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## II

(Preparatory Acts)

## COMMISSION

**Amended proposals for a Council Decision adopting a specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' (2002-2006) <sup>(1)</sup>**

(2002/C 181 E/01)

(Text with EEA relevance)

COM(2002) 43 final — 2001/0122(CNS)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 31 January 2002)

<sup>(1)</sup> OJ C 240 E, 28.8.2001, p. 194.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 166 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas:

- (1) In accordance with Article 166(3) of the Treaty, Decision No ... of the European Parliament and the Council concerning the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.
- (2) The framework programme is structured in three main blocks of activities, 'integrating research', 'structuring the European Research Area', and 'strengthening the foundations of the European Research Area', the first and the third of which, as regards indirect actions, should be implemented by this specific programme.
- (3) The rules for the participation of undertakings, research centres and universities and for the dissemination of research results, for the framework programme, adopted by the European Parliament and Council in Decision No ... (hereinafter referred to as 'the rules for participation and dissemination') should apply to this programme.

Unchanged

- (1) In accordance with Article 166(3) of the Treaty, Decision No ... of the European Parliament and the Council concerning the sixth multiannual framework programme of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.
- (2) The framework programme is structured in three main blocks of activities, 'Focusing and integrating Community research', 'structuring the European Research Area', and 'strengthening the foundations of the European Research Area', the first and the third of which, as regards indirect actions, should be implemented by this specific programme.

Unchanged



## INITIAL PROPOSAL

- (4) New instruments, involving simplified and decentralised management, and the exploitation of external technical support should, if fully exploited in this programme enable personnel and administrative expenses to be reduced to a maximum of 5,5 % of the overall amount deemed necessary for its implementation.

- (5) In implementing this programme, emphasis should be given to promoting mobility of researchers and innovation, in the Community and encouraging the participation of SMEs, as well as international co-operation activities with third countries and international organisations. Special attention should be paid to the Accession countries.

- (6) Research activities carried out within this programme should respect fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union.

- (7) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research. Gender aspects in research will be taken into account in implementing this programme.

## AMENDED PROPOSAL

- (4) The importance of the new instruments (Integrated Projects and Networks of Excellence) is recognised as being an overall priority means to attain the objectives of critical mass, management simplification and European added value contributed by Community research in relation to what is already undertaken at national level, and of the integration of the research capacities. They should enable personnel and administrative expenses to be reduced to a maximum of 6,0 % of the overall amount deemed necessary for the implementation of the programme. In 2004 an evaluation will be undertaken by independent experts of the efficiency of each of these instruments in the execution of the framework programme.

- (5) As provided for under Article 170 of the Treaty, this programme is open to the participation of countries having concluded the necessary agreements to this effect, and is also open on the project level, and on the basis of mutual benefit, to the participation of entities from third countries and of international organisations for scientific co-operation.

- (6) In implementing this programme, emphasis should be given to promoting mobility of researchers, following the Commission communication 'A mobility strategy within the European Research Area', to innovation; to the needs of SMEs and encouraging their participation, as well as to international co-operation activities with third countries and international organisations. Special attention should be paid to the candidate countries.

- (7) Research activities carried out within this programme must respect fundamental ethical principles, including those which appear in the Charter of Fundamental Rights of the European Union; no support will be provided to research aimed at military purposes.

- (8) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research, and further enhanced action is needed. Gender aspects in research will be taken into account in implementing this programme.

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

## INITIAL PROPOSAL

- (8) To achieve the full potential of this programme, the active engagement of all relevant parties, in particular the Member States and associated states, should be encouraged in a common endeavour to step up the co-ordination of research activities carried out in Europe, including through the opening up and networking of national programmes and the free circulation of information pertaining to research activities at all levels.
- (9) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities; the research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.
- (10) Since the measures necessary for the implementation of this Decision are management measures within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>, they should be adopted by use of the management procedure provided for in Article 4 of that Decision.
- (11) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme.
- (12) Within this programme, thematic priority areas of research should be implemented exclusively by means of three types of instruments: networks of excellence, integrated projects, and Community participation in national research activities implemented jointly pursuant to Article 169 of the Treaty.

## AMENDED PROPOSAL

- (9) To achieve the full potential of this programme, the active engagement of all relevant parties, in particular the Member States, associated candidate countries and other associated States, should be encouraged in a common endeavour to step up the co-ordination of research activities carried out in Europe, including through the opening up and networking of national programmes and the free circulation of information pertaining to research activities at all levels.
- (10) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities; the research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.
- (11) Participation in the activities of this programme will be encouraged through publication of the necessary information on content, conditions and procedures, to be made available in a timely and thorough manner to potential participants, including those from the associated candidate countries and other associated countries. Specific activities will be undertaken in support of participation of scientists and institutions from developing countries, Mediterranean countries including the Western Balkans as well as Russia and the NIS <sup>(1)</sup>.
- (12) Since the measures necessary for the implementation of this Decision are management measures within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>, they should be adopted by use of the management procedure provided for in Article 4 of that Decision.
- (13) The Commission will in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme, which will be done in a spirit of openness with respect to all the relevant actors.
- (14) The new instruments will be used from the start of the Sixth Framework Programme in each theme and, where deemed appropriate, as a priority means, while maintaining the use of specific targeted research projects and coordination actions.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

<sup>(1)</sup> NIS: Newly Independent States.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

HAS ADOPTED THIS DECISION:

(15) Each thematic priority area should have its own budget line in the General Budget of the European Communities,

Unchanged

*Article 1*

1. In accordance with the framework programme, a specific programme on Integrating and strengthening the European Research Area (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.

2. The objectives and scientific and technological priorities for the specific programme are set out in Annex I.

*Article 2*

In accordance with Annex II of the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 12 505 million, including a maximum of 5,5 % for the Commission's administrative expenditure. An indicative breakdown of this amount is given in Annex II.

In accordance with Annex II of the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 12 855 million, including a maximum of 6,0 % for the Commission's administrative expenditure. An indicative breakdown of this amount is given in Annex II.

*Article 3*

All research activities carried out under the specific programme must be carried out in compliance with fundamental ethical principles.

*Article 3*

1. The detailed rules for financial participation by the Community in the specific programme shall be those referred to in Article 2(2) of the framework programme.

2. The specific programme shall be implemented defined in Annexes I and III to the framework programme and described in Annex III.

3. The rules for participation and dissemination shall apply to the specific programme.

*Article 4*

Unchanged

2. The specific programme shall be implemented by means of the instruments defined in Annexes I and III to the framework programme and described in Annex III.

Unchanged

*Article 4*

1. The Commission shall draw up a work programme for the implementation of the specific programme, setting out in greater detail the objectives and scientific and technological priorities set out in Annex I, and the timetable for implementation.

*Article 5*

Unchanged

## INITIAL PROPOSAL

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States and European and international organisations. It shall be updated where appropriate.

*Article 5*

1. The Commission shall be responsible for the implementation of the specific programme.

2. The procedure laid down in Article 6 shall apply for the adoption of the following measures:

— the drawing up and updating of the work programme referred to in Article 4(1),

— any adjustment to the indicative breakdown of the amount as set out in Annex II.

*Article 6*

1. The Commission shall be assisted by a committee, composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the management procedure laid down in Article 4 of Decision 1999/468/EC<sup>(1)</sup> shall apply, in compliance with Article 7(3) thereof.

3. The period provided for in Article 4(3) of Decision 1999/468/EC shall be two months.

*Article 7*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme.

2. The Commission shall arrange for the independent assessment provided for in Article 5 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 8*

This Decision is addressed to the Member States.

## AMENDED PROPOSAL

*Article 6*

Unchanged

2. The procedure laid down in Article 7 shall apply for the adoption of the following measures:

— the drawing up and updating of the work programme referred to in Article 5(1), including the instruments to be used on a priority basis, and any subsequent adjustment to their use;

Unchanged

*Article 7*

Unchanged

*Article 8*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme; information on financial aspects shall be included.

2. The Commission shall arrange for the independent monitoring and assessment provided for in Article 6 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 9*

Unchanged

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

INITIAL PROPOSAL

AMENDED PROPOSAL

## ANNEX I

## SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND BROAD LINES OF THE ACTIVITIES

The programme is structured as follows:

1. FOCUSING AND INTEGRATING COMMUNITY RESEARCH

1.1. **Priority thematic areas of research**

1.1.1. *Genomics and biotechnology for health*

(i) Advanced genomics and its applications for health.

(ii) Combating major diseases.

