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

The titles of all other acts are printed in bold type and preceded by an asterisk.

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(Acts whose publication is obligatory)

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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

Having consulted the Committee of the Regions,

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

Whereas:

(1) Before a medicinal product for human use is placed on the market in one or more Member States, it generally has to have undergone extensive studies, including preclinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population.

(2) Such studies may not have been undertaken for use in the paediatric population and many of the medicinal products currently used to treat the paediatric population have not been studied or authorised for such use. Market forces alone have proven insufficient to stimulate adequate research into, and the development and authorisation of, medicinal products for the paediatric population.

(3) Problems resulting from the absence of suitably adapted medicinal products for the paediatric population include inadequate dosage information which leads to increased risks of adverse reactions including death, ineffective treatment through under-dosage, non-availability to the paediatric population of therapeutic advances, suitable formulations and routes of administration, as well as use of magistral or officinal formulations to treat the paediatric population which may be of poor quality.

(4) This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations. These objectives should be achieved without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation of medicinal products for other age populations.

(5) While taking into account the fact that the regulation of medicinal products must be fundamentally aimed at safeguarding public health, this aim must be achieved by means that do not impede the free movement of safe medicinal products within the Community. The differences between the national legislative, regulatory and administrative provisions on medicinal products tend to hinder intra-Community trade and therefore directly affect the operation of the internal market. Any action to promote the development and authorisation of medicinal products for paediatric use is therefore justified with a view to preventing or eliminating these obstacles. Article 95 of the Treaty is therefore the proper legal basis.

(6) The establishment of a system of both obligations and rewards and incentives has proved necessary to achieve these objectives. The precise nature of these obligations and rewards and incentives should take account of the status of the particular medicinal product concerned. This Regulation should apply to all the medicinal products required for paediatric use and therefore its scope should cover products under development and yet-to-be authorised, authorised products covered by intellectual property rights and authorised products no longer covered by intellectual property rights.

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[1] OJ C 267, 27.10.2005, p. 1.

[2] Opinion of the European Parliament of 7 September 2005 (OJ C 193 E, 17.8.2006, p. 225), Council Common Position of 10 March 2006 (OJ C 132 E, 7.6.2006, p. 1) and Position of the European Parliament of 1 June 2006 (not yet published in the Official Journal). Council Decision of 23 October 2006.

(7) Any concerns about conducting trials in the paediatric population should be balanced by the ethical concerns about giving medicinal products to a population in which they have not been appropriately tested. Public health threats from the use of untested medicinal products in the paediatric population can be safely addressed through the study of medicinal products for the paediatric population, which should be carefully controlled and monitored through the specific requirements for the protection of the paediatric population who take part in clinical trials in the Community laid down in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [1].

(8) It is appropriate to create a scientific committee, the Paediatric Committee, within the European Medicines Agency, hereinafter 'the Agency', with expertise and competence in the development and assessment of all aspects of medicinal products to treat paediatric populations. The rules on scientific committees of the Agency, as laid down in Regulation (EC) No 726/2004 [2], should apply to the Paediatric Committee. Members of the Paediatric Committee should therefore not have financial or other interests in the pharmaceutical industry which could affect their impartiality, should undertake to act in the public interest and in an independent manner, and should make an annual declaration of their financial interests. The Paediatric Committee should be primarily responsible for the scientific assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof; it should also be central to various support measures contained in this Regulation. In its work, the Paediatric Committee should consider the potential significant therapeutic benefits for the paediatric patients involved in the studies or the paediatric population at large including the need to avoid unnecessary studies. The Paediatric Committee should follow existing Community requirements, including Directive 2001/20/EC, as well as International Conference on Harmonisation (ICH) guideline E11 on the development of medicinal products for the paediatric population, and it should avoid any delay in the authorisation of medicinal products for other populations deriving from the requirements for studies in the paediatric population.

(9) Procedures should be established for the Agency to agree and modify a paediatric investigation plan, which is the document upon which the development and authorisation of medicinal products for the paediatric population should be based. The paediatric investigation plan should include details of the timing and the measures proposed to demonstrate the quality, safety and efficacy of the medicinal product in the paediatric population. Since the paediatric population is in fact composed of a number of population subsets, the paediatric investigation plan should specify which population subsets need to be studied, by what means and by when.

(10) The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that the development of medicinal products that are potentially to be used for the paediatric population becomes an integral part of the development of medicinal products, integrated into the development programme for adults. Thus, paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population, where appropriate, before marketing authorisation applications are submitted. It is appropriate to set a deadline for the submission of a paediatric investigation plan in order to ensure early dialogue between the sponsor and the Paediatric Committee. Furthermore, early submission of a paediatric investigation plan, combined with the submission of a deferral request as described below, will avoid delaying the authorisation for other populations. As the development of medicinal products is a dynamic process dependent on the result of ongoing studies, provision should be made for modifying an agreed plan where necessary.

(11) It is necessary to introduce a requirement for new medicinal products and for authorised medicinal products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new indication, new pharmaceutical form or new route of administration. The paediatric investigation plan should be the basis upon which compliance with that requirement is judged. However, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic medicinal products and traditional herbal medicinal products authorised through the simplified registration procedures of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3].

[1] OJ L 121, 1.5.2001, p. 34.

[2] 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 (OJ L 136, 30.4.2004, p. 1).

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(12) Provision should be made for research into the paediatric use of medicinal products which are not protected by a patent or supplementary protection certificate to be financed under Community research programmes.

(13) In order to ensure that research in the paediatric population is only conducted to meet their therapeutic needs, there is a need to establish procedures for the Agency to waive the requirement referred to in Recital (11) for specific products or for classes or part of classes of medicinal products, these waivers being then made public by the Agency. As knowledge of science and medicine evolves over time, provision should be made for the lists of waivers to be amended. However, if a waiver is revoked, that requirement should not apply for a given period in order to allow time for at least a paediatric investigation plan to be agreed and studies in the paediatric population to be initiated before an application for marketing authorisation is submitted.

(14) In certain cases, the Agency should defer the initiation or completion of some or all of the measures contained in a paediatric investigation plan, with a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations.

(15) Free scientific advice should be provided by the Agency as an incentive to sponsors developing medicinal products for the paediatric population. To ensure scientific consistency, the Agency should manage the interface between the Paediatric Committee and the Scientific Advice Working Group of the Committee for Medicinal Products for Human Use, as well as the interaction between the Paediatric Committee and the other Community committees and working groups concerning medicinal products.

(16) The existing procedures for the marketing authorisation of medicinal products for human use should not be changed. However, from the requirement referred to in Recital (11) it follows that competent authorities should check compliance with the agreed paediatric investigation plan and any waivers and deferrals at the existing validation step for marketing authorisation applications. The assessment of quality, safety and efficacy of medicinal products for the paediatric population and the granting of marketing authorisations should remain the remit of the competent authorities. Provision should be made for the Paediatric Committee to be asked for its opinion on compliance and on the quality, safety and efficacy of a medicinal product in the paediatric population.

(17) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population and as a transparency measure, information on the results of studies in the paediatric population, as well as on the status of the paediatric investigation plans, waivers and deferrals, should be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and should then be the basis upon which companies can obtain the rewards for compliance.

(18) In order to identify medicinal products authorised for use in the paediatric population and enable their prescription, provision should be made for the labels of medicinal products granted an indication for use in the paediatric population to display a symbol which will be selected by the Commission on a recommendation by the Paediatric Committee.

(19) In order to establish incentives for authorised products no longer covered by intellectual property rights, it is necessary to establish a new type of marketing authorisation, the Paediatric Use Marketing Authorisation. A Paediatric Use Marketing Authorisation should be granted through existing marketing authorisation procedures but should apply specifically for medicinal products developed exclusively for use in the paediatric population. It should be possible for the name of the medicinal product that has been granted a Paediatric Use Marketing Authorisation to retain the existing brand name of the corresponding product authorised for adults, in order to capitalise on existing brand recognition, while benefiting from the data exclusivity associated with a new marketing authorisation.

(20) An application for a Paediatric Use Marketing Authorisation should include the submission of data concerning use of the product in the paediatric population, collected in accordance with an agreed paediatric investigation plan. These data may be derived from the published literature or from new studies. An application for a Paediatric Use Marketing Authorisation should also be able to refer to data contained in the dossier of a medicinal product which is or has been authorised in the Community. This is intended to provide an additional incentive to encourage small and medium-sized enterprises, including generic companies, to develop off-patent medicinal products for the paediatric population.

(21) This Regulation should include measures to maximise access by the Community population to new medicinal products tested and adapted for paediatric use, and to minimise the chance of Community-wide rewards and incentives being granted without sections of the Community paediatric population benefiting from the availability of a newly authorised medicine. An application for a marketing authorisation, including an application for a Paediatric Use Marketing Authorisation, which contains the results of studies conducted in compliance with an agreed paediatric investigation plan should be eligible for the Community centralised procedure set out in Articles 5 to 15 of Regulation (EC) No 726/2004.

(22) When an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other indications, the marketing authorisation holder should be obliged to place the product on the market, taking into account the paediatric information, within two years of the date of approval of the indication. That requirement should relate only to products already authorised, but not to medicinal products authorised via a Paediatric Use Marketing Authorisation.

(23) An optional procedure should be established to make it possible to obtain a single Community-wide opinion for a nationally authorised medicinal product when data on the paediatric population following an agreed paediatric investigation plan form part of the marketing authorisation application. To achieve this, the procedure set out in Articles 32, 33 and 34 of Directive 2001/83/EC could be used. This will allow the adoption of a Community harmonised Decision on use of that medicinal product in the paediatric population and its inclusion in all national product information.

(24) It is essential to ensure that pharmacovigilance mechanisms are adapted to meet the specific challenges of collecting safety data in the paediatric population, including data on possible long-term effects. Efficacy in the paediatric population may also need additional study following authorisation. Therefore, an additional requirement for applying for a marketing authorisation that includes the results of studies conducted in compliance with an agreed paediatric investigation plan should be an obligation for the applicant to indicate how he proposes to ensure the long-term follow-up of possible adverse reactions to the use of the medicinal product and efficacy in the paediatric population. Additionally, where there is a particular cause for concern, the applicant should submit and implement a risk management system and/or perform specific post-marketing studies as a condition for the granting of the marketing authorisation.

(25) It is necessary in the interests of public health to ensure the continuing availability of safe and effective medicinal products authorised for paediatric indications developed as a result of this Regulation. If a marketing authorisation holder intends to withdraw such a medicinal product from the market then arrangements should be in place so that the paediatric population can continue to have access to the medicinal product in question. In order to help achieve this, the Agency should be informed in good time of any such intention and should make that intention public.

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92 ([1]). Any decisions by Member States' authorities as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes have no bearing on the granting of this reward.

(27) An application for an extension of the duration of the certificate pursuant to this Regulation should only be admissible where a certificate is granted pursuant to Regulation (EEC) No 1768/92.

(28) Because the reward is for conducting studies in the paediatric population and not for demonstrating that a product is safe and effective in the paediatric population, the reward should be granted even when a paediatric indication is not authorised. However, to improve the information available on the use of medicinal products in the paediatric population, relevant information on use in paediatric populations should be included in authorised product information.

(29) Under Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products ([2]), medicinal products designated as orphan medicinal products gain ten years of market exclusivity on the granting of a marketing authorisation for the orphan indication. As such products are frequently not patent-protected, the reward of supplementary protection certificate extension cannot be applied; when they are patent-protected, such an extension would provide a double incentive. Therefore, for orphan medicinal products, instead of an extension of the supplementary protection certificate, the ten-year period of orphan market exclusivity should be extended to twelve years if the requirement for data on use in the paediatric population is fully met.

(30) The measures provided for in this Regulation should not preclude the operation of other incentives or rewards. To ensure transparency on the different measures available at Community and Member State levels, the Commission should draw up a detailed list of all the incentives available, on the basis of information provided by the Member States. The measures set out in this Regulation, including the agreement of paediatric investigation plans, should not be grounds for obtaining any other Community incentives to support research, such as the funding of research projects under the multi-annual Community Framework Programmes for Research, Technological Development and Demonstration Activities.

([1]) OJ L 182, 2.7.1992, p. 1. Regulation as last amended by the 2003 Act of Accession.

([2]) OJ L 18, 22.1.2000, p. 1.

(31) In order to increase the availability of information on the use of medicinal products in the paediatric population, and to avoid unnecessary repetition of studies in the paediatric population which do not add to the collective knowledge, the European database provided for in Article 11 of Directive 2001/20/EC should include a European register of clinical trials of medicinal products for paediatric use comprising all ongoing, prematurely terminated, and completed paediatric studies conducted both in the Community and in third countries. Part of the information concerning paediatric clinical trials entered into the database, as well as details of the results of all paediatric clinical trials submitted to the competent authorities, should be made public by the Agency.

(32) An inventory of the therapeutic needs of the paediatric population should be established by the Paediatric Committee after consultation with the Commission, the Member States and interested parties, and should be regularly updated. The inventory should identify the existing medicinal products used by the paediatric population and highlight the therapeutic needs of that population and the priorities for research and development. In this way, companies should be able easily to identify opportunities for business development; the Paediatric Committee should be able better to judge the need for medicinal products and studies when assessing draft paediatric investigation plans, waivers and deferrals; and healthcare professionals and patients should have an information source available to support their decisions as to which medicinal products to choose.

(33) Clinical trials in the paediatric population may require specific expertise, specific methodology and, in some cases, specific facilities and should be carried out by appropriately trained investigators. A network, which links existing national and Community initiatives and study centres in order to build up the necessary competences at Community level, and which takes account of Community and third country data, would help facilitate cooperation and avoid unnecessary duplication of studies. This network should contribute to the work of strengthening the foundations of the European Research Area in the context of Community Framework Programmes for Research, Technological Development and Demonstration Activities, benefit the paediatric population and provide a source of information and expertise for industry.

(34) For certain authorised products, pharmaceutical companies may already hold data on safety or efficacy in the paediatric population. To improve the information available on the use of medicinal products in the paediatric populations, companies holding such data should be required to submit them to all competent authorities where the product is authorised. In this way the data could be assessed and, if appropriate, information should be included in the authorised product information aimed at healthcare professionals and patients.

(35) Community funding should be provided to cover all aspects of the work of the Paediatric Committee and of the Agency resulting from the implementation of this Regulation, such as the assessment of paediatric investigation plans, fee waivers for scientific advice, and information and transparency measures, including the database of paediatric studies and the network.

(36) 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]).

(37) Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 should therefore be amended accordingly.

(38) Since the objective of this Regulation, namely improving availability of medicinal products tested for paediatric use, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, given that this will make it possible to take advantage of the widest possible market and avoid the dispersion of limited resources, 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 this objective,

HAVE ADOPTED THIS REGULATION:

TITLE I

INTRODUCTORY PROVISIONS

CHAPTER 1

Subject matter and definitions

Article 1

This Regulation lays down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population, without subjecting the paediatric population to unnecessary clinical or other trials and in compliance with Directive 2001/20/EC.

Article 2

In addition to the definitions laid down in Article 1 of Directive 2001/83/EC, the following definitions shall apply for the purposes of this Regulation:

1) 'paediatric population' means that part of the population aged between birth and 18 years;

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

2) 'paediatric investigation plan' means a research and development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population;

3) 'medicinal product authorised for a paediatric indication' means a medicinal product which is authorised for use in part or all of the paediatric population and in respect of which the details of the authorised indication are specified in the summary of the product characteristics drawn up in accordance with Article 11 of Directive 2001/83/EC;

4) 'paediatric use marketing authorisation' means a marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate under Regulation (EEC) No 1768/92 or by a patent which qualifies for the granting of the supplementary protection certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product.

CHAPTER 2

Paediatric committee

Article 3

1. By 26 July 2007, a Paediatric Committee shall be established within the European Medicines Agency set up under Regulation (EC) No 726/2004, hereinafter 'the Agency'. The Paediatric Committee shall be considered as established once the members referred to in Article 4(1)(a) and (b) have been appointed.

The Agency shall fulfil the secretariat functions for the Paediatric Committee and shall provide it with technical and scientific support.

2. Save where otherwise provided for in this Regulation, Regulation (EC) No 726/2004 shall apply to the Paediatric Committee, including the provisions on the independence and impartiality of its members.

3. The Executive Director of the Agency shall ensure appropriate coordination between the Paediatric Committee and the Committee for Medicinal Products for Human Use, the Committee for Orphan Medicinal Products, their working parties and any other scientific advisory groups.

The Agency shall draw up specific procedures for possible consultations between them.

Article 4

1. The Paediatric Committee shall be composed of the following members:

(a) five members, with their alternates, of the Committee for Medicinal Products for Human Use, having been appointed to that Committee in accordance with Article 61(1) of Regulation (EC) No 726/2004. These five members with their alternates shall be appointed to the Paediatric Committee by the Committee for Medicinal Products for Human Use;

(b) one member and one alternate appointed by each Member State whose national competent authority is not represented through the members appointed by the Committee for Medicinal Products for Human Use;

(c) three members and three alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent health professionals;

(d) three members and three alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient associations.

The alternates shall represent and vote for the members in their absence.

For the purposes of points (a) and (b), Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Paediatric Committee, including members and alternates, covers the scientific areas relevant to paediatric medicinal products, and including at least: pharmaceutical development, paediatric medicine, general practitioners, paediatric pharmacy, paediatric pharmacology, paediatric research, pharmacovigilance, ethics and public health.

For the purposes of points (c) and (d), the Commission shall take into account the expertise provided by the members appointed under points (a) and (b).

2. The members of the Paediatric Committee shall be appointed for a renewable period of three years. At meetings of the Paediatric Committee, they may be accompanied by experts.

3. The Paediatric Committee shall elect its Chairman from among its members for a term of three years, renewable once.

4. The names and qualifications of the members shall be made public by the Agency.

Article 5

1. When preparing its opinions, the Paediatric Committee shall use its best endeavours to reach a scientific consensus. If such a consensus cannot be reached, the Paediatric Committee shall adopt an opinion consisting of the position of the majority of the members. The opinion shall mention the divergent positions, with the grounds on which they are based. This opinion shall be made accessible to the public pursuant to Article 25(5) and (7).

2. The Paediatric Committee shall draw up its rules of procedure for the implementation of its tasks. The rules of procedure shall enter into force after receiving a favourable opinion from the Management Board of the Agency and, subsequently, from the Commission.

3. All meetings of the Paediatric Committee may be attended by representatives of the Commission, the Executive Director of the Agency or his representatives.

Article 6

1. The tasks of the Paediatric Committee shall include the following:

(a) to assess the content of any paediatric investigation plan for a medicinal product submitted to it in accordance with this Regulation and formulate an opinion thereon;

(b) to assess waivers and deferrals and formulate an opinion thereon;

(c) at the request of the Committee for Medicinal Products for Human Use, a competent authority or the applicant, to assess compliance of the application for a Marketing Authorisation with the agreed paediatric investigation plan concerned and formulate an opinion thereon;

(d) at the request of the Committee for Medicinal Products for Human Use or a competent authority, to assess any data generated in accordance with an agreed paediatric investigation plan and formulate an opinion on the quality, safety or efficacy of the medicinal product for use in the paediatric population;

(e) to advise on the content and format of data to be collected for the survey referred to in Article 42;

(f) to support and advise the Agency on establishing the European network referred to in Article 44;

(g) to assist scientifically in the elaboration of any documents related to the fulfilment of the objectives of this Regulation;

(h) to provide advice on any question related to medicinal products for use in the paediatric population, at the request of the Executive Director of the Agency or the Commission;

(i) to establish a specific inventory of paediatric medicinal product needs and update it on a regular basis, as referred to in Article 43;

(j) to advise the Agency and the Commission regarding the communication of arrangements available for conducting research into medicinal products for use in the paediatric population;

(k) to make a recommendation to the Commission on the symbol referred to in Article 32(2).

2. When carrying out its tasks, the Paediatric Committee shall consider whether or not any proposed studies can be expected to be of significant therapeutic benefit to and/or fulfil a therapeutic need of the paediatric population. The Paediatric Committee shall take into account any information available to it, including any opinions, decisions or advice given by the competent authorities of third countries.

TITLE II

MARKETING AUTHORISATION REQUIREMENTS

CHAPTER 1

General authorisation requirements

Article 7

1. An application for marketing authorisation under Article 6 of Directive 2001/83/EC in respect of a medicinal product for human use which is not authorised in the Community at the time of entry into force of this Regulation shall be regarded as valid only if it includes, in addition to the particulars and documents referred to in Article 8(3) of Directive 2001/83/EC, one of the following:

(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;

(b) a decision of the Agency granting a product-specific waiver;

(c) a decision of the Agency granting a class waiver pursuant to Article 11;

(d) a decision of the Agency granting a deferral.

For the purposes of point (a), the decision of the Agency agreeing the paediatric investigation plan concerned shall also be included in the application.

2. The documents submitted pursuant to paragraph 1 shall, cumulatively, cover all subsets of the paediatric population.

Article 8

In the case of authorised medicinal products which are protected either by a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration.

For the purposes of the first subparagraph, the documents referred to in Article 7(1) shall cover both the existing and the new indications, pharmaceutical forms and routes of administration.

Article 9

Articles 7 and 8 shall not apply to products authorised under Articles 10, 10a, 13 to 16 or 16a to 16i of Directive 2001/83/EC.

Article 10

In consultation with the Member States, the Agency and other interested parties, the Commission shall draw up the detailed arrangements concerning the format and content which applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals must follow in order to be considered valid and concerning the operation of the compliance check referred to in Articles 23 and 28(3).

CHAPTER 2

Waivers

Article 11

1. Production of the information referred to in point (a) of Article 7(1) shall be waived for specific medicinal products or for classes of medicinal products, if there is evidence showing any of the following:

(a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;

(b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations;

(c) that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2. The waiver provided for in paragraph 1 may be issued with reference either to one or more specified subsets of the paediatric population, or to one or more specified therapeutic indications, or to a combination of both.

Article 12

The Paediatric Committee may of its own motion adopt an opinion, on the grounds set out in Article 11(1), to the effect that a class or a product-specific waiver, as referred to in Article 11(1), should be granted.

As soon as the Paediatric Committee adopts an opinion, the procedure laid down in Article 25 shall apply. In the case of a class waiver, only paragraphs 6 and 7 of Article 25 shall apply.

Article 13

1. The applicant may, on the grounds set out in Article 11 (1), apply to the Agency for a product-specific waiver.

2. Following receipt of the application, the Paediatric Committee shall appoint a rapporteur and shall within 60 days adopt an opinion as to whether or not a product-specific waiver should be granted.

Either the applicant or the Paediatric Committee may request a meeting during that 60-day period.

Whenever appropriate, the Paediatric Committee may request the applicant to supplement the particulars and documents submitted. Where the Paediatric Committee avails itself of this option, the 60-day time-limit shall be suspended until such time as the supplementary information requested has been provided.

3. As soon as the Paediatric Committee adopts an opinion, the procedure laid down in Article 25 shall apply.

Article 14

1. The Agency shall maintain a list of all waivers. The list shall be regularly updated (at least every year) and made available to the public.

2. The Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

In the case of a change affecting a product-specific waiver, the procedure laid down in Article 25 shall apply.

In the case of a change affecting a class waiver, paragraphs 6 and 7 of Article 25 shall apply.

3. If a particular product-specific or class waiver is revoked, the requirement set out in Articles 7 and 8 shall not apply for 36 months from the date of the removal from the list of waivers.

CHAPTER 3

Paediatric investigation plan

Section 1

Requests for agreement

Article 15

1. Where the intention is to apply for a marketing authorisation in accordance with Article 7(1)(a) or (d), Article 8 or Article 30, a paediatric investigation plan shall be drawn up and submitted to the Agency with a request for agreement.

2. The paediatric investigation plan shall specify the timing and the measures proposed to assess the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that may be concerned. In addition, it shall describe any measures to adapt the formulation of the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population.

Article 16

1. In the case of the applications for marketing authorisation referred to in Articles 7 and 8 or the applications for waiver referred to in Articles 11 and 12, the paediatric investigation plan or the application for waiver shall be submitted with a request for agreement, except in duly justified cases, not later than upon completion of the human pharmaco-kinetic studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, so as to ensure that an opinion on use in the paediatric population of the medicinal product concerned can be given at the time of the assessment of the marketing authorisation or other application concerned.

2. Within 30 days following receipt of the request referred to in paragraph 1 and in Article 15(1), the Agency shall verify the validity of the request and prepare a summary report for the Paediatric Committee.

3. Whenever appropriate, the Agency may ask the applicant to submit additional particulars and documents, in which case the time-limit of 30 days shall be suspended until such time as the supplementary information requested has been provided.

Article 17

1. Following receipt of a proposed paediatric investigation plan which is valid in accordance with the provisions of Article 15(2), the Paediatric Committee shall appoint a rapporteur and shall within 60 days adopt an opinion as to whether or not the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets thereof, and as to whether or not the expected therapeutic benefits justify the studies proposed. When adopting its opinion, the Committee shall consider whether or not the measures proposed to adapt the formulation of the medicinal product for use in different subsets of the paediatric population are appropriate.

