

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

[^{XI}TITLE VII U.K.]

AUTHORISATION

CHAPTER 1 U.K.]

Authorisation requirement

Article 55 U.K.]

Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Article 56 U.K.]

General provisions

- 1 A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
- a the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
 - b the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
 - c the date referred to in Article 58(1)(c)(i) has not been reached; or
 - d the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
 - e in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

Status: Point in time view as at 12/10/2008.

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2 A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

3 Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

4 Paragraphs 1 and 2 shall not apply to the following uses of substances:

- a uses in plant protection products within the scope of Directive 91/414/EEC;
- b uses in biocidal products within the scope of Directive 98/8/EC;
- c use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels⁽¹⁾;
- d uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

5 In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

- a uses in cosmetic products within the scope of Directive 76/768/EEC;
- b uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

6 Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:

- a for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);
- b for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.

Article 57 **U.K.**

Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
- (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

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- (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 58 **U.K.**

Inclusion of substances in Annex XIV

1 Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance:

- a the identity of the substance as specified in Section 2 of Annex VI;
- b the intrinsic property (properties) of the substance referred to in Article 57;
- c transitional arrangements:
 - (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;
 - (ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;
- d review periods for certain uses, if appropriate;
- e uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2 Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3 Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

- a PBT or vPvB properties; or
- b wide dispersive use; or
- c high volumes.

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further

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recommendations at least every second year with a view to including further substances in Annex XIV.

4 Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

The Agency shall update its recommendation, taking into account the comments received.

5 Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.

6 A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s).

7 Substances for which all uses have been prohibited under Title VIII or by other Community legislation shall not be included in Annex XIV or shall be removed from it.

8 Substances which as a result of new information no longer meet the criteria of Article 57 shall be removed from Annex XIV in accordance with the procedure referred to in Article 133(4).

Article 59 **U.K.**

Identification of substances referred to in Article 57

1 The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

2 The Commission may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available to the Member States.

3 Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available within 30 days of receipt to the other Member States.

4 The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

5 Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to the Agency.

Status: Point in time view as at 12/10/2008.

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6 If the Agency does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).

7 When comments are made or received, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.

8 If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 58(3).

9 If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 133(3).

10 The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.

CHAPTER 2 U.K.

Granting of authorisations

Article 60 U.K.

Granting of authorisations

1 The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

2 Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁽²⁾, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices⁽³⁾ or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices⁽⁴⁾.

3 Paragraph 2 shall not apply to:

- a substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;
- b substances meeting the criteria in Article 57(d) or (e);

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- c substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.

4 If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis referred to in Article 64(4)(a) and (b):

- a the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- b the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
- c the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);
- d available information on the risks to human health or the environment of any alternative substances or technologies.

5 When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

- a whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;
- b the technical and economic feasibility of alternatives for the applicant.

6 A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.

7 An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.

8 Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. The duration of the time-limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.

9 The authorisation shall specify:

- a the person(s) to whom the authorisation is granted;
- b the identity of the substance(s);
- c the use(s) for which the authorisation is granted;
- d any conditions under which the authorisation is granted;
- e the time-limited review period;
- f any monitoring arrangement.

10 Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

Status: Point in time view as at 12/10/2008.

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Article 61 **U.K.**

Review of authorisations

1 Authorisations granted in accordance with Article 60 shall be regarded as valid until the Commission decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

A holder of an authorisation granted in accordance with Article 60 shall submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 62(4)(f). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken in accordance with the procedure referred to in Article 64 applied *mutatis mutandis*.

- 2 Authorisations may be reviewed at any time if:
- a the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or
 - b new information on possible substitutes becomes available.

The Commission shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.

3 In its review decision the Commission may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation, if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 60(5) become available. In the latter case the Commission shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of his application or update.

In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality.

4 If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.

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5 If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6 If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants⁽⁵⁾, the Commission shall withdraw the authorisation for that use.

Article 62 U.K.

Applications for authorisations

1 An application for an authorisation shall be made to the Agency.

2 Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.

3 Applications may be made for one or several substances, that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.

4 An application for authorisation shall include the following information:

- a the identity of the substance(s), as referred to in Section 2 of Annex VI;
- b the name and contact details of the person or persons making the application;
- c a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;
- d unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;
- e an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
- f where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

5 The application may include:

- a a socio-economic analysis conducted in accordance with Annex XVI;
- b a justification for not considering risks to human health and the environment arising either from:
 - (i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or
 - (ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.

6 The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC.

Status: Point in time view as at 12/10/2008.

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7 An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.

Article 63 **U.K.**

Subsequent applications for authorisation

1 If an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.

2 If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

3 Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.

Article 64 **U.K.**

Procedure for authorisation decisions

1 The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and Socio-economic Analysis shall give their draft opinions within ten months of the date of receipt of the application.

2 The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

3 In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Committees shall, in consultation with each other, make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.

4 The draft opinions shall include the following elements:

- a Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;
- b Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

Status: Point in time view as at 12/10/2008.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, TITLE VII. (See end of Document for details)

5 The Agency shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.

If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The Committees shall consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the opinions, with the written argumentation attached, to the Commission, the Member States and the applicant.

6 The Agency shall determine in accordance with Articles 118 and 119 which parts of its opinions and parts of any attachments thereto should be made publicly available on its website.

7 In cases covered by Article 63(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

8 The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 133(3).

9 Summaries of the Commission decisions, including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, shall be published in the Official Journal of the European Union and shall be made publicly available in a database established and kept up to date by the Agency.

10 In cases covered by Article 63(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.

CHAPTER 3 **U.K.**

Authorisations in the supply chain

Article 65 **U.K.**

Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a preparation, shall include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

Status: Point in time view as at 12/10/2008.

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Article 66 **U.K.**

Downstream users

1 Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance.

2 The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the competent authorities of the Member States.]

Editorial Information

- X1** Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

Status: Point in time view as at 12/10/2008.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, TITLE VII. (See end of Document for details)

- (1) [^{XI}OJ L 350, 28.12.1998, p. 58. Directive as amended by Regulation (EC) No 1882/2003.]
- (2) [^{XI}OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003.]
- (3) [^{XI}OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.]
- (4) [^{XI}OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.]
- (5) [^{XI}OJ L 158, 30.4.2004, p. 7, corrected in OJ L 229, 29.6.2004, p. 5. Regulation as amended by Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 1).]

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