1.1.2. *Information Society technologies*

1.1.3. *Nanotechnologies and nanosciences, knowledge-based multi-functional materials, and new production processes and devices*

1.1.4. *Aeronautics and space*

1.1.5. *Food quality and safety*

1.1.6. *Sustainable development, global change and ecosystems*

(i) Sustainable energy systems

(ii) Sustainable surface transport

(iii) Global change and ecosystems

1.1.7. *Citizens and governance in a knowledge-based society*

1.2. **Specific activities covering a wider field of research**

1.2.1. *Supporting policies and anticipating scientific and technological needs*

1.2.2. *Horizontal research activities involving SMEs*

1.2.3. *Specific measures in support of international co-operation*

2. STRENGTHENING THE FOUNDATIONS OF THE EUROPEAN RESEARCH AREA

2.1. **Support for the co-ordination of activities**

2.2. **Support for the coherent development of policies**

## INITIAL PROPOSAL

## AMENDED PROPOSAL

**Introduction**

Unchanged

This programme will promote world class research in key priority areas of exceptional interest and added value to Europe and the competitiveness of its industry, which have been identified in the framework programme 2002-2006, as well as on topics that are identified as being of high importance during the course of implementation of the framework programme in view of the EU's policy needs and the opportunities arising in novel, leading edge research areas.

The programme will strive towards greater integration of research in Europe by means of:

- focused action in priority thematic research areas, using powerful financing instruments (integrated projects and networks of excellence) which bring together the research actors in appropriate configurations for the new challenges that these priority research areas represent, and with critical mass;

- Systematic and co-ordinated planning and execution of research to support Community policies, and to explore new and emerging scientific and technological areas, taking account of needs expressed by the relevant actors throughout the EU;

- promoting the networking and joint action of national and European frameworks for research and innovation, and the opening up of national programmes, in these priority areas, including where appropriate by the use of actions under Article 169 of the Treaty, as well as in other areas where such action would be of benefit to the performance of Europe's research base.

Unchanged

The programme is complementary to the programme 'structuring the European Research Area' and the specific programme for the JRC, and its implementation will be co-ordinated with them.

International co-operation represents an important dimension of the framework programme. In this specific programme, international activities are carried out in the two forms of:

- Participation of researchers, teams and institutions from third countries in projects within the different thematic priority fields, related to issues arising at world level and being subjects of international efforts;
- Specific international co-operation activities with some groups of countries, as a support to Community external relations and development aid policies.

The objectives and forms of the international co-operation activities in the framework programme are described under the heading 'Specific activities covering a wider field of research'.

Participation of the candidate countries in this programme will be encouraged.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

## 1. INTEGRATING RESEARCH

## 1.1. Priority thematic areas of research

The priority thematic areas represent the bulk of expenditure under the framework programme 2002-2006. Through a highly focused Community research effort, the intention is to generate a substantial leveraging effect which, together with actions in other parts of the framework programme 2002-2006 and through open co-ordination with other — regional, national, European and international — frameworks, will result in a coherent and highly effective common endeavour towards their overall objectives.

The priority thematic areas of research are:

- Genomics and biotechnology for health
- Information Society technologies
- Nanotechnologies, intelligent materials and new production processes
- Aeronautics and space
- Food Safety and health risks
- Sustainable development and global change
- Citizens and Governance in the European Knowledge-based society

The actions are therefore described in terms of:

- the overall objectives and expected achievements which are sought in each priority area;
- the research priorities to be pursued by means of Community action.

The priority thematic areas of research are described in terms of their overall objectives and the main research focus. The associated work programme will elaborate further on the detailed research content.

Participation of small and medium-sized enterprises (SMEs) will be encouraged and gender equity will, overall, be assured in the implementation of the activities.

The activities carried out within the programme will be implemented in an integrated fashion to assure coherence and synergy between their various elements and, as appropriate, with other parts of the framework programme.

## 1. FOCUSING AND INTEGRATING COMMUNITY RESEARCH

Unchanged

The priority thematic areas represent the bulk of expenditure under the sixth framework programme. Through a highly focused Community research effort, the intention is to generate a substantial leveraging effect which, together with actions in other parts of the framework programme and through open co-ordination with other — regional, national, European and international — frameworks, will result in a coherent and highly effective common endeavour towards their overall objectives.

Deleted

Unchanged

Within the thematic priority areas, the importance of the new instruments (integrated projects and networks of excellence) is recognised as being an overall priority means to attain the objectives of critical mass, management simplification and European added value contributed by Community research in relation to what is already undertaken at national level, and of the integration of the research capacities.

## INITIAL PROPOSAL

Community action in each priority area will be pursued through integrated projects and networks of excellence. which, In addition to research and technological development, may incorporate the following types of activity, where they are of specific relevance to the objectives sought: demonstration, dissemination and exploitation; co-operation with researchers and research teams from third countries; human resource development, including the promotion of training of researchers; development of research facilities and infrastructure of specific relevance to the research being undertaken; and promotion of better links between science and society, including women in science.

In order to attain the objectives of one or more of the priority thematic areas, it may also be appropriate to implement research activities falling within the scope of Articles 169 to 171 of the Treaty.

Participation of small and medium-sized enterprises (SMEs) will be encouraged and gender equity will, overall, be assured in the implementation of the activities.

Innovation is an important dimension which must be taken into account in the design and implementation of RTD activities. In particular, networks of excellence and integrated projects will include activities relating to dissemination and exploitation of knowledge and, where relevant, to ensure transfer of technology and facilitate exploitation of results. Where appropriate, special attention will be given to technology transfer to SMEs and to the creation of research-based enterprises as a means of exploiting research results.

Participation of the candidate countries in this programme will be encouraged.

International co-operation represents an important dimension of the Framework Programme. In the specific programme, 'Integrating Research', international activities are carried out on the two forms of:

- Participation of researchers, teams and institutions from third countries in networks of excellence and integrated projects, in particular on topics, within the different thematic priority fields, related to issues arising at world level and being subjects of international efforts;
- Specific international co-operation activities with some groups of countries, as a support to Community external relations and development aid policies.

The objectives and forms of the international co-operation activities in the Framework Programme are described under the heading 'Anticipating the EU's scientific and technological needs'

## AMENDED PROPOSAL

Networks of excellence and integrated projects will be used from the start of the programme in each thematic priority area and, where deemed appropriate, as a priority means, while maintaining the use of specific targeted projects and co-ordination actions. In addition to research and technological development, they may incorporate the following types of activity, where they are of specific relevance to the objectives sought: demonstration, dissemination and exploitation; co-operation with researchers and research teams from third countries; human resource development, including the promotion of training of researchers; development of research facilities and infrastructure of specific relevance to the research being undertaken; and promotion of better links between science and society, including women in science.

Specific targeted research projects and co-ordination actions, giving effect to the concept of a stairway of excellence and integration, as well as specific support actions, may also be used in the implementation of the thematic priorities.

Deleted

Unchanged

Deleted



## INITIAL PROPOSAL

The priority research areas include, in certain cases, research at the borders of traditional disciplines where advances will require interdisciplinary and multidisciplinary effort. In such cases a particular attention will be given during the implementation of the programme to the co-ordination between the different priority areas, and between these areas and actions under the heading 'anticipating the EU's scientific and technological needs'.

Consideration of the ethical social and legal aspects of the research to be undertaken and its potential applications, as well as socio-economic impacts of scientific and technological development and foresight, will where relevant form a part of the activities under this heading. Research on ethics related to scientific and technological developments will be carried out in the programme 'Structuring the European Research Area'.

During the implementation of this programme and in the research activities arising from it, fundamental ethical principles are to be respected including the following: protection of human dignity data and privacy, as well as animals and the environment in accordance with Community law relevant international conventions and codes of conduct, e.g. the Helsinki Declaration, the Convention of the Council of Europe on Human Rights and Biomedicine the Universal Declaration on the human genome and human rights adopted by UNESCO,

Current legislation and regulations in the countries where the research will be carried out. Where appropriate, participants in research projects must seek the approval of the relevant ethics committees prior to the start of the RTD activities. An ethical review will be implemented systematically for proposals dealing with sensitive issues. In specific cases, an ethical review may take place during the implementation of a project.

## AMENDED PROPOSAL

The priority research areas include, in certain cases, research at the borders of traditional disciplines where advances will require interdisciplinary and multidisciplinary effort. They will also each carry out, as appropriate, exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within them. Measurement and testing aspects will also receive necessary emphasis. A particular attention will be given during the implementation of the programme to the co-ordination between the different priority areas, and between these areas and actions under the heading 'supporting policies and anticipating scientific and technological needs'.

The principle of sustainable development, and gender equality, will be duly taken into account. Furthermore, consideration of the ethical, social, legal and wider cultural aspects of the research to be undertaken and its potential applications, as well as socio-economic impacts of scientific and technological development and foresight, will where relevant form a part of the activities under this heading. Research on ethics related to scientific and technological developments will be carried out in the programme 'Structuring the European Research Area'.

During the implementation of this programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include the principles set out in the Charter of fundamental rights of the EU, including the following: protection of human dignity and human life, protection of personal data and privacy, as well as animals and the environment in accordance with Community law and relevant international conventions and codes of conduct, e.g. the Helsinki Declaration in its latest version, the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998, the UN Convention on the Rights of the Child, the Universal Declaration on the human genome and human rights adopted by Unesco, and the relevant World Health Organisation (WHO) resolutions.

Account will also be taken to the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).