Within the same period, either the applicant or the Paediatric Committee may request a meeting.

2. Within the 60-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of 60 days. In such cases, the applicant or the Paediatric Committee may request an additional meeting during this period. The time-limit shall be suspended until such time as the supplementary information requested has been provided.

Article 18

As soon as the Paediatric Committee adopts an opinion, whether positive or negative, the procedure laid down in Article 25 shall apply.

Article 19

If, having considered a paediatric investigation plan, the Paediatric Committee concludes that Article 11(1)(a), (b) or (c) applies to the medicinal product concerned, it shall adopt a negative opinion under Article 17(1).

In such cases, the Paediatric Committee shall adopt an opinion in favour of a waiver under Article 12, whereupon the procedure laid down in Article 25 shall apply.

Section 2

Deferrals

Article 20

1. At the same time as the paediatric investigation plan is submitted under Article 16(1), a request may be made for deferral of the initiation or completion of some or all of the measures set out in that plan. Such deferral shall be justified on scientific and technical grounds or on grounds related to public health.

In any event, a deferral shall be granted when it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population or when studies in the paediatric population will take longer to conduct than studies in adults.

2. On the basis of the experience acquired as a result of the operation of this Article, the Commission may adopt provisions in accordance with the procedure referred to in Article 51(2) to define further the grounds for granting a deferral.

Article 21

1. At the same time as the Paediatric Committee adopts a positive opinion under Article 17(1), it shall, of its own motion or following a request submitted by the applicant under Article 20, adopt an opinion, if the conditions specified in Article 20 are met, in favour of deferring the initiation or completion of some or all of the measures in the paediatric investigation plan.

An opinion in favour of a deferral shall specify the time-limits for initiating or completing the measures concerned.

2. As soon as the Paediatric Committee adopts an opinion in favour of deferral, as referred to in paragraph 1, the procedure laid down in Article 25 shall apply.

Section 3

Modification of a paediatric investigation plan

Article 22

If, following the decision agreeing the paediatric investigation plan, the applicant encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, the applicant may propose changes or request a deferral or a waiver, based on detailed grounds, to the Paediatric Committee. Within 60 days, the Paediatric Committee shall review these changes or the request for a deferral or a waiver and adopt an opinion proposing their refusal or acceptance. As soon as the Paediatric Committee adopts an opinion, whether positive or negative, the procedure laid down in Article 25 shall apply.

Section 4

Compliance with the paediatric investigation plan

Article 23

1. The competent authority responsible for granting marketing authorisation shall verify whether an application for marketing authorisation or variation complies with the requirements laid down in Articles 7 and 8 and whether an application submitted pursuant to Article 30 complies with the agreed paediatric investigation plan.

Where the application is submitted in accordance with the procedure set out in Articles 27 to 39 of Directive 2001/83/EC, the verification of compliance, including, as appropriate, requesting an opinion of the Paediatric Committee in accordance with paragraph 2(b) and (c) of this Article, shall be conducted by the reference Member State.

2. The Paediatric Committee may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan:

(a) by the applicant, prior to submitting an application for marketing authorisation or variation as referred to in Articles 7, 8 and 30, respectively;

(b) by the Agency, or the national competent authority, when validating an application, as referred to in point (a), which does not include an opinion concerning compliance adopted following a request under point (a);

(c) by the Committee for Medicinal Products for Human Use, or the national competent authority, when assessing an application, as referred to in point (a), where there is doubt concerning compliance and an opinion has not been already given following a request under points (a) or (b).

In the case of point (a), the applicant shall not submit its application until the Paediatric Committee has adopted its opinion, and a copy thereof shall be annexed to the application.

3. If the Paediatric Committee is requested to give an opinion under paragraph 2, it shall do so within 60 days of receiving the request.

Member States shall take account of such an opinion.

Article 24

If, when conducting the scientific assessment of a valid application for Marketing Authorisation, the competent authority concludes that the studies are not in conformity with the agreed paediatric investigation plan, the product shall not be eligible for the rewards and incentives provided for in Articles 36, 37 and 38.

CHAPTER 4

Procedure

Article 25

1. Within ten days of its receipt, the Agency shall transmit the opinion of the Paediatric Committee to the applicant.

2. Within 30 days following receipt of the opinion of the Paediatric Committee, the applicant may submit to the Agency a written request, citing detailed grounds, for a re-examination of the opinion.

3. Within 30 days following receipt of a request for re-examination pursuant to paragraph 2, the Paediatric Committee, having appointed a new rapporteur, shall issue a new opinion confirming or revising its previous opinion. The rapporteur shall be able to question the applicant directly. The applicant may also offer to be questioned. The rapporteur shall inform the Paediatric Committee without delay in writing about details of contacts with the applicant. The opinion shall be duly reasoned and a statement of reasons for the conclusion reached shall be annexed to the new opinion, which shall become definitive.

4. If, within the 30-day period referred to in paragraph 2, the applicant does not request re-examination, the opinion of the Paediatric Committee shall become definitive.

5. The Agency shall adopt a decision within a period not exceeding 10 days following receipt of the Paediatric Committee's definitive opinion. This decision shall be communicated to the applicant in writing and shall annex the definitive opinion of the Paediatric Committee.

6. In the case of a class waiver as referred to in Article 12, the Agency shall adopt a decision within ten days following receipt of the opinion of the Paediatric Committee as referred to in Article 13(3). This decision shall annex the opinion of the Paediatric Committee.

7. Decisions of the Agency shall be made public after deletion of any information of a commercially confidential nature.

CHAPTER 5

Miscellaneous provisions

Article 26

Any legal or natural person developing a medicinal product intended for paediatric use may, prior to the submission of a paediatric investigation plan and during its implementation, request advice from the Agency on the design and conduct of the various tests and studies necessary to demonstrate the quality, safety and efficacy of the medicinal product in the paediatric population in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004.

In addition, this legal or natural person may request advice on the design and conduct of pharmacovigilance and risk management systems as referred to in Article 34.

The Agency shall provide advice under this Article free of charge.

TITLE III

MARKETING AUTHORISATION PROCEDURES

Article 27

Save where otherwise provided in this Title, marketing authorisation procedures for the marketing authorisations covered by this Title shall be governed by the provisions laid down in Regulation (EC) No 726/2004 or in Directive 2001/83/EC.

CHAPTER 1

Marketing authorisation procedures for applications falling within the scope of Articles 7 and 8

Article 28

1. Applications may be submitted in accordance with the procedure laid down in Articles 5 to 15 of Regulation (EC) No 726/2004 for a marketing authorisation as referred to in Article 7(1) of this Regulation which includes one or more paediatric indications on the basis of studies conducted in compliance with an agreed paediatric investigation plan.

Where authorisation is granted, the results of all those studies shall be included in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product, provided that the competent authority deems the information to be of use to patients, whether or not all the paediatric indications concerned were approved by the competent authority.

2. Where a marketing authorisation is granted or varied, any waiver or deferral which has been granted pursuant to this Regulation shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

3. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. For the purpose of the application of Article 45(3), this statement shall also indicate whether significant studies contained in the agreed Paediatric Investigation Plan have been completed after the entry into force of this Regulation.

Article 29

In the case of medicinal products authorised under Directive 2001/83/EC, an application as referred to in Article 8 of this Regulation may be submitted, in accordance with the procedure laid down in Articles 32, 33 and 34 of Directive 2001/83/EC, for authorisation of a new indication, including the extension of an authorisation for use in the paediatric population, a new pharmaceutical form or a new route of administration.

That application shall comply with the requirement laid down in point (a) of Article 7(1).

The procedure shall be limited to the assessment of the specific sections of the summary of product characteristics to be varied.

CHAPTER 2

Paediatric use marketing authorisation

Article 30

1. Submission of an application for a paediatric use marketing authorisation shall in no way preclude the right to apply for a marketing authorisation for other indications.

2. An application for a paediatric use marketing authorisation shall be accompanied by the particulars and documents necessary to establish quality, safety and efficacy in the paediatric population, including any specific data needed to support an appropriate strength, pharmaceutical form or route of administration for the product, in accordance with an agreed paediatric investigation plan.

The application shall also include the decision of the Agency agreeing the paediatric investigation plan concerned.

3. Where a medicinal product is or has been authorised in a Member State or in the Community, data contained in the dossier on that product may, where appropriate, be referred to, in accordance with Article 14(11) of Regulation (EC) No 726/2004 or Article 10 of Directive 2001/83/EC, in an application for a paediatric use marketing authorisation.

4. The medicinal product in respect of which a paediatric use marketing authorisation is granted may retain the name of any medicinal product which contains the same active substance and in respect of which the same holder has been granted authorisation for use in adults.

Article 31

Without prejudice to Article 3(2) of Regulation (EC) No 726/2004, an application for a paediatric use marketing authorisation may be made in accordance with the procedure laid down in Articles 5 to 15 of Regulation (EC) No 726/2004.

CHAPTER 3

Identification

Article 32

1. Where a medicinal product is granted a marketing authorisation for a paediatric indication, the label shall display the symbol agreed in accordance with paragraph 2. The package leaflet shall contain an explanation of the meaning of the symbol.

2. By 26 January 2008, the Commission shall select a symbol following a recommendation of the Paediatric Committee. The Commission shall make the symbol public.

3. The provisions of this Article shall also apply to medicinal products authorised before the entry into force of this Regulation, and to medicinal products authorised after the entry into force of this Regulation but before the symbol has been made public, if they are authorised for paediatric indications.

In this case, the symbol and the explanation referred to in paragraph 1 shall be included in the labelling and package leaflet respectively of the medicinal products concerned not later than two years after the symbol has been made public.

TITLE IV

POST-AUTHORISATION REQUIREMENTS

Article 33

Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those products have already been marketed with other indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the product on the market taking into account the paediatric indication. A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.

Article 34

1. In the following cases, the applicant shall detail the measures to ensure the follow-up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product:

(a) applications for a marketing authorisation that includes a paediatric indication;

(b) applications to include a paediatric indication in an existing marketing authorisation;

(c) applications for a paediatric use marketing authorisation.

2. Where there is particular cause for concern, the competent authority shall require, as a condition for granting marketing authorisation, that a risk management system be set up or that specific post-marketing studies be performed and submitted for review. The risk management system shall comprise a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of those interventions.

Assessment of the effectiveness of any risk management system and the results of any studies performed shall be included in the periodic safety update reports referred to in Article 104(6) of Directive 2001/83/EC and Article 24(3) of Regulation (EC) No 726/2004.

In addition, the competent authority may request submission of additional reports assessing the effectiveness of any risk minimisation system and the results of any such studies performed.

3. In addition to paragraphs 1 and 2, the provisions on pharmacovigilance as laid down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC shall apply to marketing authorisations for medicinal products which include a paediatric indication.

4. In the case of a deferral, the marketing authorisation holder shall submit an annual report to the Agency providing an update on progress with paediatric studies in accordance with the decision of the Agency agreeing the paediatric investigation plan and granting a deferral.

The Agency shall inform the competent authority if it is found that the marketing authorisation holder has failed to comply with the decision of the Agency agreeing the paediatric investigation plan and granting a deferral.

5. The Agency shall draw up guidelines relating to the application of this Article.

Article 35

If a medicinal product is authorised for a paediatric indication and the marketing authorisation holder has benefited from rewards or incentives under Article 36, 37 or 38, and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, pre-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 10c of Directive 2001/83/EC.

The marketing authorisation holder shall inform the Agency of its intention to discontinue the placing on the market of the product no less than six months before the discontinuation. The Agency shall make this fact public.

TITLE V

REWARDS AND INCENTIVES

Article 36

1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.

The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

2. The inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article.

3. Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

5. In the case of an application under Article 8 which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 14(11) of Regulation (EC) No 726/2004 or the fourth subparagraph of Article 10(1) of Directive 2001/83/EC.

Article 37

Where an application for a marketing authorisation is submitted in respect of a medicinal product designated as an orphan medicinal product pursuant to Regulation (EC) No 141/2000 and that application includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, and the statement referred to in Article 28(3) of this Regulation is subsequently included in the marketing authorisation granted, the ten-year period referred to in Article 8(1) of Regulation (EC) No 141/2000 shall be extended to twelve years.

The first paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

Article 38

1. Where a paediatric use marketing authorisation is granted in accordance with Articles 5 to 15 of Regulation (EC) No 726/2004, the data and marketing protection periods referred to in Article 14(11) of that Regulation shall apply.

2. Where a paediatric use marketing authorisation is granted in accordance with the procedures laid down in Directive 2001/83/EC, the data and marketing protection periods referred to in Article 10(1) of that Directive shall apply.

Article 39

1. In addition to the rewards and incentives provided for in Articles 36, 37 and 38, medicinal products for paediatric use may be eligible for incentives provided by the Community or by the Member States to support research into, and the development and availability of, medicinal products for paediatric use.

2. By 26 January 2008, the Member States shall communicate to the Commission detailed information concerning any measures they have enacted to support research into, and the development and availability of, medicinal products for paediatric use. This information shall be updated regularly at the request of the Commission.

3. By 26 July 2008, the Commission shall make publicly available a detailed inventory of all rewards and incentives provided by the Community and Member States to support research into, and the development and availability of, medicinal products for paediatric use. This inventory shall be updated regularly and the updates shall also be made publicly available.

Article 40

1. Funds for research into medicinal products for the paediatric population shall be provided for in the Community budget in order to support studies relating to medicinal products or active substances not covered by a patent or a supplementary protection certificate.

2. The Community funding referred to in paragraph 1 shall be delivered through the Community Framework Programmes for Research, Technological Development and Demonstration Activities or any other Community initiatives for the funding of research.

TITLE VI

COMMUNICATION AND COORDINATION

Article 41

1. The European database created by Article 11 of Directive 2001/20/EC shall include clinical trials carried out in third countries which are contained in an agreed paediatric investigation plan, in addition to the clinical trials referred to in Articles 1 and 2 of that Directive. In the case of such clinical trials carried out in third countries, the details listed in Article 11 of that Directive shall be entered into the database by the addressee of the Agency's decision on a paediatric investigation plan.

By way of derogation from the provisions of Article 11 of Directive 2001/20/EC, the Agency shall make public part of the information on paediatric clinical trials entered in the European database.

2. Details of the results of all the trials referred to in paragraph 1 and of any other trials submitted to competent authorities in compliance with Articles 45 and 46 shall be made public by the Agency, whether or not the trial was terminated prematurely. These results shall be submitted without delay to the Agency by the clinical trial sponsor, the addressee of the Agency's decision on a paediatric investigation plan, or by the marketing authorisation holder as appropriate.

3. In consultation with the Agency, Member States and interested parties, the Commission shall draw up guidance on the nature of the information referred to in paragraph 1 to be entered in the European database created by Article 11 of Directive 2001/20/EC, on which information shall be made accessible to the public in application of paragraph 1, on how clinical trial results shall be submitted and be made public in application of paragraph 2, and on the Agency's responsibilities and tasks in this regard.

Article 42

Member States shall collect available data on all existing uses of medicinal products in the paediatric population and shall communicate these data to the Agency by 26 January 2009.

The Paediatric Committee shall provide guidance on the content and the format of the data to be collected by 26 October 2007.

Article 43

1. On the basis of the information referred to in Article 42 and after consulting the Commission, the Member States and the interested parties, the Paediatric Committee shall establish an inventory of therapeutic needs, in particular with a view to identifying research priorities.

The Agency shall make the inventory public at the earliest by 26 January 2009 and at the latest by 26 January 2010 and shall update it regularly.

2. In establishing the inventory of therapeutic needs, account shall be taken of the prevalence of the conditions in the paediatric population, the seriousness of the conditions to be treated, the availability and suitability of alternative treatments for the conditions in the paediatric population, including the efficacy and the adverse reaction profile of those treatments, including any unique paediatric safety issues, and any data resulting from studies in third countries.

Article 44

1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

3. By 26 January 2008, the Management Board of the Agency shall, on a proposal from the Executive Director and following consultation with the Commission, the Member States and interested parties, adopt an implementing strategy for the launching and operation of the European network. This network must, where appropriate, be compatible with the work of strengthening the foundations of the European Research Area in the context of the Community Framework Programmes for Research, Technological Development and Demonstration Activities.

Article 45

1. By 26 January 2008, any paediatric studies already completed, by the date of entry into force, in respect of products authorised in the Community shall be submitted by the marketing authorisation holder for assessment to the competent authority.

The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly. Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

The Agency shall coordinate the exchange of information.

2. All existing paediatric studies, as referred to in paragraph 1, and all paediatric studies initiated prior to the entry into force of this Regulation shall be eligible to be included in a paediatric investigation plan, and shall be taken into consideration by the Paediatric Committee when assessing applications for paediatric investigation plans, waivers and deferrals and by competent authorities when assessing applications submitted pursuant to Article 7, 8 or 30.

3. Without prejudice to the previous paragraph, the rewards and incentives of Articles 36, 37 and 38 shall only be granted provided that significant studies contained in an agreed Paediatric Investigation Plan are completed after the entry into force of this Regulation.

4. In consultation with the Agency, the Commission shall draw up guidelines to establish assessment criteria for the significance of studies for the purposes of applying paragraph 3.

Article 46

1. Any other marketing authorisation holder-sponsored studies which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within six months of completion of the studies concerned.

2. Paragraph 1 shall apply independent of whether or not the marketing authorisation holder intends to apply for a marketing authorisation of a paediatric indication.

3. The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.

4. Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

5. The Agency shall coordinate the exchange of information.

TITLE VII

GENERAL AND FINAL PROVISIONS

CHAPTER 1

General provisions

Section 1

Fees, community funding, penalties and reports

Article 47

1. Where an application for a paediatric use marketing authorisation is submitted in accordance with the procedure laid down in Regulation (EC) No 726/2004, the amount of the reduced fees for the examination of the application and the maintenance of the marketing authorisation shall be fixed in accordance with Article 70 of Regulation (EC) No 726/2004.

2. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Medicines Agency [1] shall apply.

3. Assessments of the following by the Paediatric Committee shall be free of charge:

(a) applications for waiver;

(b) applications for deferral;

(c) paediatric investigation plans;

(d) compliance with the agreed paediatric investigation plan.

Article 48

The Community contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the work of the Paediatric Committee, including scientific support provided by experts, and of the Agency, including the assessment of paediatric investigation plans, scientific advice and any fee waivers provided for in this Regulation, and shall support the Agency's activities under Articles 41 and 44 of this Regulation.

Article 49

1. Without prejudice to the Protocol on the Privileges and Immunities of the European Communities, each Member State shall determine the penalties to be applied for infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedures laid down in Directive 2001/83/EC and shall take all measures necessary for their implementation. The penalties shall be effective, proportionate and dissuasive.

Member States shall inform the Commission of these provisions by 26 October 2007. They shall notify any subsequent alterations as soon as possible.

2. Member States shall inform the Commission immediately of any litigation instituted for infringement of this Regulation.

3. At the Agency's request, the Commission may impose financial penalties for infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down in accordance with the procedure referred to in Article 51(2) of this Regulation.

4. The Commission shall make public the names of anyone infringing the provisions of this Regulation or of any implementing measures adopted pursuant to it and the amounts of, and reasons for, the financial penalties imposed.

Article 50

1. On the basis of a report from the Agency, and at least on an annual basis, the Commission shall make public a list of the companies and of the products that have benefited from any of the rewards and incentives in this Regulation and the companies that have failed to comply with any of the obligations in this Regulation. The Member States shall provide this information to the Agency.

2. By 26 January 2013, the Commission shall present to the European Parliament and the Council a general report on experience acquired as a result of the application of this Regulation. This shall include in particular a detailed inventory of all medicinal products authorised for paediatric use since its entry into force.

3. By 26 January 2017, the Commission shall present a report to the European Parliament and the Council on the experience acquired as a result of the application of Articles 36, 37 and 38. The report shall include an analysis of the economic impact of the rewards and incentives, together with an analysis of the estimated consequences for public health of this Regulation, with a view to proposing any necessary amendments.

4. Provided that there are sufficient data available to allow robust analyses to be made, the provisions of paragraph 3 shall be fulfilled at the same time as the provisions of paragraph 2.

[1] OJ L 35, 15.2.1995, p. 1. Regulation as last amended by Regulation (EC) No 1905/2005 (OJ L 304, 23.11.2005, p. 1).

Section 2

Standing committee

Article 51

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use set up by Article 121 of Directive 2001/83/EC, hereinafter referred to as 'the Committee'.

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

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

3. The Committee shall adopt its rules of procedure.

CHAPTER 2

Amendments

Article 52

Regulation (EEC) No 1768/92 is hereby amended as follows:

1) in Article 1, the following definition shall be added:

'(e) "Application for an extension of the duration" means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and of Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (*).

(*) OJ L 378, 27.12.2006, p. 1.'

2) in Article 7, the following paragraphs shall be added:

'3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Articles 8(1)(d) or 8(1a), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.';

3) Article 8 shall be amended as follows:

(a) in paragraph 1, the following point shall be added:

'(d) where the application for a certificate includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

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

(b) the following paragraphs shall be inserted:

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

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

(c) paragraph 2 shall be replaced by the following:

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

4) Article 9 shall be amended as follows:

(a) in paragraph 1, the following subparagraph shall be added:

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

(b) in paragraph 2, the following point shall be added:

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

(c) the following paragraph shall be added:

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

5) in Article 10, the following paragraph shall be added:

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

6) in Article 11, the following paragraph shall be added:

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

7) in Article 13, the following paragraph shall be added:

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

8) the following Article shall be inserted:

'Article 15a

Revocation of an extension of the duration

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

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

9) Article 16 shall be amended as follows:

(a) the text of Article 16 becomes that Article's paragraph 1;

(b) the following paragraph shall be added:

'2. If the extension of the duration is revoked in accordance with Article 15a, notification thereof shall be published by the authority referred to in Article 9 (1).';

10) Article 17 shall be replaced by the following:

'Article 17

Appeals

The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 15a(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.'.

Article 53

In Article 11 of Directive 2001/20/EC, the following paragraph shall be added:

'4. By way of derogation from paragraph 1, the Agency shall make public part of the information on paediatric clinical trials entered in the European database in accordance with the provisions of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (*).

(*) OJ L 378, 27.12.2006, p. 1.'

Article 54

In Article 6 of Directive 2001/83/EC, the first subparagraph of paragraph 1 shall be replaced by the following:

'1. No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or unless an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (*).

(*) OJ L 378, 27.12.2006, p. 1.'

Article 55

Regulation (EC) No 726/2004 is hereby amended as follows:

1) Article 56(1) shall be replaced by the following:

'1. The Agency shall comprise:

(a) the Committee for Medicinal Products for Human Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use;

(b) the Committee for Medicinal Products for Veterinary Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for veterinary use;

(c) the Committee on Orphan Medicinal Products;

(d) the Committee on Herbal Medicinal Products;

(e) the Paediatric Committee;

(f) a Secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them;

(g) an Executive Director, who shall exercise the responsibilities set out in Article 64;

(h) a Management Board, which shall exercise the responsibilities set out in Articles 65, 66 and 67.';

2) in Article 57(1), the following point shall be added:

'(t) taking decisions as referred to in Article 7(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (*).

(*) OJ L 378, 27.12.2006, p. 1.'

3) the following Article shall be inserted:

'Article 73a

Decisions taken by the Agency under Regulation (EC) No 1901/2006 may form the subject of an action before the Court of Justice of the European Communities under the conditions laid down in Article 230 of the Treaty.'.

CHAPTER 3

Final provisions

Article 56

The requirement laid down in Article 7(1) shall not apply to valid applications pending at the time of entry into force of this Regulation.

Article 57

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

2. Article 7 shall apply from 26 July 2008.

Article 8 shall apply from 26 January 2009.

Articles 30 and 31 shall apply from 26 July 2007.

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

Done at Strasbourg, 12 December 2006.

For the European Parliament
The President
J. BORRELL FONTELLES

For the Council
The President
M. PEKKARINEN

COMMISSION STATEMENT

In view of the risks of carcinogens, mutagens and substances toxic to reproduction, the Commission will request the Committee for Medicinal Products for Human Use of the European Medicines Agency to draw up an opinion on the use of these categories of substances as excipients of medicinal products for human use, on the basis of Articles 5(3) and 57(1)(p) of Regulation (EC) No 726/2004 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.

The Commission will transmit the opinion of the Committee for Medicinal Products for Human Use to the European Parliament and the Council.

Within six months of the opinion of the Committee for Medicinal Products for Human Use, the Commission will inform the European Parliament and the Council of any necessary action it intends to take to follow-up on this opinion.

REGULATION (EC) No 1902/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

amending Regulation 1901/2006 on medicinal products for paediatric use

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [1],

Whereas:

(1) The measures necessary for the implementation of Regulation (EC) No 1901/2006 [2] 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 [3].

