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Note to the reader (see page 3 of the cover)

EN

[1] Text with relevance for the EEA and for Switzerland
[2] Text with EEA relevance

III

(Preparatory Acts)

COUNCIL

COMMON POSITION (EC) No 1/2009

adopted by the Council on 17 December 2008

with a view to the adoption of Regulation (EC) No …/2009 of the European Parliament and of the Council of … amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of its annexes

(Text with relevance for the EEA and for Switzerland)

(2009/C 33 E/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 42 and 308 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) Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [3] provides for the content of Annexes II, X and XI to that Regulation to be determined before its date of application.

(2) Annexes I, III, IV, VI, VII, VIII and IX to Regulation (EC) No 883/2004 should be adapted in order to take into account both the requirements of the Member States which have acceded to the European Union since that Regulation was adopted and recent developments in other Member States.

(3) Articles 56(1) and 83 of Regulation (EC) No 883/2004 provide for special provisions for the implementation of the legislation of certain Member States to be set out in Annex XI to that Regulation. Annex XI is intended to take account of the particularities of the various social security systems of Member States in order to facilitate the application of the rules on coordination. A number of Member States have asked for entries concerning the application of their social security legislation to be included in this Annex and have provided the Commission with legal and practical explanations of their legislation and systems.

(4) In accordance with the need for rationalisation and simplification, a common approach is needed in order to ensure that entries in respect of different Member States which are of a similar nature or pursue the same objective are in principle dealt with in a similar manner.

(5) As the aim of Regulation (EC) No 883/2004 is to coordinate social security legislation for which Member States are exclusively responsible, entries which are not compatible with its purpose or objectives, and entries seeking solely to clarify the interpretation of national legislation, should not be included in that Regulation.

(6) Some requests raised issues that were common to several Member States: it is therefore appropriate to deal with those issues at a more general level, either by clarification in the body of Regulation (EC) No 883/2004 or in another of its Annexes, which should therefore be amended accordingly, or through a provision in the implementing Regulation referred to in Article 89 of Regulation (EC) No 883/2004, rather than by inserting similar entries in Annex XI for several Member States.

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[1] OJ C 161, 13.7.2007, p. 61.

[2] Opinion of the European Parliament of 9 July 2008 (not yet published in the Official Journal), Council Common Position of 17 December 2008 and Position of the European Parliament of … (not yet published in the Official Journal).

[3] OJ L 166, 30.4.2004, p. 1. Corrected version in OJ L 200, 7.6.2004, p. 1.

(7) Article 28 of Regulation (EC) No 883/2004 should be amended in order to clarify and extend its scope and to ensure that the members of the family of former frontier workers may also benefit from the possibility of continuing medical treatment in the former country of employment of the insured person after his/her retirement, unless the Member State where the frontier worker last pursued his/her last activity is listed in Annex III.

(8) It is also appropriate to deal with certain specific issues in other Annexes to Regulation (EC) No 883/2004, according to their purpose and content, rather than in Annex XI thereto, in order to ensure consistency in the Annexes to that Regulation.

(9) Some Member States' entries in Annex VI of Regulation (EEC) No 1408/71 are now covered by certain general provisions in Regulation (EC) No 883/2004. Consequently, a number of entries in Annex VI of Regulation (EEC) No 1408/71 have become superfluous.

(10) In order to facilitate the use of Regulation (EC) No 883/2004 by citizens when asking for information or making claims to the institutions of the Member States, references to the legislation of the Member States concerned should also be made in the original language wherever necessary in order to avoid any possible misunderstanding.

(11) Regulation (EC) No 883/2004 should therefore be amended accordingly.

(12) Regulation (EC) No 883/2004 provides that it is to apply from the date of entry into force of the implementing Regulation. This Regulation should therefore apply from the same date,

HAVE ADOPTED THIS REGULATON:

Article 1

Regulation (EC) No 883/2004 is hereby amended as follows:

1) the following recital shall be inserted after recital (17):

'(17a) Once the legislation of a Member State becomes applicable to a person under Title II of this Regulation, the conditions for affiliation and entitlement to benefits should be defined by the legislation of the competent Member State while respecting Community law.';

2) the following recital shall be inserted after recital (18):

'(18a) The principle of single applicable legislation is of great importance and should be enhanced. This should not mean, however, that the grant of a benefit alone, in accordance with this Regulation and comprising the payment of insurance contributions or insurance coverage for the beneficiary, renders the legislation of the Member State, whose institution has granted that benefit, the applicable legislation for that person.';

3) in Article 1, the following point shall be inserted:

'(va) "Benefits in kind" means:

(i) for the purposes of Title III, Chapter 1 (sickness, maternity and equivalent paternity benefits), benefits in kind provided for under the legislation of a Member State which are intended to supply, make available, pay directly or reimburse the cost of medical care and products and services ancillary to that care. This includes long-term care benefits in kind.

(ii) for the purposes of Title III, Chapter 2 (accidents at work and occupational diseases), all benefits in kind relating to accidents at work and occupational diseases as defined in point (i) above and provided for under the Member States' accidents at work and occupational diseases schemes.';

4) Article 3(5) shall be replaced by the following:

'5. This Regulation shall not apply to:

(a) social and medical assistance or

(b) benefits in relation to which a Member State assumes the liability for damages to persons and provides for compensation, such as those for victims of war and military action or their consequences; victims of crime, assassination or terrorist acts; victims of damage occasioned by agents of the Member State in the course of their duties; or victims who have suffered a disadvantage for political or religious reasons or for reasons of descent.';

5) Article 14(4) shall be replaced by the following:

'4. Where the legislation of a Member State makes admission to voluntary insurance or optional continued insurance conditional upon residence in that Member State or upon previous activity as an employed or self-employed person, Article 5(b) shall apply only to persons who have been subject, at some earlier stage, to the legislation of that Member State on the basis of an activity as an employed or self-employed person.';

6) in Article 15, the term 'auxiliary staff' shall be replaced by 'contract staff';

7) Article 18(2) shall be replaced by the following:

'2. The members of the family of a frontier worker shall be entitled to benefits in kind during their stay in the competent Member State.

Where the competent Member State is listed in Annex III however, the members of the family of a frontier worker who reside in the same Member State as the frontier worker shall be entitled to benefits in kind in the competent Member State only under the conditions laid down in Article 19(1).

The list contained in Annex III shall be reviewed no later than … (*) on the basis of a report from the Administrative Commission. In the light of this report, the European Commission may, if necessary, submit a proposal to revise the list.';

8) Article 28(1) shall be replaced by the following:

'1. A frontier worker who has retired because of old-age or invalidity is entitled in the event of sickness to continue to receive benefits in kind in the Member State where he/she last pursued his/her activity as an employed or self-employed person, insofar as this is a continuation of treatment which began in that Member State. "Continuation of treatment" means the continued investigation, diagnosis and treatment of an illness for its entire duration.

The first subparagraph shall apply *mutatis mutandis* to the members of the family of the former frontier worker unless the Member State where the frontier worker last pursued his/her activity is listed in Annex III.

The list contained in Annex III shall be reviewed no later than … (*) on the basis of a report from the Administrative Commission. In the light of this report, the European Commission may, if necessary, submit a proposal to revise the list.';

9) Article 36(1) shall be replaced by the following:

'1. Without prejudice to any more favourable provisions in paragraphs 2 and 2a of this Article, Articles 17, 18(1), 19(1) and 20(1) shall also apply to benefits relating to accidents at work or occupational diseases.';

10) in Article 36, the following paragraph shall be inserted:

'2a. The competent institution may not refuse to grant the authorisation provided for in Article 20(1) to an employed or self-employed person who has sustained an accident at work or has contracted an occupational disease and who is entitled to benefits chargeable to that institution, where the treatment appropriate to his/her condition cannot be given in the Member State in which the person resides within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his illness.';

11) Article 51(3) shall be replaced by the following:

'3. Where the legislation or specific scheme of a Member State makes the acquisition, retention or recovery of the right to benefits conditional upon the person concerned being insured at the time of the materialisation of the risk, this condition shall be regarded as having been satisfied if that person has been previously insured under the legislation or specific scheme of that Member State and is, at the time of the materialisation of the risk, insured under the legislation of another Member State for the same risk or, failing that, if a benefit is due under the legislation of another Member State for the same risk. The latter condition shall, however, be deemed to be fulfilled in the cases referred to in Article 57.';

12) Article 52(4) shall be replaced by the following:

'4. Where the calculation pursuant to paragraph 1(a) in one Member State invariably results in the independent benefit being equal to or higher than the pro rata benefit, calculated in accordance with paragraph 1(b), the competent institution shall waive the pro rata calculation, provided that:

(i) such a situation is set out in Part 1 of Annex VIII;

(ii) no legislation containing rules against overlapping, as referred to in Articles 54 and 55, is applicable unless the conditions laid down in Article 55(2) are fulfilled; and

(iii) Article 57 is not applicable in relation to periods completed under the legislation of another Member State in the specific circumstances of the case.';

13) the following paragraph shall be added to Article 52:

'5. Notwithstanding the provisions of paragraphs 1, 2 and 3, the pro rata calculation shall not apply to schemes providing benefits in respect of which periods of time are of no relevance to the calculation, subject to such schemes being listed in part 2 of Annex VIII. In such cases, the person concerned shall be entitled to the benefit calculated in accordance with the legislation of the Member State concerned.';

14) in Article 56(1)(c), the words 'where necessary' shall be inserted before 'in accordance with the procedures laid down in Annex XI';

15) in Article 56(1), the following point shall be added:

'(d) In the event that point(c) is not applicable because the legislation of a Member State provides for the benefit to be calculated on the basis of elements other than periods of insurance or residence which are not linked to time, the competent institution shall take into account, in respect of each period of insurance or residence completed under the legislation of any other Member State, the amount of the capital accrued, the capital which is considered as having been accrued or any other element for the calculation under the legislation it administers divided by the corresponding units of periods in the pension scheme concerned.';

16) in Article 57, the following paragraph shall be added:

'4. This Article shall not apply to schemes listed in part 2 of Annex VIII.';

(*) 5 years from the date of application of this Regulation.

17) in Article 62(3), the term 'frontier workers' shall be replaced by 'unemployed persons';

18) the following Article shall be inserted:

'*Article 68a*

Provision of benefits

In the event that family benefits are not used by the person to whom they should be provided for the maintenance of the members of the family, the competent institution shall discharge its legal obligations by providing those benefits to the natural or legal person in fact maintaining the members of the family, at the request and through the agency of the institution in their Member State of residence or of the designated institution or body appointed for that purpose by the competent authority of their Member State of residence.';

19) Article 87 shall be amended as follows:

(a) paragraph 8 shall be replaced by the following:

'8. If, as a result of this Regulation, a person is subject to the legislation of a Member State other than that determined in accordance with Title II of Regulation (EEC) No 1408/71, that legislation shall continue to apply while the relevant situation remains unchanged and in any case for no longer than 10 years from the date of application of this Regulation unless the person concerned requests that he/she be subject to the legislation applicable under this Regulation. The request shall be submitted within three months after the date of application of this Regulation to the competent institution of the Member State whose legislation is applicable under this Regulation if the person concerned is to be subject to the legislation of that Member State as of the date of application of this Regulation. If the request is made after the time limit indicated, the change of applicable legislation shall take place on the first day of the following month.';

(b) the following paragraph shall be inserted:

'(10a) The entries in Annex III corresponding to Estonia, Spain, Italy, Lithuania, Hungary and the Netherlands shall cease to have effect 4 years after the date of application of this Regulation';

20) the Annexes shall be amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from the date of entry into force of the implementing Regulation referred to in Article 89 of Regulation (EC) No 883/2004.