Participants in research projects must conform to current legislation and regulations in the countries where the research will be carried out. Where appropriate, participants in research projects must seek the approval of the relevant ethics committees prior to the start of the RTD activities. An ethical review will be implemented systematically for proposals dealing with sensitive issues. In specific cases, an ethical review may take place during the implementation of a project.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

The following fields of research shall not be financed under this programme:

- research activity aiming at human cloning for reproductive purposes;
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable <sup>(1)</sup>;
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In accordance with the Amsterdam protocol on animal protection and welfare, animal experiments must be replaced with alternatives wherever possible. Suffering by animals must be avoided or kept to a minimum. This particularly applies (pursuant to Directive 86/609/EEC) to animal experiments involving species which are closest to human beings. Altering the genetic heritage of animals and cloning of animals may be considered only if the aims are ethically justified and the conditions are such that the animals' welfare is guaranteed and the principles of biodiversity are respected.

#### 1.1.1. *Genomics and biotechnology for health* <sup>(1)</sup>

The sequencing of the human genome and many other genomes heralds a new age in human biology, offering unprecedented opportunities to improve human health and to stimulate industrial and economic activity. In making its contribution to realising these benefits, this theme will focus on integrating post-genomic research into the more established biomedical and biotechnological approaches, and will facilitate the integration of research capacities (both public and private) across Europe to increase coherence and achieve critical mass. Integrated multidisciplinary research, which enables a strong interaction between technology and biology, is vital in this theme for translating genome data into practical applications. In addition, an essential element will be to involve key stakeholders, in particular, industry, healthcare providers and practitioners policy makers, regulatory authorities and patient associations, in implementing the theme. Gender equity in the research will also be ensured <sup>(2)</sup>.

<sup>(1)</sup> In this and other areas of activity within the framework programme, human cloning for reproductive purposes will not be supported; no research activities modifying or aiming to modify the genetic heritage of human beings will be carried out; nor will any research activity involving the creation of a human embryo for research or therapeutic purposes be carried out. As far as possible, animal experiments and testing should be replaced by in vitro or alternative methods. Animal suffering must be avoided or kept to a minimum and, in this regard, special attention must be paid to animal experimentation involving species that are the closest to human beings (in accordance with Directive 86/609/CEE). The modification of the genetic heritage of animals and animal cloning will be envisaged only for objectives that are justified on ethical grounds and when carried out under conditions respecting animal welfare and the principles of genetic diversity.

<sup>(2)</sup> Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women and men. Therefore, all activities funded within this thematic priority must take the possibility of gender differences into account in their research protocols, methodologies and analysis of results.

#### 1.1.1. *Genomics and biotechnology for health*

The sequencing of the human genome and many other genomes heralds a new age in human biology, offering unprecedented opportunities to improve human health and to stimulate industrial and economic activity. In making its contribution to realising these benefits, this theme will focus on integrating post-genomic research into the more established biomedical and biotechnological approaches, and will facilitate the integration of research capacities (both public and private) across Europe to increase coherence and achieve critical mass. Integrated multidisciplinary research, which enables a strong interaction between technology and biology, is vital in this theme for translating genome data into practical applications. In addition, an essential element will be to involve key stakeholders, for example, as appropriate industry, healthcare providers and physicians, policy makers, regulatory authorities, patient associations, and experts on ethical matters, etc. in implementing the theme. Gender equity in the research will also be ensured <sup>(2)</sup>.

<sup>(1)</sup> Research relating to cancer treatment of the gonads can be financed.

<sup>(2)</sup> Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women and men. Therefore, all activities funded within this thematic priority must take the possibility of gender differences into account in their research protocols, methodologies and analysis of results.

## INITIAL PROPOSAL

This thematic priority area will stimulate and sustain multidisciplinary basic research to exploit the full potential of genome information to underpin applications to human health.

It will be an integral component of the European Community effort to enhance the European biotechnology industry in line with the conclusions of the Stockholm Council. It will endeavour to create strong links with all activities that improve the framework conditions for innovation in the health sector of the biotechnology industry, especially in SMEs, including stimulating entrepreneurship and opportunities for investment through venture capital and the involvement of the European Investment Bank. Attention will also be paid to the identification of regulatory bottlenecks in the development of new applications for genomics, to the anticipation at the earliest possible stage of the ethical implications and to the broader implications of developments in genomics research for society and citizens.

This thematic priority area will also foster the implementation and development of the health strategy of the European Community.

Throughout the thematic priority, international collaboration will be encouraged. Where appropriate, due account will be given to the European Community's commitment to poverty reduction in developing countries and the importance that improved health will bring to the process — in line with Article 177 of the Treaty and with the European Community's accelerated actions to combat HIV/AIDS, malaria and tuberculosis.

#### Research priorities

##### (i) *Fundamental knowledge and basic tools for functional genomics*

The strategic objective of this line is to foster the basic understanding of genomic information, by developing the knowledge base, tools and resources needed to decipher the function of genes and gene products relevant to human health (including animal, plant and microbial genomes) and to explore their interactions with each other and with their environment. Research actions will encompass the following:

- Gene expression and proteomics: The objectives are to enable researchers to better decipher the functions of genes and gene products as well as to define the complex regulatory networks (biocomplexity) that control fundamental biological processes.

## AMENDED PROPOSAL

This thematic priority area will stimulate and sustain multidisciplinary basic research to exploit the full potential of genome information to underpin applications to human health. The emphasis will be put on research aimed at bringing basic knowledge through to application, to enable real and consistent progress in medicine and improve the quality of life. This research may also have implications for research on areas such as agriculture and environment, which are addressed under other thematic priorities.

Unchanged

##### (i) *Advanced genomics and its applications for health*

Fundamental knowledge and basic tools for functional genomics in all organisms

The strategic objective of this line is to foster the basic understanding of genomic information, by developing the knowledge base, tools and resources needed to decipher the function of genes and gene products relevant to human health and to explore their interactions with each other and with their environment. Research actions will encompass the following:

Unchanged

## INITIAL PROPOSAL

Research will focus on: developing high throughput tools and approaches for monitoring gene expression and protein profiles and for determining protein function and protein interactions.

- Structural genomics: The objectives are to enable researchers to determine, more effectively and at a higher rate than is currently feasible, the 3-D structure of proteins and other macromolecules, which is important for elucidating protein function and essential for drug design.

Research will focus on: developing high throughput approaches for determining high-resolution 3-D structures of macromolecules.

- Comparative genomics and population genetics: The objectives are to enable researchers to use well-characterised model organisms for predicting and testing gene function and to take full advantage of specific population cohorts available in Europe to determine the relationship between gene function and health or disease.

Research will focus on: developing model organisms and transgenic tools; developing genetic epidemiology tools and standardised genotyping protocols.

- Bioinformatics: The objectives are to enable researchers to access efficient tools for managing and interpreting the ever-increasing quantities of genome data and for making it available to the research community in an accessible and usable form.

Research will focus on: developing bioinformatic tools and resources for data storage, mining and processing; developing computational biology approaches for in silico prediction of gene function and for the simulation of complex regulatory networks.

(ii) *Applications of genomics and biotechnology for health*

The strategic objective of this line is to foster the competitiveness of Europe's biotechnology industry by exploiting the wealth of biological data produced by genomics and advances in biotechnology. Research actions will encompass the following:

## AMENDED PROPOSAL

- Multidisciplinary functional genomics approaches to basic biological processes: The objectives are to enable researchers to study fundamental biological processes by integrating the above innovative approaches.

Research will focus on: elucidation of the mechanisms underlying fundamental cellular processes, to identify the genes involved and to decipher their biological functions in living organisms.

Applications of knowledge and technologies in the field of genomics and biotechnology for health

Unchanged

## INITIAL PROPOSAL

- Technological platforms for the developments in the fields of new diagnostic, prevention and therapeutic tools: The objectives are to foster academic and industrial collaboration through technological platforms where multidisciplinary approaches using cutting edge technologies arising from genomic research (such as pharmacogenomics) may contribute to health care progress and cost reduction through more precise diagnosis, individualised treatment and more efficient development pathways for new drugs and therapies, and other novel products of the new technologies.

Research will focus on: rational and accelerated development of new, safer, more effective drugs; development of new diagnostics; development of new in vitro tests to replace animal experimentation; development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (including stem cell therapies) and immunotherapies;

- Support for innovative research in genomics start-up companies: The objectives are to facilitate the creation of research-based start-ups in Europe, to help sustain their early growth and to foster their further development in a multinational environment.

Research will focus on: innovative aspects of post-genomics, which have high potential for application to health related issues and which are also expected to lead to entrepreneurial initiatives in start-up companies.

With a view to ensuring socially responsible choices, public acceptance and an efficient development pathway for these new technologies, an active and early involvement of regulators, patients and society at large will be necessary.

