall be repealed with effect from 1 January 2010.

It shall continue to apply to data pertaining to reference periods before 1 January 2010.

Article 13

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2010.

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

Done at Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

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