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

Done at, …

For the European Parliament	*For the Council*
The President	*The President*
…	…

ANNEX

Amendments to the Annexes to Regulation (EC) No 883/2004

A. Annex I is amended as follows:

1) In Part I (advances of maintenance payments):

(a) The heading 'A. BELGIUM' is replaced by 'BELGIUM'

(b) After the entry 'BELGIUM' the following entry is inserted:

'BULGARIA

Maintenance payments made by the state under Article 92 of the Family Code.';

(c) The headings 'B. DENMARK' and 'C. GERMANY' are replaced respectively by 'DENMARK' and 'GERMANY';

(d) After the entry under the heading 'GERMANY' the following entries are inserted:

'ESTONIA

Maintenance allowances under the Maintenance Allowance Act of 21 February 2007;

SPAIN

Advances of maintenance payments under the Royal Decree 1618/2007 of 7 December 2007.';

(e) The heading 'D. FRANCE' is replaced by 'FRANCE';

(f) After the entry under the heading 'FRANCE' the following entries are inserted:

'LITHUANIA

Payments from the Children's Maintenance Fund under the Law on the Children's Maintenance Fund.

LUXEMBOURG

Advances and recovery of maintenance payments within the meaning of the Act of 26 July 1980.';

(g) The heading 'E. AUSTRIA' is replaced by 'AUSTRIA';

(h) After the entry under the heading 'AUSTRIA' the following entry is inserted:

'POLAND

Benefits from the Alimony Fund under the Act of Assistance to the Persons Entitled to Alimony';

(i) The heading 'F. PORTUGAL' is replaced by 'PORTUGAL';

(j) After the entry under the heading 'PORTUGAL' the following entries are inserted:

'SLOVENIA

Maintenance replacement in accordance with the Act of Public Guarantee and Maintenance Fund of the Republic of Slovenia of 25 July 2006.

SLOVAKIA

Substitute alimony benefit (substitute maintenance payment) pursuant to the Act No 452/2004 Coll. on substitute alimony benefit as amended by later regulations.';

(k) The headings 'G. FINLAND' and 'H. SWEDEN' are replaced respectively by 'FINLAND' and 'SWEDEN'.

2) In Part II (special childbirth and adoption allowances):

(a) The heading 'A. BELGIUM' is replaced by 'BELGIUM'

(b) After the entry under the heading 'BELGIUM' the following entries are inserted:

'BULGARIA

Maternity lump sum allowance (Law on Family Allowances for Children).

CZECH REPUBLIC

Childbirth allowance.

ESTONIA

(a) Childbirth allowance;

(b) Adoption allowance.';

(c) The headings 'B. SPAIN' and 'C. FRANCE' are replaced respectively by 'SPAIN' and 'FRANCE';

(d) The entry under the heading 'SPAIN' is replaced by the following:

'SPAIN

Single payment birth and adoption grants';

(e) In the entry under the heading 'FRANCE' the following words are added:

', except when they are paid to a person who remains subject to French legislation pursuant to Article 12 or Article 16';

(f) After the entry under the heading 'FRANCE' the following entries are inserted:

'LATVIA

(a) Childbirth grant;

(b) Adoption allowance.

LITHUANIA

Child lump sum grant.';

(g) The heading 'D. LUXEMBOURG' is replaced by 'LUXEMBOURG';

(h) After the entry under the heading 'LUXEMBOURG' the following entries are inserted:

'HUNGARY

Maternity grant.

POLAND

Single payment birth grant (Act on Family Benefits).

ROMANIA

(a) Childbirth allowance;

(b) Layette for newborn children.

SLOVENIA

Childbirth grant.

SLOVAKIA

(a) Childbirth allowance;

(b) Supplement to childbirth allowance.';

(i) The heading 'E. FINLAND' is replaced by 'FINLAND'.

B. Annex II is replaced by the following:

'*ANNEX II*

PROVISIONS OF CONVENTIONS WHICH REMAIN IN FORCE AND WHICH, WHERE APPLICABLE, ARE RESTRICTED TO THE PERSONS COVERED THEREBY (Article 8(1))

General comments

It is to be noted that the provisions of bilateral conventions which do not fall within the scope of this Regulation and which remain in force between Member States are not listed in this Annex. This includes obligations between Member States arising from conventions providing, for example, for provisions regarding aggregation of insurance periods fulfilled in a third country.

Provisions of social security conventions remaining applicable:

BELGIUM-GERMANY

Articles 3 and 4 of the Final Protocol of 7 December 1957 to the General Convention of that date, as set out in the Complementary Protocol of 10 November 1960 (reckoning of insurance periods completed in some border regions before, during and after the Second World War).

BELGIUM-LUXEMBOURG

Convention of 24 March 1994 on social security for frontier workers (relating to the complementary flat rate reimbursement)

BULGARIA-GERMANY

Article 28(1)(b) of the Convention on social security of 17 December 1997 (maintenance of conventions concluded between Bulgaria and the former German Democratic Republic for persons who already received a pension before 1996).

BULGARIA-AUSTRIA

Article 38(3) of the Convention on social security of 14 April 2005 (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by that Convention.

BULGARIA-SLOVENIA

Article 32(2) of the Convention on Social Security of 18 December 1957 (reckoning of periods of insurance completed until 31 December 1957).

CZECH REPUBLIC-GERMANY

Article 39(1)(b) and (c) of the Convention on Social Security of 27 July 2001 (maintenance of the convention concluded between the former Czechoslovak Republic and the former German Democratic Republic for persons who already received a pension before 1996; reckoning of periods of insurance completed in one of the contracting States for persons who already received a pension for these periods on 1 September 2002 from the other contracting State, while residing in its territory).

CZECH REPUBLIC-CYPRUS

Article 32(4) of the Convention on Social Security of 19 January 1999 (determining competence for the calculation of periods of employment completed under the relevant Convention of 1976); the application of that provision remains restricted to the persons covered by it.

CZECH REPUBLIC-LUXEMBOURG

Article 52(8) of the Convention on Social Security of 17 November 2000 (reckoning of pension insurance periods for political refugees).

CZECH REPUBLIC-AUSTRIA

Article 32(3) of the Convention on social security of 20 July 1999 (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by it.

CZECH REPUBLIC-SLOVAKIA

Articles 12, 20 and 33 of the Convention on Social Security of 29 October 1992 (Article 12 determines competence for a grant of survivor's benefits; Article 20 determines competence for calculation of insurance periods completed until the day of dissolution of the Czech and Slovak Federal Republic; Article 33 determines competence for payment of pensions awarded before the day of the dissolution of the Czech and Slovak Federal Republic).

DENMARK-FINLAND

Article 7 of the Nordic Convention on social security of 18 August 2003 (concerning coverage of extra travel expenses in case of sickness during stay in another Nordic country increasing the cost of return travel to the country of residence).

DENMARK-SWEDEN

Article 7 of the Nordic Convention on social security of 18 August 2003 (concerning coverage of extra travel expenses in case of sickness during stay in another Nordic country increasing the cost of return travel to the country of residence).

GERMANY-SPAIN

Article 45(2) of the Social Security Convention of 4 December 1973 (representation by diplomatic and consular authorities).

GERMANY-FRANCE

(a) Complementary Agreement No 4 of 10 July 1950 to the General Convention of the same date, as set out in Supplementary Agreement No 2 of 18 June 1955 (reckoning of periods of insurance completed between 1 July 1940 and 30 June 1950);

(b) Title I of that Supplementary Agreement No 2 (reckoning of periods of insurance completed before 8 May 1945);

(c) points 6, 7 and 8 of the General Protocol of 10 July 1950 to the General Convention of the same date (administrative arrangements);

(d) Titles II, III and IV of the Agreement of 20 December 1963 (social security in the Saar).

GERMANY-LUXEMBOURG

Articles 4, 5, 6 and 7 of the Convention of 11 July 1959 (reckoning of insurance periods completed between September 1940 and June 1946).

GERMANY-HUNGARY

Article 40(1)(b) of the Convention on social security of 2 May 1998 (maintenance of the convention concluded between the former German Democratic Republic and Hungary for persons who already received a pension before 1996).

GERMANY-NETHERLANDS

Articles 2 and 3 of Complementary Agreement No 4 of 21 December 1956 to the Convention of 29 March 1951 (settlement of rights acquired under the German social insurance scheme by Dutch workers between 13 May 1940 and 1 September 1945).

GERMANY-AUSTRIA

(a) Article 1(5) and Article 8 of the Convention on Unemployment Insurance of 19 July 1978 and Article 10 of the Final Protocol to this Convention (granting of unemployment allowances to frontier workers by the previous State of employment) shall continue to apply to persons who have exercised an activity as a frontier worker on or before 1 January 2005 and become unemployed before 1 January 2011.

(b) Article 14(2)(g), (h), (i) and (j) of the Convention on social security of 4 October 1995 (determination of competencies between both countries with regard to former insurance cases and acquired insurance periods); the application of that provision remains restricted to the persons covered by it.

GERMANY-POLAND

(a) Convention of 9 October 1975 on old-age and work injury provisions, under the conditions and the scope defined by Article 27(2) to (4) of the Convention on social security of 8 December 1990 (maintenance of legal status, on the basis of the convention of 1975, of the persons who had established their residence in the territory of Germany or Poland before 1 January 1991 and who continue to reside there);

(b) Articles 27(5) and 28(2) of the Convention on social security of 8 December 1990 (maintenance of entitlement to a pension paid on the basis of the convention of 1957 concluded between the former German Democratic Republic and Poland; reckoning of periods of insurance completed by Polish employees under the convention of 1988 concluded between the former German Democratic Republic and Poland).

GERMANY-ROMANIA

Article 28(1)(b) of the Convention on social security of 8 April 2005 (maintenance of the convention concluded between the former German Democratic Republic and Romania for persons who already received a pension before 1996).

GERMANY-SLOVENIA

Article 42 of the Convention on social security of 24 September 1997 (settlement of rights acquired before 1 January 1956 under the social security scheme of the other contracting state); the application of that provision remains restricted to the persons covered by it.

GERMANY-SLOVAKIA

Article 29(1), second and third subparagraphs of the Agreement of 12 September 2002 (maintenance of the convention concluded between the former Czechoslovak Republic and the former German Democratic Republic for persons who already received a pension before 1996; reckoning of periods of insurance completed in one of the contracting States for persons who already received a pension for these periods on 1 December 2003 from the other contracting State, while residing in its territory).

GERMANY-UNITED KINGDOM

(a) Article 7(5) and (6) of the Convention on social security of 20 April 1960 (legislation applicable to civilians serving in the military forces);

(b) Article 5(5) and (6) of the Convention on unemployment insurance of 20 April 1960 (legislation applicable to civilians serving in the military forces).

IRELAND-UNITED KINGDOM

Article 19(2) of the Agreement of 14 December 2004 on social security (concerning the transfer and reckoning of certain disability credits).

SPAIN-PORTUGAL

Article 22 of the General Convention of 11 June 1969 (export of unemployment benefits). This entry will remain valid for two years from the date of application of this Regulation.

ITALY-SLOVENIA

(a) Agreement on regulation of mutual obligations in social insurance with reference to paragraph 7 of Annex XIV to the Peace Treaty, concluded by exchange of notes on 5 February 1959 (reckoning of periods of insurance completed before 18 December 1954); the application of that provision remains restricted to the persons covered by that Agreement.

(b) Article 45(3) of the Convention on social security of 7 July 1997 concerning ex-Zone B of the Free Territory of Trieste (reckoning of periods of insurance completed before 5 October 1956); the application of that provision remains restricted to the persons covered by that Convention.

LUXEMBOURG-PORTUGAL

Agreement of 10 March 1997 (on the recognition of decisions by institutions in one contracting party concerning the state of invalidity of applicants for pensions from institutions in the other contracting party).

LUXEMBOURG-SLOVAKIA

Article 50(5) of the Convention on Social Security of 23 May 2002 (reckoning of pension insurance periods for political refugees).

HUNGARY-AUSTRIA

Article 36(3) of the Convention on social security of 31 March 1999 (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by it.