(ii) *Combating major diseases*(iii) *Application in medicine and public health*

The strategic objective of this line is to develop improved strategies for the prevention and management of human disease and for living and ageing healthily. It will concentrate exclusively on integrating the genomic approach into more established medical approaches for investigating disease and health determinants. Research actions will focus on the following:

## AMENDED PROPOSAL

- Technological platforms for the developments in the fields of new diagnostic, prevention and therapeutic tools: The objectives are to foster academic and industrial collaboration through technological platforms where multidisciplinary approaches using cutting edge technologies arising from genomic research may contribute to health care progress and cost reduction through more precise diagnosis, individualised treatment and more efficient development pathways for new drugs and therapies, and other novel products of the new technologies.

Research will focus on: rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches; development of new diagnostics; development of new in vitro tests to replace animal experimentation; development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies) and immunotherapies; innovative research in post-genomics, which has high potential for application.

Deleted

With a view to ensuring socially responsible choices, public acceptance and an efficient development pathway for these new technologies, an active and early involvement in the above activities of regulators, experts on ethics, patients and society at large will be necessary.

Unchanged

Application-oriented genomic approaches to medical knowledge and technologies

The strategic objective of this line is to develop improved strategies for the prevention and management of human disease and for living and ageing healthily. It will concentrate exclusively on integrating genomic approach through all relevant organisms into more established medical approaches for investigating disease and health determinants. The emphasis will be put on translational research aimed at bringing basic knowledge through to clinical application. Research actions will focus on the following:

## INITIAL PROPOSAL

- Combating cancer, cardiovascular disease, and rare diseases: The objectives are to improve the prevention and management of the two major causes of ill health and mortality in Europe and to pool Europe's research resources for tackling rare diseases.

Research will focus on: integrating clinical expertise and resources with relevant model systems and advanced tools in functional genomics to generate breakthroughs in the prevention and management of these diseases.

- Combating resistance to drugs: The objectives are to confront the major threat to public health caused by drug resistant pathogens.

Research will focus on: exploitation of the knowledge of microbial genomes and on host-pathogen interactions for the development of vaccines and alternative therapeutic strategies to circumvent the problem of antimicrobial drug resistance; development of strategies for optimal usage of antimicrobials; support to the European Community network for epidemiological surveillance and control of communicable diseases.

- Studying the brain and combating diseases of the nervous system: The objectives are to use genome information to understand better the functioning and dysfunctioning of the brain, in order to gain new insight into mental processes, to combat neurological disorders and diseases, and to improve brain repair.

Research will focus on: understanding the molecular and cellular bases of brain function, damage, plasticity and repair, learning, memory and cognition; developing strategies for prevention and management of neurological disorders and diseases.

- Studying human development and the ageing process: The objective is to better understand human development, with special emphasis on the ageing process, in order to develop the evidence base for improving public health strategies to promote healthy living and healthy ageing.

Research will focus on: understanding human development from conception to adolescence; exploring the molecular and cellular determinants of healthy ageing including their interactions with environmental, behavioural and gender factors.

## AMENDED PROPOSAL

- Combating, cardiovascular disease, diabetes, and rare diseases: The objectives are to improve the prevention and management of important causes of mortality and ill health in Europe and to pool Europe's research resources for tackling rare diseases.

Unchanged

- Combating resistance to antibiotics and other drugs: The objectives are to confront the major threat to public health caused by drug resistant pathogens.

Research will focus on: exploitation of the knowledge of microbial genomes and on host-pathogen interactions for the development of vaccines and alternative therapeutic strategies to circumvent the problem of antimicrobial and other drug resistance; development of strategies for optimal usage of antimicrobials; support to the European Community network for epidemiological surveillance and control of communicable diseases.

Unchanged

Research will focus on: understanding the molecular and cellular bases of brain function, damage, plasticity and repair, learning, memory and cognition; developing strategies for prevention and management of neurological and mental disorders and diseases.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

## Combating cancer

The objective is to develop improved patient-oriented strategies, from prevention to diagnosis and treatment, for combating cancer. The research will therefore concentrate on translating the new knowledge being created by genomics and other fields of basic research into applications that improve clinical practice and public health.

The patient-oriented approach will include three interlinked components. Research will focus on:

- Establishing facilities for the exploitation of research on cancer in Europe; encouraging the development of evidence-based guidelines for good clinical practice and improved public health strategies by accelerating the translation of existing research results into applications.
- Supporting clinical research, particularly clinical trials, aimed at validating new and improved interventions.
- Supporting translational research aimed at bringing basic knowledge through to applications in clinical practice and public health.

(iv) *Confronting the major communicable diseases linked to poverty*

The strategic objective of this line is to confront the global emergency caused by the three major communicable diseases — HIV/AIDS, malaria and tuberculosis — through the development of effective disease interventions, particularly for use in developing countries. It is envisaged that developing countries will be significant partners in the implementation of this line, in particular through the European Platform.

Research will focus on: developing promising candidate interventions (vaccines, therapies and HIV microbicides) against the target diseases by sponsoring research over the full spectrum from basic molecular research, taking advantage of microbial genomics, through to pre-clinical testing and proof-of-principle; establishing a European platform to unite and support Europe's clinical trial activities specifically targeted at interventions for use in developing countries; establishing an AIDS Therapy Trials Network in Europe to improve the coherence and complementarity of clinical trials of AIDS therapies for European use.

## Confronting the major communicable diseases linked to poverty

The strategic objective of this line is to confront the global emergency caused by the three major communicable diseases — HIV/AIDS, malaria and tuberculosis — through the development of effective disease interventions, particularly for use in developing countries. It is envisaged that developing countries will be significant partners in the implementation of this line and, as appropriate, participate directly in specific activities within it, in particular through the clinical trials programme

Research will focus on: developing promising candidate interventions (vaccines, therapies and HIV microbicides) against the target diseases by sponsoring research over the full spectrum from basic molecular research, taking advantage of microbial genomics, through to pre-clinical testing and proof-of-principle; establishing a clinical trials programme to unite and support Europe's clinical trial activities specifically targeted at interventions for use in developing countries; establishing an AIDS Therapy Trials Network in Europe to improve the coherence and complementarity of clinical trials of AIDS therapies for European use.

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

1.1.2. *Information Society technologies*

Unchanged

Information society technologies (IST) are transforming the economy and society. Not only are they creating new ways of working and new types of business, but provide solutions to major societal challenges such as healthcare, environment, safety, mobility and employment, and have far reaching implications on our everyday life. The IST sector is now one of the most important of the economy, with an annual turnover of EUR 2 000 billion, providing employment for more than 12 million people in Europe.

The IST thematic priority will contribute directly to realising European policies for the knowledge society as agreed at the Lisbon Council of 2000, the Stockholm Council of 2001, and reflected in the e-Europe Action Plan. It will ensure European leadership in the generic and applied technologies at the heart of the knowledge economy. It aims to increase innovation and competitiveness in European businesses and industry and to contribute to greater benefits for all European citizens.

Successes, like those achieved in Europe in mobile communications or consumer electronics, will not be repeated unless a real effort is made to achieve critical mass in key domains of IST research. The actions will therefore mobilise the community of researchers around medium to long term objectives, facilitating the integration of public and private effort on a European scale, to build essential competencies and strengthen innovation. They will involve high-risk and long term RTD such as the development of the next generation of mobile and wireless systems beyond 3G and will include underpinning research to investigate and experiment with future and emerging technologies within the specific context of the priority research areas indicated

Successes, like those achieved in Europe in mobile communications or consumer electronics, will not be repeated unless a real effort is made to achieve critical mass in key domains of IST research. The actions will therefore mobilise the community of researchers around medium to long term objectives, facilitating the integration of public and private effort on a European scale, to build essential competencies and strengthen innovation. They will involve high-risk and long term RTD such as the development of the next generation of mobile and wireless systems beyond 3G.

Although substantial advances have been achieved, we are still far from taking full advantage of the potential of knowledge-based services in real life. Products and services are still hard to use and out of reach for many people, and the 'digital divide' is widening within Europe and across the world. Research will focus on the future generation of technologies in which computers and networks will be integrated into the everyday environment, rendering accessible a multitude of services and applications through easy-to-use human interfaces. This vision of 'ambient intelligence' places the user, the individual, at the centre of future developments for an inclusive knowledge-based society for all.

Unchanged

The IST priority in support of the eEurope action plan, will help build an information and knowledge based society across Europe, encouraging the participation of least developed regions. It will also include activities linking the EU effort to the international context. The aim is to achieve thematic area global consensus when appropriate e.g. through the Intelligent Manufacturing Systems (IMS) initiative or the dialogue on dependability issues, to integrate further the research of the Newly Associated States within the EU effort and to facilitate co-operation with developing countries.



## INITIAL PROPOSAL

## AMENDED PROPOSAL

## Research priorities

## Unchanged

- (i) *Applied IST research addressing major societal and economic challenges*

The objective is to extend the scope and efficiency of IST-based solutions addressing major societal and economic challenges, and to make them accessible in the most trusted and natural way, anywhere and anytime to citizens, businesses and organisations.

- Research on confidence: The objective is to develop technologies for key security challenges posed by the 'all-digital' world and by the need to secure the rights of individuals and communities.