(2) In particular, the Commission should be empowered to define further the grounds for granting a deferral for the initiation or completion of some or all of the measures in the paediatric investigation plan and to specify the maximum amounts as well as the conditions and methods for collection of the financial penalties for infringement of the provisions of Regulation (EC) No 1901/2006 or the implementing measures adopted pursuant to it. Since these measures are of general scope and are designed to supplement Regulation (EC) No 1901/2006 by the addition of new non-essential elements, these measures should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(3) It is necessary to amend Regulation (EC) No 1901/2006 accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1901/2006 is hereby amended as follows:

1) in Article 20, paragraph 2 shall be replaced by the following:

'2. On the basis of the experience acquired as a result of the operation of this Article, the Commission may adopt provisions, in accordance with the regulatory procedure with scrutiny referred to in Article 51(2), amending or supplementing non-essential elements of this Regulation to define further the grounds for granting a deferral.';

2) in Article 49, paragraph 3 shall be replaced by the following:

'3. At the Agency's request, the Commission may impose financial penalties for infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004. Measures amending or supplementing non-essential elements of this Regulation concerning the maximum amounts as well as the conditions and methods for collection of those penalties shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 51(2).';

3) in Article 51, paragraph 2 shall be replaced by the following:

'2. 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 2

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

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[1] Opinion of the European Parliament of 14 December 2006 (not yet published in the Official Journal) and Council Decision of 19 December 2006.

[2] See page 1 of this Official Journal

[3] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

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

Done at Brussels, 20 December 2006

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	J. KORKEAOJA

DECISION No 1903/2006/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

establishing the Culture Programme (2007-2013)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the first indent of Article 151(5) thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the Committee of the Regions [1],

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

Whereas:

(1) It is essential to promote cooperation and cultural exchanges in order to respect and promote the diversity of cultures and languages in Europe and improve knowledge among European citizens of European cultures other than their own, while at the same time heightening their awareness of the common European cultural heritage they share. Promoting cultural and linguistic cooperation and diversity thus helps to make European citizenship a tangible reality by encouraging direct participation by European citizens in the integration process.

(2) An active cultural policy aimed at the preservation of European cultural diversity and the promotion of its common cultural elements and cultural heritage can contribute to improving the external visibility of the European Union.

(3) For citizens to give their full support to, and participate fully in, European integration, greater emphasis should be placed on their common cultural values and roots as a key element of their identity and their membership of a society founded on freedom, equity, democracy, respect for human dignity and integrity, tolerance and solidarity, in full compliance with the Charter of Fundamental Rights of the European Union.

(4) It is essential that the cultural sector contribute to, and play a role in, broader European political developments. The cultural sector is an important employer in its own right and there is, in addition, a clear link between investment in culture and economic development, hence the importance of reinforcing cultural policies at regional, national and European level. Accordingly, the place of cultural industries in the developments taking place under the Lisbon Strategy should be strengthened, as these industries are making an increasingly large contribution to the European economy.

(5) It is also necessary to promote active citizenship and strengthen the fight against exclusion in all its forms, including racism and xenophobia. Improving access to culture for as many as possible can be a means of combating social exclusion.

(6) Article 3 of the Treaty stipulates that, in all the activities referred to in that Article, the Community is to aim at eliminating inequalities, and at promoting equality, between men and women.

(7) The Kaleidoscope, Ariane, Raphaël and Culture 2000 cultural programmes, set out respectively in Decisions Nos 719/96/EC [3], 2085/97/EC [4], 2228/97/EC [5] and 508/2000/EC [6], marked positive stages in the implementation of Community action on culture. Considerable experience has thus been acquired, particularly through the evaluation of these cultural programmes. It is at present worthwhile to rationalise and strengthen Community cultural action on the basis of the results of these evaluations, the results of consultation with all interested parties and recent work by the European institutions. It is therefore appropriate to establish a programme to this end.

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[1] OJ C 164, 5.7.2005, p. 65.

[2] Position of the European Parliament of 25 October 2005 (OJ C 272 E, 9.11.2006, p. 233), Council Common Position of 18 July 2006 (OJ C 238 E, 3.10.2006, p. 18) and Position of the European Parliament of 24 October 2006 (not yet published in the Official Journal). Council Decision of 11 December 2006.

[3] Decision No 719/96/EC of the European Parliament and of the Council of 29 March 1996 establishing a programme to support artistic and cultural activities having a European dimension (Kaleidoscope) (OJ L 99, 20.4.1996, p. 20). Decision as amended by Decision No 477/1999/EC (OJ L 57, 5.3.1999, p. 2).

[4] Decision No 2085/97/EC of the European Parliament and of the Council of 6 October 1997 establishing a programme of support, including translation, in the field of books and reading (Ariane) (OJ L 291, 24.10.1997, p. 26). Decision as amended by Decision No 476/1999/EC (OJ L 57, 5.3.1999, p. 1).

[5] Decision No 2228/97/EC of the European Parliament and of the Council of 13 October 1997 establishing a Community action programme in the field of cultural heritage (The Raphael Programme) (OJ L 305, 8.11.1997, p. 31). Decision as repealed by Decision No 508/2000/EC (OJ L 63, 10.3.2000, p. 1).

[6] Decision No 508/2000/EC of the European Parliament and of the Council of 14 February 2000 establishing the Culture 2000 programme (OJ L 63, 10.3.2000, p. 1). Decision as last amended by Council Regulation (EC) No 885/2004 (OJ L 168, 1.5.2004, p. 1).

(8) The European institutions have themselves spoken out on many occasions on subjects relating to Community cultural action and the challenges of cultural cooperation, in particular in Council Resolutions of 25 June 2002 on a new work plan on European cooperation in the field of culture ([1]) and of 19 December 2002 implementing the work plan for European cooperation in the field of culture ([2]), resolutions of the European Parliament of 5 September 2001 on cultural cooperation in the European Union ([3]), of 28 February 2002 on the implementation of the Culture 2000 Programme ([4]), of 22 October 2002 on the importance and dynamism of the theatre and the performing arts in an enlarged Europe ([5]), and of 4 September 2003 on Cultural Industries ([6]), and the opinion of the Committee of the Regions of 9 October 2003 on the extension of the Culture 2000 Programme.

(9) The Council, in its abovementioned resolutions, has stressed the need to adopt a more coherent approach at Community level with regard to culture, and that European added value is an essential and determining concept in the context of European cultural cooperation, and a general condition for Community measures in the field of culture.

(10) In order to make this common cultural area for the peoples of Europe a reality, it is important to promote the transnational mobility of cultural players and the transnational circulation of artistic and cultural works and products, and to encourage dialogue and cultural exchanges.

(11) The Council, in its conclusions of 16 November 2004 relating to the work plan on culture (2005-2006), the European Parliament in its resolution of 4 September 2003 on Cultural Industries, and the European Economic and Social Committee in its opinion of 28 January 2004 on cultural industries in Europe, have expressed their views on the need to take greater account of the specific economic and social features of non-audiovisual cultural industries. Moreover, the preparatory actions for cooperation on cultural matters promoted between 2002-2004 should be taken into account in the new programme.

(12) In this context, there is a case for promoting increased cooperation between cultural players by encouraging them to form multi-annual cooperation projects, thus enabling them to develop common activities, to provide support for more targeted measures with a real European added value, to support symbolic cultural events, to support European cultural cooperation organisations and to encourage analyses on chosen themes of European interest, as well as the collection and dissemination of information and activities aimed at maximising the impact of projects in the field of European cultural cooperation and European cultural policy development.

(13) Under Decision No 1622/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Community action for the European Capital of Culture event for the years 2007 to 2019 ([7]) significant funding should be given to this event, which has a high profile among Europeans and helps to strengthen the feeling of belonging to a common cultural area. In the context of this event, the accent should be on trans-European cultural cooperation.

(14) Support should be given to the operation of organisations working for European cultural cooperation and thus playing the role of ambassadors of European culture, based on the experience acquired by the European Union in the context of Decision No 792/2004/EC of the European Parliament and of the Council of 21 April 2004 establishing a Community action programme to promote bodies active at European level in the field of culture ([8]).

(15) It is necessary for the Programme, in compliance with the principle of freedom of expression, to contribute to the European Union's efforts to promote sustainable development and to combat all forms of discrimination.

(16) The European Union candidate countries and EFTA countries which are members of the EEA Agreement should be recognised as potential participants in Community programmes in accordance with the agreements concluded with those countries.

(17) The European Council of 19 and 20 June 2003 adopted the 'Thessaloniki Agenda for the Western Balkans: moving towards European integration', laying down that Community programmes should be open to the countries in the Stabilisation and Association Process on the basis of framework agreements to be signed between the Community and those countries. If they wish, those countries should be able, depending on budgetary considerations or political priorities, to take part in the Programme or benefit from a more limited formula for cooperation, on the basis of supplementary appropriations and specific procedures to be agreed between the parties concerned.

(18) The Programme should also be open to cooperation with other third countries which have signed agreements with the Community containing a cultural strand, in accordance with procedures to be defined.

([1]) OJ C 162, 6.7.2002, p. 5.
([2]) OJ C 13, 18.1.2003, p. 5.
([3]) OJ C 72 E, 21.3.2002, p. 142.
([4]) OJ C 293 E, 28.11.2002, p. 105.
([5]) OJ C 300 E, 11.12.2003, p. 156.
([6]) OJ C 76 E, 25.3.2004, p. 459.
([7]) OJ L 304, 3.11.2006, p. 1.
([8]) OJ L 138, 30.4.2004, p. 40.

(19) It is necessary, in order to increase the added value of the Community action, to ensure coherence and complementarity between actions carried out within the framework of this Decision and other relevant Community policies, actions and instruments, in compliance with Article 151 (4) of the Treaty. Particular attention should be paid to the interface of Community measures in the fields of culture and education and to actions which promote exchanges of best practice and closer cooperation at European level.

(20) With regard to the implementation of Community support, the specific nature of the cultural sector in Europe should be taken into account, and particular care should be taken to ensure that administrative and financial procedures are simplified as much as possible and adapted to the objectives pursued as well as to practices and developments in the cultural sector.

(21) The Commission, Member States and the cultural contact points should work to encourage the participation of smaller operators in the multi-annual cooperation projects and the organisation of activities aimed at bringing together potential project partners.

(22) The Programme should bring together the specific qualities and expertise of cultural operators from throughout Europe. Where necessary, the Commission and Member States should take measures to address low participation rates of cultural operators in any Member State or participating country.

(23) It is worthwhile ensuring, within the framework of cooperation between the Commission and Member States, ongoing monitoring and evaluation of the Programme in order to enable readjustments, particularly within the priorities for the implementation of measures. The evaluation should include an external evaluation to be conducted by independent, impartial bodies.

(24) The procedures for monitoring and evaluating the Programme should make use of objectives and indicators which are specific, measurable, achievable, relevant, and timed.

(25) Suitable measures should be implemented to prevent irregularities and fraud and to recover funds which have been lost or transferred or used improperly.

(26) It is appropriate to establish a single financing and programming instrument for cultural cooperation, entitled the 'Culture Programme', for the period from 1 January 2007 to 31 December 2013.

(27) This Decision lays down, for the entire duration of the Programme, a financial envelope constituting the prime reference, within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [1].

(28) The measures necessary for the implementation of this Decision 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 [2].

(29) The measures necessary for the financial implementation of this Decision should be adopted in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [3] (hereinafter referred to as 'the Financial Regulation'), and with Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 [4].

(30) Community action is complementary to national or regional action in the field of cultural cooperation. Since the objectives of this Decision, namely to enhance the European cultural area based on common cultural heritage (transnational mobility of cultural players in Europe, transnational circulation of works of art and cultural and artistic products and intercultural dialogue) cannot be sufficiently achieved by the Member States owing to their transnational character, and can therefore, by reason of the scale or effects of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.

(31) There should be transitional provisions in order to ensure a smooth transition between the programmes drawn up by Decisions No 508/2000/EC and No 792/2004/EC on the one hand and, on the other, the Programme established by this Decision,

HAVE DECIDED AS FOLLOWS:

Article 1

Establishment and duration

1. This Decision establishes the Culture Programme, a single multi-annual programme for Community measures in the field of culture open to all cultural sectors and all categories of cultural operators (hereinafter referred to as 'the Programme').

[1] OJ C 139, 14.6.2006, p. 1.
[2] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
[3] OJ L 248, 16.9.2002, p. 1.
[4] OJ L 357, 31.12.2002, p. 1. Regulation as last amended by Regulation (EC, Euratom) No 1248/2006 (OJ L 227, 19.8.2006, p. 3).

2. The Programme shall be implemented for the period from 1 January 2007 to 31 December 2013.

Article 2

Budget

1. The financial envelope for the implementation of the Programme for the period referred to in Article 1 is hereby set at EUR 400 million.

2. Annual appropriations shall be authorised by the budgetary authority within the limits of the financial framework.

Article 3

Objectives

1. The general objective of the Programme shall be to enhance the cultural area shared by Europeans and based on a common cultural heritage through the development of cultural cooperation between the creators, cultural players and cultural institutions of the countries taking part in the Programme, with a view to encouraging the emergence of European citizenship. The Programme shall be open to the participation of non-audiovisual cultural industries, in particular small cultural enterprises, where such industries are acting in a non-profit-making cultural capacity.

2. The specific objectives of the Programme are:

(a) to promote the transnational mobility of cultural players;

(b) to encourage the transnational circulation of works and cultural and artistic products;

(c) to encourage intercultural dialogue.

Article 4

Fields of action

1. The objectives of the Programme shall be pursued through the implementation of the following measures, as described in the Annex:

(a) support for cultural actions, as follows:

— multi-annual cooperation projects,

— cooperation measures,

— special actions;

(b) support for bodies active at European level in the field of culture;

(c) support for analyses and the collection and dissemination of information and for activities maximising the impact of projects in the field of European cultural cooperation and European cultural policy development.

2. These measures shall be carried out in accordance with the provisions set out in the Annex.

Article 5

Provisions concerning third countries

1. The Programme shall be open to the participation of the following countries:

(a) EFTA countries which are members of the EEA, in accordance with the provisions of the EEA Agreement;

(b) candidate countries benefiting from a pre-accession strategy for accession to the Union, in accordance with the general principles and with the general conditions and procedures for the participation of these countries in the Community programmes established in the framework agreements;

(c) the countries of the Western Balkans in accordance with the procedures defined with these countries following the framework agreements providing for their participation in Community programmes.

Provided that the conditions are met and additional appropriations are paid, the countries referred to in this paragraph shall participate fully in the Programme.

2. The Programme shall also be open to cooperation with other third countries which have concluded association or cooperation agreements with the Community which include cultural clauses, on the basis of supplementary appropriations and specific procedures to be laid down.

The countries of the Western Balkans referred to in paragraph 1 (c) which do not wish to benefit from full participation in the Programme may benefit from cooperation with the Programme under the conditions laid down in this paragraph.

Article 6

Cooperation with international organisations

The Programme shall permit joint action with international organisations competent in the field of culture, such as UNESCO or the Council of Europe, on the basis of joint contributions and in accordance with the various rules prevailing in each institution or organisation for the realisation of the measures listed in Article 4.

Article 7

Complementarity with other Community instruments

The Commission shall ensure a link between the Programme and other Community instruments, particularly those relating to the Structural Funds and those in the fields of education, vocational training, research, information society, citizenship, youth, sport, languages, social inclusion, EU external relations and combating all forms of discrimination.

Article 8

Implementation

1. The Commission shall implement the Community actions which form the subject of the Programme, in accordance with the Annex.

2. The following measures shall be adopted in accordance with the procedure referred to in Article 9(2):

(a) the annual work plan, including priorities, selection criteria and procedures;

(b) the annual budget and the breakdown of funds among the different actions of the Programme;

(c) the procedures for monitoring and evaluating the Programme;

(d) the financial support to be provided by the Community under Article 4(1)(a), first indent: amounts, duration, distribution and beneficiaries.

3. All other measures necessary for the implementation of this Decision shall be adopted in accordance with the procedure referred to in Article 9(3).

Article 9

Committee

1. The Commission shall be assisted by a committee.

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

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The committee shall adopt its Rules of Procedure.

Article 10

Cultural contact points

1. The cultural contact points as defined in section I.3.1 of the Annex shall act as implementing bodies for the dissemination of information on the Programme at national level, having regard to Article 54(2)(c) and (3) of the Financial Regulation.

2. The cultural contact points shall comply with the following criteria:

(a) have an adequate number of staff, with professional and linguistic capacities appropriate for work in an environment of international cooperation;

(b) have an appropriate infrastructure, in particular as regards information and communications technology;

(c) operate in an administrative context which enables them to carry out their tasks satisfactorily and to avoid conflicts of interest.

Article 11

Financial provisions

1. Financial aid shall take the form of grants to legal persons. Grants may in certain cases be awarded to natural persons under the terms of Article 114(1) of the Financial Regulation. The Commission may also award prizes to natural or legal persons for actions or projects implemented under the Programme. Depending on the nature of the action, flat-rate financing and/or the application of unit cost rates may be authorised.

2. The Commission may decide, in accordance with the characteristics of the beneficiaries and the nature of the actions, whether to exempt them from verification of the professional competencies and qualifications required to complete the proposed action or work programme.

3. Specific activities by the European Capitals of Culture designated pursuant to Decision 1419/1999/EC may receive a grant or a prize.

Article 12

Contribution to other Community objectives

The Programme shall contribute to the strengthening of the transversal objectives of the Community, in particular by:

(a) promoting the fundamental principle of freedom of expression;

(b) encouraging greater awareness of the importance of contributing to sustainable development;

(c) seeking to promote mutual understanding and tolerance within the European Union;

(d) contributing to the elimination of all discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

Particular attention shall be given to coherence and complementarity between the Programme and Community policies in the field of cultural cooperation with third countries.

Article 13

Monitoring and evaluation

1. The Commission shall ensure regular monitoring of the Programme against its objectives. The results of the monitoring and evaluation process shall be used when implementing the Programme.

Monitoring shall include in particular the drawing up of the reports referred to in paragraph 3(a) and (c).

The specific objectives of the Programme may, on the basis of the results of monitoring reports, be revised in accordance with the procedure laid down in Article 251 of the Treaty.

2. The Commission shall ensure regular, external and independent evaluation of the Programme.

3. The Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions:

(a) an interim evaluation report on the results obtained and on the qualitative and quantitative aspects of the implementation of the Programme not later than 31 December 2010;

(b) a communication on the continuation of the Programme not later than 31 December 2011;

(c) an ex post evaluation report not later than 31 December 2015.

Article 14

Transitional provisions

Actions initiated before 31 December 2006 on the basis of Decisions No 508/2000/EC and No 792/2004/EC shall continue to be administered until their closure in accordance with the provisions of these Decisions.

The committee set up under the terms of Article 5 of Decision No 508/2000/EC shall be replaced by the committee provided for in Article 9 of this Decision.

Article 15

Entry into force

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

Done at Strasbourg, 12 December 2006.

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	Mauri PEKKARINEN

ANNEX

I. DESCRIPTION OF ACTIVITIES AND EVENTS

1. First strand: support for cultural actions

1.1. *Multi-annual cooperation projects*

The Programme shall support sustainable and structured cultural cooperation projects in order to bring together the specific quality and expertise of cultural operators throughout the whole of Europe. This support is intended to assist the cooperation projects in their start-up and structuring phase or in their geographical extension phase. The aim shall be to encourage them to establish sustainable foundations and achieve financial autonomy.

Each cooperation project shall involve at least six operators from six different countries participating in the Programme. Its purpose shall be to bring together a variety of operators from one or more sectors for various multi-annual activities, which may be sectoral or cross-sectoral in nature but which must pursue a common objective.

Each cooperation project shall be intended to carry out a number of structured, multi-annual cultural activities. These activities are to be implemented throughout the duration of Community financing. They must have at least two of the three specific objectives indicated in Article 3(2). Priority will be given to cooperation projects intending to develop activities meeting the three specific objectives in that Article.

The cooperation projects shall be selected following calls for proposals pursuant to the Financial Regulation. In this context, selection will be made on the basis, among other things, of the recognised expertise of co-organisers in their field of activity, their financial and operational capacity to carry out the proposed activities, and the quality of these activities and the extent to which they meet the general objective and specific objectives of the Programme, as set out in Article 3.

The cooperation projects must be founded on a cooperation agreement, i.e. a common document with a legal form in one of the participating countries and signed by all co-organisers.

Community support may not exceed 50 % of the project budget and shall be degressive in nature. It may not exceed EUR 500 000 per year for all activities of the cooperation projects. This support shall be granted for a period of three to five years.

By way of illustration, approximately 32 % of the total budget allocated to the Programme shall be devoted to this type of support.

1.2. *Cooperation measures*

The Programme shall support sectoral or cross-sectoral cultural cooperation actions between European operators. Priority shall be given to creativity and innovation. Actions aimed at exploring avenues for cooperation in order to develop them over the longer term will be particularly encouraged.

Each action shall be designed and carried out in partnership by at least three cultural operators in three different participating countries, whether or not these operators come from one or more sectors.

Actions shall be selected following calls for proposals pursuant to the Financial Regulation. In this context, selection will be made on the basis of the recognised expertise of co-organisers, their financial and operational capacity to carry out the proposed activities, the quality of these activities and the extent to which they meet the general objective and specific objectives of the Programme, as set out in Article 3.

Community support may not exceed 50 % of the project budget. It may not be less than EUR 50 000 nor more than EUR 200 000. This support shall be granted for a maximum of 24 months.

The conditions set out for this action concerning the minimum number of operators required in order to present projects, as well as the minimum and maximum amounts for Community support, may be adapted to take account of the specific conditions of literary translation.

By way of illustration, approximately 29 % of the total budget allocated to the Programme shall be devoted to this type of support.

1.3. *Special actions*

The Programme shall also support special actions. These actions shall be special in that they should be substantial in scale and scope, strike a significant chord with the peoples of Europe and help to increase their sense of belonging to the same community, make them aware of the cultural diversity of Member States, and also contribute to intercultural and international dialogue. They must meet at least two of the three specific objectives set out in Article 3.
These special actions shall also help to raise the visibility of Community cultural action both within and beyond the European Union. They shall also contribute to raising global awareness of the wealth and diversity of European culture.

Significant support will be given to the 'European Capitals of Culture' in order to help implement activities stressing European visibility and trans-European cultural cooperation.

Special actions may also include the awarding of prizes, in so far as they highlight artists, works or cultural or artistic achievements, make them known beyond national borders and thus encourage mobility and exchanges.

Support may also be given in this context to cooperation with third countries and international organisations, as set out in Article 5(2) and Article 6.

The examples given above do not constitute an exhaustive list of measures likely to be supported under this sub-strand of the Programme.

The selection procedures for special actions will depend on the action in question. Financing will be granted following calls for proposals and invitations to tender, except in the cases referred to in Articles 54 and 168 of the Financial Regulation. Account will also be taken of the extent to which each action meets the general objective and specific objectives of the Programme, as set out in Article 3 of this Decision.

Community support may not exceed 60 % of the project budget.

By way of illustration, approximately 16 % of the total budget allocated to the Programme shall be devoted to this type of support.

2. **Second strand: support for bodies active at European level in the field of culture**

This support shall take the form of an operating grant to co-finance expenditure associated with the permanent work programme of a body which pursues an aim of general European interest in the field of culture or an objective forming part of the Union's policy in this area.

Provision shall be made for these grants to be awarded on the basis of annual calls for proposals.

By way of illustration, approximately 10 % of the total budget allocated to the Programme shall be devoted to this strand.

Support may be given to bodies working for cultural cooperation in one or more of the following ways:

— providing representation at Community level,

— collecting or disseminating information for facilitating trans-European Community cultural cooperation,

— networking at European level for bodies active in the field of culture,

— participating in cultural cooperation projects or acting as ambassadors for European culture.

These bodies must present a real European dimension. In this regard, they must carry out their activities at European level, alone or in the form of various coordinated associations, and their structure (registered members) and activities must have a potential influence at European Union level or cover at least seven European countries.

This strand shall be open to the bodies supported under Part 2 of Annex I to Decision No 792/2004/EC as well as any other body active at European level in the field of culture, provided that they meet the objectives set out in Article 3 of this Decision and comply with the terms and conditions of this Decision.

The beneficiaries of these operating grants shall be selected through a call for proposals. This shall be done on the basis of matching the bodies' work programme with the specific objectives set out in Article 3.

The total operating grant awarded under this strand may not exceed 80 % of the body's admissible expenditure for the year in which the grant is awarded.

3. **Third strand: support for analyses and for the collection and dissemination of information and for maximising the impact of projects in the field of cultural cooperation**

By way of illustration, approximately 5 % of the total budget allocated to the Programme shall be devoted to this strand.