HUNGARY-SLOVENIA

Article 31 of the Convention on social security of 7 October 1957 (reckoning of periods of insurance completed before 29 May 1956); the application of that provision remains restricted to the persons covered by it.

HUNGARY-SLOVAKIA

Article 34(1) of the Convention on social security of 30 January 1959 (Article 34(1) of that Convention provides that the insurance periods awarded before the day of signing that Convention are the insurance periods of the contracting State on which territory the entitled person had a residence); the application of that provision remains restricted to the persons covered by it.

AUSTRIA-POLAND

Article 33(3) of the Convention on social security of 7 September 1998 (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by it.

AUSTRIA-ROMANIA

Article 37(3) of the Agreement on social security of 28 October 2005 (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by it.

AUSTRIA-SLOVENIA

Article 37 of the Convention on social security of 10 March 1997 (reckoning of periods of insurance completed before 1 January 1956); the application of that provision remains restricted to the persons covered by it.

AUSTRIA-SLOVAKIA

Article 34(3) of the Convention of 21 December 2001 on Social Security (reckoning of periods of insurance completed before 27 November 1961); the application of that provision remains restricted to the persons covered by it.

FINLAND-SWEDEN

Article 7 of the Nordic Convention on social security of 18 August 2003 (concerning coverage of extra travel expenses in case of sickness during stay in another Nordic country increasing the cost of return travel to the country of residence).'

C. Annex III is replaced by the following:

'*ANNEX III*

RESTRICTION OF RIGHTS TO BENEFITS IN KIND FOR MEMBERS OF THE FAMILY OF A FRONTIER WORKER (referred to in Article 18(2))

DENMARK

ESTONIA (this entry will be valid during the period referred to in Article 87(10a))

IRELAND

SPAIN (this entry will be valid during the period referred to in Article 87(10a))

ITALY (this entry will be valid during the period referred to in Article 87(10a))

LITHUANIA (this entry will be valid during the period referred to in Article 87(10a))

HUNGARY (this entry will be valid during the period referred to in Article 87(10a))

NETHERLANDS (this entry will be valid during the period referred to in Article 87(10a))

FINLAND

SWEDEN

UNITED KINGDOM'.

D. Annex IV is amended as follows:

1) After the entry 'BELGIUM', the following entries are inserted:

'BULGARIA

CZECH REPUBLIC';

2) The entry 'ITALY' is deleted;

3) After the entry 'FRANCE', the entry 'CYPRUS' is inserted;

4) After the entry 'LUXEMBOURG', the following entries are inserted:

'HUNGARY

THE NETHERLANDS';

5) After the entry 'AUSTRIA', the following entries are inserted:

'POLAND

SLOVENIA'.

E. Annex VI is amended as follows:

1) At the beginning of the Annex the following entries are inserted:

'CZECH REPUBLIC

Full disability pension for persons whose total disability arose before reaching eighteen years of age and who were not insured for the required period (Section 42 of the Pension Insurance Act No 155/1995 Coll.).

ESTONIA

(a) Invalidity pensions granted before 1 April 2000 under the State Allowances Act and which are retained under the State Pension Insurance Act.

(b) National pensions granted on the basis of invalidity according to the State Pension Insurance Act.

(c) Invalidity pensions granted according to the Defence Forces Service Act, Police Service Act, Prosecutor's Office Act, Status of Judges Act, Members of the Riigikogu Salaries, Pensions and Other Social Guarantees Act and President of the Republic Official Benefits Act.';

2) The headings 'A. GREECE' and 'B. IRELAND' are replaced respectively by 'GREECE' and 'IRELAND';

3) The entry under the heading 'IRELAND' is removed and reinserted before the entry under the heading 'GREECE' and is replaced by the following:

'Part 2, Chapter 17 of the Social Welfare Consolidation Act 2005';

4) After the entry under the heading 'GREECE' the following entry is inserted:

'LATVIA

Invalidity pensions (third group) under Article 16(1)(2) of the Law on State Pensions of 1 January 1996.';

5) The heading 'C. FINLAND' is replaced by 'FINLAND' and the corresponding entry is replaced by the following:

'FINLAND

National Pensions to persons who are born disabled or become disabled at an early age (the National Pension Act, 568/2007);

Invalidity pensions determined according to transitional rules and awarded prior to 1 January 1994 (Act on Enforcement of the National Pensions Act, 569/2007).';

6) The headings 'D. SWEDEN' and 'E. UNITED KINGDOM'. are replaced respectively by 'SWEDEN' and 'UNITED KINGDOM'.

F. Annex VII is amended as follows:

1) In the tables headed 'BELGIUM' and 'FRANCE', the rows relating to Luxembourg are deleted;

2) The table headed 'LUXEMBOURG' is deleted.

G. Annex VIII is replaced by the following:

'*ANNEX VIII*

CASES IN WHICH THE PRO RATA CALCULATION SHALL BE WAIVED OR SHALL NOT APPLY (Article 52(4) and 52(5))

Part 1: Cases in which the pro rata calculation shall be waived pursuant to Article 52(4)

DENMARK

All applications for pensions referred to in the law on social pensions, except for pensions mentioned in Annex IX.

IRELAND

All applications for state pension (transition), state pension (contributory), widow's (contributory) pension and widower's (contributory) pension.

CYPRUS

All applications for old age, invalidity, widow's and widower's pensions.

LATVIA

(a) All applications for invalidity pensions (Law on State Pensions of 1 January 1996);

(b) All applications for survivor's pensions (Law on State pensions of 1 January 1996; Law on State funded pensions of 1 July 2001).

LITHUANIA

All applications for State social insurance survivor's pensions calculated on the basis of the basic amount of survivor's pension (Law on State Social Insurance Pensions).

NETHERLANDS

All applications for old-age pensions under the law on general old-age insurance (AOW).

AUSTRIA

(a) All applications for benefits under the Federal Act of 9 September 1955 on General Social Insurance — ASVG, the Federal Act of 11 October 1978 on social insurance for self-employed persons engaged in trade and commerce — GSVG, the Federal Act of 11 October 1978 on social insurance for self-employed farmers — BSVG and the Federal Act of 30 November 1978 on social insurance for the self-employed in the liberal professions (FSVG);

(b) All applications for invalidity pensions based on a pension account pursuant to the General Pensions Act (APG) of 18 November 2004;

(c) All applications for survivors' pensions based on a pension account pursuant to the General Pensions Act (APG) of 18 November 2004, if no increase in benefits is to be applied in respect of additional months of insurance pursuant to Article 7(2) of the General Pensions Act (APG);

(d) All applications for invalidity and survivors' pensions of the Austrian Provincial Chambers of Physicians (Landesärztekammer) based on basic provision (basic and any supplementary benefit, or basic pension);

(e) All applications for permanent occupational invalidity support and survivors' support from the pension fund of the Austrian Chamber of Veterinary Surgeons;

(f) All applications for benefits from occupational invalidity, widows and orphans pensions according to the statutes of the welfare institutions of the Austrian bar associations, Part A.

POLAND

All applications for disability pensions, old-age pensions under the defined benefits scheme and survivors' pensions.

PORTUGAL

All applications for invalidity, old-age and survivors' pension claims, except for the cases where the totalised periods of insurance completed under the legislation of more than one Member State are equal to or longer than 21 calendar years, the national periods of insurance are equal or inferior to 20 years, and the calculation is made under Article 11 of Decree-Law No 35/2002, 19 February.

SLOVAKIA

(a) All applications for survivors' pension (widow's pension, widower's and orphan's pension) calculated according to the legislation in force before 1 January 2004, the amount of which is derived from a pension formerly paid to the deceased;

(b) All applications for pensions calculated pursuant to Act No 461/2003 Coll. on social security as amended.

SWEDEN

All applications for guarantee pension in the form of old-age pension (Act 1998:702) and old-age pension in the form of supplementary pension (Act 1998:674).

UNITED KINGDOM

All applications for retirement pension, widows' and bereavement benefits, with the exception of those for which:

(a) during a tax year beginning on or after 6 April 1975:

(i) the party concerned had completed periods of insurance, employment or residence under the legislation of the United Kingdom and another Member State; and one (or more) of the tax years was not considered a qualifying year within the meaning of the legislation of the United Kingdom;

(ii) the periods of insurance completed under the legislation in force in the United Kingdom for the periods prior to 5 July 1948 would be taken into account for the purposes of Article 52(1)(b) of the Regulation by application of the periods of insurance, employment or residence under the legislation of another Member State.

All applications for additional pension pursuant to the Social Security Contributions and Benefits Act 1992, section 44, and the Social Security Contributions and Benefits (Northern Ireland) Act 1992, section 44.

Part 2: Cases in which Article 52(5) applies

BULGARIA

Old age pensions from the Supplementary Compulsory Pension Insurance, under Part II, Title II, of the Social Insurance Code.

ESTONIA

Mandatory funded old-age pension scheme.

FRANCE

Basic or supplementary schemes in which old-age benefits are calculated on the basis of retirement points.

LATVIA

Old-age pensions (Law on State pensions of 1 January 1996; Law on State funded pensions of 1 July 2001).

HUNGARY

Pension benefits based on membership of private pension funds.

AUSTRIA

(a) Old-age pensions based on a pension account pursuant to the General Pensions Act (APG) of 18 November 2004;

(b) Compulsory allowances under Article 41 of the Federal Law of 28 December 2001, BGBl I Nr. 154 on the general salary fund of Austrian pharmacists (Pharmazeutische Gehaltskasse für Österreich);

(c) Retirement and early retirement pensions of the Austrian Provincial Chambers of Physicians based on basic provision (basic and any supplementary benefit, or basic pension), and all pension benefits of the Austrian Provincial Chambers of Physicians based on additional provision (additional or individual pension);

(d) Old-age support from the pension fund of the Austrian Chamber of Veterinary Surgeons;

(e) Benefits according to the statutes of the welfare institutions of the Austrian bar associations, Parts A and B, with the exception of applications for benefits from disability, widows' and orphans' pensions according to the statutes of the welfare institutions of the Austrian bar associations, Part A;

(f) Benefits by the welfare institutions of the Federal Chamber of Architects and Consulting Engineers under the Austrian Civil Engineers' Chamber Act (Ziviltechnikerkammergesetz) 1993 and the statutes of the welfare institutions, with the exception of benefits on grounds of occupational invalidity and survivors' benefits deriving from the last-named benefits;

(g) Benefits according to the statute of the welfare institution of the Federal Chamber of Professional Accountants and Tax Advisors under the Austrian Professional Accountants and Tax Advisors' Act (Wirtschaftstreuhandberufsgesetz).

POLAND

Old-age pensions under the defined contribution scheme.

SLOVENIA

Pension from compulsory supplementary pension insurance.

SLOVAKIA

Mandatory old-age pension saving.

SWEDEN

Income-based pension and premium pension (Act 1998:674).

UNITED KINGDOM

Graduated retirement benefits paid pursuant to the National Insurance Act 1965, sections 36 and 37, and the National Insurance Act (Northern Ireland) 1966, sections 35 and 36.';

H. Annex IX is amended as follows:

1) In Part I:

(a) The headings 'A. BELGIUM', 'B. DENMARK', 'C. GREECE', 'D. SPAIN', 'E. FRANCE', 'F. IRELAND', 'G. NETHERLANDS', 'H. FINLAND' and 'I. SWEDEN' are respectively replaced by 'BELGIUM', 'DENMARK', 'GREECE', 'SPAIN', 'FRANCE', 'IRELAND', 'NETHERLANDS', 'FINLAND' and 'SWEDEN';

(b) The entry under the heading 'IRELAND' is moved after the entry under the heading 'DENMARK' and before the entry under the heading 'GREECE';

(c) After the entry under the heading 'FRANCE' the following entry is inserted:

'LATVIA

Invalidity pensions (third group) under Article 16(1)(2) of the Law on State Pensions of 1 January 1996.';

(d) In the entry under the heading 'NETHERLANDS' the following text is added:

'The law of 10 November 2005 on work and income according to labour capacity (WIA).';

(e) The entry under the heading 'FINLAND' is replaced by the following:

'National pensions to persons who are born disabled or become disabled at an early age (the National Pensions Act, 568/2007);

National pensions and spouse's pensions determined according to the transitional rules and awarded prior to the 1 January 1994 (Act on Enforcement of the National Pensions Act, 569/2007);

The additional amount of child's pension when calculating independent benefit according to the National Pension Act (the National Pension Act, 568/2007).';

(f) The entry under the heading 'SWEDEN' is replaced by the following:

'Swedish income-related sickness compensation and activity compensation (Act 1962:381).