Research will focus on basic security mechanisms and their interoperability, dynamic security processes, advanced cryptography, privacy enhancing technologies, technologies to handle digital assets and technologies for dependability to support business and organisational functions in dynamic and mobile systems.

- Research addressing societal challenges: The focus is on 'ambient intelligence' for a broader inclusion of citizens in the Information Society, for more effective health, security, mobility and environment management and support systems, and for the preservation of cultural heritage, integration of multiple functionalities across these different domains will be also supported.

Research activities on 'e-inclusion' will concentrate on systems enabling access for all, on barrier-free technologies for full participation in the information society and on assistive systems that will restore functions or compensate for disabilities thereby enabling a higher quality of life for citizens with special needs and their carers. In the area of health, the work will focus on intelligent systems aimed at supporting health professionals, at providing patients with personalised healthcare and information, and at stimulating health promotion and disease prevention in the general population. Research will also address intelligent systems to enhance the protection of people and property and for securing and safeguarding civil infrastructures.

In addition to the above, the priority thematic area will support research to investigate and experiment with future visions and emerging technologies at the frontier of knowledge in the IST field.

Within the context of the priorities identified below, the priority thematic area will also include activities relating to the further development of Géant and GRIDs.

- Technologies for trust and security: The objective is to develop technologies for key security challenges posed by the 'all-digital' world and by the need to secure the rights of individuals and communities.

## Unchanged

## INITIAL PROPOSAL

In the area of mobility, research will focus on vehicle infrastructure and portable systems to provide integrated safety, comfort and efficiency and allow for the provision of advanced logistics infomobility and location based services. Research in the area of environment will focus on knowledge-based systems for natural resource management and for risk prevention and crisis management. In the area of leisure, research will focus on intelligent and mobile systems and application for entertainment and tourism. For cultural heritage, the effort will focus on intelligent systems for dynamic access to and preservation of tangible and intangible cultural and scientific resources.

- Research addressing work and business challenges: The objective is to provide businesses, individuals, public administrations, and other organisations with the means to fully contribute to, and benefit from, the development of a trusted knowledge-based economy, whilst at the same time improving the quality of work and working life and support life-long continuous learning to improve work skills. Research will also aim at a better understanding of the socio-economic drivers and impact of IST development.

Research in e-business and e-government will focus on providing European organisations, private and public, and especially SMEs, with interoperable systems and services to enhance innovation capacities, value creation and competitive performance in the knowledge economy and on supporting new business ecosystems. Research in organisational knowledge management will aim at supporting organisational innovation and responsiveness through elicitation, sharing, trading, and delivery of knowledge. Work on electronic and mobile commerce will target interoperable, multimodal applications and services across heterogeneous networks. It will include anytime-anywhere trading, collaboration, workflow, and electronic services covering the whole value creation cycle of extended products and services.

Research into e-work systems will focus on new workplace designs incorporating innovative technologies to facilitate creativity and collaboration, on increasing resource-use efficiency and on extending work opportunities to all in local communities. Work on e-learning will focus on personalised access to, and delivery of, learning as well as on advanced learning environments at school, university and in the workplace that take advantage of the development of ambient intelligence.

## AMENDED PROPOSAL

In the area of mobility, research will focus on vehicle infrastructure and portable systems to provide integrated safety, comfort and efficiency and allow for the provision of advanced logistics infomobility and location based services. Research in the area of environment will focus on knowledge-based systems for natural resource management and for risk prevention and crisis management including humanitarian mine clearance. In the area of leisure, research will focus on intelligent and mobile systems and application for entertainment and tourism. For cultural heritage, the effort will focus on intelligent systems for dynamic access to and preservation of tangible and intangible cultural and scientific resources.

Unchanged

Research into e-work systems will focus on new workplace designs incorporating innovative technologies to facilitate creativity and collaboration, on increasing resource-use efficiency and on extending work opportunities to all in local communities. Work on e-learning will focus on personalised access to, and delivery of, learning as well as on advanced learning environments at school, university, in the workplace and in lifelong learning in general, taking advantage of the development of ambient intelligence.

## INITIAL PROPOSAL

- Complex problem solving in science, engineering, businesses and for society: The objective is to develop technologies for harnessing computing and storage resources which are distributed in geographically dispersed locations, and for making them accessible, in a seamless way, for complex problem solving in science, industry, business and society. Application fields include environment, energy, health, transport, industrial engineering, finance and new media.

Research will focus on new computational models, including computing and information GRIDs, peer-to-peer technologies and the associated middleware to make use of large scale highly distributed computing and storage resources and to develop scalable, dependable and secure platforms. It will include novel collaborative tools and programming methods supporting interoperability of applications and new generations of simulation, visualisation and data mining tools.

(ii) *Communication and computing infrastructures*

The objectives are to consolidate and further develop European strengths in areas such as mobile communications, consumer electronics and embedded software, and to improve the performance, cost-efficiency, functionality and adaptive capabilities of communications and computing technologies.

- Communication and network technologies: The objective is to develop the new generations of mobile and wireless systems and networks that allow optimal service connection anywhere as well as all-optical networks to increase network transparency and capacity, solutions to improve network interoperation and adaptability, and technologies for personalised access to networked audio-visual systems.

Work on terrestrial and satellite <sup>(1)</sup> based, mobile and wireless systems and networks beyond 3G will focus on the next generation of technologies, ensuring co-operation and seamless inter-working at service and control planes of multiple wireless technologies over a common IP (Internet Protocol) platform as well as novel spectral efficient protocols, tools and technologies, to build wireless re-configurable IP enabled devices, systems and networks.

## AMENDED PROPOSAL

Unchanged

(ii) *Communication, computing and software technologies*

The objectives are to consolidate and further develop European strengths in areas such as mobile communications, consumer electronics and embedded software and systems, and to improve the performance, cost-efficiency, functionality and adaptive capabilities of communications and computing technologies. Work will also lead to the next generation Internet.

Unchanged

<sup>(1)</sup> The activity on satellite communications is done in coordination with the activities in priority 4 'aeronautics and space'.

## INITIAL PROPOSAL

Research in all optical networks will focus on the management of optical wavelength channels enabling flexibility and speed in service deployment and provisioning and solutions for fibre to the LAN. Research on interoperable network solutions, including end-to-end network management will support generic services provision and interworking, and interoperation between heterogeneous networks and platforms. It will include programmable networks to provide adaptive and real-time allocation of network resources and enhanced service management capabilities by customers.

Research will also address the enabling technologies for personalised access to networked audio-visual systems and applications as well as cross-media service platforms and networks, trusted digital TV architectures and appliances able to process, encode, store, sense and display hybrid 3D multimedia signals and objects.

- Software technologies, services and distributed systems: The objective is to develop new software technologies, multifunctional service creation environments as well as tools for the control of complex distributed systems for the realisation of an ambient intelligence landscape and for coping with the expected growth and spread of applications and services.

Research will focus on new technologies for software systems and services, that address composability, scalability, reliability and robustness as well as autonomous self-adaptation. It will address middleware for the management, control and use of fully distributed resources. Work on multifunctional service creation environments and new component frameworks will aim at the development of service functionality, including meta-information, semantics and taxonomy of the building blocks.

New strategies, algorithms, and tools for systematic and accurate design, prototyping and control of complex distributed systems will be addressed. e.g. with embedded controllers and ubiquitous computing resources. Work will include cognitive techniques for generic object and event recognition.

## AMENDED PROPOSAL

- Software technologies, embedded systems and distributed systems: The objective is to develop new software technologies, multifunctional service creation environments as well as tools for the control of complex distributed systems for the realisation of an ambient intelligence landscape and for coping with the expected growth and spread of applications and services.

Research will focus on new technologies for software and systems that address composability, scalability, reliability and robustness as well as autonomous self-adaptation. It will include middleware for the management, control and use of fully distributed resources. Work on multifunctional service creation environments and new component frameworks will aim at the development of service functionality, including meta-information, semantics and taxonomy of the building blocks.

New strategies, algorithms, and tools for systematic and accurate design, prototyping and control of complex distributed systems will be addressed. Work will include networked embedded systems, distributed sensing, computing, storage resources and related inter-communication. Dynamic resources allocation will be a key feature as well as cognitive techniques for generic object and events recognition.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

(iii) *Components and microsystems*

Unchanged

- Micro-, Nano- and optoelectronics: The objective is to reduce the cost, increase the performance and improve reconfigurability, scalability, adaptability and self-adjusting capabilities of micro-, nano- and optoelectronic components and systems-on-a-chip.

Research will focus on pushing the limits of CMOS process and equipment technologies and enhancing device functionality, performance and integration of functions. It will address alternative process technologies, device types, materials and architectures to meet demands of communication and computing. Particular emphasis will be put on RF, mixed-signal and low power design. Work on optical, optoelectronic, and photonic functional components, will address devices and systems for information processing, communication, switching, storage, sensing and imaging. Research on electron based nano-devices, as well as on molecular electronics devices and technologies, will target those that promise broad functionality and have integration- and mass fabrication potential.