3.1. *Support for cultural contact points*

In order to ensure targeted, effective grass-roots dissemination of practical information on the Programme, it shall provide for support from cultural contact points. These bodies, acting at national level, shall be set up on a voluntary basis according to Article 39 of Regulation (EC, Euratom) No 2342/2002.

The task of the cultural contact points shall be to:

— promote the Programme,

— facilitate access to the Programme for, and encourage participation in its activities by, as many professionals and operators in the cultural field as possible, by means of an effective dissemination of information and by developing appropriate networking initiatives between themselves,

— provide an efficient link with the various institutions providing aid to the cultural sector in Member States, thus contributing to complementarity between the measures taken under the Programme and national support measures,

— provide information on other Community programmes open for cultural projects if required.

3.2. *Support for analysesin the field of cultural cooperation*

The Programme shall support the carrying out of studies and analyses in the field of European cultural cooperation and European cultural policy development. The aim of this support shall be to increase the volume and quality of information and data to develop comparative data and analysis on cultural cooperation at European level, particularly with regard to the mobility of creators and cultural players, the circulation of works of art and artistic and cultural products and intercultural dialogue.

Studies and analyses contributing to increasing knowledge of the phenomenon of trans-European cultural cooperation and to creating favourable conditions for it to flourish may be supported under this strand. Projects aimed at collecting and analysing statistics will be particularly encouraged.

3.3. *Support for the collection and dissemination of information and for maximising the impact of projects in the field of cultural cooperation*

The Programme shall support the collection and dissemination of information and activities aimed at maximising the impact of projects via the development of an Internet tool targeted at the needs of culture professionals in the field of trans-European cultural cooperation.

This tool should make possible the exchange of experience and good practice and the dissemination of information concerning the Programme as well as trans-European cultural cooperation in the broad sense.

II. PROGRAMME MANAGEMENT

The Programme's financial allocation may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities, required directly for the management and the realisation of the objectives of the Programme, in particular, studies, meetings, information and publication actions, expenses linked to computer networks focusing on information exchange, together with all other technical and administrative assistance expense to which the Commission may have recourse for the management of the Programme.

III. CONTROLS AND AUDITS

For projects selected in accordance with the procedure described in Article 11(2), a sampling audit system will be established.

The beneficiary of a grant shall make available to the Commission all supporting documents relating to expenditure for a period of five years reckoned from the date of the final payment. The beneficiary of a grant shall ensure that, where applicable, supporting documents in the possession of partners or members are made available to the Commission.

The Commission may have an audit of the use made of the grant carried out either directly by its own staff or by any other qualified outside body of its choice. Such audits may be carried out throughout the lifetime of the contract and for a period of five years from the date of payment of the balance. Where appropriate, the audit findings may lead to recovery decisions by the Commission.

Commission staff and outside personnel authorised by the Commission shall have appropriate access to the offices of the beneficiary and to all the information, including information in electronic format, needed in order to conduct such audits.

The Court of Auditors and the European Anti-Fraud Office (OLAF) shall enjoy the same rights, especially those of access, as the Commission.

In order to protect the financial interests of the Community against fraud and other irregularities, the Commission may carry out on-the-spot checks and inspections under the Programme in accordance with Council Regulation (Euratom, EC) No 2185/96 ([1]). Where necessary, investigations shall be conducted by OLAF in accordance with Regulation (EC) No 1073/1999 of the European Parliament and of the Council ([2]).

([1]) OJ L 292, 15.11.1996, p. 2.
([2]) OJ L 136, 31.5.1999, p. 1.

IV. INFORMATION, COMMUNICATION AND ACTIVITIES AIMED AT MAXIMISING THE IMPACT OF PROJECTS

1. Commission

The Commission may organise seminars, conferences or meetings in order to facilitate the implementation of the Programme, and undertake information, publication, dissemination and other activities aimed at maximising the impact of projects as appropriate, as well as the monitoring and evaluation of the Programme. Such activities may be financed by means of grants, or the public procurement process, or be organised and financed directly by the Commission.

2. Contact points

The Commission and Member States shall organise on a voluntary basis and reinforce the exchange of information useful for the implementation of the Programme via the cultural contact points acting as implementing bodies at national level, under the terms of Article 54(2)(c) and (3) of the Financial Regulation.

3. Member States

Without prejudice to Article 87 of the Treaty, Member States may, if necessary, establish support schemes for individual mobility of cultural players in order to address their low participation in the Programme. This support may take the form of travel grants for cultural operators in order to facilitate the preparatory phase of transnational cultural projects.

V. OVERALL BUDGET BREAKDOWN

Breakdown of the annual budget for the Programme

	Percentage of the budget
Strand 1 (support for cultural actions)	Approximately 77 %
— multi-annual cooperation projects	Approximately 32 %
— cooperation measures	Approximately 29 %
— special actions	Approximately 16 %
Strand 2 (support for bodies active at European level in the field of culture)	Approximately 10 %
Strand 3 (support for analysis, collection and dissemination of information)	Approximately 5 %
Total operational expenditure	Approximately 92 %
Programme management	Approximately 8 %

These percentages are indicative and subject to change by the Committee provided for in Article 9 in accordance with the procedure referred to in Article 9(2).

DECISION No 1904/2006/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

establishing for the period 2007 to 2013 the programme 'Europe for Citizens' to promote active European citizenship

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 151 and 308 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee ([1]),

Having regard to the Opinion of the Committee of the Regions ([2]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([3]),

Whereas:

(1) The Treaty establishes citizenship of the Union, which complements national citizenship of the respective Member States. It is an important element in strengthening and safeguarding the process of European integration.

(2) The Community should make citizens fully aware of their European citizenship, its benefits as well as its rights and obligations, which are to be promoted with due regard for subsidiarity and in the interest of cohesion.

(3) It is especially urgent to make European citizens fully aware of their citizenship of the European Union in the context of the broad reflection on the future of Europe launched by the Brussels European Council of 16 and 17 June 2005. The 'Europe for Citizens' programme should therefore complement, but not overlap with, other initiatives taken in this context.

(4) For citizens to give their full support to European integration, greater emphasis should therefore be placed on their common values, history and culture as key elements of their membership of a society founded on the principles of freedom, democracy and respect for human rights, cultural diversity, tolerance and solidarity, in accordance with the Charter of Fundamental Rights of the European Union ([4]) proclaimed on 7 December 2000.

(5) Encouraging active citizenship is a key element in strengthening not only the fight against racism, xenophobia and intolerance but also cohesion and the development of democracy.

(6) In the context of the EU information and communication strategy, a broad dissemination and a high impact of the activities supported through the programme should be ensured.

(7) In order to bring Europe closer to its citizens and to enable them to participate fully in the construction of an ever closer Europe, there is a need to address all nationals and legal residents in the participating countries and to involve them in transnational exchanges and cooperation activities, contributing to developing a sense of belonging to common European ideals.

(8) The European Parliament, in a Resolution adopted in 1988, considered it desirable that a major effort be undertaken to step up contacts between citizens of different Member States and stated that specific support from the European Union for the development of twinning schemes between municipalities in different Member States was both rational and desirable.

(9) The European Council has recognised on several occasions the need to bring the European Union and its institutions closer to the citizens of the Member States. It has encouraged the Union's institutions to maintain and foster open, transparent and regular dialogue with organised civil society, thus promoting citizens' participation in public life and in decision-making, while emphasising the essential values that are shared by the citizens of Europe.

(10) The Council established in its Decision 2004/100/EC of 26 January 2004 establishing a Community action programme to promote active European citizenship (civic participation) ([5]), an action programme which has confirmed the need to promote sustained dialogue with civil society organisations and municipalities and to support the active involvement of citizens.

([1]) OJ C 28, 3.2.2006, p. 29.
([2]) OJ C 115, 16.5.2006, p. 81.
([3]) Opinion of the European Parliament of 5 April 2006 (not yet published in the Official Journal), Council Common Position of 25 September 2006 (not yet published in the Official Journal) and Position of the European Parliament of 25 October 2006 (not yet published in the Official Journal). Council Decision of 11 December 2006.
([4]) OJ C 364, 18.12.2000, p. 1.
([5]) OJ L 30, 4.2.2004, p. 6.

(11) Citizens' projects with a transnational and cross-sectoral dimension are important tools to reach citizens and promote European awareness, European political integration, social inclusion and mutual understanding.

(12) Civil society organisations at European, national, regional and local levels are important elements of citizens' active participation in society and help to invigorate all aspects of public life. They are also intermediaries between Europe and its citizens. Their transnational cooperation should therefore be promoted and encouraged.

(13) European public policy research organisations can provide ideas and reflections to feed the debate at European level. It is therefore also advisable to support, as a link between the European institutions and the citizens, activities that reflect their commitment to creating a European identity and citizenship, by establishing procedures with transparent criteria to promote networks for information and exchange.

(14) It is also worthwhile pursuing the action begun by the European Union in the context of Decision No 792/2004/EC of the European Parliament and of the Council of 21 April 2004 establishing a Community action programme to promote bodies active at European level in the field of culture [1] for the preservation and commemoration of the main sites and archives associated with deportations. An awareness of the full dimensions and tragic consequences of the second world war may thus be maintained and universal remembrance promoted, as a means of moving beyond the past and building the future.

(15) The Declaration on Sport adopted by the Nice European Council of 7-9 December 2000 noted that, 'even though not having any direct powers in this area, the Community must, in its action under the various Treaty provisions, take account of the social, educational and cultural functions inherent in sport.'

(16) Special attention should be paid to the balanced integration of citizens and civil society organisations from all Member States into transnational projects and activities.

(17) The candidate countries and the EFTA countries party to the EEA Agreement are recognised as potential participants in Community programmes, in accordance with the agreements concluded with those countries.

(18) The European Council of 19 and 20 June 2003 adopted the 'Thessaloniki Agenda for the Western Balkans: Moving towards European integration', which invited the Western Balkan countries to participate in Community programmes and agencies; therefore, the Western Balkans countries should be recognised as potential participants in Community programmes.

(19) The programme should be monitored regularly and evaluated independently in cooperation with the Commission and the Member States in order to allow for the readjustments which are necessary if the measures are to be properly implemented.

(20) The procedures for monitoring and evaluating the programme should make use of objectives and indicators which are specific, measurable, achievable, relevant and timed.

(21) Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [2] (hereinafter 'the Financial Regulation') and Commission Regulation (EC, Euratom) No 2342/2002 of 19 November 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [3], which safeguard the Community's financial interests, have to be applied taking into account the principles of simplicity and consistency in the choice of budgetary instruments, a limitation on the number of cases where the Commission retains direct responsibility for their implementation and management, and the required proportionality between the amount of resources and the administrative burden related to their use.

(22) Appropriate measures should also be taken to prevent irregularities and fraud and to recover funds lost or incorrectly paid or used.

(23) Following the principle of sound financial management, the implementation of the programme may be simplified by recourse to lump sum funding, in respect either of support awarded to programme participants or of Community support for the structures established at national level for the administration of the programme.

(24) This Decision lays down, for the entire duration of the programme, a financial envelope constituting the prime reference, within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [4], for the budgetary authority during the annual budgetary procedure.

[1] OJ L 138, 30.4.2004, p. 40.

[2] OJ L 248, 16.9.2002, p. 1.

[3] OJ L 357, 31.12.2002, p. 1. Regulation as last amended by Commission Regulation (EC, Euratom) No 1248/2006 (OJ L 227, 19.8.2006, p. 3).

[4] OJ C 139, 14.6.2006, p. 1.

(25) Since the objectives of this Decision cannot be sufficiently achieved by the Member States and can therefore, by reason of the transnational and multilateral nature of the programme's actions and measures, 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 Decision does not go beyond what is necessary in order to achieve those objectives.

(26) The measures necessary for the implementation of this Decision 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].

(27) Transitional measures to monitor actions started before 31 December 2006 should be adopted, pursuant to Decision 2004/100/EC,

HAVE DECIDED AS FOLLOWS:

Article 1

Subject matter and scope of the programme

1. This Decision establishes the programme 'Europe for Citizens' (hereinafter referred to as 'the programme') for the period from 1 January 2007 to 31 December 2013.

2. The programme shall contribute to the following general objectives:

(a) giving citizens the opportunity to interact and participate in constructing an ever closer Europe, which is democratic and world-oriented, united in and enriched through its cultural diversity, thus developing citizenship of the European Union;

(b) developing a sense of European identity, based on common values, history and culture;

(c) fostering a sense of ownership of the European Union among its citizens;

(d) enhancing tolerance and mutual understanding between European citizens respecting and promoting cultural and linguistic diversity, while contributing to intercultural dialogue.

[1] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

Article 2

Specific objectives of the programme

The programme shall have the following specific objectives in line with the fundamental goals of the Treaty, which shall be implemented on a transnational basis:

(a) bringing together people from local communities across Europe to share and exchange experiences, opinions and values, to learn from history and to build for the future;

(b) fostering action, debate and reflection related to European citizenship and democracy, shared values, common history and culture through cooperation within civil society organisations at European level;

(c) bringing Europe closer to its citizens by promoting Europe's values and achievements, while preserving the memory of its past;

(d) encouraging interaction between citizens and civil society organisations from all participating countries, contributing to intercultural dialogue and bringing to the fore both Europe's diversity and unity, with particular attention to activities aimed at developing closer ties between citizens from Member States of the European Union as constituted on 30 April 2004 and those from Member States which have acceded since that date.

Article 3

Actions

1. The objectives of the programme shall be pursued through support for the following actions, details of which may be found in Part I of the Annex:

(a) Active citizens for Europe, consisting of:

— town twinning,

— citizens' projects and support measures;

(b) Active civil society in Europe, consisting of:

— structural support for European public policy research organisations (think-tanks),

— structural support for civil society organisations at European level,

— support for projects initiated by civil society organisations;

(c) Together for Europe, consisting of:

— high visibility events, such as commemorations, awards, artistic events, European-wide conferences,

— studies, surveys and opinion polls,

— information and dissemination tools;

(d) Active European Remembrance, consisting of:

— preservation of the main sites and archives associated with the deportations and the commemoration of the victims.

2. In each action, priority may be given to the balanced integration of citizens and civil society organisations from all Member States, as provided for in the specific objective set out in Article 2(d).

Article 4

Forms of Community measures

1. Community measures may take the form of grants or public procurement contracts.

2. Community grants may be provided through specific forms such as operating grants, action grants, scholarships, prizes.

3. Public procurement contracts will cover the purchase of services, such as for organising events, studies and research, information and dissemination tools, monitoring and evaluation.

4. To be eligible for a Community grant, the beneficiaries must satisfy the requirements set out in Part II of the Annex.

Article 5

Participation in the programme

The programme shall be open to the participation of the following countries, hereinafter referred to as the 'participating countries':

(a) the Member States;

(b) the EFTA countries party to the EEA Agreement, in accordance with the provisions of that Agreement;

(c) the candidate countries benefiting from a pre-accession strategy, in accordance with the general principles and the general terms and conditions laid down in the framework agreements concluded with these countries for their participation in Community programmes;

(d) the countries of the western Balkans, in accordance with the arrangements to be established with these countries under the framework agreements on the general principles for their participation in Community programmes.

Article 6

Access to the programme

The programme shall be open to all stakeholders promoting active European citizenship, in particular local authorities and organisations, European public policy research organisations (think-tanks), citizens' groups and other civil society organisations.

Article 7

Cooperation with international organisations

The programme may cover joint and innovative activities in the field of active European citizenship, with relevant international organisations such as the Council of Europe and UNESCO, on the basis of joint contributions and in accordance with the Financial Regulation and various rules of each institution or organisation.

Article 8

Implementing measures

1. The Commission shall adopt the measures necessary for the implementation of the programme in accordance with the provisions of the Annex.

2. The following measures shall be adopted in accordance with the procedure referred to in Article 9(2):

(a) the arrangements for the implementation of the programme, including the annual work plan, the selection criteria and the selection procedures;

(b) the general balance between the various actions of the programme;

(c) the procedures for monitoring and evaluating the programme;

(d) the financial support (amount, duration, distribution and beneficiaries) provided by the Community in relation to all operating grants, multi-annual twinning agreements under Action 1 and high visibility events under Action 3.

3. All other measures necessary for the implementation of the programme shall be adopted in accordance with the procedure referred to in Article 9(3).

4. As part of the procedure mentioned in paragraph 2, the Commission may draw up guidelines for each of the actions in the Annex in order to adapt the programme to any changes of priority in the field of active European citizenship.

Article 9

Committee

1. The Commission shall be assisted by a committee.

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

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The committee shall adopt its rules of procedure.

Article 10

Coherence with other Community and European Union instruments

1. The Commission shall ensure coherence and complementarity between the programme and instruments in other areas of Community action, especially education, vocational training, culture, youth, sport, the environment, the audiovisual sector and the media, fundamental rights and freedoms, social inclusion, gender equality, combating all forms of discrimination, racism and xenophobia, scientific research, information society and Community external action, in particular at the level of European Neighbourhood policy.

2. The programme may share resources with other Community and European Union instruments in order to implement actions meeting the objectives of both the programme and these other instruments.

Article 11

The financial envelope

1. The financial envelope for the implementation of the programme for the period referred to in Article 1 is hereby set at EUR 215 million.

2. The annual appropriations shall be authorised by the budgetary authority within the limits of the financial framework.

Article 12

Financial provisions

1. Financial aid shall take the form of grants to legal persons. Depending on the nature of the action and the objective pursued, grants may also be awarded to natural persons.

2. The Commission may award prizes to natural or legal persons for actions or projects implemented under the programme.

3. In accordance with Article 181 of Regulation (EC, Euratom) No 2342/2002, and depending on the nature of the action, flat-rate financing and/or the application of unit-cost rates may be authorised.

4. Co-financing in kind may be permitted.

5. The Commission may decide, in view of the characteristics of the beneficiaries and the nature of the actions, to exempt beneficiaries from verification of the professional competencies and qualifications required to complete the proposed action or work programme.

6. The amount of information to be provided by the beneficiary may be limited in the case of small grants.

7. In specific cases such as the award of a small grant, the beneficiary need not be required to demonstrate its financial capacity to perform the planned project or the work programme.

8. Operating grants awarded under the programme to bodies pursuing an aim of general European interest, as defined in Article 162 of Regulation (EC, Euratom) No 2342/2002, shall not be automatically decreased in the event of renewal.

Article 13

Protection of the Community's financial interests

1. The Commission shall ensure that, when actions financed under this Decision are implemented, the financial interests of the Community are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests ([1]), Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities ([2]) and with Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) ([3]).

2. For the Community actions financed under the programme, the notion of irregularity referred to in Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Community law or any breach of a contractual obligation resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the general budget of the Union or budgets managed by the Communities, by an unjustified item of expenditure.

([1]) OJ L 312, 23.12.1995, p. 1.
([2]) OJ L 292, 15.11.1996, p. 2.
([3]) OJ L 136, 31.5.1999, p. 1.

3. The Commission shall reduce, suspend or recover the amount of financial assistance granted for an action if it finds irregularities, including non-compliance with the provisions of this Decision or the individual decision or the contract or agreement granting the financial support in question, or if it transpires that, without Commission approval having being sought, the action has been subjected to a change which conflicts with the nature or implementing conditions of the project.

4. If the time limits have not been observed or if only part of the allocated financial assistance is justified by the progress made with implementing an action, the Commission shall request the beneficiary to submit observations within a specified period. If the beneficiary does not give a satisfactory answer, the Commission may cancel the remaining financial assistance and demand repayment of sums already paid.

5. Any undue payment shall be repaid to the Commission. Interest shall be added to any sums not repaid in good time under the conditions laid down by the Financial Regulation.

Article 14

Monitoring and evaluation

1. The Commission shall ensure regular monitoring of the programme. The results of the monitoring and evaluation process shall be utilised in implementing the programme. Monitoring shall include in particular the drawing up of the reports referred to in paragraph 3 points (a) and (c).

The specific objectives may be revised in accordance with Article 251 of the Treaty.

2. The Commission shall ensure regular, external and independent evaluation of the programme and shall report to the European Parliament on a regular basis.

3. The Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions:

(a) an interim evaluation report on the results obtained and on the qualitative and quantitative aspects of the implementation of the programme no later than 31 December 2010;

(b) a communication on the continuation of the programme no later than 31 December 2011;

(c) an ex-post evaluation report no later than 31 December 2015.

Article 15

Transitional provision

Actions started before 31 December 2006 pursuant to Decision 2004/100/EC shall continue to be governed, until their completion, by that Decision.

As provided for by Article 18 of the Financial Regulation, the appropriations corresponding to assigned revenue arising from the repayment of amounts wrongly paid pursuant to Decision 2004/100/EC may be made available to the Programme.

Article 16

Entry into force

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

It shall apply from 1 January 2007.

Done at Strasbourg, on 12 December 2006

For the European Parliament	*For the Council*
The President	*The President*
Josep BORRELL FONTELLES	Mauri PEKKARINEN

ANNEX

I. DESCRIPTION OF ACTIONS

Complementary information on access to the programme

Civil society organisations as mentioned in Article 6 include, inter alia, trade unions, educational institutions and organisations active in the field of voluntary work and amateur sport.

ACTION 1: Active citizens for Europe

This action forms that part of the programme directed specifically at activities involving citizens. These activities fall under two types of measures as follows:

Town-twinning

This measure is aimed at activities that involve or promote direct exchanges between European citizens through their participation in town-twinning activities. These may be one-off or pilot activities, or take the form of structured, multi-annual, multi-partner agreements following a more programmed approach and comprising a set of activities ranging from citizens' meetings to specific conferences or seminars on subjects of common interest, along with related publications, organised in the context of town-twinning activities. This measure will actively contribute to strengthening mutual knowledge and understanding between citizens and between cultures.

For the years 2007, 2008 and 2009, structural support may be provided directly to the Council of European Municipalities and Regions (CEMR), a body pursuing an aim of general European interest, active in the field of town twinning.

Citizens' projects and support measures

Under this measure, a variety of projects of a transnational and cross-sectoral dimension, directly involving citizens, will be supported. Priority is given to projects aimed at encouraging local level participation. The scale and scope of such projects will depend on the developments within the society and will explore, through innovative approaches, the possible responses to the identified needs. The use of new technologies, in particular information society technologies (IST), will be encouraged. Those projects will gather citizens from different horizons, who will act together or debate on common European issues, thereby developing mutual understanding as well as raising awareness of the process of European integration.

In order to improve town-twinning and citizens' projects, it is also necessary to develop support measures to exchange best practices, to pool experiences between stakeholders at local and regional levels including public authorities, and to develop new skills, for example through training.

As an indication, at least 45 % of the total budget allocated to the programme will be devoted to this action.

ACTION 2: Active civil society in Europe

Structural support for European public policy research organisations (think-tanks)

Bodies providing new ideas and reflections on European issues are important institutional interlocutors able to provide independent strategic, cross-sectoral recommendations to the EU institutions. They can undertake activities that feed the debate notably on citizenship of the European Union and on European values and cultures. This measure is aimed at strengthening the institutional capacity of those organisations, which are representative, provide real European added value, can bring about important multiplier effects and, finally, are able to cooperate with other beneficiaries of the programme. The strengthening of transeuropean networks is an important element in this area. Grants may be awarded on the basis of a multi-annual work programme bringing together a range of themes or activities.

For the years 2007, 2008 and 2009, structural support may be provided directly for the association '*Groupement d'études et de recherches Notre Europe*' and for the '*Institut für Europäische Politik*', as bodies pursuing an aim of general European interest.

Structural support for civil society organisations at European level

Civil society organisations are an important part of the civic, educational, cultural and political activities for participating in society. They need to exist and to be able to operate and cooperate at European level. They should also be able to participate in policy-making through consultation. This measure will provide them with the capacity and stability to act in a cross-sectoral and horizontal dimension as transnational catalysts for their members and for civil society at European level, thus contributing to the objectives of the programme. The strengthening of transeuropean networks and European associations is an important element of this area of work. Grants may be awarded on the basis of a multi-annual work programme bringing together a range of themes or activities.

For the years 2007, 2008 and 2009, structural support may be provided directly for three bodies pursuing an aim of general European interest: the Platform of European Social NGOs, the European Movement and the European Council on Refugees and Exiles.

Support for projects initiated by civil society organisations

Civil society organisations at local, regional, national or European level involve citizens or represent their interests through debate, publications, advocacy, and other concrete transnational projects. Introducing or building on a European dimension in the activities of civil society organisations, will enable them to enhance their capacities and reach wider audiences. Direct cooperation among civil society organisations from different Member States will contribute to mutual understanding for the different cultures and points of view and to the identification of shared concerns and values. While this may be in the form of single projects, a longer-term approach will also ensure a more sustainable impact and the development of networks and synergies.

As an indication, approximately 31 % of the total budget allocated to the programme will be devoted to this action.

ACTION 3: Together for Europe

High-visibility events

This measure will support events organised by the Commission, where appropriate in cooperation with the Member States or other relevant partners, which are substantial in scale and scope, strike a chord with the peoples of Europe, help to increase their sense of belonging to the same community, make them aware of the history, achievements and values of the European Union, involve them in intercultural dialogue and contribute to the development of their European identity.