Swedish guarantee pension and guaranteed compensation which replaced the full Swedish state pensions provided under the legislation on the state pension which applied before 1 January 1993, and the full state pension awarded under the transitional rules of the legislation applying from that date.';

2) In Part II:

(a) The headings 'A. GERMANY', 'B. SPAIN', 'C. ITALY', 'D. LUXEMBOURG', 'E. FINLAND' and 'F. SWEDEN' are respectively replaced by 'GERMANY', 'SPAIN', 'ITALY', 'LUXEMBOURG', 'FINLAND' and 'SWEDEN';

(b) After the entry under the heading 'ITALY' the following entries are inserted:

'LATVIA

Survivors' pension calculated on the basis of assumed insurance periods (Article 23(8) of the Law on State Pensions of 1 January 1996).

LITHUANIA

(a) State social insurance work incapacity pensions, paid under the Law on State Social Insurance Pensions.

(b) State social insurance survivors' and orphans' pensions, calculated on the basis of the work incapacity pension of the deceased under the Law on State Social Insurance Pensions.';

(c) After the entry under the heading 'LUXEMBOURG' the following entry is inserted:

'SLOVAKIA

(a) Slovak invalidity pension and survivors' pension derived therefrom;

(b) Invalidity pension for a person who became invalid as a dependent child and who is always deemed to have fulfilled the required period of insurance (Article 70(2), Article 72(3) and Article 73(3) and (4) of Act No 461/2003 on social insurance, as amended).'.

3) In Part III:

The entry 'Nordic Convention of 15 June 1992 on social security' is replaced by the following: 'Nordic Convention on social security of 18 August 2003.'

I. Annex X is replaced by the following:

'*ANNEX X*

SPECIAL NON-CONTRIBUTORY CASH BENEFITS (Article 70(2)(c))

BELGIUM

(a) Income replacement allowance (Law of 27 February 1987);

(b) Guaranteed income for elderly persons (Law of 22 March 2001).

BULGARIA

Social Pension for old age (Article 89 of the Social Insurance Code).

CZECH REPUBLIC

Social allowance (State Social Support Act No 117/1995 Sb.).

DENMARK

Accommodation expenses for pensioners (Law on individual accommodation assistance, consolidated by Law No 204 of 29 March 1995).

GERMANY

(a) Basic subsistence income for the elderly and for persons with reduced earning capacity under Chapter 4 of Book XII of the Social Code;

(b) Benefits to cover subsistence costs under the basic provision for jobseekers unless, with respect to these benefits, the eligibility requirements for a temporary supplement following receipt of unemployment benefit (Article 24(1) of Book II of the Social Code) are fulfilled.

ESTONIA

(a) Disabled adult allowance (Social Benefits for Disabled Persons Act of 27 January 1999);

(b) State unemployment allowance (Labour Market Services and Support Act of 29 September 2005).

IRELAND

(a) Jobseekers' allowance (Social Welfare Consolidation Act 2005, Part 3, Chapter 2);

(b) State pension (non-contributory) (Social Welfare Consolidation Act 2005, Part 3, Chapter 4);

(c) Widow's (non-contributory) pension and widower's (non-contributory) pension (Social Welfare Consolidation Act 2005, Part 3, Chapter 6);

(d) Disability allowance (Social Welfare Consolidation Act 2005, Part 3, Chapter 10);

(e) Mobility allowance (Health Act 1970, Section 61);

(f) Blind pension (Social Welfare Consolidation Act 2005, Part 3, Chapter 5).

GREECE

Special benefits for the elderly (Law 1296/82).

SPAIN

(a) Minimum income guarantee (Law No 13/82 of 7 April 1982);

(b) Cash benefits to assist the elderly and invalids unable to work (Royal Decree No 2620/81 of 24 July 1981);

(c) (i) Non-contributory invalidity and retirement pensions as provided for in Article 38(1) of the Consolidated Text of the General Law on Social Security, approved by Royal Legislative Decree No 1/1994 of 20 June 1994; and

(ii) the benefits which supplement the above pensions, as provided for in the legislations of the Comunidades Autonómas, where such supplements guarantee a minimum subsistence income having regard to the economic and social situation in the Comunidades Autonómas concerned;

(d) Allowances to promote mobility and to compensate for transport costs (Law No 13/1982 of 7 April 1982).

FRANCE

(a) Supplementary allowances of:

(i) the Special Invalidity Fund, and

(ii) the Old Age Solidarity Fund in respect of acquired rights

(Law of 30 June 1956, codified in Book VIII of the Social Security Code);

(b) Disabled adults' allowance (Law of 30 June 1975, codified in Book VIII of the Social Security Code);

(c) Special allowance (Law of 10 July 1952, codified in Book VIII of the Social Security Code) in respect of acquired rights;

(d) Old-age solidarity allowance (ordinance of 24 June 2004, codified in Book VIII of the Social Security Code) as of 1 January 2006.

ITALY

(a) Social pensions for persons without means (Law No 153 of 30 April 1969);

(b) Pensions and allowances for the civilian disabled or invalids (Laws No 118 of 30 March 1971, No 18 of 11 February 1980 and No 508 of 23 November 1988);

(c) Pensions and allowances for the deaf and dumb (Laws No 381 of 26 May 1970 and No 508 of 23 November 1988);

(d) Pensions and allowances for the civilian blind (Laws No 382 of 27 May 1970 and No 508 of 23 November 1988);

(e) Benefits supplementing the minimum pensions (Laws No 218 of 4 April 1952, No 638 of 11 November 1983 and No 407 of 29 December 1990);

(f) Benefits supplementing disability allowances (Law No 222 of 12 June 1984);

(g) Social allowance (Law No 335 of 8 August 1995);

(h) Social increase (Article 1(1) and (12) of Law No 544 of 29 December 1988 and successive amendments).

CYPRUS

(a) Social Pension (Social Pension Law of 1995 (Law 25(I)/95), as amended);

(b) Severe motor disability allowance (Council of Ministers' Decisions Nos 38210 of 16 October 1992, 41370 of 1 August 1994, 46183 of 11 June 1997 and 53675 of 16 May 2001);

(c) Special grant to blind persons (Special Grants Law of 1996 (Law 77(I)/96), as amended).

LATVIA

(a) State Social Security Benefit (Law on State Social Benefits of 1 January 2003);

(b) Allowance for the compensation of transportation expenses for disabled persons with restricted mobility (Law on State Social Benefits of 1 January 2003).

LITHUANIA

(a) Social assistance pension (Law of 2005 on State Social Assistance Benefits, Article 5);

(b) Relief compensation (Law of 2005 on State Social Assistance Benefits, Article 15);

(c) Transport compensation for the disabled who have mobility problems (Law of 2000 on Transport Compensation, Article 7).

LUXEMBOURG

Income for the seriously disabled (Article 1(2), Law of 12 September 2003), with the exception of persons recognised as being disabled workers and employed on the mainstream labour market or in a sheltered environment.

HUNGARY

(a) Invalidity annuity (Decree No 83/1987 (XII 27) of the Council of Ministers on Invalidity Annuity);

(b) Non-contributory old age allowance (Act III of 1993 on Social Administration and Social Benefits);

(c) Transport allowance (Government Decree No 164/1995 (XII 27) on Transport Allowances for Persons with Severe Physical Handicap).

MALTA

(a) Supplementary allowance (Section 73 of the Social Security Act (Cap. 318) 1987);

(b) Age pension (Social Security Act (Cap. 318) 1987).

NETHERLANDS

(a) Disablement Assistance Act for Handicapped Young Persons, of 24 April 1997 (Wajong);

(b) Supplementary Benefits Act of 6 November 1986 (TW).

AUSTRIA

Compensatory supplement (Federal Act of 9 September 1955 on General Social Insurance — ASVG, Federal Act of 11 October 1978 on Social insurance for persons engaged in trade and commerce — GSVG and Federal Act of 11 October 1978 on Social insurance for farmers — BSVG).

POLAND

Social pension (Act of 27 June 2003 on social pensions).

PORTUGAL

(a) Non-contributory State old-age and invalidity pension (Decree-Law No 464/80 of 13 October 1980);

(b) Non-contributory widowhood pension (Regulatory Decree No 52/81 of 11 November 1981);

(c) Solidarity supplement for the elderly (Decree — Law No 232/2005 of 29 December 2005, amended by Decree — Law No 236/2006 of 11 December 2006).

SLOVENIA

(a) State pension (Pension and Disability Insurance Act of 23 December 1999);

(b) Income support for pensioners (Pension and Disability Insurance Act of 23 December 1999);

(c) Maintenance allowance (Pension and Disability Insurance Act of 23 December 1999).

SLOVAKIA

(a) Adjustment awarded before 1 January 2004 to pensions constituting the sole source of income;

(b) Social pension which has been awarded before 1 January 2004.

FINLAND

(a) Housing allowance for pensioners (Act concerning the Housing Allowance for pensioners, 571/2007);

(b) Labour market support (Act on Unemployment Benefits 1290/2002);

(c) Special assistance for immigrants (Act on Special Assistance for Immigrants, 1192/2002).

SWEDEN

(a) Housing supplements for persons receiving a pension (Law 2001: 761);

(b) Financial support for the elderly (Law 2001: 853).

UNITED KINGDOM

(a) State Pension Credit (State Pension Credit Act 2002 and State Pension Credit Act (Northern Ireland) 2002);

(b) Income-based allowances for jobseekers (Jobseekers Act 1995 and Jobseekers (Northern Ireland) Order 1995);

(c) Income Support (Social Security Contributions and Benefits Act 1992 and Social Security Contributions and Benefits (Northern Ireland) Act 1992);

(d) Disability Living Allowance mobility component (Social Security Contributions and Benefits Act 1992 and Social Security Contributions and Benefits (Northern Ireland) Act 1992).'

J. Annex XI is replaced by the following:

'*ANNEX XI*

SPECIAL PROVISIONS FOR THE APPLICATION OF THE LEGISLATION OF THE MEMBER STATES (Articles 51(3), 56(1) and 83)

BELGIUM

None.

BULGARIA

Article 33(1) of the Bulgarian Health Insurance Act shall apply to all persons for whom Bulgaria is the competent Member State under Chapter 1 of Title III of this Regulation.;

CZECH REPUBLIC

For the purposes of defining members of the family according to Article 1(i), "spouse" also includes registered partners as defined in the Czech act no. 115/2006 Coll., on registered partnership.;

DENMARK

1. (a) For the purpose of calculating the pension under the "lov om social pension" (Social Pension Act), periods of activity as an employed or self-employed person completed under Danish legislation by a frontier worker or a worker who has gone to Denmark to do work of a seasonal nature are regarded as periods of residence completed in Denmark by the surviving spouse insofar as, during those periods, the surviving spouse was linked to the above-mentioned worker by marriage without separation from bed and board or de facto separation on grounds of incompatibility, and provided that, during those periods, the spouse resided in the territory of another Member State. For the purposes of this point, "work of a seasonal nature" means work which, being dependent on the succession of the seasons, automatically recurs each year.