- Micro and nano technologies, microsystems, displays: The objective is to improve the cost-efficiency, performance and functionality of subsystems and microsystems and to increase the level of integration and miniaturisation allowing for improved interfacing with their surrounding and with networked services and systems.

Research will focus on new applications and functions that take advantage of multi-disciplinary interactions (electronics, mechanics, chemistry, biology, etc.) combined with the use of micro and nano-structures and new materials. The aim is to develop innovative, cost-effective and reliable microsystems and reconfigurable, miniaturised subsystem modules. Work will also include low cost, information-rich and higher resolution displays as well as advanced sensors including low cost vision and biometric sensors, and haptic devices. Work on nano-devices and nano-systems will address the exploitation of basic phenomena, processes and structures that promise novel or improved sensing or actuating functionality as well as their integration and fabrication.

(iv) *Knowledge and interface technologies*

The objective is to improve usability of IST applications and services and access to the knowledge they embody in order to encourage their wider adoption and faster deployment.

## INITIAL PROPOSAL

- Knowledge technologies and digital content: The objective is to provide automated solutions for creating and organising virtual knowledge spaces (e.g. collective memories) so as to stimulate radically new content and media services and applications.

Work will focus on technologies to support the process of acquiring and modelling, representing and visualising, interpreting and sharing knowledge. These functions will be integrated in new semantic-based and context-aware systems including cognitive and agent-based tools. Work will address extensible knowledge resources and ontologies so as to facilitate service interoperability and enable next-generation semantic-web applications. Research will also address technologies to support the design, creation, management and publishing of multimedia content, across fixed and mobile networks and devices, with the ability to self-adapt to user expectations. The aim is to stimulate the creation of rich interactive content for personalised broadcasting and advanced trusted media and entertainment applications.

- Intelligent interfaces and surfaces: The objective is to provide more effective ways of accessing ubiquitous information and easier and natural interaction modes with intelligence that surrounds us.

Research will focus on interfaces and interactive surfaces that are natural, adaptive and multi-sensorial, for an ambient landscape that is aware of our presence, personality and needs, and which is capable of responding intelligently to speech, or gesture. The aim is to hide the complexity of technology by supporting a seamless human interaction with devices, virtual and physical objects and the knowledge embedded in everyday environments.

Work will also address technologies for multilingual and multicultural access and communication that support timely and cost effective provisions of interactive information-rich services meeting the personal, professional and business requirements of all members of linguistically and culturally diverse communities.

## AMENDED PROPOSAL

Work will focus on technologies to support the process of acquiring and modelling, navigating and retrieving, representing and visualising, interpreting and sharing knowledge. These functions will be integrated in new semantic-based and context-aware systems including cognitive and agent-based tools. Work will address extensible knowledge resources and ontologies so as to facilitate service interoperability and enable next-generation semantic-web applications. Research will also address technologies to support the design, creation, management and publishing of multimedia content, across fixed and mobile networks and devices, with the ability to self-adapt to user expectations. The aim is to stimulate the creation of rich interactive content for personalised broadcasting and advanced trusted media and entertainment applications.

Unchanged

Research will focus on interfaces and interactive surfaces that are natural, adaptive and multi-sensorial, for an ambient landscape that is aware of our presence, personality and needs, and which is capable of responding intelligently to speech, gesture or other senses. The aim is to hide the complexity of technology by supporting a seamless interaction between humans, between humans and devices, virtual and physical objects and the knowledge embedded in everyday environments. This includes research on virtual and augmented reality

Unchanged

IST future and emerging technologies: in this area, the objective is to help new IST-related science and technology fields and communities to emerge, some of which will become strategic for economic and social development in the future and will feed into the mainstream IST activities in the future. To ensure openness to unforeseeable ideas, critical mass of research where strategic focus is needed, and seamless coverage of the IST frontier, two complementary approaches will be utilised: one receptive and open — the other proactive.

## INITIAL PROPOSAL

**1.1.3. Nanotechnologies, intelligent materials and new production processes**

The twofold transition toward a knowledge-based society and of sustainable development demands new paradigms of production and new concepts of product-services. European production industry as a whole needs to move from resource-based towards knowledge-based approaches, from quantity to quality, from mass produced single-use products to manufactured-on-demand multi-use, upgradable product-services; from 'material and tangible' to 'intangible' value-added products, processes and services.

These changes are associated with radical shifts in industrial structures, involving a stronger presence of innovative enterprises, with capabilities in networks and mastering new hybrid technologies combining nanotechnologies, material sciences, engineering, information technologies, bio and environmental sciences. Such an evolution implies a strong collaboration across traditional scientific frontiers. Leading edge industrial developments involve also a strong synergy between technology and organisation, the performance of both being highly dependent on new skills.

Successful technological solutions have to be sought more and more upstream in the design and production processes; new materials and nanotechnologies have a crucial role to play in this respect, as drivers of innovation. This requires changes of emphasis in Community research activities from short to longer term and in innovation which must move from incremental to breakthrough strategies. Community research will benefit greatly from an international dimension.

**Research priorities****(i) Nanotechnologies**

Nanotechnologies represent a new approach to materials science and engineering. Europe enjoys a strong position in the nanosciences, that needs to be translated into a real competitive advantage for European industry. The objective is twofold: to promote the creation of an RTD-intensive European nanotechnology related industry, and to promote the uptake of nanotechnologies in existing industrial sectors. Research may be long-term and high risk, but will be oriented towards industrial application. An active policy of encouraging industrial companies and SMEs, including start-ups, will be pursued, amongst others through the promotion of strong industry/research interactions in consortia undertaking projects with substantial critical mass.

## AMENDED PROPOSAL

**1.1.3. Nanotechnologies and nanosciences, knowledge-based multifunctional materials and new production processes and devices**

The twofold transition toward a knowledge-based society and of sustainable development demands new paradigms of production and new concepts of product-services. European production industry as a whole needs to move from resource-based towards knowledge-based, more environment-friendly approaches, from quantity to quality, from mass produced single-use products to manufactured-on-demand multi-use, upgradable product-services; from 'material and tangible' to 'intangible' value-added products, processes and services.

Unchanged

**(i) Nanotechnologies and Nanosciences**

Unchanged

## INITIAL PROPOSAL

- Long-term interdisciplinary research into understanding phenomena, harnessing processes and developing research tools: The objectives are to expand the generic underlying knowledge base of application oriented nano-science and nanotechnology, and to develop leading edge research tools and techniques.

Research will focus on: molecular and mesoscopic scale phenomena; self-assembling materials and structures; molecular and bio-molecular mechanisms and engines; multi-disciplinary and new approaches to integrate developments in inorganic, organic and biological materials and processes.

- Nanobiotechnologies: The objective is to support research into the integration of biological and non-biological entities, opening new horizons in many applications, such as for processing and for medical and environmental analysis systems.

Research will focus on: lab-on-chip, interfaces to biological entities, surface modified nano-particles, advanced drug delivery and other areas of integrating nano-systems or nanoelectronics with biological entities; processing, manipulation and detection of biological molecules or complexes, electronic detection of biological entities, micro-fluidics, promotion and control of growth of cells on substrates.

- Nanometre-scale engineering techniques to create materials and components: The objective is to develop novel functional and structural materials of superior performance, by controlling their nano-structure. This will include technologies for their production and processing.

Research will focus on: nano-structured alloys and composites, advanced functional polymeric materials, and nano-structured functional materials.

- Development of handling and control devices and instruments: The objective is to develop a new generation of instrumentation for analysis and manufacture at the nano-scale. A guiding target will be a feature size or resolution of the order of 10 nm.

Research will focus on: a variety of advanced techniques for nano-scale manufacture (lithography or microscopy based techniques); breakthrough technologies, methodologies or instruments exploiting the self-assembling properties of matter and developing nano-scale machines.

## AMENDED PROPOSAL

- Long-term interdisciplinary research into understanding phenomena, mastering processes and developing research tools: The objectives are to expand the generic underlying knowledge base of application oriented nano-science and nanotechnology, and to develop leading edge research tools and techniques.

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## INITIAL PROPOSAL

- Applications in areas such as health, chemistry, energy, optics and the environment: The objective is to foster the potential of nanotechnologies in breakthrough applications through the integration of research developments in materials and technological devices in an industrial context.

Research will focus on: computational modelling, advanced production technologies; development of innovative materials with improved characteristics.

(ii) *Intelligent Materials*

New, high knowledge-content materials, providing new functionalities and improved performance, will be critical drivers of innovation in technologies, devices and systems, benefiting sustainable development and competitiveness in sectors such as transport, energy, medicine, electronics, and construction. To assure Europe's strong positions in emerging technology markets, which are expected to grow by one or two orders of magnitude within the next decade, the various actors need to be mobilised through leading edge RTD partnerships, including high risk research and through integration between research on materials and industrial applications.