These events may include the commemoration of historical events, the celebration of European achievements, artistic events, awareness-raising around specific issues, European-wide conferences and the awarding of prizes to highlight major accomplishments. The use of new technologies, in particular IST, shall be encouraged.

Studies

In order to get a better understanding of active citizenship at European level, the Commission will carry out studies, surveys and opinion polls.

Information and dissemination tools

Given the focus on citizens and the variety of initiatives in the field of active citizenship, comprehensive information on the various activities of the programme, on other European actions related to citizenship and on other relevant initiatives needs to be provided through an Internet portal and other tools.

For the years 2007, 2008 and 2009, structural support may be provided directly for the '*Association Jean Monnet*', the '*Centre européen Robert Schuman*' and the '*Maisons de l'Europe*' federated at national and European level, as bodies pursuing an aim of general European interest.

As an indication, approximately 10 % of the total budget allocated to the programme will be devoted to this action.

ACTION 4: Active European Remembrance

Under this action projects of the following types may be supported:

— for the preservation of the main sites and memorials associated with the mass deportations, the former concentration camps and other large-scale martyrdom and extermination sites of Nazism, as well as the archives documenting these events and for keeping alive the memory of the victims, as well as the memory of those who, under extreme conditions, rescued people from the Holocaust;

— for the commemoration of the victims of mass exterminations and mass deportations associated with Stalinism, as well as the preservation of the memorials and archives documenting these events.

Approximately 4 % of the total budget allocated to the programme will be devoted to this action.

II. **PROGRAMME MANAGEMENT**

The implementation of the programme will be guided by the principles of transparency as well as openness, to a large variety of organisations and projects. As a consequence, projects and activities will be selected, as a general rule, by means of open calls for proposals. Derogations will be possible only in very specific circumstances and in full compliance with Article 168(1) points (c) and (d) of Regulation (EC, Euratom) No 2342/2002.

The programme will develop the principle of multi-annual partnerships based on agreed objectives, building on the analysis of the results, in order to ensure mutual benefits for both civil society and the European Union. The maximum duration of funding allocated through a single grant agreement under the programme shall be limited to 3 years.

For some actions, it might be necessary to adopt indirect centralised management by an executive agency or, especially for action 1, by national agencies.

All actions will be implemented on a transnational basis. They will encourage mobility of citizens and ideas within the European Union.

The elements of networking and focussing on the multiplier effects, including the use of information and communication technologies (ICT), will be important and will be reflected both in the types of activities and the range of organisations involved. The development of interaction and synergy among the various types of stakeholders involved in the programme will be encouraged.

The programme budget may also cover expenditure associated with the preparation, follow-up, monitoring, auditing and evaluation activities directly necessary for the management of the programme and the realisation of its objectives, in particular studies, meetings, information and publication activities, expenditure associated with the IT networks for the exchange of information and any other administrative and technical support expenditure on which the Commission may decide for the management of the programme.

The overall administrative expenditure of the programme should be proportional to the tasks provided for in the programme concerned and, as an indication, should represent approximately 10 % of the total budget allocated to the programme.

The Commission may undertake information, publication and dissemination activities as appropriate, thereby ensuring broad knowledge and a high impact of the activities supported by the programme.

III. **CONTROLS AND AUDITS**

For projects selected in accordance with this Decision, a sampling audit system will be established.

The beneficiary of a grant must make available to the Commission all supporting documents relating to expenditure for a period of five years from the date of the final payment. The beneficiary of a grant must ensure that, where applicable, supporting documents in the possession of partners or members are made available to the Commission.

The Commission may have an audit of the use made of the grant carried out either directly by its own staff or by any other qualified outside body of its choice. Such audits may be carried out throughout the lifetime of the contract and for a period of five years from the date of payment of the balance. Where appropriate, the audit findings may lead to recovery decisions by the Commission.

Commission staff and outside personnel authorised by the Commission must have appropriate access to the offices of the beneficiary and to all the information, including information in electronic format, necessary for such audits.

The Court of Auditors and the European Anti-Fraud Office (OLAF) will have the same rights, especially of access, as the Commission.

REGULATION (EC) No 1905/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

establishing a financing instrument for development cooperation

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 179(1) thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [1],

Whereas:

(1) A new framework for planning and delivering assistance is proposed in order to make the Community's external assistance more effective. Council Regulation (EC) No 1085/2006 [2] establishes an Instrument for Pre Accession (IPA) for Community assistance to candidate and potential candidate countries. Regulation (EC) No 1638/2006 [3] lays down general provisions establishing a European Neighbourhood and Partnership Instrument (ENPI). Council Regulation (EC) No 1934/2006 [4] establishes a financing instrument for cooperation with industrialised and other high-income countries and territories. Regulation (EC) No 1717/2006 [5] establishes an instrument for stability. Regulation (EC) No …/2007 (*) establishes an instrument for nuclear safety cooperation. Regulation (EC) No 1889/2006 [6] establishes a financing instrument for the promotion of democracy and human rights worldwide. Council Regulation (EC) No 1257/96 [7] concerns humanitarian aid. This Regulation establishes a financing instrument for development cooperation providing direct support for the Community's development cooperation policy.

(2) The Community pursues a development cooperation policy aimed at achieving the objectives of poverty reduction, sustainable economic and social development and the smooth and gradual integration of developing countries into the world economy.

(3) The Community pursues a cooperation policy that fosters cooperation, partnerships and joint undertakings between economic players in the Community and partner countries and regions, and promotes dialogue between political, economic and social partners in relevant sectors.

(4) The Community's development cooperation policy and international action are guided by the Millennium Development Goals (MDGs), such as the eradication of extreme poverty and hunger, adopted by the United Nations General Assembly on 8 September 2000, and the main development objectives and principles approved by the Community and its Member States in the context of the United Nations (UN) and other competent international organisations in the field of development cooperation.

(5) With a view to policy coherence for development, it is important that Community non-development policies assist developing countries' efforts in achieving the MDGs in line with Article 178 of the Treaty establishing the European Community.

(6) A political environment which guarantees peace and stability, respect for human rights, fundamental freedoms, democratic principles, the rule of law, good governance and gender equality is fundamental to long-term development.

(7) Sound and sustainable economic policies are a prerequisite for development.

(8) The members of the World Trade Organization (WTO) committed themselves at the 4th Ministerial Conference in Doha to mainstreaming trade in development strategies and to providing trade-related technical and capacity-building assistance as well as the necessary measures seeking to facilitate the transfer of technology through and for trade, to enhance the relationship between foreign direct investment and trade, and the mutual interrelation of trade and environment, and to help developing countries take part in new trade negotiations and implement their results.

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[1] Opinion of the European Parliament of 18 May 2006 (not yet published in the Official Journal), Council Common Position of 23 October 2006 (not yet published in the Official Journal) and Position of the European Parliament of 12 December 2006 (not yet published in the Official Journal).
[2] OJ L 210, 31.7.2006, p. 82.
[3] OJ L 310, 9.11.2006, p. 1.
[4] OJ L 405, 30.12.2006, p. 40.
[5] OJ L 327, 24.11.2006, p. 1.
(*) This Regulation will be adopted at a later date.
[6] OJ L 386, 29.12.2006, p. 1.
[7] OJ L 163, 2.7.1996, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(9) The Joint Statement by the Council and the Representatives of the Governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus' ([1]), of 20 December 2005, and any subsequent modifications thereto, provides the general framework for action by the Community on development matters. It should steer the planning and implementation of the development assistance and cooperation strategies.

(10) Development cooperation should be implemented through geographic and thematic programmes. Geographic programmes should support the development of, and reinforce the cooperation with, countries and regions in Latin America, Asia, Central Asia, the Middle East and South Africa.

(11) The Community and its Member States have concluded partnership and cooperation agreements with some of these partner countries and regions aimed at making a significant contribution to the long-term development of the partner countries and the wellbeing of their people. The essential elements on which these partnership and cooperation agreements are based are the common and universal values of respect for, and promotion of, human rights, fundamental freedoms, democratic principles and the rule of law. In this context, attention should also be given to the right to decent work and the rights of people with disabilities. The pursuit and deepening of bilateral relations between the Community and partner countries and the consolidation of multilateral institutions are important factors in making a significant contribution to balancing and developing the world economy and also in strengthening the Community's and partner countries' and regions' role and place in the world.

(12) While thematic programmes should primarily support developing countries, two beneficiary countries as well as the overseas countries and territories (OCTs), whose characteristics do not meet the requirements to be defined as Official Development Assistance (ODA) recipients by the Development Assistance Committee of the Organisation for Economic Cooperation and Development (OECD/DAC) and which are covered by Article 2(4), second subparagraph, first indent, should also be eligible for thematic programmes under the conditions set out in this Regulation. The Community should finance thematic programmes in countries, territories and regions eligible for assistance under a geographic programme provided for under this Regulation, for assistance under Regulation (EC) No 1638/2006 or for geographic cooperation in accordance with the European Development Fund (EDF). Council Decision 2001/822/EC of 27 November 2001 on the association of the overseas countries and territories with the European Community ('Overseas Association Decision') ([2]), which is applicable until 31 December 2011, lays down the conditions for the eligibility of OCTs for the thematic activities of development assistance funded by the general budget of the European Union, which are not altered by this Regulation.

([1]) OJ C 46, 24.2.2006, p. 1.
([2]) OJ L 314, 30.11.2001, p. 1.

(13) Thematic programmes should provide distinctive added value and complement programmes of a geographic nature, which constitute the main framework for Community cooperation with third countries. Development cooperation implemented through thematic programmes should be subsidiary to the geographic programmes set out in this Regulation and in Regulation (EC) No 1638/2006 and to cooperation under the EDF. Thematic programmes encompass a specific area of activity of interest to a group of partner countries not determined by geography, or cooperation activities addressed to various regions or groups of partner countries, or an international operation that is not geographically specific. They also have an important role in developing Community policies externally and ensuring sectoral consistency and visibility.

(14) Thematic programmes should support actions in the areas of human and social development, environment and sustainable management of natural resources, including energy, non-State actors and local authorities, food security and migration and asylum. The contents of the thematic programmes have been prepared on the basis of the corresponding communications from the Commission to the European Parliament and the Council.

(15) The thematic programme on the environment and the sustainable management of resources, including energy should, *inter alia*, promote international environmental governance and Community environmental and energy policies abroad.

(16) The thematic programme on migration and asylum should contribute to the realisation of the objective set out in the Conclusions of the European Council held in Brussels on 15 and 16 December 2005, namely to intensify Community financial assistance in areas concerning or related to migration in respect of its relations with third countries.

(17) Community policy on food security has evolved towards supporting broad-based food security strategies at national, regional and global level, limiting the use of food aid to humanitarian situations and food crises and avoiding disruptive effects on local production and markets, and needs to take into account the specific situation of countries that are structurally fragile and highly dependent on support for food security, in order to avoid a steep reduction of Community assistance to these countries.

(18) In line with the Council Conclusions of 24 May 2005 actions should be supported to improve reproductive and sexual health in developing countries and to secure respect for the rights relating thereto; financial assistance and appropriate expertise should be provided with a view to promoting a holistic approach to, and the recognition of, reproductive and sexual health and rights as defined in the Programme of Action of the International Conference on Population and Development (ICPD), including safe motherhood and universal access to a comprehensive range of safe and reliable reproductive and sexual health care and services. When cooperation measures are implemented, the decisions adopted at the ICPD must be rigorously observed, where relevant.

(19) Following up on Regulation (EC) No 266/2006 of the European Parliament and of the Council of 15 February 2006 establishing accompanying measures for Sugar Protocol countries affected by the reform of the EU sugar regime ([1]), assistance to ACP Sugar Protocol countries affected by the reform of the Common Market Organisation for sugar should also be provided and aim at supporting their adjustment process.

(20) In implementing the Community's development policy, more effective aid, greater complementarity and better harmonisation, alignment and coordination of procedures, both between the Community and its Member States and in relations with other donors and development actors, are essential to ensuring the consistency and relevance of aid whilst at the same time reducing the costs borne by partner countries as approved in the Declaration on Aid Effectiveness adopted by the High Level Forum on Aid Effectiveness, held in Paris, on 2 March 2005.

(21) In order to achieve the objectives of this Regulation, it is necessary to pursue a differentiated approach depending on development contexts and needs, supporting partner countries or regions with specific, tailor-made programmes, based on their own needs, strategies, priorities and assets.

(22) The key to the success of development policies is whether the partner countries take ownership of the development strategies, and, to this end, the greatest possible involvement of all sections of society, including disabled people and other vulnerable groups, should be encouraged. With a view to ensuring efficiency and transparency and encouraging countries to take ownership, donors' cooperation strategies and implementation procedures should, where possible, be aligned on those of the partner countries.

(23) Taking into consideration the need to ensure effective bridging between humanitarian relief and long-term development assistance, measures eligible under Regulation (EC) No 1717/2006 should not, in principle, be funded under this Regulation, except where there is a need to ensure continuity of cooperation from crisis to stable conditions for development.

(24) Untying aid in line with best practices of the OECD/DAC is a key factor in adding value to aid and in building local capacity. Rules on participation in tenders and grant contracts, as well as rules concerning the origin of supplies should be set down in accordance with most recent developments concerning the untying of aid.

(25) Assistance should be managed in accordance with the rules for external aid contained in Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ([2]), with due provisions aimed at protecting the financial interests of the Community. Continued efforts should be made to improve the implementation of development cooperation to achieve a sound balance between financial resources allocated and absorption capacity, as well as to reduce outstanding commitments.

(26) This Regulation lays down a financial envelope for the period 2007-2013 constituting the prime reference for the budgetary authority, within the meaning of Point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management ([3]).

(27) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([4]). Programming documents and some specific implementation measures should be adopted by the management committee procedure.

([1]) OJ L 50, 21.2.2006, p. 1.

([2]) OJ L 248, 16.9.2002, p. 1.
([3]) OJ C 139, 14.6.2006, p. 1.
([4]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(28) Since the objectives of this Regulation, namely the proposed cooperation with developing countries, territories and regions that are not Community Member States and are not eligible for Community aid under Regulation (EC) No 1085/2006 or Regulation (EC) No 1638/2006 cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.

(29) This Regulation makes it necessary to repeal the current set of Regulations, in view of the restructuring of the external action instruments, notably in the field of development cooperation,

HAVE ADOPTED THIS REGULATION:

Article 1

Overall purpose and scope

1. The Community shall finance measures aimed at supporting cooperation with developing countries, territories and regions included in the list of aid recipients of the Development Assistance Committee of the Organization for Economic Cooperation and Development (OECD/DAC), and set out in Annex I (hereinafter referred to as 'partner countries and regions'). The Commission shall amend Annex I in accordance with regular OECD/DAC reviews of its list of aid recipients and inform the European Parliament and the Council thereof.

2. The Community shall finance thematic programmes in countries, territories and regions eligible for assistance under a geographic programme of this Regulation, set out in Articles 5 to 10, for assistance under Regulation (EC) No 1638/2006 or for geographic cooperation under the European Development Fund (EDF).

3. For the purposes of this Regulation, a region is defined as a geographical entity comprising more than one developing country.

TITLE I

OBJECTIVES AND GENERAL PRINCIPLES

Article 2

Objectives

1. The primary and overarching objective of cooperation under this Regulation shall be the eradication of poverty in partner countries and regions in the context of sustainable development, including pursuit of the Millennium Development Goals (MDGs), as well as the promotion of democracy, good governance and respect for human rights and for the rule of law. Consistently with this objective, cooperation with partner countries and regions shall:

— consolidate and support democracy, the rule of law, human rights and fundamental freedoms, good governance, gender equality and related instruments of international law;

— foster the sustainable development — including political, economic, social and environmental aspects — of partner countries and regions, and more particularly the most disadvantaged among them;

— encourage their smooth and gradual integration into the world economy;

— help develop international measures to preserve and improve the quality of the environment and the sustainable management of global natural resources, in order to ensure sustainable development, including addressing climate change and biodiversity loss; and

— strengthen the relationship between the Community and partner countries and regions.

2. Community cooperation under this Regulation shall comply with the commitments and objectives in the field of development cooperation that the Community has approved in the context of the United Nations (UN) and other competent international organisations in the field of development cooperation.

3. Community development policy, as laid down in Title XX of the Treaty, shall provide the legal framework for cooperation with partner countries and regions. The Joint Statement by the Council and the Representatives of the Governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus', of 20 December 2005, and any subsequent modifications thereto, shall provide the general framework, orientations and focus to steer the implementation of Community cooperation with partner countries and regions under this Regulation.

4. Measures referred to in Article 1(1) shall be designed so as to fulfil the criteria for Official Development Assistance (ODA) established by the OECD/DAC.

Programmes referred to in Article 1(2) shall be designed so as to fulfil the criteria for ODA established by the OECD/DAC, unless:

— the characteristics of the beneficiary require otherwise, or

— the programme implements a global initiative, a community policy priority or an international obligation or commitment of the Community, as referred to in Article 11(2), and the measure does not have the characteristics to fulfil such criteria.

At least 90 % of the expenditure foreseen under thematic programmes shall be designed so as to fulfil the criteria for ODA established by the OECD/DAC, without prejudice to Article 2(4), second subparagraph, first indent.

5. Community assistance under this Regulation shall not be used to finance the procurement of arms or ammunition, and operations having military or defence implications.

6. Measures covered by Regulation (EC) No 1717/2006 and in particular Article 4 thereof, and eligible for funding thereunder shall not, in principle, be funded under this Regulation, except where there is a need to ensure continuity of cooperation from crisis to stable conditions for development.

Without prejudice to the need to ensure continuity of cooperation from crisis to stable conditions for development, measures covered by, and eligible for funding under, Council Regulation (EC) No 1257/96, shall not be funded under this Regulation.

Article 3

General principles

1. The Community is founded on the values of democracy, the rule of law, respect for human rights and fundamental freedoms and seeks to develop and consolidate commitment to these values in partner countries and regions through dialogue and cooperation.

2. In the implementation of this Regulation, a differentiated approach depending on development contexts and needs shall be pursued so that partner countries or regions are provided with specific, tailor-made cooperation, based on their own needs, strategies, priorities and assets.

Least developed countries and low income countries shall be given priority in terms of overall resource allocation in order to achieve the MDGs. Appropriate attention shall be given to support the pro-poor development of middle income countries, particularly the lower middle income countries many of which face problems similar to those of low income countries.

3. Mainstreaming of the following cross-cutting issues shall be undertaken in all programmes: the promotion of human rights, gender equality, democracy, good governance, the rights of the child and indigenous peoples' rights, environmental sustainability and combating HIV/AIDS. In addition, particular attention shall be given to strengthening the rule of law, improving access to justice and supporting civil society, as well as promoting dialogue, participation and reconciliation, and institution-building.

4. The Community shall take account of the objectives laid down in Title XX of the Treaty and in Article 2 of this Regulation, in all policies which are likely to affect partner countries and regions. For measures financed under this Regulation, the Community shall also aim to ensure coherence with other areas of its external action. This shall be ensured in formulating policy, strategic planning and the programming and implementation of measures.

5. The Community and the Member States shall improve coordination and complementarity of their policies on development cooperation by responding to partner countries' and regions' priorities at country and regional level. Community policy in the sphere of development cooperation shall be complementary to the policies pursued by the Member States.

6. The Commission and the Member States shall seek regular and frequent exchanges of information, including with other donors, and promote better donor coordination and complementarity by working towards joint multiannual programming, based on partner countries' poverty reduction or equivalent strategies and partner countries' own budget processes, by common implementation mechanisms including shared analysis, by joint donor-wide missions and by the use of co-financing arrangements.

7. Within their respective spheres of competence, the Community and the Member States shall promote a multilateral approach to global challenges and foster cooperation with multilateral and regional organisations and bodies such as international financial institutions, UN agencies, funds and programmes, and other bilateral donors.

8. The Community shall promote effective cooperation with partner countries and regions in line with international best practice. It shall promote:

(a) a development process that is partner country led and owned. The Community shall increasingly align its support with partners' national development strategies, reform policies and procedures. The Community shall contribute to strengthening the process of mutual accountability between partner governments and donors and promote local expertise and local employment;

(b) inclusive and participatory approaches to development and a broad involvement of all segments of society in the development process and in national dialogue, including political dialogue;

(c) effective cooperation modalities and instruments as set out in Article 25 in line with OECD/DAC best practices, adapted to the particular circumstances of each partner country or region, with a focus on programme-based approaches, delivery of predictable aid funding, the development and use of country systems and on results-based approaches to development including, where appropriate, MDG targets and indicators;

(d) improved impact of policies and programming through coordination and harmonisation between donors to reduce overlap and duplication, to improve complementarity and to support donor-wide initiatives. Coordination shall take place in partner countries and regions using agreed guidelines and best practice principles on coordination and aid effectiveness;

(e) an MDG profile in Country Strategy Papers and in its multi-annual programming.

9. The Commission shall inform and have regular exchanges of views with the European Parliament.

10. The Commission shall seek regular exchanges of information with civil society.

TITLE II

GEOGRAPHIC AND THEMATIC PROGRAMMES

Article 4

Implementation of Community assistance

Consistently with the overall purpose and scope, objectives and general principles of this Regulation, Community assistance shall be implemented through geographic and thematic programmes set out in Articles 5 to 16 and the programme set out in Article 17.

Article 5

Geographic programmes

1. A geographic programme shall encompass cooperation in appropriate areas of activity with partner countries and regions determined on a geographical basis.

2. Consistently with the overall purpose and scope, objectives and general principles of this Regulation, Community assistance to the countries of Latin America, Asia, Central Asia, and the Middle East as set out in Annex I, as well as South Africa, shall include actions within the following areas of cooperation:

(a) supporting the implementation of policies aimed at poverty eradication and at the achievement of the MDGs;

Human development:

(b) addressing the essential needs of the population with prime attention to primary education and health, in particular by:

Health:

(i) increasing access to and provision of health services for lower income population groups and marginalised groups, including women and children, persons belonging to groups subject to ethnic, religious or any other discrimination and persons with disabilities, with a central focus on the related MDGs, namely reducing child mortality, improving maternal and child health and sexual and reproductive health and rights as set out in the Cairo Agenda of the International Conference on Population and Development (ICPD), addressing poverty diseases, in particular HIV/AIDS, tuberculosis and malaria;

(ii) strengthening health systems in order to prevent human resource crises in the health sector;

(iii) enhancing capacities particularly in areas such as public health and research and development;

Education:

(iv) giving priority in primary education to achieving quality primary education followed by vocational training and to reduce inequalities in terms of access to education; promoting compulsory and free education up to the age of 15 to combat all forms of child labour;

(v) aiming at achieving universal primary education by 2015, and at eliminating gender disparity in education;

(vi) promoting vocational training, higher education, lifelong learning, cultural, scientific and technological cooperation, academic and cultural exchanges as well as enhancing mutual understanding between partner countries and regions and the Community;

Social cohesion and employment:

(c) promoting social cohesion as a priority policy of the relations between the Community and partner countries, with a focus on decent work and social and fiscal policies, thereby fighting against poverty, inequality, unemployment and exclusion of vulnerable and marginalised groups;

(d) combating all forms of group-based discrimination and promoting and protecting gender equality, indigenous peoples' rights and the rights of the child, including supporting implementation of the UN Convention on the Rights of the Child, and actions to address the problems faced by street children and children undertaking forms of labour that are hazardous and/or hinder full-time education;

(e) strengthening the institutional framework to promote and facilitate the creation of small and medium sized enterprises with a view to stimulating job creation;

Governance, democracy, human rights and support for institutional reforms:

(f) promoting and protecting fundamental freedoms and human rights, strengthening democracy, the rule of law, access to justice and good governance including actions to combat corruption, which may include, but are not limited to, capacity building and strengthening the institutional and legislative framework, particularly in the areas of national administration, design and implementation of policies and management of public finances and national resources in a transparent way;

(g) supporting an active civil society, including civil society organisations representing people living in poverty, as well as promoting civic dialogue, participation and reconciliation, and institution-building;

(h) fostering cooperation and policy reform in the fields of security and justice, especially as regards asylum and migration, the fight against drugs and other trafficking including trafficking in human beings, corruption and money laundering;

(i) fostering cooperation and policy reform in the field of migration and asylum with partner countries and promoting capacity building initiatives to ensure the formulation and implementation of pro-development migration policies to address the root causes of migration;

(j) supporting effective multilateralism, in particular through compliance with, and the effective implementation of, international law and multilateral agreements relevant to the field of development;

Trade and regional integration:

(k) assisting partner countries and regions on trade, investment and regional integration including technical assistance and capacity building to design and implement sound trade policies, favouring a more conducive business environment, sound economic and financial policies and private sector development, with a view to partner countries and regions benefiting from their integration into the world economy and to supporting social justice and pro-poor growth;

(l) supporting accession to the World Trade Organization (WTO) and implementation of WTO agreements by technical assistance and capacity building, in particular the implementation of the Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement), notably in the area of public health;

(m) supporting economic and trade cooperation and strengthening investment relations between the Community and partner countries and regions, including by actions to promote and ensure that private actors, including local and European businesses, contribute to socially responsible and sustainable economic development, including respect for the core labour standards of the International Labour Organization (ILO) and by actions to promote local capacity building;

Environment and sustainable development of natural resources:

(n) promoting sustainable development through environmental protection and sustainable management of natural resources, including protection of biodiversity, and of forests, including activities for the conservation and sustainable management of forests with active participation of local communities and forest-dependent peoples;

(o) supporting improvements in the urban environment;

(p) promoting sustainable patterns of production and consumption and the safe and sustainable management of chemicals and waste, taking into account their impacts on health;

(q) ensuring respect for and supporting the implementation of international environment agreements such as the Convention on Biological Diversity, the UN Convention to Combat Desertification and the UN Framework Convention on Climate Change in line with the EU Action Plan on Climate Change, and their protocols and any subsequent modifications;

(r) developing capacities for emergency preparedness and prevention of natural disasters;

Water and energy:

(s) supporting sustainable integrated water resource management, with particular emphasis on universal access to safe drinking water and sanitation in line with the MDGs and sustainable and efficient use of water resources, including for agricultural and industrial purposes;

(t) fostering greater use of sustainable energy technologies;

Infrastructure, communication and transport:

(u) contributing to the development of economic infrastructure, including support to regional integration, and promoting the increased use of information and communication technologies;

Rural development, territorial planning, agriculture and food security:

(v) supporting sustainable rural development, including decentralisation and empowerment, particularly with a view to ensuring food security;

Post-crisis situations and fragile States:

(w) reconstructing and rehabilitating, in the medium- and long-term, regions and countries affected by conflict, man-made and natural disasters, including support for mine-action, demobilisation and reintegration actions, while ensuring the continuum between relief, rehabilitation and development in accordance with Article 2(6), bearing in mind the competences of the Community and its Member States;

(x) carrying out medium- and long-term activities aimed at the self-sufficiency and integration or reintegration of uprooted people, ensuring that an integrated and consistent approach between humanitarian aid, rehabilitation, aid to uprooted people and development cooperation is pursued. Community action shall facilitate the move from the emergency stage to that of development, encouraging the socio-economic integration or reintegration of the people affected, and encourage the establishment or strengthening of democratic structures and the role of the population in the development process;

(y) in fragile or failing States, supporting the delivery of basic services and building of legitimate, effective and resilient public institutions;

(z) addressing development challenges common to the Community and its partners, in particular support to sectoral dialogues, to the implementation of bilateral agreements and to any other area of action consistent with the scope of this Regulation.