   (b) For the purpose of calculating the pension under the "lov om social pension" (Social Pension Act), periods of activity as an employed or self-employed person completed under Danish legislation before 1 January 1984 by a person to whom point 1(a) does not apply shall be regarded as periods of residence completed in Denmark by the surviving spouse, insofar as, during those periods, the surviving spouse was linked to the person by marriage without separation from bed and board or de facto separation on grounds of incompatibility, and provided that, during those periods, the spouse resided in the territory of another Member State.

   (c) Periods to be taken into account under points (a) and (b) shall not be taken into consideration if they coincide with the periods taken into account for the calculation of the pension due to the person concerned under the legislation on compulsory insurance of another Member State or with the periods during which the person concerned received a pension under such legislation. These periods shall, however, be taken into consideration if the annual amount of the said pension is less than half the basic amount of the social pension.

2. (a) Notwithstanding the provisions of Article 6 of this Regulation, persons who have not been gainfully employed in one or more Member States are entitled to a Danish social pension only if they have been, or have previously been, permanent residents of Denmark for at least three years, subject to the age limits prescribed by Danish legislation. Subject to Article 4 of this Regulation, Article 7 does not apply to a Danish social pension to which entitlement has been acquired by such persons.

   (b) The above-mentioned provisions do not apply to Danish social pension entitlement for the members of the family of persons who are or have been gainfully employed in Denmark, or for students or the members of their families.

3. The temporary benefit for unemployed persons who have been admitted to the ledighedsydelse ("flexible job" scheme) (Law No 455 of 10 June 1997) is covered by Title III, Chapter 6 of this Regulation. As regards unemployed persons going to another Member State, Articles 64 and 65 will be applicable when this Member State has similar employment schemes for the same category of persons.

4. Where the beneficiary of a Danish social pension is also entitled to a survivor's pension from another Member State, these pensions for the implementation of Danish legislation shall be regarded as benefits of the same kind within the meaning of Article 53(1) of this Regulation, subject to the condition, however, that the person whose periods of insurance or of residence serve as the basis for the calculation of the survivor's pension had also acquired a right to a Danish social pension.

GERMANY

1. Notwithstanding Article 5(a) of this Regulation and Article 5(4) point 1 of the Sozialgesetzbuch VI (Volume VI of the Social Code), a person who receives a full old-age pension under the legislation of another Member State may request to be compulsorily insured under the German pension insurance scheme.

2. Notwithstanding Article 5(a) of this Regulation and Article 7(1) and (3) of the Sozialgesetzbuch VI (Volume VI of the Social Code), a person who is compulsorily insured in another Member State or receives an old-age pension under the legislation of another Member State may join the voluntary insurance scheme in Germany.

3. For the purpose of granting cash benefits under § 47(1) of SGB V, § 47(1) of SGB VII and § 200(2) of the Reichsversicherungsordnung to insured persons who live in another Member State, German insurance schemes calculate net pay, which is used to assess benefits, as if the insured person lived in Germany, unless the insured person requests an assessment on the basis of the net pay which he actually receives.

4. Nationals of other Member States whose place of residence or usual abode is outside Germany and who fulfil the general conditions of the German pension insurance scheme may pay voluntary contributions only if they had been voluntarily or compulsorily insured in the German pension insurance scheme at some time previously; this also applies to stateless persons and refugees whose place of residence or usual abode is in another Member State.

5. The pauschale Anrechnungszeit (fixed credit period) pursuant to Article 253 of the Sozialgesetzbuch VI (Volume VI of the Social Code) shall be determined exclusively with reference to German periods.

6. In cases where the German pension legislation, in force on 31 December 1991, is applicable for the recalculation of a pension, only the German legislation applies for the purposes of crediting German Ersatzzeiten (substitute periods).

7 The German legislation on accidents at work and occupational diseases to be compensated for under the law governing foreign pensions and on benefits for insurance periods which can be credited under the law governing foreign pensions in the territories named in paragraph 1(2)(3) of the Act on affairs of displaced persons and refugees (Bundesvertriebenengesetz) continues to apply within the scope of application of this Regulation, notwithstanding the provisions of paragraph 2 of the Act on foreign pensions (Fremdrentengesetz).

8. For the calculation of the theoretical amount referred to in Article 52(1)(b)(i) of this Regulation, in pension schemes for liberal professions, the competent institution shall take as a basis, in respect of each of the years of insurance completed under the legislation of any other Member State, the average annual pension entitlement acquired during the period of membership of the competent institution through the payment of contributions.

ESTONIA

For the purpose of calculating parental benefits, periods of employment in Member States other than Estonia shall be considered to be based on the same average amount of Social Tax as paid during the periods of employment in Estonia with which they are aggregated. If during the reference year the person has been employed only in other Member States, the calculation of the benefit shall be considered to be based on the average Social Tax paid in Estonia between the reference year and the maternity leave.

IRELAND

1. Notwithstanding Articles 21(2) and 62 of this Regulation, for the purposes of calculating the prescribed reckonable weekly earnings of an insured person for the grant of sickness or unemployment benefit under Irish legislation, an amount equal to the average weekly wage of employed persons in the relevant prescribed year shall be credited to that insured person in respect of each week of activity as an employed person under the legislation of another Member State during that prescribed year.

2. Where Article 46 of this Regulation applies, if the person concerned suffers incapacity for work leading to invalidity while subject to the legislation of another Member State, Ireland shall, for the purposes of Section 118(1)(a) of the Social Welfare Consolidation Act 2005, take account of any periods during which, in respect of the invalidity that followed that incapacity for work, he/she would have been regarded as being incapable of work under Irish legislation.

GREECE

1. Law No 1469/84 concerning voluntary affiliation to the pension insurance scheme for Greek nationals and foreign nationals of Greek origin is applicable to nationals of other Member States, stateless persons and refugees, where the persons concerned, regardless of their place of residence or stay, have at some time in the past been compulsorily or voluntarily affiliated to the Greek pension insurance scheme.

2. Notwithstanding Article 5 (a) of this Regulation and Article 34 of Law 1140/1981, a person who receives a pension in respect of accidents at work or occupational diseases under the legislation of another Member State may request to be compulsorily insured under the legislation applied by OGA, to the extent that he/she pursues an activity falling within the scope of that legislation.

SPAIN

1. For the purposes of implementing Article 52(1)(b)(i) of this Regulation, the years which the worker lacks to reach the pensionable or compulsory retirement age as stipulated under Article 31(4) of the consolidated version of the Ley de Clases Pasivas del Estado (Law on State Pensioners) shall be taken into account as actual years of service to the State only if at the time of the event in respect of which invalidity or death pensions are due, the beneficiary was covered by Spain's special scheme for civil servants or was performing an activity assimilated under the scheme, or if, at the time of the event in respect of which the pensions are due, the beneficiary was performing an activity that would have required the person concerned to be included under the State's special scheme for civil servants, the armed forces or the judiciary, had the activity been performed in Spain.

2. (a) Under Article 56(1)(c) of this Regulation, the calculation of the theoretical Spanish benefit shall be carried out on the basis of the actual contributions of the person during the years immediately preceding payment of the last contribution to Spanish social security. Where, in the calculation of the basic amount for the pension, periods of insurance and/or residence under the legislation of other Member States have to be taken into account, the contribution basis in Spain which is closest in time to the reference periods shall be used for the aforementioned periods, taking into account the development of the retail price index.

   (b) The amount of the pension obtained shall be increased by the amount of the increases and revaluations calculated for each subsequent year for pensions of the same nature.

3. Periods completed in other Member States which must be calculated in the special scheme for civil servants, the armed forces and the judicial administration, will be treated in the same way, for the purposes of Article 56 of this Regulation, as the periods closest in time covered as a civil servant in Spain.

4 The additional amounts based on age referred to in the Second Transitional Provision of the General Law on Social Security shall be applicable to all beneficiaries of the Regulation who have contributions to their name under the Spanish legislation prior to 1 January 1967; it shall not be possible, by application of Article 5 of this Regulation, to treat periods of insurance credited in another Member State prior to the aforementioned date as being the same as contributions paid in Spain, solely for the present purposes. The date corresponding to 1 January 1967 shall be 1 August 1970 for the Special Scheme for Seafarers and 1 April 1969 for the Special Social Security Scheme for Coal Mining.

FRANCE

1. Nationals of other Member States whose place of residence or usual abode is outside France and who fulfil the general conditions of the French pension insurance scheme may pay voluntary contributions to it only if they had been voluntarily or compulsorily insured in the French pension insurance scheme at some time previously; this also applies to stateless persons and refugees whose place of residence or usual abode is in another Member State.

2. For persons receiving benefits in kind in France pursuant to Articles 17, 24 or 26 of this Regulation who are resident in the French departments of Haut-Rhin, Bas-Rhin or Moselle, benefits in kind provided on behalf of the institution of another Member State which is responsible for bearing their cost include benefits provided by both the general sickness insurance scheme and the obligatory supplementary local sickness insurance scheme of Alsace-Moselle.

3. French legislation applicable to a person engaged, or formerly engaged, in an activity as an employed or self-employed person for the application of Chapter 5 of Title III of this Regulation includes both the basic old-age insurance scheme(s) and the supplementary retirement scheme(s) to which the person concerned was subject.

ITALY

None.

CYPRUS

For the purpose of applying the provisions of Articles 6, 51 and 61 of this Regulation, for any period commencing on or after 6 October 1980, a week of insurance under the legislation of the Republic of Cyprus is determined by dividing the total insurable earnings for the relevant period by the weekly amount of the basic insurable earnings applicable in the relevant contribution year, provided that the number of weeks so determined shall not exceed the number of calendar weeks in the relevant period.

LATVIA

None.

LITHUANIA

None.

LUXEMBOURG

None.

HUNGARY

None.

MALTA

Special provisions for civil servants

(a) Solely for the purposes of the application of Articles 49 and 60 of this Regulation, persons employed under the Armed Forces Act (Chapter 220 of the Laws of Malta), the Police Act (Chapter 164 of the Laws of Malta) and the Prisons Act (Chapter 260 of the Laws of Malta) shall be treated as civil servants.

(b) Pensions payable under the above Acts and under the Pensions Ordinance (Chapter 93 of the Laws of Malta) shall, solely for the purposes of Article 1(e) of the Regulation, be considered as "special schemes for civil servants".

NETHERLANDS

1. Health care insurance

(a) As regards entitlement to benefits in kind under Dutch legislation, persons entitled to benefits in kind for the purpose of the implementation of Chapters 1 and 2 of Title III of this Regulation shall mean:

(i) persons who, under Article 2 of the Zorgverzekeringswet (Health Care Insurance Act), are obliged to take out insurance under a health care insurer, and

(ii) insofar as they are not already included under point (i), members of the family of active military personnel who are living in another Member State and persons who are resident in another Member State and who, under this Regulation are entitled to health care in their state of residence, the costs being borne by the Netherlands.

(b) The persons referred to in point 1(a)(i) must, in accordance with the provisions of the Zorgverzekeringswet (Health Care Insurance Act) take out insurance with a health care insurer, and the persons referred to in point 1(a)(ii) must register with the College voor zorgverzekeringen (Health Care Insurance Board).

(c) The provisions of the Zorgverzekeringswet (Health Care Insurance Act) and the Algemene Wet Bijzondere Ziektekosten (General Act on Exceptional Medical Expenses) concerning liability for the payment of contributions shall apply to the persons referred to in point (a) and the members of their families. In respect of members of the family, the contributions shall be levied on the person from whom the right to health care is derived with the exception of the members of the family of military personnel living in another Member State, who shall be levied directly.

(d) The provisions of the Zorgverzekeringswet (Health Care Insurance Act) concerning late insurance shall apply mutatis mutandis in the event of late registration with the College voor zorgverzekeringen (Health Care Insurance Board) in respect of the persons referred to in point 1(a)(ii).