- Development of fundamental knowledge: The objective is to understand complex physico-chemical and biological phenomena relevant to the mastering and processing of intelligent materials with the help of experimental, theoretical and modelling tools. This will provide the basis for synthesising larger complex or self-assembling structures with defined physical, chemical or biological characteristics.

Research will focus on: long-term, trans-disciplinary and high industrial risk activities to design and develop new structures with defined characteristics; development of supra-molecular and macromolecular engineering, focusing on the synthesis, exploitation and potential use of novel highly complex molecules and their compounds.

- Technologies associated with the production, transformation of new materials: The objective is the sustainable production of new 'smart' materials with tailor-made functionalities and for building up macro-structures. These novel materials, serving multisectorial applications should incorporate in-built characteristics to be exploited under predetermined circumstances as well as enhanced bulk properties or barrier and surface characteristics for higher performance.

Research will focus on: new materials; engineered and self-repairing materials; crosscutting technologies including surface science and engineering.

## AMENDED PROPOSAL

(ii) *Knowledge-based multifunctional materials*

Unchanged

- Technologies associated with the production, transformation and processing of knowledge-based multifunctional materials, and biomaterials: The objective is the sustainable production of new 'smart' materials with tailor-made functionalities and for building up macro-structures. These novel materials, serving multisectorial applications should incorporate in-built characteristics to be exploited under predetermined circumstances as well as enhanced bulk properties or barrier and surface characteristics for higher performance.

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## INITIAL PROPOSAL

- Engineering support for materials development: The objective is to bridge the gap from 'knowledge production' to 'knowledge use', thus overcoming the EU industry's weaknesses in the integration of materials and manufacturing. This will be achieved by the development of new tools enabling the production of new materials in a context of sustainable competitiveness.

Research will focus on: inherent aspects of optimising materials design, processing and tools; mechanical testing, validation and up-scaling; incorporation of life-cycle approaches, obsolescence, bio-compatibility and eco-efficiency.

(iii) *New Production Processes*

New production concepts which are more flexible, integrated, safe and clean will depend on breakthrough organisational and technological developments, supporting new products, processes and services, and at the same time decreasing (internal and external) costs. The objective is to provide the industrial systems of the future with the necessary tools for efficient life-cycle design, production, use and recovery as well as appropriate organisational models and improved knowledge management.

- Development of flexible and intelligent manufacturing systems. The objective is to encourage industry's transition towards more knowledge-based production and systems organisation and to considering production from a more holistic perspective, encompassing not only hardware and software, but also people and the way in which they learn and share knowledge.

Research will focus on: innovative, reliable, smart and cost-effective manufacturing processes, and systems, and their incorporation into the factory of the future: integrating hybrid technologies based on new materials and their processing, micro-systems and automation, high-precision production equipment, as well as integration of ICT, sensing and control technologies.

- Systems research and hazard control. The objective is to contribute to an improved sustainability of industrial systems and a substantial and measurable reduction in environmental and health impact, through new industrial approaches as well as enhancement of resource efficiency and resource consumption.

## AMENDED PROPOSAL

Research will focus on: inherent aspects of optimising materials design, processing and tools; testing, validation and up-scaling; incorporation of life-cycle approaches, obsolescence, bio-compatibility and eco-efficiency.

(iii) *New production processes and devices*

Unchanged

- Development of new processes and flexible and intelligent manufacturing systems. The objective is to encourage industry's transition towards more knowledge-based production and systems organisation and to considering production from a more holistic perspective, encompassing not only hardware and software, but also people and the way in which they learn and share knowledge.

Research will focus on: innovative, reliable, smart and cost-effective manufacturing processes, and systems, and their incorporation into the factory of the future: integrating hybrid technologies based on new materials and their processing, micro-systems and automation, high-precision production equipment, as well as integration of ICT, sensing and control technologies, and innovative robotics.

- Systems research and hazard control. The objective is to contribute to an improved sustainability of industrial systems and a substantial and measurable reduction in environmental and health impact, through new industrial approaches, as well as enhancement of resource efficiency and reduction in consumption of primary resources.

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Research will focus on: development of new devices and systems for clean, safe and less carbon-intensive production; enhancing company responsibility on products, resource consumption and industrial waste management; studying 'production-use-consumption' interactions, as well as socio-economic implications.

- Optimising the life-cycle of industrial systems, products and services. Products and production should become increasingly life-cycle and service oriented, in addition to the requirements of intelligence, cost-effectiveness, safety and cleanliness. The key challenge is therefore new industrial concepts based on life-cycle approaches, which must allow new products, organisational innovation and the efficient management of information and its transformation into useable knowledge within the value chain.

Research will focus on: innovative product-services systems that optimise the 'design-production-service-end-of-life' value chain through use of hybrid technologies and new organisational structures.

## AMENDED PROPOSAL

Research will focus on: development of new devices and systems for clean, and safe production; non-polluting, sustainable waste management and hazard reduction in production and manufacturing, including bio-processes; enhancing company responsibility on products, resource consumption and industrial waste management; studying 'production-use-consumption' interactions, as well as socio-economic implications.

Unchanged

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

#### 1.1.4. *Aeronautics and space*

Unchanged

Over the last decades, Europe's outstanding technological and industrial capabilities in aeronautics and the exploitation of space have made many and various contributions to the standard of living of its citizens and the development and growth of its economies, as well as to those outside Europe. The economic benefits they bring can be seen in highly skilled employment and the balance of trade surplus, and they can have a strong leverage effect in upgrading the competitiveness of other related economic sectors.

Although aeronautics and space are distinct domains, they share common features, being extremely R & D intensive, with long development lead-times and very large investment requirements. Fierce competition, strategic significance, and increasingly severe environmental constraints combine to make it necessary to strive continually towards higher levels of technological excellence by consolidating and concentrating RTD efforts in Europe, with the ultimate aim of better serving society.

Although aeronautics and space are distinct domains, they share common features, being extremely R & D intensive, with long development lead-times and very large investment requirements. Fierce competition, strategic significance, and increasingly severe environmental constraints combine to make it necessary to strive continually towards higher levels of technological excellence by consolidating and concentrating RTD efforts, with the ultimate aim of better serving society.

## INITIAL PROPOSAL

Aeronautics research will be planned against a Strategic Research Agenda (SRA) agreed by all stakeholders at European level in the context of the new Advisory Council for Aeronautics Research in Europe, which will also be the planning base for national programmes. The result will be a greater level of complementarity and co-operation between the national and Community efforts in the field. The European Strategy for Space will serve as a reference in planning space research, with the objective of gathering key players on projects of common interest and close liaison will be ensured with RTD activities carried out by other actors, such as space agencies, Eurocontrol and industry. Furthermore, the application of relevant Treaty articles will be explored to support, as appropriate, these initiatives.

## Research priorities

(i) *Aeronautics*

In their report 'Vision 2020', leaders of the sector in Europe have highlighted the need to optimise the Community and national research efforts around a common vision and a strategic research agenda. Consistent with this, research will concentrate on the following 4 main strands. The scope of the research action will be medium and large-sized commercial aircraft including their systems and components, as well as the on-board and ground-based elements of air-traffic management systems.

- Strengthening competitiveness: The objective is to enable the three sectors of the manufacturing industry: airframe, engines and equipment, to increase their competitiveness, by reducing, in the short and long term, respectively, aircraft development costs by 20 % and 50 %, and aircraft direct operating cost by 20 % and 50 %, and improving passenger comfort.

Research will focus on: integrated design systems and processes for the realisation of the extended multi-site enterprise concept, as well as for more intelligent production technologies; new aircraft configurations, advanced aerodynamics, materials and structures, engine technologies; mechanical, electrical and hydraulic systems; improved cabin-environmental conditions and utilisation of multimedia services to improve passenger comfort.

- Improving environmental impact with regard to engine emissions and noise. Concerning emissions, the objectives are to meet Kyoto goals and to compensate for the increase in future air traffic, by reducing CO<sub>2</sub> by 50 % in the long term and NO<sub>x</sub> by 20 % and 80 %, in the short and long term, respectively. Concerning noise to limit the noise nuisance outside the airport boundary, the target is to reduce noise levels by 4-5 dB in the short term and 10 dB in the long term.

## AMENDED PROPOSAL

Unchanged

In their report 'Vision 2020', leaders of the sector in Europe have highlighted the need to optimise the Community and national research efforts around a common vision and a strategic research agenda. Consistent with this, research will concentrate on the following four main strands. The scope of the research action will be commercial transport aircraft including their systems and components, as well as the on-board and ground-based elements of air-traffic management systems.

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- Improving environmental impact with regard to emissions and noise. Concerning emissions, the objectives are to meet Kyoto goals and to compensate for the increase in future air traffic, by reducing fuel consumption and emissions of CO<sub>2</sub> by 50 % in the long term and of NO<sub>x</sub> by 20 % and 80 %, in the short and long term, respectively. Concerning noise, to limit the noise nuisance outside the airport boundary, the target is to reduce noise levels by 4-5 dB in the short term and 10 dB in the long term.