Article 6

Latin America

Community assistance to Latin America shall support actions consistent with Article 5 and with the overall purpose and scope, objectives and general principles of this Regulation. Additional attention shall be paid to the following areas of cooperation, reflecting the specific situation in Latin America:

(a) promoting social cohesion as a shared goal and priority policy of Community-Latin America relations thereby fighting against poverty, inequality and exclusion. Particular attention shall be paid to social welfare and tax policies, productive investment for more and better jobs, policies to combat discrimination and production, consumption and trafficking of drugs, and improvements in basic social services, in particular health and education;

(b) encouraging greater regional integration, including the support to different processes of regional integration and to the interconnection of network infrastructures, while ensuring complementarity with activities supported by European Investment Bank (EIB) and other institutions;

(c) supporting the reinforcement of good governance and public institutions, and of the protection of human rights, including the rights of the child and indigenous peoples' rights;

(d) supporting the creation of a common EU-Latin American higher education area;

(e) promoting sustainable development in all its dimensions, with particular attention to the protection of forests and biodiversity.

Article 7

Asia

Community assistance to Asia shall support actions consistent with Article 5 and with the overall purpose and scope, objectives and general principles of this Regulation. Additional attention shall be paid to the following areas of cooperation, reflecting the specific situation in Asia:

(a) pursuing MDGs in the field of health, including HIV/AIDS, and education, *inter alia*, through policy dialogue for sectoral reform;

(b) addressing governance issues in particular in fragile States so as to help build legitimate, effective and resilient public institutions and an active and organised civil society, and to enhance the protection of human rights, including the rights of the child;

(c) encouraging greater regional integration and cooperation through support to different processes of regional integration and dialogue;

(d) contributing to the control of epidemics and zoonoses as well as to the rehabilitation of the affected sectors;

(e) promoting sustainable development in all its dimensions, with particular attention to the protection of forests and biodiversity;

(f) fighting against production, consumption and trafficking of drugs and against other trafficking.

Article 8

Central Asia

Community assistance to Central Asia shall support actions consistent with Article 5 and with the overall purpose and scope, objectives and general principles of this Regulation. Additional attention shall be paid to the following areas of cooperation, reflecting the specific situation in Central Asia:

(a) promoting constitutional reforms and legislative, administrative and regulatory approximation with the Community, including strengthening of national institutions and bodies responsible for the effective implementation of policies in areas covered in the Partnership and Cooperation Agreements, such as election bodies, parliaments, public administration reform and public financial management;

(b) promoting the development of a market economy and partner countries' integration into the WTO, while addressing the social aspects of the transition;

(c) supporting efficient border management and cross-border cooperation to promote sustainable economic, social and environmental development in border regions;

(d) fighting against production, consumption and trafficking of drugs and against other trafficking;

(e) fighting against HIV/AIDS;

(f) promoting regional cooperation, dialogue and integration, including with countries covered by Regulation (EC) No 1638/2006 and other Community instruments, in particular promoting cooperation in the environment — notably water and sanitation —, education, energy and transport sectors, including the security and safety of international energy supply and transport operations, on interconnections, the networks and their operators, renewable energy sources, energy efficiency.

Article 9

Middle East

Community assistance to the Middle East shall support actions consistent with Article 5 and with the overall purpose and scope, objectives and general principles of this Regulation. Additional attention shall be paid to the following areas of cooperation, reflecting the specific situation in the Middle East:

(a) encouraging social cohesion to ensure social equity, notably in relation to the use of domestic national resources and to ensure political equality in particular through the promotion of human rights, including gender equality;

(b) promoting economic diversification, the development of a market economy, and partner countries' integration in the WTO;

(c) promoting regional cooperation, dialogue and integration, including with countries covered by Regulation (EC) No 1638/2006 and other Community instruments via the support to integration efforts within the region, for example on the economy, energy, transportation and refugees;

(d) supporting the conclusion of international agreements and the effective implementation of international law, in particular UN resolutions and multilateral conventions;

(e) addressing governance issues in particular in fragile States so as to help build legitimate, effective and resilient public institutions and an active and organised civil society, and to enhance the protection of human rights, including the rights of the child.

Article 10

South Africa

Community assistance to South Africa shall support actions consistent with Article 5 and with the overall purpose and scope, objectives and general principles of this Regulation. Additional attention shall be paid to the following areas of cooperation, reflecting the specific situation in South Africa:

(a) supporting the consolidation of a democratic society, good governance and a State governed by the rule of law and contributing to regional and continental stability and integration;

(b) providing support to the adjustment efforts occasioned in the region by the establishment of free-trade areas under the Trade, Development and Cooperation Agreement between the Community and South Africa [1] and other regional arrangements;

(c) supporting the fight against poverty, inequality and exclusion, including by addressing the basic needs of the previously disadvantaged communities;

(d) addressing the HIV/AIDS pandemic and its impacts on the South African society.

Article 11

Thematic programmes

1. A thematic programme shall be subsidiary to programmes referred to in Articles 5 to 10 and shall encompass a specific area of activity of interest to a group of partner countries not determined by geography, or cooperation activities addressed to various regions or groups of partner countries, or an international operation that is not geographically specific.

2. Consistently with the overall purpose and scope, objectives and general principles of this Regulation, the actions undertaken through thematic programmes shall add value to and be additional to, and coherent with, actions funded under geographic programmes. The following principles shall apply to these actions:

(a) Community policy objectives cannot be achieved in an appropriate or effective manner through geographic programmes and the thematic programme is implemented by or through an intermediary organisation such as non-governmental organisations, other non-State actors, international organisations or multilateral mechanisms. This includes global initiatives supporting the MDGs, sustainable development or global public goods and actions in Member States and acceding countries by way of derogation from Article 24 as envisaged in the relevant thematic programme, and/or

(b) actions are of the following nature:

— multi-regional and/or cross-cutting actions, including pilot projects and innovatory policies;

— actions in cases where there is no agreement on the action with the partner government(s);

— actions relevant to the purpose of a specific thematic programme which respond to a Community policy priority or an international obligation or commitment of the Community;

— where appropriate, actions in cases where there is no geographic programme or it has been suspended.

Article 12

Investing in people

1. The objective of Community assistance under the thematic programme 'Investing in People' shall be to support actions in areas which directly affect people's living standards and well-being defined below and focusing on the poorest and least developed countries and the most disadvantaged sections of the population.

2. To achieve the objective referred to in paragraph 1 and consistent with Article 11, the programme shall include the following areas of activity:

(a) Good health for all:

(i) fight against poverty diseases targeting the major communicable diseases such as laid down in the European Programme for action to confront HIV/AIDS, malaria and tuberculosis, in particular:

— increase the affordability of key pharmaceuticals and diagnostics for the three diseases in accordance with the provisions of the TRIPS Agreement as clarified in the Doha Declaration on the TRIPS Agreement and Public Health;

— encourage public and private investment in research and development for new treatments, new medicines, particularly vaccines, microbicides and innovative treatments;

— support global initiatives targeting the major communicable diseases in the context of poverty reduction, including the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria;

[1] Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part (OJ L 311, 4.12.1999, p. 3.)

(ii) in line with the principles agreed at the ICPD and ICPD + 5, support actions to improve reproductive and sexual health in developing countries and to secure the right of women, men and adolescents to good reproductive and sexual health and provide financial assistance and appropriate expertise with a view to promoting a holistic approach to, and the recognition of, reproductive and sexual health and rights as defined in the ICPD Programme of Action, including safe motherhood and universal access to a comprehensive range of safe and reliable reproductive and sexual health care and services, supplies, education and information, including information on all kinds of family planning methods, including:

— reducing maternal mortality and morbidity rates, with particular reference to the countries and populations where these are highest;

(iii) improve equitable access to health providers, commodities and health services by supporting:

— interventions to address the human resources crisis in health;

— health information systems with the ability to generate, measure and analyse disaggregated performance data to ensure better health and development outcomes and sustainability of delivery systems;

— improved vaccination and immunisation coverage and promotion of the availability of, and access to, existing or new vaccines;

— fair mechanisms for financing equitable access to health care.

(iv) keeping a balanced approach between prevention, treatment and care, with prevention as a key priority, acknowledging that its effectiveness is increased when linked with treatment and care.

(b) Education, knowledge and skills:

(i) special attention to actions taken in the context of the MDGs to achieve universal primary education by 2015 and the Dakar Framework for Action on Education for All;

(ii) basic, secondary and higher education as well as vocational education and training to improve access to education for all children and, increasingly, for women and men of all ages, with a view to increasing knowledge, skills and employability on the job market, contributing to active citizenship and individual fulfilment on a life-long basis;

(iii) the promotion of high quality basic education, with particular focus on access for girls, children in conflict-affected areas and children from marginalised and more vulnerable social groups to education programmes; the promotion of compulsory and free education up to the age of 15 to combat all forms of child labour;

(iv) developing ways to measure learning outcomes in order to better assess the quality of education, especially in literacy, numeracy and essential life skills;

(v) promoting donor harmonisation and alignment to promote universal, compulsory, free and high quality education through international or multi-country initiatives;

(vi) supporting an inclusive knowledge-based society and contributing to bridging the digital divide, knowledge and information gaps;

(vii) improving knowledge and innovation through science and technology as well as development of, and access to, electronic communication networks in order to improve socio-economic growth and sustainable development in conjunction with the international dimension of EU research policy.

(c) Gender equality:

(i) the promotion of gender equality and women's rights, implementing global commitments as detailed in the Beijing Declaration and Platform for Action and the UN Convention on the Elimination of All Forms of Discrimination Against Women, activities include:

— supporting programmes that contribute to achieving the objectives of the Beijing Platform for Action with a special emphasis on gender equality in governance and political and social representation and other actions to empower women;

— strengthening institutional and operational capacities of key stakeholders, civil society organisations, women's organisations and networks, in their endeavours to promote gender equality and economic and social empowerment, including north-south and south-south networking and advocacy;

— including a gender perspective in monitoring and statistical capacity building, by supporting the development and dissemination of data and indicators disaggregated by sex, as well as gender equality data and indicators;

— reducing the adult illiteracy rate, with particular emphasis on female literacy;

— actions against violence against women.

(d) Other aspects of human and social development:

(i) Culture:

— promotion of inter-cultural dialogue, cultural diversity and respect for the equal dignity of all cultures;

— promotion of international cooperation to stimulate the contribution of cultural industries to economic growth in developing countries to fully exploit its potential for fighting poverty, including addressing issues such as market access and intellectual property rights;

— promotion of respect for the social, cultural and spiritual values of indigenous peoples and minorities to enhance equality and justice in multi-ethnic societies in compliance with universal human rights to which everyone is entitled, including indigenous peoples and persons belonging to minorities;

— supporting culture as a promising economic sector for development and growth.

(ii) Employment and social cohesion:

— promotion of an integrated social and economic approach including promotion of productive employment, decent work for all, social cohesion, development of human resources, equity, social security and mapping employment issues and enhancing the quality of jobs in the informal sector and empowering labour associations, in accordance with the principles of the related ILO Conventions and the Community's international commitments in these areas;

— promotion of the 'decent work for all' agenda as a universal objective, including through global and other multi-country initiatives to implement internationally agreed ILO core labour standards, assessment of trade impact on decent work, sustained and adequate mechanisms for fair financing, effective functioning — and wider coverage — of social protection systems;

— support for initiatives to promote the improvement of working conditions as well as the adjustment to trade liberalisation, including an employment dimension in development policies, to help spread European social values;

— help to promote the positive social dimension of globalisation and the EU's experience.

(iii) Youth and children:

— combating all forms of child labour, trafficking of and violence against children and promotion of policies taking into consideration youth's and children's particular vulnerability and potentials, protection of their rights and interests, education, health and livelihoods, starting with participation and empowerment;

— enhancing developing countries' attention and capacity to develop policies benefiting youth and children;

— advocacy for concrete strategies and interventions to address particular problems and challenges affecting youth and children taking their best interests into account in all relevant action. Participation by children and youth should be ensured;

— using the Community's position as the principal donor of ODA among international institutions to urge the multilateral donors to exert pressure for the framing of policies to eliminate the worst forms of child labour, particularly the hazardous ones with a view to promoting the effective elimination of all forms of child labour, combating trafficking of, and violence against, children and promoting the role of children and youth as actors for development.

Article 13

Environment and sustainable management of natural resources including energy

1. The objective of the thematic programme on environment and sustainable management of natural resources, including water, and energy, shall be to integrate environmental protection requirements into the Community's development and other external policies as well as to help promote the Community's environmental and energy policies abroad in the common interest of the Community and partner countries and regions.

2. To achieve the objective referred to in paragraph 1 and consistent with Article 11, the programme shall include the following areas of activity:

(a) working upstream in assisting developing countries to achieve the MDG on environmental sustainability through capacity building for environmental integration in developing countries, supporting civil society actors, local authorities and consultative platforms, environmental monitoring and assessment, developing innovative approaches and twinning to share experience and reinforce cooperation in these areas with key countries;

(b) promoting implementation of Community initiatives and agreed commitments at international and regional level and/or of a transboundary character through support for sustainable development including activities to address current and future climate change issues, biodiversity, desertification, forests, land degradation fisheries and marine resources, compliance with environmental standards (for products and production processes), sound chemicals and wastes management, fight against pollution, sustainable production and consumption and environment-related migration. This also includes efforts to promote good forest governance and combat illegal logging, particularly through FLEGT, and innovative activities for the conservation and sustainable management of forests with active participation of local communities and forest dependent peoples.

With regard to water, the thematic programme will aim at establishing a framework for long term protection of water resources and promoting sustainable water use through support for policy coordination;

(c) better integration of environmental objectives through support for methodological work, enhancing environmental expertise available for policy work, integration and innovative actions of the Community and promoting coherence;

(d) strengthening environmental governance and supporting international policy development by working for coherence between the environmental and the other pillars of international governance for sustainable development and by assisting regional and international environmental monitoring and assessment, providing additional support to the Secretariats of multilateral environmental agreements, promoting effective compliance and enforcement measures for multilateral environmental agreements including through capacity building, supporting international organisations and processes, supporting civil society and policy think tanks, and improving the efficiency of international negotiations;

(e) supporting sustainable energy options in partner countries and regions, through integration of sustainable energy in development plans and strategies, developing institutional support and technical assistance, creating a favourable legislative and policy framework to attract new business and investors in renewable energy, enhancing the role of energy as a means to create income generation for the poor, promoting innovative financing approaches, and encouraging regional cooperation between governments, non-governmental organisations and the private sector in the above areas. The Community's strategic actions will give particular encouragement to the use of renewable energy sources, increased energy efficiency, and the development of appropriate energy regulatory frameworks in the countries and regions concerned and the replacement of especially damaging energy sources by others which are less so.

Article 14

Non-State actors and local authorities in development

1. The objective of the thematic programme on non-State actors and local authorities in development shall be to co-finance initiatives proposed and/or carried out by civil society organisations and local authorities originating from the Community and partner countries in the area of development. At least 85 % of the funding foreseen under this thematic programme shall be allocated to non-State actors. The programme shall be implemented in consistency with the objective of this Regulation and to strengthen the capacity of non-State actors and local authorities in the policy making process, so as to:

(a) promote an inclusive and empowered society in order to:

(i) benefit populations out of reach of mainstream services and resources and excluded from policy making processes;

(ii) strengthen the capacity of civil society organisations and local authorities in partner countries, with a view to facilitating their participation in defining and implementing poverty reduction and sustainable development strategies;

(iii) facilitate interaction between State and non-State actors in different contexts and support an increased role for local authorities in decentralisation processes;

(b) increase the level of awareness of the European citizen regarding development issues and mobilise active public support in the Community and acceding countries for poverty reduction and sustainable development strategies in partner countries, for fairer relations between developed and developing countries, and reinforce civil society and local authority roles for these purposes;

(c) achieve more efficient cooperation, foster synergies and facilitate a structured dialogue between civil society networks and local authorities' associations, within their organisations and with Community institutions.

2. To achieve the objective referred to in paragraph 1 and consistent with Article 11, the programme shall include the following areas of activity:

(a) interventions in developing countries and regions which:

(i) strengthen participatory development and processes and inclusion of all actors, especially vulnerable and marginalised groups;

(ii) support capacity development processes of the actors concerned at country, regional or local level;

(iii) promote mutual understanding processes;

(iv) facilitate citizens' active engagement in development processes and at strengthening their capacity to take action;

(b) raising public awareness of development issues and promoting education for development in the Community and in acceding countries, to anchor development policy in European societies, to mobilise greater public support in the Community and acceding countries for action against poverty and for fairer relations between developed and developing countries, to raise awareness in the Community of the issues and difficulties facing developing countries and their peoples, and to promote the social dimension of globalisation;

(c) coordination and communication between civil society and local authority networks, within their organisations and between different types of stakeholders active in the European and global public debate on development.

3. Support to local authorities in partner countries shall normally be carried out in the framework of country strategy papers except where the latter do not provide appropriate support, particularly in situations such as difficult partnerships, fragile states and post-conflict.

Support to local authorities and their associations will take account of their contributing capacity in the calculation of Community co-financing.

Article 15

Food security

1. The objective of the thematic programme on food security shall be to improve food security in favour of the poorest and most vulnerable people and contribute to achieving the MDG on poverty and hunger, through a set of actions which ensure overall coherence, complementarity and continuity of Community interventions, including in the area of the transition from relief to development.

2. To achieve the objective referred to in paragraph 1 and consistently with Article 11, the programme shall include the following areas of activity:

(a) contributing to the provision of international public goods, in particular pro-poor demand driven research and technological innovation, as well as capacity development, scientific and technical South-South and South-North cooperation and twinning;

(b) supporting global, continental and regional programmes which notably:

(i) support food security information and early warning;

(ii) support food security in specific fields such as agriculture, including formulation of regional agricultural policies and access to land, agricultural trade and natural resource management;

(iii) promote, strengthen and complement national food security and poverty reduction strategies in the short, medium and longer-term; and

(iv) support networking of policy experts and non-State actors to foster the global food security agenda;

(c) advocating and advancing the food security agenda. The Community shall continue to address key food security issues in the international debate, and shall promote harmonisation, coherence and alignment of policies and aid delivery modes of development partners and donors. In particular, the promotion of the role of civil society in food security issues should be strengthened;

(d) addressing food insecurity in exceptional situations of transition and State fragility, playing a central role in linking relief, rehabilitation and development. The thematic programme shall:

(i) support interventions to protect, maintain and recover productive and social assets vital for food security, to facilitate economic integration and longer term rehabilitation; and

(ii) support crisis prevention and management, to address vulnerability to shocks and to strengthen people's resilience;

(e) developing innovative food security policies, strategies and approaches, and strengthening the potential for their replication and South-South dissemination. Areas for intervention may include agriculture, including land reform and land policy, sustainable management of and access to natural resources, food security in relation to rural and local development, including infrastructure, nutrition, demography and labour, migration, health and education. Consistency and complementarity with other Community programmes in these areas shall be ensured.

Article 16

Migration and asylum

1. The objective of the thematic programme on cooperation with third countries in the areas of migration and asylum shall be to support them in their efforts to ensure better management of migratory flows in all their dimensions. While the subject of the thematic programme shall be primarily migration to the Community, it shall also take account of relevant south/south migratory flows.

2. To achieve the objective referred to in paragraph 1 and consistent with Article 11, the programme shall include the following areas of activity:

(a) fostering the links between migration and development, especially by encouraging the contribution of diasporas to the development of their country of origin and increasing the value of migrants' return; mitigating brain drain and promoting the circular movement of skilled migrants; facilitating financial transfers of migrants to their country of origin; supporting voluntary return and reintegration of migrants and building capacities for migration management; fostering capacity building efforts to help countries in the formulation of pro-development migration policies and in their capacity to jointly manage migration flows;

(b) promoting well-managed labour migration, in particular by informing about legal migration and conditions of entry in and stay on the territory of the Member States of the Community; providing information on labour migration opportunities and needs in Member States and on qualifications of third country candidates for migration; supporting pre-departure training for candidates for legal migration; and encouraging the definition and implementation of legislative frameworks for migrant workers in third countries;

(c) fighting illegal immigration and facilitating the readmission of illegal immigrants, including between third countries, and in particular, fighting the smuggling of and trafficking in human beings; discouraging illegal immigration and raising awareness of the risks related to it; improving capacities in the areas of border, visa and passport management, including the security of documents and the introduction of biometric data, and detection of forged documents; implementing effectively readmission agreements concluded with the Community and obligations arising out of international agreements; and assisting third countries in the management of illegal immigration and in the coordination of their policies;

(d) protecting migrants, including the most vulnerable such as women and children against exploitation and exclusion through measures such as developing third countries' legislation in the field of migration; supporting integration and non-discrimination as well as measures to protect migrants from racism and xenophobia; preventing and fighting the smuggling of and trafficking in human beings and any form of slavery;

(e) promoting asylum and international protection, including through regional protection programmes, in particular in strengthening institutional capacities; supporting the registration of asylum applicants and refugees; promoting international standards and instruments on the protection of refugees; supporting the improvement of reception conditions and local integration, and working towards lasting solutions.

Article 17

ACP Sugar Protocol countries

1. ACP Sugar Protocol countries listed in Annex III affected by the Community sugar reform shall benefit from a programme of accompanying measures. Community assistance to these countries shall aim at supporting their adjustment process as they are faced with new conditions on the sugar market due to the reform of the common organisation of the market in sugar. Community assistance shall take into account the countries' adaptation strategies and shall pay specific attention to the following areas of cooperation:

(a) enhancing the competitiveness of the sugar and cane sector, where this is a sustainable process, taking into account the situation of the different stakeholders in the chain;

(b) promoting the economic diversification of sugar-dependent areas;

(c) addressing broader impacts generated by the adaptation process, possibly related, but not restricted, to employment and social services, land use and environmental restoration, the energy sector, research and innovation and macro-economic stability.

2. Within the amount referred to in Annex IV, the Commission shall fix the maximum amount available to each Sugar Protocol country for financing the actions referred to in paragraph 1 on the basis of the needs of each country, related in particular to the impact of the reform of the sugar sector in the country concerned and to the importance of the sugar sector to the economy. The measurement of the allocation criteria shall be based on data of campaigns preceding 2004.