(e) Persons entitled to benefits in kind by virtue of the legislation of a Member State other than the Netherlands who reside in the Netherlands or stay temporarily in the Netherlands shall be entitled to benefits in kind in accordance with the policy offered to insured persons in the Netherlands by the institution of the place of residence or the place of stay, taking into account Article 11(1), (2) and (3) and Article 19(1) of the Zorgverzekeringswet (Health Care Insurance Act), as well as to benefits in kind provided for by the Algemene Wet Bijzondere Ziektekosten (General Act on Exceptional Medical Expenses).

(f) For the purposes of Articles 23 to 30 of this Regulation, the following benefits (in addition to pensions covered by Title III, Chapters 4 and 5 of this Regulation) shall be treated as pensions due under Dutch legislation:

— pensions awarded under the Law of 6 January 1966 on pensions for civil servants and their survivors (Algemene burgerlijke pensioenwet) (Netherlands Civil Service Pensions Act);

— pensions awarded under the Law of 6 October 1966 on pensions for military personnel and their survivors (Algemene militaire pensioenwet) (Military Pensions Act);

— benefits for incapacity for work awarded under the Law of 7 June 1972 on benefits for incapacity for work for military personnel (Wetarbeidsongeschiktheidsvoorziening militairen) (Military Personnel Incapacity for Work Act);

— pensions awarded under the Law of 15 February 1967 on pensions for employees of the NV Nederlandse Spoorwegen (Dutch Railway Company) and their survivors (Spoorwegpensioenwet) (Railway Pensions Act);

— pensions awarded under the Reglement Dienstvoorwaarden Nederlandse Spoorwegen (Regulation governing conditions of employment of the Netherlands Railway Company);

— benefits awarded to retired persons before reaching the pensionable age of 65 years under a pension designed to provide income for former employed persons in their old age, or benefits provided in the event of premature exit from the labour market under a scheme set up by the state or by an industrial agreement for persons aged 55 or over;

— benefits awarded to military personnel and civil servants under a scheme applicable in the event of redundancy, superannuation and early retirement.

(g) For the purposes of Chapters 1 and 2 of Title III of this Regulation, the no-claims refund provided for in the Netherlands scheme in the event of limited use of health care facilities shall be deemed to be a sickness benefit in cash.

2. Application of the Algemene Ouderdomswet (AOW) (Dutch legislation on general old-age insurance)

(a) The reduction referred to in Article 13(1) of the Algemene Ouderdomswet (AOW) (Dutch legislation on general old-age insurance) shall not be applied for calendar years before 1 January 1957 during which a recipient not satisfying the conditions for having such years treated as periods of insurance:

— resided in the Netherlands between the ages of 15 and 65, or

— while residing in another Member State, worked in the Netherlands for an employer established in the Netherlands, or

— worked in another Member State during periods regarded as periods of insurance under the Dutch social security system.

By way of derogation from Article 7 of the AOW, anyone who resided or worked in the Netherlands in accordance with the above conditions only prior to 1 January 1957 shall also be regarded as being entitled to a pension.

(b) The reduction referred to in Article 13(1) of the AOW shall not apply to calendar years prior to 2 August 1989 during which, between the ages of 15 and 65, a person who is or was married was not insured under the above legislation, while being resident in the territory of a Member State other than the Netherlands, if these calendar years coincide with periods of insurance completed by the person's spouse under that legislation or with calendar years to be taken into account under point 2(a), provided that the couple's marriage subsisted during that time.

By way of derogation from Article 7 of the AOW, such a person shall be regarded as entitled to a pension.

(c) The reduction referred to in Article 13(2) of the AOW shall not apply to calendar years before 1 January 1957 during which a pensioner's spouse who fails to satisfy the conditions for having such years treated as periods of insurance:

— resided in the Netherlands between the ages of 15 and 65, or

— while residing in another Member State, worked in the Netherlands for an employer established in the Netherlands, or

— worked in another Member State during periods regarded as periods of insurance under the Netherlands social security system.

(d) The reduction referred to in Article 13(2) of the AOW shall not apply to calendar years prior to 2 August 1989 during which, between the ages of 15 and 65, a pensioner's spouse resident in a Member State other than the Netherlands was not insured under the above legislation, if those calendar years coincide with periods of insurance completed by the pensioner under that legislation or with calendar years to be taken into account under point 2(a), provided that the couple's marriage subsisted during that time.

(e) Points 2(a), 2(b), 2(c) and 2(d) shall not apply to periods which coincide with:

— periods which may be taken into account for calculating pension rights under the old-age insurance legislation of a Member State other than the Netherlands, or

— periods for which the person concerned has drawn an old-age pension under such legislation.

Periods of voluntary insurance under the system of another Member State shall not be taken into account for the purposes of this provision.

(f) Points 2(a), 2(b), 2(c) and 2(d) shall apply only if the person concerned has resided in one or more Member States for six years after the age of 59 and only for such time as that person is resident in one of those Member States.

(g) By way of derogation from Chapter IV of the AOW, anyone resident in a Member State other than the Netherlands whose spouse is covered by compulsory insurance under that legislation shall be authorised to take out voluntary insurance under that legislation for periods during which the spouse is compulsorily insured.

This authorisation shall not cease where the spouse's compulsory insurance is terminated as a result of his death and where the survivor receives only a pension under the Algemene nabestaandenwet (Dutch legislation on general law for surviving dependants).

In any event, the authorisation in respect of voluntary insurance ceases on the date on which the person reaches the age of 65.

The contribution to be paid for voluntary insurance shall be set in accordance with the provisions relating to the determination of the contribution for voluntary insurance under the AOW. However, if the voluntary insurance follows on from a period of insurance as referred to in point 2(b), the contribution shall be set in accordance with the provisions relating to the determination of the contribution for compulsory insurance under the AOW, with the income to be taken into account being deemed to have been received in the Netherlands.

(h) The authorisation referred to in point 2(g) shall not be granted to anyone insured under another Member State's legislation on pensions or survivors' benefits;

(i) Anyone wishing to take out voluntary insurance under point 2(g) shall be required to apply for it to the Social Insurance Bank (Sociale Verzekeringsbank) not later than one year after the date on which the conditions for participation are fulfilled.

3. Application of the Algemene nabestaandenwet (ANW) (Dutch general law on insurance for surviving dependants)

(a) Where the surviving spouse is entitled to a survivor's pension under the Algemene Nabestaandenwet (ANW) (General Surviving Relatives Act) pursuant to Article 51(3) of this Regulation, that pension shall be calculated in accordance with Article 52(1)(b) of this Regulation.

For the application of these provisions, periods of insurance prior to 1 October 1959 shall also be regarded as periods of insurance completed under Dutch legislation if during those periods the insured person, after the age of 15:

— resided in the Netherlands, or

— while resident in another Member State, worked in the Netherlands for an employer established in the Netherlands, or

— worked in another Member State during periods regarded as periods of insurance under the Dutch social security system.

(b) Account shall not be taken of the periods to be taken into consideration under point 3(a) which coincide with periods of compulsory insurance completed under the legislation of another Member State in respect of survivor's pensions.

(c) For the purposes of Article 52(1)(b) of this Regulation, only periods of insurance completed under Dutch legislation after the age of 15 shall be taken into account as periods of insurance.

(d) By way of derogation from Article 63a(1) of the ANW, a person resident in a Member State other than the Netherlands whose spouse is compulsorily insured under the ANW shall be authorised to take out voluntary insurance under that legislation, provided that such insurance has already begun by the date of application of this Regulation, but only for periods during which the spouse is compulsorily insured.

This authorisation shall cease as from the date of termination of the spouse's compulsory insurance under the ANW, unless the spouse's compulsory insurance is terminated as a result of his death and where the survivor only receives a pension under the ANW.

In any event, the authorisation in respect of voluntary insurance ceases on the date on which the person reaches the age of 65.

The contribution to be paid for voluntary insurance shall be set in accordance with the provisions relating to the determination of contributions for voluntary insurance under the ANW. However, if the voluntary insurance follows on from a period of insurance as referred to in point 2(b), the contribution shall be set in accordance with the provisions relating to the determination of contributions for compulsory insurance under the ANW, with the income to be taken into account being deemed to have been received in the Netherlands.

4. Application of Dutch legislation relating to incapacity for work

(a) Where, pursuant to Article 51(3) of this Regulation, the person concerned is entitled to a Netherlands invalidity benefit, the amount referred to in Article 52(1)(b) of this Regulation for calculating that benefit shall be determined:

(i) where, prior to the occurrence of incapacity for work, the person last exercised an activity as an employed person within the meaning of Article 1(a) of this Regulation:

— in accordance with the provisions laid down in the Wet op arbeidsongeschiktheidsverzekering (WAO) (Act on Incapacity for Work) if the incapacity for work occurred before 1 January 2004, or

— in accordance with the provisions laid down in the Wet Werk en inkomen naar arbeidsvermogen (WIA) (Work and Income according to labour capacity Act) if the incapacity for work occurred on or after 1 January 2004.

(ii) where, prior to the occurrence of the incapacity for work, the person concerned last exercised an activity as a self-employed person within the meaning of Article 1 (b) of this Regulation, in accordance with the provisions laid down in the Wet arbeidsongeschiktheidsverzekering zelfstandigen (WAZ) (Self-employed Persons Act on Incapacity for Work) if the incapacity for work occurred before 1 August 2004.

(b) In calculating benefits under either the WAO, WIA or the WAZ, the Netherlands institutions shall take account of:

— periods of paid employment, and periods treated as such, completed in the Netherlands before 1 July 1967;

— periods of insurance completed under the WAO;

— periods of insurance completed by the person concerned, after the age of 15, under the Algemene Arbeidsongeschiktheidswet (AAW) (General Act on Incapacity for Work), insofar as these do not coincide with the periods of insurance completed under the WAO;

— periods of insurance completed under the WAZ;

— periods of insurance completed under the WIA.

AUSTRIA

1. For the purpose of acquiring periods in the pension insurance, attendance at a school or comparable educational establishment in another Member State shall be regarded as equivalent to attendance at a school or educational establishment pursuant to Articles 227(1)(1) and 228(1)(3) of the Allgemeines Sozialversicherungsgesetz (ASVG) (General Social Security Act), Article 116(7) of the Gewerbliches Sozialversicherungsgesetz (GSVG) (Federal Act on Social Insurance for Persons engaged in Trade and Commerce) and Article 107(7) of the Bauern-Sozialversicherungsgesetz (BSVG) (Social Security Act for Farmers), when the person concerned was subject at some time to Austrian legislation on the grounds that he pursued an activity as an employed or self-employed person, and the special contributions provided for under Article 227(3) of the ASVG, Article 116(9) of the GSVG and Article 107(9) of the BSGV for the purchase of such periods of education, are paid.

2. For the calculation of the pro rata benefit referred to in Article 52(1)(b) of this Regulation, special increments for contributions for supplementary insurance and the miners' supplementary benefit under Austrian legislation shall be disregarded. In these cases the pro rata benefit calculated without those contributions shall, if appropriate, be increased by unreduced special increments for contributions for supplementary insurance and the miners' supplementary benefit.

3. Where pursuant to Article 6 of this Regulation substitute periods under an Austrian pension insurance scheme have been completed, but these cannot form a basis for calculation pursuant to Articles 238 and 239 of the Allgemeines Sozialversicherungsgesetz (ASVG) (General Social Security Act), Articles 122 and 123 of the Gewerbliches Sozialversicherungsgesetz (GSVG) (Federal Act on Social Insurance for Persons engaged in Trade and Commerce) and Articles 113 and 114 of the Bauern-Sozialversicherungsgesetz (BSVG) (Social Security Act for Farmers), the calculation basis for periods of childcare pursuant to Article 239 of the ASVG, Article 123 of the GSVG and Article 114 of the BSVG shall be used.

POLAND

None.

PORTUGAL

None.

ROMANIA

None.

SLOVENIA

None.

SLOVAKIA

None.

FINLAND

1. For the purposes of determining entitlement and of calculating the amount of the Finnish national pension under Articles 52 to 54 of this Regulation, pensions acquired under the legislation of another Member State are treated in the same way as pensions acquired under Finnish legislation.

2. When applying Article 52(1)(b)(i) of this Regulation for the purpose of calculating earnings for the credited period under Finnish legislation on earnings-related pensions, where an individual has pension insurance periods based on activity as an employed or self-employed person in another Member State for part of the reference period under Finnish legislation, the earnings for the credited period shall be equivalent to the sum of earnings obtained during the part of the reference period in Finland, divided by the number of months for which there were insurance periods in Finland during the reference period.

SWEDEN

1. When parental leave allowance is paid under Article 67 of this Regulation to a member of the family who is not employed, the parental leave allowance is paid at a level corresponding to the basic or lowest level.

2. For the purpose of calculating parental leave allowance in accordance with Chapter 4, paragraph 6 of the Lag (1962:381) om allmän försäkring (the National Insurance Act) for persons eligible for a work-based parental leave allowance, the following shall apply:

   For a parent for whom sickness benefit generating income is calculated on the basis of income from gainful employment in Sweden, the requirement to have been insured for sickness benefit above the minimum level for at least 240 consecutive days preceding the child's birth shall be satisfied if, during the period mentioned, the parent had income from gainful employment in another Member State corresponding to insurance above the minimum level.

3. The provisions of this Regulation on the aggregation of insurance periods and periods of residence shall not apply to the transitional provisions in the Swedish legislation on entitlement to guarantee pension for persons born in or before 1937 who have been resident in Sweden for a specified period before applying for a pension (Act 2000:798).

4. For the purpose of calculating income for notional income-related sickness compensation and income-related activity compensation in accordance with Chapter 8 of the Lag (1962:381) om allmän försäkring (the National Insurance Act), the following shall apply:

   (a) where the insured person, during the reference period, has also been subject to the legislation of one or more other Member States on account of activity as an employed or self-employed person, income in the Member State(s) concerned shall be deemed to be equivalent to the insured person's average gross income in Sweden during the part of the reference period in Sweden, calculated by dividing the earnings in Sweden by the number of years over which those earnings accrued;

   (b) where the benefits are calculated pursuant to Article 46 of this Regulation and persons are not insured in Sweden, the reference period shall be determined in accordance with Chapter 8, paragraphs 2 and 8 of the abovementioned Act as if the person concerned were insured in Sweden. If the person concerned has no pension-generating income during this period under the Act on income-based old-age pension (1998:674), the reference period shall be permitted to run from the earlier point in time when the insured person had income from gainful activity in Sweden.

5. (a) For the purpose of calculating notional pension assets for income-based survivor's pension (Act 2000:461), if the requirement in Swedish legislation for pension entitlement in respect of at least three out of the five calendar years immediately preceding the insured person's death (reference period) is not met, account shall also be taken of insurance periods completed in other Member States as if they had been completed in Sweden. Insurance periods in other Member States shall be regarded as based on the average Swedish pension base. If the person concerned has only one year in Sweden with a pension base, each insurance period in another Member State shall be regarded as constituting the same amount.

   (b) For the purpose of calculating notional pension credits for widows' pensions relating to deaths on or after 1 January 2003, if the requirement in Swedish legislation for pension credits in respect of at least two out of the four years immediately preceding the insured person's death (reference period) is not met and insurance periods were completed in another Member State during the reference period, those years shall be regarded as being based on the same pension credits as the Swedish year.

UNITED KINGDOM

1. Where, in accordance with United Kingdom legislation, a person may be entitled to a retirement pension if:

   (a) the contributions of a former spouse are taken into account as if they were that person's own contributions; or

   (b) the relevant contribution conditions are satisfied by that person's spouse or former spouse, then provided, in each case, that the spouse or former spouse is or had been exercising an activity as an employed or self-employed person, and had been subject to the legislation of two or more Member States, the provisions of Chapter 5 of Title III of this Regulation shall apply in order to determine entitlement under United Kingdom legislation. In this case, references in the said Chapter 5 to "periods of insurance" shall be construed as references to periods of insurance completed by:

      (i) a spouse or former spouse where a claim is made by:

         — a married woman; or

         — a person whose marriage has terminated otherwise than by the death of the spouse, or

      (ii) a former spouse, where a claim is made by:

         — a widower who immediately before pensionable age is not entitled to widowed parent's allowance; or

— a widow who immediately before pensionable age is not entitled to widowed mother's allowance, widowed parent's allowance or widow's pension, or who is only entitled to an age-related widow's pension calculated pursuant to Article 52(1)(b) of this Regulation, and for this purpose "age-related widow's pension" means a widow's pension payable at a reduced rate in accordance with section 39(4) of the Social Security Contributions and Benefits Act 1992.

2. For the purposes of applying Article 6 of this Regulation to the provisions governing entitlement to attendance allowance, carer's allowance and disability living allowance, a period of employment, self-employment or residence completed in the territory of a Member State other than the United Kingdom shall be taken into account insofar as is necessary to satisfy conditions as to required periods of presence in the United Kingdom, prior to the day on which entitlement to the benefit in question first arises.

3. For the purposes of Article 7 of this Regulation, in the case of invalidity, old-age or survivors' cash benefits, pensions for accidents at work or occupational diseases and death grants, any beneficiary under United Kingdom legislation who is staying in the territory of another Member State shall, during that stay, be considered as if he resided in the territory of that other Member State.

4. Where Article 46 of this Regulation applies, if the person concerned suffers incapacity for work leading to invalidity while subject to the legislation of another Member State, the United Kingdom shall, for the purposes of Section 30A (5) of the Social Security Contributions and Benefits Act 1992, take account of any periods during which the person concerned has received, in respect of that incapacity for work:

(i) cash sickness benefits or wages or salary in lieu thereof, or

(ii) benefits within the meaning of Chapters 4 and 5 of Title III of this Regulation granted in respect of the invalidity which followed that incapacity for work, under the legislation of the other Member State, as though they were periods of short-term incapacity benefit paid in accordance with Sections 30A (1)-(4) of the Social Security Contributions and Benefits Act 1992.

In applying this provision, account shall only be taken of periods during which the person would have been incapable of work within the meaning of United Kingdom legislation.

5. (1) For the purpose of calculating an earnings factor in order to determine entitlement to benefits under United Kingdom legislation, for each week of activity as an employed person under the legislation of another Member State, and which commenced during the relevant income tax year within the meaning of United Kingdom legislation, the person concerned shall be deemed to have paid contributions as an employed earner, or have earnings on which contributions have been paid, on the basis of earnings equivalent to two-thirds of that year's upper earnings limit.

(2) For the purposes of Article 52(1)(b)(ii) of this Regulation, where:

(a) in any income tax year starting on or after 6 April 1975, a person carrying out activity as an employed person has completed periods of insurance, employment or residence exclusively in a Member State other than the United Kingdom, and the application of point 5(1) above results in that year being counted as a qualifying year within the meaning of United Kingdom legislation for the purposes of Article 52(1)(b)(i) of this Regulation, he shall be deemed to have been insured for 52 weeks in that year in that other Member State;

(b) any income tax year starting on or after 6 April 1975 does not count as a qualifying year within the meaning of United Kingdom legislation for the purposes of Article 52(1)(b)(i) of this Regulation, any periods of insurance, employment or residence completed in that year shall be disregarded.

(3) For the purpose of converting an earnings factor into periods of insurance, the earnings factor achieved in the relevant income tax year within the meaning of United Kingdom legislation shall be divided by that year's lower earnings limit. The result shall be expressed as a whole number, any remaining fraction being ignored. The figure so calculated shall be treated as representing the number of weeks of insurance completed under United Kingdom legislation during that year, provided that such figure shall not exceed the number of weeks during which in that year the person was subject to that legislation.'

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 29 April 2004, the European Parliament and the Council adopted Regulation (EC) No 883/2004 ([1]) on the coordination of social security systems (hereinafter referred to as the 'basic Regulation') which is intended to replace Regulation (EEC) No 1408/71 ([2]).

The basic Regulation includes Annexes that contain provisions in respect of individual Member States. The contents of certain of these annexes had not yet been determined when the Regulation was adopted. The basic Regulation therefore provides that the contents of its Annexes II (provisions of conventions which remain in force), X (special non-contributory cash benefits) and XI (special provisions for the application of the legislation of the Member States), which were left empty, should be determined before the date of application of the Regulation.

Some of the Annexes had also to be adapted to take into account the requirements of the Member States that have acceded to the European Union since the adoption of the Regulation, as well as recent developments in other Member States.

This is the purpose of the two proposals for Regulations which the Commission presented on 24 January 2006 and 3 July 2007, respectively:

— Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of Annex XI;

— Proposal for a Regulation of the European Parliament and of the Council amending the annexes to Regulation (EC) No 883/2004 on the coordination of social security systems.

The two proposals are based on Articles 42 and 308 of the Treaty.

Acting in accordance with Article 251 of the Treaty, the European Parliament adopted, on 9 July 2008, a single Opinion in first reading consisting in 77 amendments to the proposal for a Regulation amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of Annex XI. ([3]) It considered that the procedure relating to the second proposal had lapsed as a result of the incorporation of its contents into the procedure relating to the first proposal.

The Economic and Social Committee delivered its opinions on 26 October 2006 ([4]).

The Commission presented its amended proposals on 15 October 2008. Taking into consideration amendment 1 of the European Parliament, the amended proposals acknowledge the merging of the two original proposals into a single text. The Commission accepted all the amendments adopted by the European Parliament.

In accordance with Article 251(2) of the EC Treaty, the Council adopted its Common Position by unanimity on 17 December 2008. The Common Position also relates to both the original proposals which have been merged into a single text.

II. OBJECTIVE

While the proposal for an implementing Regulation provides for horizontal rules, the proposal for a Regulation determining the content of Annex XI, for its part, provides for supplementary provisions regarding specific aspects of individual Member States' legislation in order to ensure that the basic Regulation is smoothly applied in the Member States concerned. In accordance with the general objective of simplification, the proposal contains fewer entries than the corresponding Annex VI in the current Regulation (EEC) No 1408/71.

Annexes II and X of Regulation 883/2004, which had been left empty, have equivalent provisions in Annexes III and IIa of Regulation 1408/71. The remainder of the Annexes being amended by this proposal already contain provisions in respect of several Member States, but need to be completed to take account of the Member States which acceded to the EU after 29 April 2004. Some of these Annexes also have corresponding provisions in Regulation 1408/71. However, Annex I Part 1 (advances of maintenance payments) and Annexes III and IV (special rules for health care benefits) only apply to Regulation 883/2004.

([1]) OJ L 166, 30.4.2004, corrected version in OJ L 200, 7.6.2004, p. 1.
([2]) Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, OJ L 149 of 5.7.1971, p. 2. Regulation last amended by Regulation (EC) No 1992/2006 (OJ L 392 of 30.12.2006, p. 1).
([3]) Not yet published in the Official Journal.
([4]) OJ C 161, 13.7.2007, p. 61.

III. **ANALYSIS OF THE COMMON POSITION**

1. **General observations**

a) *Commission's amended proposal*

The European Parliament adopted 77 amendments to the Commission's proposal. All of these amendments were incorporated into the amended Commission proposals in whole, in part or after being reworded (amendments Nos 1-5, 7-11, 13-24 and 26-78 rev).

b) *Council's Common Position:*

The Council could accept 70 of the 77 amendments, as wholly or partially incorporated into the Commission's amended proposal, namely amendments Nos 1-5, 7, 8, 10, 13-19, 21, 22 and 25-77.

However, the Council did not deem it advisable to take up amendments Nos 6, 11, 12, 20, 23, 24 and 78 rev. Moreover, while agreeing on the substance of amendment 9 concerning the definition of 'benefits in kind', the Council considered that this definition should be clarified further (Article 1(3)(va) of the Common Position).