Further instructions regarding the allocation of the overall amount among beneficiaries shall be defined by the Commission, acting in accordance with the procedure referred to in Article 35(2).

TITLE III

PROGRAMMING AND ALLOCATION OF FUNDS

Article 18

General framework for programming and allocating funds

1. In the case of geographic programmes, the Commission shall draw up a strategy paper and a multiannual indicative programme for each partner country or region, as provided for in Article 19, and adopt an annual action programme for each partner country or region, as provided for in Article 22.

In the case of thematic programmes, the Commission shall draw up thematic strategy papers as provided for in Article 20, and adopt action programmes as provided for in Article 22.

In exceptional circumstances, Community support may also take the form of special measures not covered in strategy papers or multiannual indicative programmes, as provided for in Article 23.

2. The Commission shall determine the multiannual indicative allocations within each geographic programme using standard, objective and transparent resource allocation criteria, based on the needs and performance of the partner country or region concerned and bearing in mind the particular difficulties faced by countries or regions in crisis, conflict or disaster prone, alongside the specificity of the different programmes.

The needs criteria include population, income per capita and the extent of poverty, income distribution and the level of social development. The performance criteria include political, economic and social progress, progress in good governance and the effective use of aid, and in particular the way a country uses scarce resources for development, beginning with its own resources.

3. The Commission may include a specific financial allocation for the purpose of strengthening cooperation between the EU's outermost regions and neighbouring partner countries and regions.

Article 19

Geographic strategy papers and multiannual indicative programmes

1. The preparation and implementation of strategy papers shall apply principles of aid effectiveness: national ownership, partnership, coordination, harmonisation, alignment to recipient country or regional systems and results orientation as laid down in Article 3(5) to (8).

2. Strategy papers shall cover no more than the period of validity of this Regulation and aim to provide a coherent framework for cooperation between the Community and the partner country or region concerned, consistent with the overall purpose and scope, objectives, principles and policy prescriptions of, and Annex IV to, this Regulation. Multiannual indicative programmes shall be based on strategy papers.

Strategy papers shall be reviewed at mid-term, or *ad hoc* if necessary, in accordance where appropriate with the principles and procedures laid down in the Partnership and Cooperation Agreements concluded with the partner countries and regions.

3. Strategy papers shall, in principle, be based on a dialogue with the partner country or region which involves civil society and regional and local authorities, so as to ensure that the country or region concerned takes sufficient ownership of the process and to encourage support for national development strategies, particularly those for reducing poverty.

4. Multiannual indicative programmes shall be drawn up on the basis of the strategy papers for each partner country or region. They shall be the subject of an agreement with the country or region where possible.

Multiannual indicative programmes shall set out the priority areas selected for Community financing, the specific objectives, the expected results and the performance indicators.

The programmes shall also set out the indicative financial allocation, both overall and per priority area; this may be given in the form of a range, where appropriate. These allocations shall be consistent with the indicative allocations set out in Annex IV.

The programmes shall be adjusted where necessary, taking into account any mid-term or ad hoc reviews of strategy papers.

A multiannual indicative allocation may be increased or decreased as a result of reviews, particularly in the light of special needs such as those of a post-crisis situation, or where performance has been exceptional or unsatisfactory.

5. In circumstances such as crises, post conflict situations or threats to democracy, the rule of law, human rights or fundamental freedoms, a special emergency procedure may be used to conduct an ad hoc review of the country's or region's cooperation strategy. Such reviews may propose a country or region strategy to make the transition to long-term cooperation and development.

6. In accordance with Article 2(6), the strategy shall ensure that measures taken under this Regulation are consistent with, and avoid duplication with, measures eligible for funding under other Community instruments, in particular Regulation (EC) No 1717/2006 and Regulation (EC) No 1257/96. Where partner countries or groups of partner countries are directly involved in, or affected by, a crisis or post-crisis situation, multiannual indicative programmes shall place special emphasis on stepping up coordination between relief, rehabilitation and development to help them make the transition from an emergency situation to the development phase; programmes for countries and regions regularly subject to natural disasters shall provide for disaster preparedness and prevention and the management of the consequences of such disasters.

7. To foster regional cooperation, the Commission may decide when adopting annual action programmes of the type referred to in Article 22, or the special measures referred to in Article 23 for cooperation measures under this Chapter, that projects or programmes of a regional or cross-border nature carried out with countries listed in Annex V are eligible, in accordance with the first subparagraph of Article 2(4). Provisions may be made for this in the strategy papers and multiannual indicative programmes, referred to in this Article, and in Article 20.

8. The Commission and the Member States shall consult each other, as well as other donors and development actors including representatives of civil society and regional and local authorities, at an early stage of the programming process in order to promote complementarity among their cooperation activities.

Article 20

Strategy papers for thematic programmes

1. Thematic strategy papers shall cover no more than the period of validity of this Regulation. They shall set out the Community's strategy for the theme concerned, the Community's priorities, the international situation and the activities of the main partners. They shall be consistent with the overall purpose and scope, objectives, principles and policy prescriptions of, and Annex IV to, this Regulation.

Thematic strategy papers shall set out the priority areas selected for financing by the Community, the specific objectives, the expected results and the performance indicators.

The thematic strategy papers shall also give the indicative financial allocation, both overall and per priority area; this may be given in the form of a range, where appropriate.

Strategy papers shall be reviewed at mid-term, or *ad hoc* if necessary.

2. The Commission and the Member States shall consult each other, as well as other donors and development actors including representatives of civil society and local authorities, at an early stage of the programming process in order to promote complementarity among their cooperation activities.

3. Resources and intervention priorities shall be laid down for participation in global initiatives.

Article 21

Adoption of strategy papers and multiannual indicative programmes

Strategy papers and multiannual indicative programmes referred to in Articles 19 and 20, and any reviews thereof referred to in Article 19(2) and Article 20(1), as well as accompanying measures referred to in Article 17, shall be adopted by the Commission in accordance with the procedure referred to in Article 35(2).

TITLE IV

IMPLEMENTATION

Article 22

Adoption of annual action programmes

1. The Commission shall adopt annual action programmes based on the strategy papers and multiannual indicative programmes referred to in Articles 19 and 20.

Exceptionally, for instance where an action programme has not yet been adopted, the Commission may, on the basis of the strategy papers and multiannual indicative programmes referred to in Articles 19 and 20, adopt measures not provided for in an annual action programme under the same rules and procedures as for action programmes.

2. Annual action programmes shall specify the objectives pursued, the fields of intervention, the expected results, the management procedures and total amount of financing planned. They shall contain a description of the operations to be financed, an indication of the amounts allocated for each operation and an indicative implementation timetable. Objectives shall be measurable and have time bound benchmarks.

3. The annual action programmes shall be adopted by the Commission in accordance with the procedure referred to in Article 35(2).

4. Appropriate environmental screening shall be undertaken at project level including environmental impact assessment (EIA) for environmentally sensitive projects, in particular for major new infrastructure. Where relevant, strategic environmental assessments (SEA) shall be used in the implementation of sectoral programmes. The involvement of interested stakeholders in environmental assessments and public access to the results shall be ensured.

Article 23

Adoption of special measures not provided for in the strategy papers or multiannual indicative programmes

1. In the event of unforeseen and duly justified needs or circumstances related to natural disasters, civil strife or crises, and which cannot be funded under Regulation (EC) No 1717/2006 or Regulation (EC) No 1257/96, the Commission shall adopt special measures not provided for in the strategy papers or multiannual indicative programmes (hereinafter referred to as 'special measures').

Special measures may also be used to fund measures to ease the transition from emergency aid to long-term development operations, including those to better prepare people to deal with recurring crises.

2. Special measures shall specify the objectives pursued, the intervention areas, the expected results, the management procedures and the total amount of financing. They shall contain a description of the operations to be financed, an indication of the amounts allocated for each operation and the indicative timetable for their implementation. They shall include a definition of the type of performance indicators that will have to be monitored when implementing the special measures.

3. Where the cost of such measures exceeds EUR 10 million, the Commission shall adopt them under the management procedure referred to in Article 35(2). For special measures below EUR 10 million, the Commission shall send the measures to the Member States and the European Parliament for information within one month of adopting its decision.

4. The procedure referred to in Article 35(2) need not be used for amendments to special measures, such as those making technical adjustments, extending the implementation period, reassigning funds within the forecast budget, or increasing or reducing the size of the budget by less than 20 % of the initial budget, provided these amendments do not affect the initial objectives set out in the Commission decision. Any such technical adjustments shall be communicated within one month to the European Parliament and to the Member States.

Article 24

Eligibility

1. Without prejudice to Article 31, the following, *inter alia*, shall be eligible for funding under this Regulation for the purposes of implementing the annual action programmes referred to in Article 22 or the special measures referred to in Article 23:

(a) partner countries and regions, and their institutions;

(b) decentralised bodies in the partner countries, such as municipalities, provinces, departments and regions;

(c) joint bodies set up by the partner countries and regions with the Community;

(d) international organisations, including regional organisations, UN bodies, departments and missions, international and regional financial institutions and development banks, in so far as they contribute to the objectives of this Regulation;

(e) Community institutions and bodies, but only for the purposes of implementing the support measures referred to in Article 26;

(f) EU agencies;

(g) the following entities and bodies of the Member States, partner countries and regions and any other third country complying with the rules on access to the Community's external assistance set out in Article 31, insofar as they help to achieve the objectives of this Regulation:

(i) public or para-Statal bodies, local authorities and consortia or representative associations thereof;

(ii) companies, firms and other private organisations and businesses;

(iii) financial institutions that grant, promote and finance private investment in partner countries and regions;

(iv) non-State actors as defined in paragraph 2;

(v) natural persons.

2. The non-State, non-profit making actors eligible for financial support under this Regulation operating on an independent and accountable basis include: non governmental organisations, organisations representing indigenous peoples, organisations representing national and/or ethnic minorities, local traders' associations and citizens' groups, cooperatives, trade unions, organisations representing economic and social interests, organisations fighting corruption and fraud and promoting good governance, civil rights organisations and organisations combating discrimination, local organisations (including networks) involved in decentralised regional cooperation and integration, consumer organisations, women's and youth organisations, teaching, cultural, research and scientific organisations, universities, churches and religious associations and communities, the media and any non governmental associations and independent foundations, including independent political foundations, likely to contribute to the implementation of the objectives of this Regulation.

Article 25

Types of financing

1. Community financing may take the following forms:

(a) projects and programmes;

(b) budget support if the partner country's management of public spending is sufficiently transparent, reliable and effective, and where it has put in place properly formulated sectoral or macroeconomic policies positively assessed by its principal donors; including, where relevant, the international financial institutions. The Commission shall consistently use an approach based on results and performance indicators and shall clearly define and monitor its conditionality and support efforts of partner countries to develop parliamentary control and audit capacities and to increase transparency and public access to information. Disbursement of budgetary support shall be conditional on satisfactory progress towards achieving the objectives in terms of impact and results;

(c) sectoral support;

(d) in exceptional cases, sectoral and general import programmes, which may take the form of:

(i) sectoral import programmes in kind;

(ii) sectoral import programmes providing foreign exchange to finance imports for the sector in question; or

(iii) general import programmes providing foreign exchange to finance general imports of a wide range of products;

(e) funds made available to the EIB or other financial intermediaries on the basis of Commission programmes for the purpose of providing loans (in particular to support investment in and development of the private sector), risk capital (in the form of subordinated or conditional loans) or other temporary minority holdings in business capital, and contributions to guarantee funds in accordance with Article 32, to the extent that the financial risk of the Community is limited to these funds;

(f) interest-rate subsidies, especially for environment related loans;

(g) debt-relief, under internationally agreed debt relief programmes;

(h) grants to finance projects submitted by entities of the type listed in Article 24(1)(b), (c), (d), (f) and (g)(i) to (v);

(i) grants to finance the operating costs of entities of the type listed in Article 24(1)(b), (c), (d), (f) and (g)(i), (iii) and (iv);

(j) funding for twinning programmes between public institutions, local authorities, national public bodies or private-law entities entrusted with public service tasks of a Member State and those of a partner country or region;

(k) contributions to international funds, such as those managed by international or regional organisations;

(l) contributions to national funds set up by partner countries and regions to attract joint financing from a number of donors, or contributions to funds set up by one or more donors for the purpose of the joint implementation of projects;

(m) capital investments in international financial institutions and regional development banks;

(n) human and material resources required for effective administration and supervision of projects and programmes by partner countries and regions.

2. Community assistance shall not be used for paying taxes, duties or charges in beneficiary countries.

Article 26

Support measures

1. Community financing may cover expenditure associated with the preparation, follow up, monitoring, audit and evaluation activities directly necessary for the implementation of this Regulation and the achievement of its objectives, e.g. studies, meetings, information, awareness-raising, training and publication activities, expenditure associated with computer networks for the exchange of information, and any other administrative or technical assistance expenditure necessary for the management of the programme. It shall also cover expenditure at Commission delegations on the administrative support needed to manage operations financed under this Regulation.

2. These support measures are not necessarily covered by multiannual indicative programmes and may therefore be financed outside the scope of strategy papers and multiannual indicative programmes. However, they may also be financed under multiannual indicative programmes.

The Commission shall adopt support measures not covered by the multiannual indicative programmes in accordance with Article 23(3) and (4).

Article 27

Co-financing

1. Measures shall be eligible for co-financing from the following, *inter alia*:

(a) Member States and their regional and local authorities, and in particular their public and para-Statal agencies;

(b) other donor countries, and in particular their public and para-Statal agencies;

(c) international organisations, including regional organisations, and in particular international and regional financial institutions;

(d) companies, firms, other private organisations and businesses, and other non-State actors;

(e) partner countries and regions in receipt of funding.

2. In the case of parallel co-financing, the project or programme is split into a number of clearly identifiable components, which are each financed by the different partners providing co-financing in such a way that the end-use of the financing can always be identified.

In the case of joint co-financing, the total cost of a project or programme is shared between the partners providing the co-financing and the resources are pooled in such a way that it is no longer possible to identify the source of financing for any given activity undertaken as part of the project or programme.

3. In the case of joint co-financing, the Commission may receive and manage funds on behalf of the bodies referred to in paragraph 1(a), (b) and (c) for the purpose of implementing joint measures. Such funds shall be treated as assigned revenue, in accordance with Article 18 of Regulation (EC, Euratom) No 1605/2002.

Article 28

Management procedures

1. The measures financed under this Regulation shall be implemented in accordance with Regulation (EC, Euratom) No 1605/2002 and any revision thereof.

2. In the event of co-financing and in other duly justified cases, the Commission may entrust tasks of public authority, and in particular budget implementation tasks, to the bodies referred to in Article 54(2)(c) of Regulation (EC, Euratom) No 1605/2002.

3. In the case of decentralised management, the Commission may decide to use the procurement or grant procedures of the beneficiary partner country or region after verifying that they respect the relevant criteria of Regulation (EC, Euratom) No 1605/2002, provided that:

— the procedures of the beneficiary partner country or region satisfy the principles of transparency, proportionality, equal treatment and non-discrimination and prevent any conflict of interests,

— the beneficiary partner country or region undertakes to check regularly that the operations financed by the General Budget of the European Union have been properly implemented, to take appropriate measures to prevent irregularities and fraud, and, if necessary, to take legal action to recover unduly paid funds.

Article 29

Budget commitments

1. Budget commitments shall be made on the basis of decisions taken by the Commission in accordance with Articles 22 (1), 23(1) and 26(1).

2. Community financing may take one of the following legal forms, *inter alia*:

— financing agreements,

— grant agreements,

— procurement contracts,

— employment contracts.

Article 30

Protecting the Community's financial interests

1. Any agreements resulting from this Regulation shall contain provisions ensuring the protection of the Community's financial interests, in particular with respect to irregularities, fraud, corruption and any other illegal activity, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests ([1]), Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities ([2]) and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Antifraud Office (OLAF) ([3]).

2. Agreements shall expressly entitle the Commission and the Court of Auditors to perform audits, including document audits or on the spot audits of any contractor or subcontractor who has received Community funds. They shall also expressly authorise the Commission to carry out on-the-spot checks and inspections as provided for in Regulation (Euratom, EC) No 2185/96.

3. All contracts resulting from the implementation of assistance shall ensure the rights of the Commission and the Court of Auditors under paragraph 2 during and after the performance of the contracts.

([1]) OJ L 312, 23.12.1995, p. 1.
([2]) OJ L 292, 15.11.1996, p. 2.
([3]) OJ L 136, 31.5.1999, p. 1.

Article 31

Public procurement procedures, grant award procedures, rules of origin

1. Participation in the award of procurement or grant contracts financed under this Regulation shall be open to all natural persons who are nationals of, or legal persons who are established in, a Member State of the Community, in an official candidate country as recognised by the European Community or in a Member State of the European Economic Area.

Participation in the award of procurement or grant contracts financed under a geographic programme as defined in Articles 5 to 10 shall be open to all natural persons who are nationals of, or legal persons who are established in, any developing country eligible by virtue of Annex I.

Participation in the award of procurement or grant contracts financed under a thematic programme as defined in Articles 11 to 16, and the programme set out in Article 17, shall be open to all natural persons who are nationals of, or legal persons who are established in, a developing country, as specified by the OECD/DAC and in Annex II, in addition to natural or legal persons eligible by virtue of the thematic programme or the programme set out in Article 17. The Commission shall publish and update Annex II in accordance with regular reviews of the list of aid recipients of the OECD/DAC, and inform the Council thereof.

2. Participation in the award of procurement or grant contracts financed under this Regulation shall also be open to all natural persons who are nationals of or legal persons who are established in any country other than those referred in paragraph 1, where reciprocal access to their external assistance has been established.

Reciprocal access shall be granted whenever a country grants eligibility on equal terms to the Member States and to the recipient country concerned.

Reciprocal access shall be established by means of a specific decision concerning a given country or a given regional group of countries. Such a decision shall be adopted in accordance with the procedure referred to in Article 35(2) and shall be in force for a minimum period of one year.

The granting of reciprocal access shall be based on a comparison between the Community and other donors and shall proceed at sectoral level, as defined by the OECD/DAC categories, or at country level, whether it be a donor or a recipient country. The decision to grant such reciprocity to a donor country shall be based on the transparency, consistency and proportionality of the aid provided by that donor, including its qualitative and quantitative nature. The recipient countries shall be consulted as part of the procedure described in this paragraph.

Reciprocal access in the least developed countries as defined by the OECD/DAC shall be automatically granted to OECD/DAC members.

3. Participation in the award of procurement or grant contracts financed under a Community instrument shall be open to international organisations.

4. The above is without prejudice to the participation of categories of eligible organisations by nature or by localisation in regard to the objectives of the action to carry out.

5. Experts may be of any nationality, without prejudice to the qualitative and financial requirements set out in the Community's procurement rules.

6. All supplies and materials purchased under a contract financed under this Regulation shall originate from the Community or from an eligible country as defined in paragraph 1 and 2. The term 'origin' for the purpose of this Regulation is defined in the relevant Community legislation on rules of origin for customs purposes.

7. The Commission may, in duly substantiated cases, authorise the participation of natural and legal persons from countries having traditional economic, trade or geographical links with neighbouring countries or other third countries, and the use of supplies and materials of different origin.

8. The Commission may, in duly substantiated exceptional cases, authorise the participation of natural persons who are nationals of or legal persons who are established in other countries than those referred to in paragraph 1 and 2, or the purchase of supplies and materials of different origins from that set out in paragraph 6.

Derogations may be justified on the basis of the unavailability of products and services in the markets of the countries concerned, for reasons of extreme urgency, or if the eligibility rules would make the realisation of a project, a programme or an action impossible or exceedingly difficult.

9. Whenever Community funding covers an operation implemented through an international organisation, participation in the appropriate contractual procedures shall be open to all natural or legal persons who are eligible pursuant to paragraph 1 and 2 as well as to all natural or legal persons who are eligible pursuant to the rules of that organisation, care being taken to ensure that equal treatment is afforded to all donors. The same rules shall apply in respect of supplies, materials and experts.

Whenever Community funding covers an operation co-financed with a third country, subject to reciprocity as defined in paragraph 2, or with a regional organisation, or with a Member State, participation in the appropriate contractual procedures shall be open to all natural or legal persons who are eligible pursuant to paragraph 1, 2 and 3 as well as to all natural or legal persons who are eligible under the rules of such third country, regional organisation or Member State. The same rules shall apply in respect of supplies, materials and experts.

10. For the purposes of aid channelled directly through non-State actors under the thematic programme defined in Article 14, the provisions of paragraph 1 shall not apply to the eligibility criteria established for the selection of grant beneficiaries.

Beneficiaries of these grants shall abide by the rules established in this Article where the implementation of aid requires the award of procurement contracts.

11. In order to accelerate the eradication of poverty through the promotion of local capacities, markets and purchases, special consideration shall be given to local and regional procurement in partner countries.

Tenderers who have been awarded contracts shall respect internationally agreed core labour standards, e.g. the ILO core labour standards, conventions on freedom of association and collective bargaining, elimination of forced and compulsory labour, elimination of discrimination in respect of employment and occupation, and the abolition of child labour.

Access by developing countries to Community assistance shall be rendered possible by all such technical assistance as is deemed appropriate.

Article 32

Funds made available to the European Investment Bank or other financial intermediaries

1. The funds referred to in Article 25(1)(e) shall be managed by the EIB, other financial intermediaries or any other bank or organisation with the capacity to manage such funds.

2. The Commission shall adopt implementing provisions for paragraph 1 on a case-by-case basis to cover risk sharing, the remuneration of the intermediary responsible for implementation, the use and recovery of profits on funds, and the closure of the operation.

Article 33

Evaluation

1. The Commission shall regularly monitor and review its programmes, and evaluate the results of the implementation of geographical and thematic policies and programmes, and of sectoral policies and the effectiveness of programming, where appropriate by means of independent external evaluations, in order to ascertain whether the objectives have been met and enable it to formulate recommendations with a view to improving future operations. Proposals by the European Parliament or the Council for independent external evaluations will be taken into due account. Particular attention shall be given to social sectors and to progress made towards achieving the MDGs.

2. The Commission shall send its evaluation reports to the European Parliament and to the Committee referred to in Article 35 for information. Member States may request to discuss specific evaluations in the Committee referred to in Article 35(3). The results shall feed back into programme design and resource allocation.

3. The Commission shall associate all relevant stakeholders, including non-State actors and local authorities, in the evaluation phase of the Community assistance provided under this Regulation.

TITLE V

FINAL PROVISIONS

Article 34

Annual report

1. The Commission shall examine the progress made in implementing the measures taken under this Regulation and shall submit to the European Parliament and the Council an annual report on the implementation and the results and, as far as possible, on the main outcomes and impacts of the assistance. This report shall also be submitted to the European Economic and Social Committee and to the Committee of the Regions.

2. The annual report shall contain information relating to the previous year on the measures financed, the results of monitoring and evaluation exercises, the involvement of the relevant partners, and the implementation of budget commitments and payments, broken down by country, region and cooperation sector. It shall assess the results of the assistance, using as far as possible, specific and measurable indicators of its role in meeting the objectives of this Regulation. Particular attention shall be given to social sectors and to progress made towards achieving the MDGs.

Article 35

Committee

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 4(3) of the Decision shall be set at 30 days.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The committee shall adopt its rules of procedure.

5. An observer from the EIB shall take part in the committee's proceedings, with regard to questions concerning the Bank.

Article 36

Participation by a third country not eligible under this Regulation

Without prejudice to Article 3(5), to ensure the coherence and effectiveness of Community assistance, the Commission may decide when adopting action programmes referred to in Article 22 or the special measures referred to in Article 23 that countries, territories and regions eligible for Community assistance under Regulation (EC) No 1085/2006 or Regulation (EC) No 1638/2006 and the EDF are eligible for measures under this Regulation where the geographic or thematic project or programme to be implemented is of a global, regional or cross border nature. Provision may be made for this method of financing in the strategy papers and multiannual indicative programmes referred to in Articles 19 and 20. The provisions of Article 10 concerning eligibility and the provisions of Article 31 concerning participation in public procurement and grant award procedures and rules of origin shall be adapted to allow the countries, territories and regions concerned to take part.

Article 37

Suspension of assistance

Without prejudice to the provisions on suspension of aid in partnership and cooperation agreements with partner countries and regions, where a partner country fails to observe the principles referred to in Article 3(1), and where consultations with the partner country do not lead to a solution acceptable to both parties, or if consultations are refused or in cases of special urgency, the Council, acting by a qualified majority on a proposal from the Commission, may take appropriate measures in respect of any assistance granted to the partner country under this Regulation. Such measures may include full or partial suspension of assistance.

Article 38

Financial provisions

1. The financial reference amount for the implementation of this Regulation over the period 2007-2013 is EUR 16 897 million.

2. The indicative amounts allocated to each programme referred to in Articles 5 to 10 and 11 to 16 and 17 are laid down in Annex IV. These amounts are established for the period 2007-2013.