2. **Council's position on amendment 20 and the other related amendments**

This issue concerns the right of the members of the family of a frontier worker to receive health care in the Member State where the worker is employed on the same conditions as those which are applicable to him/her.

Article 18(2) of the basic Regulation provides that 'the members of the family of a frontier worker shall be entitled to benefits in kind during their stay in the competent Member State, unless this Member State is listed in Annex III'. Annex III of the basic Regulation lists the seven Member States which apply restrictions of the rights to benefits in kind for members of the family of a frontier worker.

Amendment 20 of the European Parliament (to which amendments Nos 6, 11 and 12 closely relate) states that a new paragraph 10a should be inserted into Article 87 of the basic Regulation which would provide that 'Annex III shall be repealed 5 years after the date of application of the Regulation.'

The Council could not reach agreement by unanimity on this amendment in view of the opposition of five delegations. These delegations consider, as a matter of principle, that the provision set out in Article 18(2) of the basic Regulation should not be put into jeopardy in view, in particular, of the lack of experience with the application of the new Regulation. They stress that the delicate compromise adopted in Regulation No 883/2004, in which Parliament played an important role, should not be changed. Before taking any further step, they would prefer not to extend the rights of the family members of cross-border workers as regards health care beyond that which is provided for in Regulation (EEC) 1408/71 as, in their view, a decision, at this stage, to repeal Annex III after a period of 5 years, would be premature.

On the other hand, all the other delegations could accept this amendment in a spirit of compromise. Moreover, the delegations of six of the Member States listed in Annex III to the Common Position took an even more flexible stance, as they could accept to repeal Annex III after a period of four years. In this context, the Italian delegation, which could not accept amendment 24 as it considered it necessary to have an entry in Annex III, took a compromise stance on amendment 20 as it accepted that the period of validity of its entry be limited to four years.

In view of this situation, and bearing in mind the importance of this issue for the European Parliament, a compromise solution was eventually reached by unanimity according to which:

— Articles 18(2) and 28(1) of the basic Regulation would be amended to provide that Annex III would be reviewed 5 years after its application, and

— A new paragraph (10a) would be added to Article 87 of the basic Regulation to provide that the period of validity of some Member States' entries in Annex III would be limited to 4 years.

The Council considers that this represents a both realistic and balanced solution which clearly goes in the direction of the European Parliament's position. It hopes that Parliament will be able to accept it.

3. **Council's position on amendment 23**

Amendment 23 relates to Annex II to the basic Regulation (Provisions of Conventions which remain in force and which, where applicable, are restricted to the persons covered thereby). In point 36 of this Annex, under the Portugal-United Kingdom entry, Parliament includes a reference to Article 2(1) of the Protocol on medical treatment of 15 November 1978 which is already covered by Annex III of Council Regulation (EEC) No 1408/71.

This Protocol does not appear in Annex II in the Council's Common Position as the two Member States concerned have indicated that they have decided not to apply Article 2(1) of this Protocol as from 1 September 2008.

4. **Council's position on amendment 78 rev**

Amendment 78 rev aims, among others, to maintain the entry 'Italy' in Annex IV of the basic Regulation, which provides that the Member States listed in this Annex will provide more rights for pensioners returning to the competent Member State (Article 27(2) of the basic Regulation). As far as this entry is concerned, this amendment was not acceptable to the Council acting on the basis of unanimity.

After the adoption of the basic Regulation, the Italian competent authorities reassessed their position, preferring not to grant, for the time being, additional rights for pensioners. In the light of these new developments, the Commission proposed, in its original proposal amending the annexes to Regulation (EEC) No 883/2004, that the entry 'Italy' should be deleted from Annex IV. The Italian delegation could go along with the Commission's proposal.

The Commission has accepted the Common Position agreed by the Council.

5. **Specific comments**

The Council considered it necessary to make the following changes to the Commission proposal:

— Article 15 of the basic Regulation: the terms 'auxiliary staff' have been replaced by the terms 'contract staff' in the Common Position in accordance with the Staff Regulations;

— Article 36(1) of the basic Regulation: the Council considered it necessary to provide that Articles 17, 18(1), 19(1) and 20(1) will also apply to benefits relating to accidents at work or occupational diseases;

— Furthermore, the Council was of the view that a new paragraph 2a should be added to Article 36 of the basic Regulation in order to include the principle set out in Article 33 of the Commission proposal for a Regulation laying down the procedure for implementing Regulation (EC) No 883/2004;

— Article 87(8) of the basic Regulation: the Council considered it necessary to replace the current paragraph 8 with a new paragraph to specify the maximum time period during which a person will be subject to the legislation of a Member State other than the one determined in accordance with Title II of Council Regulation (EEC) No 1408/71.

IV. **CONCLUSION**

The Council welcomes the spirit of cooperation which prevailed with the European Parliament during the first reading of this significant element of ancillary legislation and which allowed the two institutions already to reduce to a very large extent the scope of potential disagreement.

In particular, the Council appreciates the European Parliament's initiative with regard to the merging of the proposal amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of Annex XI, with the proposal amending the annexes to that Regulation.

It considers that its Common Position goes largely in the direction of the concerns voiced by Parliament.

It looks forward to pursuing this constructive discussion with the European Parliament, with a view to reaching final agreement on this complementary legislation as soon as possible, in view of the overriding interest of the early entry into application of the complete package of new rules regarding the modernisation and simplification of the coordination of social security systems.

COMMON POSITION (EC) No 2/2009

adopted by the Council on 18 December 2008

with a view to the adoption of Regulation (EC) No …/2009 of the European Parliament and of the Council of … laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 2377/90

(Text with EEA relevance)

(2009/C 33 E/02)

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.

(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.

([1]) OJ C 10, 15.1.2008, p. 51.
([2]) Opinion of the European Parliament of 17 June 2008 (not yet published in the OJ) and Council Common Position of 18 December 2008.
([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.

(8) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-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.

(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 ([6]). 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

([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 version in OJ L 191, 28.5.2004, p. 1.
([5]) OJ L 136, 30.4.2004, p. 1.
([6]) OJ L 123, 24.4.1998, p. 1.

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 [1] requires that each consignment imported from a third country is subject to veterinary controls, and Commission Decision 2005/34/EC of 11 January 2005 [2] 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 [3]. 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 [4], 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 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.

[1] OJ L 24, 30.1.1998, p. 9.

[2] OJ L 16, 20.1.2005, p. 61.

[3] OJ L 268, 18.10.2003, p. 29.

[4] OJ L 125, 23.5.1996, p. 10.

(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:

(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.

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

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 … (*);

(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.

(*) The date of entry into force of this Regulation.

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 … (*), 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 … (**), the Commission shall submit a report to the European Parliament and 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.

(*) 60 days after the entry into force of this Regulation.
(**) Five years after the entry into force of this Regulation.

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 …/2009 of the European Parliament and of the Council of … laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (*).

(*) OJ L …'.

Article 32

Entry into force

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

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

Done at, …

For the European Parliament	*For the Council*
The President	*The President*
…	…

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 17 April 2007, the Commission submitted to the Council the abovementioned proposal based on Article 152(4)(b) of the EC Treaty (codecision).

2. The European Parliament delivered its first reading opinion on 17 June 2008. The Economic and Social Committee delivered its Opinion on 26 September 2007. The Committee of the Regions decided not to deliver any opinion on this proposal.

3. The Council concluded its first reading and adopted its Common Position during its session of 18 December 2008, in accordance with the procedure laid down in Article 251 of the Treaty.

II. OBJECTIVES

1. The proposal aims at reviewing and completing existing provisions related to the establishment of Maximum Residue Limits (MRLs) for pharmacologically active substances in foodstuffs of animal origin. The main objectives foreseen are:

   — to improve the availability of veterinary medicinal products for food producing animals whilst ensuring a high level of human health protection;

   — to create a specific legal framework to establish MRLs for pharmacologically active substances not intended for use in veterinary medicinal products in the EU;

   — to improve the consistency of EU legislation with international standards via the introduction of the obligation to include MRLs set by the *Codex Alimentarius* in Community legislation, when supported by the Community;

   — to provide clear references for control purposes (i.e. Reference Points for Action) in some cases where MRLs have not been set.

2. The proposal provides also for some improvements in terms of simplification and better regulation.

III. ANALYSIS OF THE COMMON POSITION

A. General observations

The Council's Common Position broadly accords with the positions taken by the Commission and the Parliament, inasmuch as it:

— confirms the objectives and most of the arrangements proposed by the Commission and supported by the European Parliament;

— includes a very large number of the amendments passed at first reading by the European Parliament.

The Council also considered it was appropriate to introduce a number of amendments — in addition to those made at the suggestion of the Parliament — either to clarify the scope of some provisions, or to make the wording of the Regulation more explicit and guarantee legal certainty, or to increase its consistency with other Community instruments.

B. Specific comments

1. *Main amendments to the Commission proposal*

(a) Improvement of the availability of veterinary medicinal products

At the suggestion of the Parliament, amendments were made to a few provisions in order to try to improve the availability of veterinary medicinal products for food producing animals, in particular with regard to minor species and minor uses (e.g. Articles 9 and 30).

More specifically, with regard to Article 9, the Council wanted to clarify the cases in which Member States and the Commission may ask an opinion on MRLs to the Agency. In substance, identical coverage to that foreseen by the Parliament's opinion is proposed. In addition, the Council judged preferable to add provisions on the modalities of financing of MRL evaluations for active substances included in biocidal products: the main reason was to differentiate between substances included in products already on the market and new substances and to take duly account of fees already collected for the evaluation having been or to be carried out under Directive 98/8/EC.

Besides, the Council recalled the importance of ensuring a high degree of human health protection and made some changes to insist on this aspect (e.g. Articles 5, 7(d) or 16).

(b) Establishment/review and functioning of reference points for action

Following a series of Parliament amendments, several provisions were adapted to clarify the Commission proposal regarding in particular the definition of reference points for action and conditions for their establishment and review. Further, the conditions for placing food of animal origin on the market were specified. Likewise the measures to be taken when a forbidden or non authorised substance is found were defined.

(c) Report to European Parliament and the Council

The Council also followed Parliament in asking the Commission to present a report on the experience gained from the application of the regulation, not later than 5 years after its entry into force. In addition, the Council requested that the report considers in particular substances classified under the regulation and having a multiple use.

2. *Council's position on the European Parliament's amendments*

The Council has incorporated the following amendments without modification in its Common Position:

— 4, 6, 9, 10, 14 and 16;

and incorporated part of, or retained the principle of amendments

— 2, 3, 5, 45, 8, 11, 15, 17, 18, 21, 23, 24, 25, 26, 28, 30, 31, 32, 34, 35, 37, 38, 39, 40, 41, 42, 43 and 44.

The Council, like the Commission, could not accept the following five amendments and did not incorporate them:

— 1, 20, 27, 33, and 36.

On amendment 1, contrary to the Parliament the Council deemed essential to maintain a double legal basis as the proposal is relevant to the functioning of the internal market for products of animal origin included in Annex I to the Treaty.

To amendment 20, the Council preferred Amendment 31 which establishes also an urgent procedure but still with an a priori evaluation by the Agency.

On amendment 27, the Council could not accept the wording proposed by the Parliament as a prohibition of the presence of a pharmacologically active substance would not be possible to enforce (e.g. occurrence of a natural metabolite in the animal).

On amendment 33, the Council could not accept the comitology procedure with scrutiny considering the fixing of MRLs for specific substances to be a purely implementing measure with no quasi-legislative character.

On amendment 36, the Council could not accept the complete deletion of the free circulation clause. In addition, the wording proposed by the Parliament was judged unenforceable as at the time of import control it is not possible to establish with certainty that the residue found results from illegal administration. However the Council could agree on drafting improvements to make the free circulation clause clearer.

NOTE TO THE READER

The institutions have decided no longer to quote in their texts the last amendment to cited acts.

Unless otherwise indicated, references to acts in the texts published here are to the version of those acts currently in force.