3. Annual appropriations shall be authorised by the budgetary authority within the limits of the multiannual financial framework.

4. An indicative amount of EUR 465 million has been included in the total amount for thematic programmes to finance activities that benefit the ENPI countries.

Article 39

Repeals

1. The following Regulations are hereby repealed:

(a) Regulation (EC) No 2110/2005 of the European Parliament and of the Council of 14 December 2005 on access to Community external assistance ([1]);

(b) Regulation (EC) No 806/2004 of the European Parliament and of the Council of 21 April 2004 on promoting gender equality in development cooperation ([2]);

(c) Regulation (EC) No 491/2004 of the European Parliament and of the Council of 10 March 2004 establishing a programme for financial and technical assistance to third countries in the areas of migration and asylum (AENEAS) ([3]);

(d) Regulation (EC) No 1568/2003 of the European Parliament and of the Council of 15 July 2003 on aid to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries ([4]);

(e) Regulation (EC) No 1567/2003 of the European Parliament and of the Council of 15 July 2003 on aid for policies and actions on reproductive and sexual health and rights in developing countries ([5]);

(f) Regulation (EC) No 2130/2001 of the European Parliament and of the Council of 29 October 2001 on operations to aid uprooted people in Asia and Latin American developing countries ([6]);

(g) Regulation (EC) No 2494/2000 of the European Parliament and of the Council of 7 November 2000 on measures to promote the conservation and sustainable management of tropical forests and other forests in developing countries ([7]);

(h) Regulation (EC) No 2493/2000 of the European Parliament and of the Council of 7 November 2000 on measures to promote the full integration of the environmental dimension in the development process of developing countries ([8]);

(i) Regulation (EC) No 1726/2000 of the European Parliament and of the Council of 29 June 2000 on development cooperation with South Africa ([9]);

(j) Council Regulation (EC) No 1659/98 of 17 July 1998 on decentralised cooperation ([10]);

([1]) OJ L 344, 27.12.2005, p. 1.
([2]) OJ L 143, 30.4.2004, p. 40.
([3]) OJ L 80, 18.3.2004, p. 1.
([4]) OJ L 224, 6.9.2003, p. 7. Regulation as amended by Regulation (EC) No 2110/2005.
([5]) OJ L 224, 6.9.2003, p. 1. Regulation as amended by Regulation (EC) No 2110/2005.
([6]) OJ L 287, 31.10.2001, p. 3. Regulation as last amended by Regulation (EC) No 2110/2005.
([7]) OJ L 288, 15.11.2000, p. 6. Regulation as amended by Regulation (EC) No 2110/2005.
([8]) OJ L 288, 15.11.2000, p. 1. Regulation as amended by Regulation (EC) No 2110/2005.
([9]) OJ L 198, 4.8.2000, p. 1. Regulation as last amended by Regulation (EC) No 2110/2005
([10]) OJ L 213, 30.7.1998, p. 6. Regulation as last amended by Regulation (EC) No 625/2004 of the European Parliament and of the Council (OJ L 99, 3.4.2004, p. 1).

(k) Council Regulation (EC) No 1658/98 of 17 July 1998 on co-financing operations with European non-governmental organisations (NGOs) in fields of interest to the developing countries ([1]);

(l) Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security ([2]);

(m) Council Regulation (EEC) No 443/92 of 25 February 1992 on financial and technical assistance to, and economic cooperation with, the developing countries in Asia and Latin America ([3]) (ALA).

2. The repealed Regulations shall continue to apply for legal acts and commitments of pre 2007 budget years. Any reference to the repealed Regulations shall be deemed to be a reference to this Regulation.

Article 40

Review

Not later than 31 December 2010, the Commission shall submit to the European Parliament and the Council a report evaluating the implementation of this Regulation in the first three years with, if appropriate, a legislative proposal introducing the necessary modifications, including the indicative financial allocations set out in Annex IV.

Article 41

Entry into force

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 1 January 2007 to 31 December 2013.

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

Done at Brussels, 18 December 2006

For the European Parliament
The President
J. BORRELL FONTELLES

For the Council
The President
J.-E. ENESTAM

([1]) OJ L 213, 30.7.1998, p. 1. Regulation as last amended by Regulation (EC) No 2110/2005.
([2]) OJ L 166, 5.7.1996, p. 1. Regulation as amended by Regulation (EC) No 1726/2001 of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 10).
([3]) OJ L 52, 27.2.1992, p. 1. Regulation as last amended by Regulation (EC) No 2112/2005 (OJ L 344, 27.12.2005, p. 23).

ANNEX I

COUNTRIES ELIGIBLE UNDER ARTICLE 1(1)

Latin America

1. Argentina
2. Bolivia
3. Brazil
4. Chile
5. Colombia
6. Costa Rica
7. Cuba
8. Ecuador
9. El Salvador
10. Guatemala
11. Honduras
12. Mexico
13. Nicaragua
14. Panama
15. Paraguay
16. Peru
17. Uruguay
18. Venezuela

Asia

19. Afghanistan
20. Bangladesh
21. Bhutan
22. Cambodia
23. China
24. India
25. Indonesia
26. Democratic People's Republic of Korea
27. Laos
28. Malaysia
29. Maldives
30. Mongolia
31. Myanmar/Burma
32. Nepal
33. Pakistan
34. Philippines
35. Sri Lanka
36. Thailand
37. Viet Nam

Central Asia

38. Kazakhstan
39. Kyrgyz Republic
40. Tajikistan
41. Turkmenistan
42. Uzbekistan

Middle East

43. Iran
44. Iraq
45. Oman
46. Saudi Arabia
47. Yemen

South Africa

48. South Africa

ANNEX II

OECD/DAC LIST OF ODA RECIPIENTS

Effective from 2006 for reporting on 2005, 2006 and 2007

Least Developed Countries	Other Low Income Countries (per capita GNI < USD 825 in 2004)	Lower Middle Income Countries and Territories (per capita GNI USD 826-USD 3 255 in 2004)	Upper Middle Income Countries and Territories (per capita GNI USD 3 256-USD 10 065 in 2004)
Afghanistan	Cameroon	Albania	* Anguilla
Angola	Republic of the Congo	Algeria	Antigua and Barbuda
Bangladesh	Côte d'Ivoire	Armenia	Argentina
Benin	Ghana	Azerbaijan	Barbados
Bhutan	India	Belarus	Belize
Burkina Faso	Kenya	Bolivia	Botswana
Burundi	Democratic People's	Bosnia and Herzegovina	Chile
Cambodia	Republic of Korea	Brazil	Cook Islands
Cape Verde	Kyrgyz Rep.	China	Costa Rica
Central African Rep.	Moldova	Colombia	Croatia
Chad	Mongolia	Cuba	Dominica
Comoros	Nicaragua	Dominican Republic	Gabon
Democratic Republic of the Congo	Nigeria	Ecuador	Grenada
Djibouti	Pakistan	Egypt	Lebanon
Equatorial Guinea	Papua New Guinea	El Salvador	Libya
Eritrea	Tajikistan	Fiji	Malaysia
Ethiopia	Uzbekistan	Georgia	Mauritius
Gambia	Viet Nam	Guatemala	* Mayotte
Guinea	Zimbabwe	Guyana	Mexico
Guinea-Bissau		Honduras	* Montserrat
Haiti		Indonesia	Nauru
Kiribati		Iran	Oman
Laos		Iraq	Palau
Lesotho		Jamaica	Panama
Liberia		Jordan	Saudi Arabia (1)
Madagascar		Kazakhstan	Seychelles
Malawi		Macedonia, Former Yugoslav	South Africa
Maldives		Republic ofMarshall Islands	* St. Helena
Mali		Micronesia, Fed. States	St. Kitts-Nevis
Mauritania		Morocco	St. Lucia
Mozambique		Namibia	St. Vincent & Grenadines
Myanmar		Niue	Trinidad & Tobago
Nepal		Palestinian Adm. Areas	Turkey
Niger		Paraguay	* Turks & Caicos Islands
Rwanda		Peru	Uruguay
Samoa		Philippines	Venezuela
Sao Tome & Principe		Serbia & Montenegro	
Senegal		Sri Lanka	
Sierra Leone		Suriname	
Solomon Islands		Swaziland	
Somalia		Syria	
Sudan		Thailand	
Tanzania		* Tokelau	
Timor-Leste		Tonga	
Togo		Tunisia	
Tuvalu		Turkmenistan	
Uganda		Ukraine	
Vanuatu		* Wallis & Futuna	
Yemen			
Zambia			

* Territory

(1) Saudi Arabia passed the high income country threshold in 2004. In accordance with the OECD/DAC rules for revision of this list, it will graduate from the list in 2008 if it remains a high income country in 2005 and 2006. Its net ODA receipts from OECD/DAC Members were USD 9,9 million in 2003 and USD 9,0 million (preliminary) in 2004.

ANNEX III

ACP SUGAR PROTOCOL COUNTRIES

1. Barbados
2. Belize
3. Guyana
4. Jamaica
5. Saint Kitts and Nevis
6. Trinidad and Tobago
7. Fiji
8. Republic of the Congo
9. Côte d'Ivoire
10. Kenya
11. Madagascar
12. Malawi
13. Mauritius
14. Mozambique
15. Swaziland
16. Tanzania
17. Zambia
18. Zimbabwe

ANNEX IV

INDICATIVE FINANCIAL ALLOCATIONS FOR THE PERIOD 2007-2013 (IN EUR MILLION)

Total	**16 897**
Geographic programmes:	*10 057*
Latin America	2 690
Asia	5 187
Central Asia	719
Middle East	481
South Africa	980
Thematic programmes:	*5 596*
Investing in people	1 060
Environment and sustainable management of natural resources	804
Non-State actors and local authorities in development	1 639
Food security	1 709
Migration and asylum	384
ACP Sugar Protocol countries	*1 244*

ANNEX V

NON-DEVELOPING COUNTRIES AND TERRITORIES

1. Australia
2. Bahrain
3. Brunei
4. Canada
5. Chinese Taipei
6. Hong Kong
7. Japan
8. Korea
9. Macao
10. New Zealand
11. Kuwait
12. Qatar
13. Singapore
14. United Arab Emirates
15. United States of America

II

(Acts whose publication is not obligatory)

EUROPEAN PARLIAMENT AND COUNCIL

RECOMMENDATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

on the protection of minors and human dignity and on the right of reply in relation to the competitiveness of the European audiovisual and on-line information services industry

(2006/952/EC)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 157 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) The Charter of Fundamental Rights of the European Union [3] ('the Charter') declares in Article 1 the inviolability of human dignity, providing that it must be respected and protected. Article 24 of the Charter provides that children have the right to such protection and care as is necessary for their well-being and that in all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration.

(2) The European Union should gear its political action to preventing any form of violation of the principle of respect for human dignity.

(3) Legislative measures need to be enacted at Union level on the protection of the physical, mental and moral development of minors in relation to the content of all audiovisual and information services and the protection of minors from access to inappropriate adult programmes or services.

(4) The constant development of new information and communication technologies makes it urgent for the Community to ensure full and adequate protection for citizens' interests in this field on the one hand, by guaranteeing the free delivery and free provision of information services and, on the other hand, by ensuring that their content is legal, respects the principle of human dignity and does not impair the overall development of minors.

(5) The Community has already intervened in the field of audiovisual and information services in order to create the necessary conditions to ensure the free movement of television broadcasts and other information services, in compliance with the principles of free competition and freedom of expression and information, but it should act with greater determination in this area with the aim of adopting measures to protect consumers from incitement to discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation and of combating any such discrimination. Such action should strike a balance between the protection of individual rights on the one hand and freedom of expression on the other, in particular with respect to Member States' responsibility for defining the notion of incitement to hatred or discrimination in accordance with their national legislation and moral values.

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[1] OJ C 221, 8.9.2005, p. 87.

[2] Opinion of the European Parliament of 7 September 2005 (OJ C 193 E, 17.8.2006, p. 217), Council Common Position of 21 September 2006 (not yet published in the Official Journal) and Position of the European Parliament of 12 December 2006 (not yet published in the Official Journal).

[3] OJ C 364, 18.12.2000, p. 1.

(6) Council Recommendation 98/560/EC of 24 September 1998 on the development of the competitiveness of the European audiovisual and information services industry by promoting national frameworks aimed at achieving a comparable and effective level of protection of minors and human dignity ([1]) is the first legal instrument at Community level which in its recital (5) addresses issues of the protection of minors and of human dignity in relation to audiovisual and information services made available to the public, whatever the means of conveyance. Article 22 of Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities ([2]) ('Television without Frontiers Directive') has already specifically addressed the question of the protection of minors and human dignity in television broadcasting activities.

(7) It is suggested that the Council and the Commission should pay special attention to the implementation of this Recommendation when revising, negotiating or concluding new partnership agreements or new cooperation programmes with third countries, bearing in mind the global character of producers, distributors or providers of audiovisual content and Internet access.

(8) By Decision No 276/1999/EC ([3]), the European Parliament and the Council adopted a multiannual Community Action plan on promoting safer use of the Internet by combating illegal and harmful content on global networks (the 'Safer Internet Action Plan').

(9) Decision No 1151/2003/EC of the European Parliament and of the Council ([4]) extended the Safer Internet Action Plan for two years and amended its scope to include measures to encourage exchange of information and coordination with the relevant actors at national level as well as special provisions for the accession countries.

(10) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ([5]) clarifies some legal concepts and harmonises certain aspects in order to enable information society services to fully benefit from the internal market principles. A number of the provisions of Directive 2000/31/EC are also relevant to the protection of minors and human dignity, in particular Article 16(1)(e), according to which Member States and the Commission are to encourage the drawing up of codes of conduct regarding the protection of minors and human dignity.

(11) The changing media landscape, resulting from new technologies and media innovation, makes it necessary to teach children, and also parents, teachers and trainers to use audiovisual and on-line information services effectively.

(12) On the whole, self-regulation of the audiovisual sector is proving an effective additional measure, but it is not sufficient to protect minors from messages with harmful content. The development of a European audiovisual area based on freedom of expression and respect for citizens' rights should be based on continuous dialogue between national and European legislators, regulatory authorities, industries, associations, citizens and civil society.

(13) In the public consultation concerning Directive 97/36/EC of the European Parliament and of the Council of 30 June 1997 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities ([6]), it was suggested that the need to adopt measures in relation to media literacy be included among the subjects covered by Recommendation 98/560/EC.

(14) The Commission encourages cooperation and the sharing of experience and best practices between existing self- and co-regulatory bodies, which deal with the rating or classification of audiovisual content, regardless of the means by which it is delivered, with a view to enabling all users, but especially parents, teachers and trainers, to report illegal content and assess the content of audiovisual and on-line information services, as well as any legal content which could harm the physical, mental or moral development of minors.

(15) As suggested during the public consultation concerning Directive 97/36/EC, it is appropriate for the right of reply or equivalent remedies to apply to on-line media, and to take into account the specific features of the medium and service concerned.

([1]) OJ L 270, 7.10.1998, p. 48.
([2]) OJ L 298, 17.10.1989, p. 23. Directive as amended by Directive 97/36/EC of the European Parliament and of the Council (OJ L 202, 30.7.1997, p. 60).
([3]) Decision No 276/1999/EC of the European Parliament and of the Council of 25 January 1999 adopting a multiannual Community action plan on promoting safer use of the Internet by combating illegal and harmful content on global networks (OJ L 33, 6.2.1999, p. 1). Decision as last amended by Decision No 787/2004/EC (OJ L 138, 30.4.2004, p. 12).
([4]) Decision No 1151/2003/EC of the European Parliament and of the Council of 16 June 2003 amending Decision No 276/1999/EC adopting a multiannual Community action plan on promoting safer use of the Internet by combating illegal and harmful content on global networks (OJ L 162, 1.7.2003, p. 1).
([5]) OJ L 178, 17.7.2000, p. 1.
([6]) OJ L 202, 30.7.1997, p. 60.

(16) The Council Resolution of 5 October 1995 on the image of women and men portrayed in advertising and the media [1] invites the Member States and the Commission to take adequate measures to promote a diversified and realistic picture of the skills and potential of women and men in society.

(17) When tabling its proposal for a Council Directive implementing the principle of equal treatment between men and women in the access to and supply of goods and services, the Commission noted that the portrayal of the sexes in the media and in advertising raises important questions about the protection of the dignity of men and women, but concluded that, in the light of other fundamental rights, including the freedom and pluralism of the media, it would not be appropriate to address these questions in that proposal but that it should take stock of these questions.

(18) The audiovisual and on-line information services industry should be encouraged at Member State level to avoid and to combat any type of discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation in such media and all advertising, including new advertising techniques, without infringing freedom of expression or of the press.

(19) This Recommendation covers new technological developments and complements Recommendation 98/560/EC. Its scope, on account of technological advances, includes audiovisual and on-line information services made available to the public via fixed or mobile electronic networks.

(20) Nothing in this Recommendation prevents Member States from applying their constitutional provisions and other legislation and legal practices regarding freedom of expression,

HEREBY RECOMMEND THAT:

I. The Member States, in the interests of promoting the development of the audiovisual and on-line information services industry, take the necessary measures to ensure the protection of minors and human dignity in all audiovisual and on-line information services by:

1. considering the introduction of measures into their domestic law or practice regarding the right of reply or equivalent remedies in relation to on-line media, with due regard for their domestic and constitutional legislative provisions, and without prejudice to the possibility of adapting the manner in which it is exercised to take into account the particularities of each type of medium;

2. promoting, in order to encourage the take-up of technological developments, in addition to and consistently with existing legal and other measures regarding broadcasting services, and in close cooperation with the parties concerned:

   (a) action to enable minors to make responsible use of audiovisual and on-line information services, notably by improving the level of awareness among parents, teachers and trainers of the potential of the new services and of the means whereby they may be made safe for minors, in particular through media literacy or media education programmes and, for instance, by continuous training within school education,

   (b) action to facilitate, where appropriate and necessary, the identification of, and access to, quality content and services for minors, including through the provision of means of access in educational establishments and public places,

   (c) action to inform citizens more about the possibilities offered by the Internet;

   examples of possible actions concerning media literacy are outlined in Annex II;

3. promoting a responsible attitude on the part of professionals, intermediaries and users of new communication media such as the Internet by:

   (a) encouraging the audiovisual and on-line information services industry, without infringing freedom of expression or of the press, to avoid all discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, in all audiovisual and on-line information services, and to combat such discrimination,

   (b) encouraging vigilance and the reporting of pages considered illegal, without prejudice to Directive 2000/31/EC,

   (c) drawing up a code of conduct in cooperation with professionals and regulatory authorities at national and Community level;

4. promoting measures to combat all illegal activities harmful to minors on the Internet and make the Internet a much more secure medium; consideration could be given inter alia to the following measures:

   (a) adopting a quality label for service providers, so that users can easily check whether or not a given provider subscribes to a code of conduct,

   (b) establishing appropriate means for the reporting of illegal and/or suspicious activities on the Internet.

[1] OJ C 296, 10.11.1995, p. 15.

II. The audiovisual and on-line information services industry and other parties concerned:

1. develop positive measures for the benefit of minors, including initiatives to facilitate their wider access to audiovisual and on-line information services, while avoiding potentially harmful content, for instance by means of filtering systems. Such measures could include harmonisation through cooperation between the regulatory, self-regulatory and co-regulatory bodies of the Member States, and through the exchange of best practices concerning such issues as a system of common descriptive symbols or warning messages indicating the age category and/or which aspects of the content have led to a certain age recommendation, which would help users to assess the content of audiovisual and on-line information services. This could take place, for instance, through the actions outlined in Annex III;

2. examine the possibility of creating filters which would prevent information offending against human dignity from passing through the Internet;

3. develop measures to increase the use of content labelling systems for material distributed over the Internet;

4. consider effective means of avoiding and combating discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation in audiovisual and on-line information services and of promoting a diversified and realistic picture of the skills and potential of men and women in society.

TAKE NOTE THAT THE COMMISSION:

1. Intends to promote, in connection with the 2005-2008 multiannual Community programme on promoting safer use of the Internet and new on-line technologies, information actions aimed at citizens Europe-wide using all communications media, to inform the public about the benefits and possible risks of the Internet, how to use it responsibly and safely, how to make complaints and how to activate parental control. Specific campaigns could be aimed at target groups such as schools, parents' associations and users;

2. intends to explore the possibility of introducing a European freephone number or of extending an existing service to assist Internet users by directing them to available complaint mechanisms and information resources and providing information for parents about the effectiveness of filtering software;

3. intends to explore the possibility of supporting the establishment of a generic second level domain name reserved for monitored sites committed to respecting minors and their rights, such as .KID.eu;

4. continues to maintain a constructive and ongoing dialogue with content providers' organisations, consumer organisations and all parties concerned;

5. intends to facilitate and support the formation of networks by self-regulatory bodies and the exchanging of experience among them, so as to assess the effectiveness of codes of conduct and approaches based on self-regulation in order to ensure the highest possible standards of protection for minors;

6. intends to submit to the European Parliament and the Council, on the basis of information supplied by the Member States, a report on the implementation and effectiveness of the measures specified in this Recommendation, and to review this Recommendation if and when the need arises.

Done at Brussels, on 20 December 2006

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	J. KORKEAOJA

ANNEX I

INDICATIVE GUIDELINES FOR THE IMPLEMENTATION, AT NATIONAL LEVEL, OF MEASURES IN DOMESTIC LAW OR PRACTICE SO AS TO ENSURE THE RIGHT OF REPLY OR EQUIVALENT REMEDIES IN RELATION TO ON-LINE MEDIA

Objective: introducing measures in the domestic law or practice of the Member States in order to ensure the right of reply or equivalent remedies in relation to on-line media, with due regard for their domestic and constitutional provisions and without prejudice to the possibility of adjusting its exercise to the particularities of each type of medium.

The term 'medium' refers to any means of communication for dissemination to the public of edited information on-line such as newspapers, periodicals, radio, television and Internet-based news services.

Without prejudice to other provisions adopted by the Member States under civil, administrative or criminal law, any natural or legal person, regardless of nationality, whose legitimate interests, in particular, but not limited to, reputation and good name, have been affected by an assertion of facts in a publication or transmission should have the right of reply or equivalent remedies. Member States should ensure that the actual exercise of the right of reply or equivalent remedies is not hindered by the imposition of unreasonable terms or conditions.

The right of reply or equivalent remedies should exist in relation to on-line media under the jurisdiction of a Member State.

Member States should adopt the measures needed to establish the right of reply or equivalent remedies and should determine the procedure to be followed for the exercise thereof. In particular, they should ensure that a sufficient time span is allowed and that the procedures are such that the right of reply or equivalent remedies can be exercised appropriately by natural or legal persons resident or established in other Member States.

The right of reply can be ensured not only through legislation, but also through co-regulatory or self-regulatory measures.

The right of reply is a particularly appropriate remedy in the on-line environment because it allows for an instant response to contested information and it is technically easy to attach the replies from the persons affected. However, the reply should be within a reasonable time after the request has been substantiated and at a time and in a manner appropriate to the publication or transmission to which the request refers.

Provision should be made for procedures whereby disputes as to the exercise of the right of reply or the equivalent remedies could be subject to review by the courts or similar independent bodies.

An application for exercise of right of reply or the equivalent remedies may be rejected if the claimant does not have a legitimate interest in the publication of such a reply, or if the reply would involve a punishable act, would render the content provider liable to civil law proceedings or would transgress standards of public decency.

The right of reply is without prejudice to other remedies available to persons whose right to dignity, honour, reputation or privacy have been breached by the media.

ANNEX II

Examples of possible actions concerning media literacy:

(a) continuing education of teachers and trainers, in liaison with child protection associations, on using the Internet in the context of school education so as to maintain awareness of the possible risks of the Internet with particular regard to chatrooms and fora;

(b) introduction of specific Internet training aimed at children from a very early age, including sessions open to parents;

(c) an integrated educational approach forming part of school curricula and media literacy programmes, so as to provide information on using the Internet responsibly;

(d) organisation of national campaigns aimed at citizens, involving all communications media, to provide information on using the Internet responsibly;

(e) distribution of information packs on possible risks of the Internet ('how to surf the Internet safely', 'how to filter unwanted messages') and the setting up of hotlines to which reports or complaints concerning harmful or illegal content could be addressed;

(f) adequate measures to establish or improve the performance of telephone hotlines, so as to make it easier to lodge complaints and to make it possible to report harmful or illegal content.

ANNEX III

Examples of possible actions by the industries and the parties concerned for the benefit of minors:

(a) systematically providing users with an effective, updatable and easy-to-use filtering system when they subscribe to an access provider;

(b) offering access to services specifically intended for children which are equipped with automatic filtering systems operated by access providers and mobile telephone operators;

(c) introducing incentives to provide a regularly updated description of the sites available, making it easier to classify sites and assess their content;

(d) posting banners on search engines drawing attention to the availability both of information about responsible use of the Internet and of telephone hotlines.