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Work will focus on low-emission combustion and propulsion concepts, engine technologies and related control systems, low-drag aerodynamic concepts, low-weight airframe structures and high temperature materials, as well as improved flight operational procedures engine and power-plant technologies, aeroacoustics for airframe noise reduction, advanced noise-control systems as well as novel flight operational procedures in the vicinity of airports.

- Improving aircraft safety. The objective is to obtain a two-fold reduction in accident rates in the short-term, and a five-fold reduction in the long term, in order to compensate for the growth in air transport movements.

Concerning preventive safety, research will focus on: investigation of systemic safety models, improve fault-tolerant systems and human-centred cockpit design enabling a controllable situation awareness for the crew. Research on accident mitigation will focus on improved materials and structures as well as advanced safety systems.

- Increasing operational capacity and safety of the air transport system. The objective is to optimise airspace and airport utilisation, and consequently reduce flight delays, through a seamlessly integrated European air traffic management system, which would facilitate the achievement of the 'Single European-Sky' initiative.

Research will focus on on-board and ground automation aids, communication, navigation and surveillance systems as well as flight operation procedures that will enable the introduction of new concepts including the free-flight concept in the future European ATM system.

(ii) *Space*

The aim is to contribute to the implementation of the European Strategy for Space, notably by targeting and focusing efforts with ESA and Member States on a small number of joint actions of common interest. Emphasis will be put on activities complementing those of space agencies (integration of terrestrial and space systems/services and demonstration of end-to-end services). This will include the following areas of activity:

- Galileo: the European Satellite Navigation system GALILEO, developed by the Joint Undertaking in close co-operation with the European Space Agency, will be fully operational by 2008. The use of the services

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Concerning emissions, research will focus on: low-emission combustion and propulsion concepts, engine technologies and related control systems, low-drag aerodynamic concepts, low-weight airframe structures and high temperature materials, as well as improved flight operational procedures. Research on noise will focus on: engine and power-plant technologies, aeroacoustics for airframe noise reduction, advanced noise-control systems as well as novel flight operational procedures in the vicinity of airports.

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provided by this infrastructure will span over wide ranges of activities of European society. The availability of precise navigation and timing services will have profound impacts in many domains.

It is important to build the necessary expertise and knowledge in Europe in order to exploit this emerging technology in the most efficient way.

Research will focus on: development of multisectorial concepts, systems and tools, which will rely on precise navigation and timing service provision; spreading of high level, coherent and seamless quality services in all environments (cities, indoors and outdoors, land, sea, air, etc.), in synergy with other service provision (telecommunication, surveillance, observation, etc.).

- GMES: the objective is to stimulate the development of markets for satellite-based information services, by development of technologies to bridge the gap between supply and demand

Research will focus on: sensors, data, and information models, developed in Europe or elsewhere, as well as developing prototypes of operational services responding to specific types of demand (for example global environment, land-use, desertification, disaster management). Research, including on data acquisition, assembly and qualification of models combining spatial and terrestrial data in an integrated operational information system, would use existing satellite data, for example provided by Envisat, future EarthWatch projects and other systems.

- Satellite telecommunications: Satellite communications should be integrated with the wider area of telecommunications systems, notably terrestrial systems <sup>(1)</sup>.

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Research will focus on: development of multisectorial concepts, systems and tools, user equipment including receivers, which will rely on precise navigation and timing service provision; spreading of high level, coherent and seamless quality services in all environments (cities, indoors and outdoors, land, sea, air, etc.), in synergy with other service provision (telecommunication, surveillance, observation, etc.).

- GMES: the objective is to stimulate the evolution of satellite-based information services, by development of technologies to bridge the gap between supply and demand, and to build up a European capability in the field of monitoring for environment and security.

Unchanged

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

<sup>(1)</sup> Considering the tight links between communications satellites and terrestrial technologies, the related work is presented in the context of the relevant actions of the 'Information society technologies' thematic priority area.

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**1.1.5. Food and health risks**

This priority area is aimed at assuring the health and well-being of European citizens through a better understanding of the influence of food intake and environmental factors on human health and to provide them with safer, and health-promoting foods, including seafoods, relying on fully controlled and integrated production systems originating in agriculture, and fisheries. By re-addressing the classical approach 'from farm to fork', this thematic priority area aims at ensuring that consumer protection is the main driver for developing new and safer food and feed production chains, i.e. 'from fork to farm'.

This end-user driven approach is reflected in the seven specific research objectives. Priority will be given to integrated research approaches crossing several specific objectives

**Research priorities**

- Epidemiology of food-related diseases genetic susceptibilities. The objective is to examine the complex interactions between food intake and metabolism, immune system, genetic background and environmental factors to identify key risk factors and develop common European databases.

Research will focus on: epidemiological studies of the effect of diet, food composition and lifestyle factors, on health, and the prevention or development of specific diseases, allergies and disorders; methodologies for measuring and analysing food composition and dietary intake, risk assessment, epidemiological and intervention models; influences of genetic variability using advances in functional genomics.

- Impact of food and in particular products containing genetically modified organisms: The objective is to provide the scientific basis for improving health through diet, and the development of new health-promoting foods, on health by means of an improved understanding of food metabolism and by harnessing the opportunities now available from proteomics and biotechnology.

## AMENDED PROPOSAL

**1.1.5. Food quality and safety**

This priority area is aimed at assuring the health and well-being of European citizens through a better understanding of the influence of food intake and environmental factors on human health and to provide them with safer, high-quality and health-promoting foods, including seafoods, relying on fully controlled and integrated production systems originating in agriculture, aquaculture and fisheries. By re-addressing the classical approach 'from farm to fork', this thematic priority area aims at ensuring that consumer protection is the main driver for developing new and safer food and feed production chains, i.e. 'from fork to farm', relying in particular on biotechnology tools taking into account the latest results of genomics research.

This end-user driven approach is reflected in the seven specific research objectives. Priority will be given to integrated research approaches crossing several specific objectives. Given that small enterprises constitute a major part of the food sector, the success of activities undertaken will rely on the adaptation of knowledge and processes to the specific characteristics of these enterprises.

**Unchanged**

- Epidemiology of food-related diseases and allergies. The objective is to examine the complex interactions between food intake and metabolism, immune system, genetic background and environmental factors to identify key risk factors and develop common European databases.

Research will focus on: epidemiological studies of the effect of diet, food composition and lifestyle factors, on the health of consumers and specific population groups such as children, and the prevention or development of specific diseases, allergies and disorders; methodologies for measuring and analysing food composition and dietary intake, risk assessment, epidemiological and intervention models; influences of genetic variability using advances in functional genomics.

- Impact of food on health: The objective is to provide the scientific basis for improving health through diet, and the development of new health-promoting foods, considering for instance new products, products resulting from organic farming, functional foods, products containing genetically modified organisms, and those arising from recent biotechnology developments, by means of an improved understanding of food metabolism and by harnessing the opportunities now available from proteomics and biotechnology.

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Research will focus on: overall relationship between diet and health; health promoting and disease prevention properties of foods; effects of food components, pathogens, chemical contaminants and new agents of prion type on body function; nutrient requirements and health promoting intervention strategies; determinants of consumer attitudes towards food products and production; methodologies for risk/benefit assessment of nutrients and of bioactive compounds; specificities of different age groups, particularly older consumers

- 'Traceability' processes in particular relating to genetically modified organisms including systems based on recent biotechnology developments. The objective is to strengthen the scientific and technological basis for ensuring complete traceability of genetically modified organisms, including based on recent biotechnology developments from raw material origin to purchased food products, and thereby increase consumer confidence in the food supply.

Research will focus on: development, validation and harmonisation of technologies and methodologies to ensure complete traceability throughout the food chain; scale-up, implementation and validation of methods in whole food chains; assurance of authenticity; validity of labelling and new HACCP criteria.

- Methods of analysis and detection: The objective is to contribute to the development, improvement, validation and harmonisation of reliable and cost-effective sampling and measurement strategies for controlling the safety of the food and feed supply and ensuring accurate data for risk analysis.

Research will focus on: methods and standards for analysing and detecting food-borne pathogens and chemical contaminants, including pre-normative aspects; modelling and approaches to improve existing prevention and measurement control strategies; detection tests and geographical mapping of prions; material transfer of prions and environmental influences.

## AMENDED PROPOSAL

Research will focus on: overall relationship between diet and health; health promoting and disease prevention properties of foods; effects of food components, pathogens, chemical contaminants and new agents of prion type on health; nutrient requirements and health promoting intervention strategies; determinants of consumer attitudes towards food products and production; methodologies for risk/benefit assessment of nutrients and of bioactive compounds; specificities of different population groups, particularly the elderly and children.

- 'Traceability' processes all along the production chain. The objective is to strengthen the scientific and technological basis for ensuring complete traceability for instance of genetically modified organisms, including those based on recent biotechnology developments from raw material origin to purchased food products, and thereby increase consumer confidence in the food supply.

Research will focus on: development, validation and harmonisation of technologies and methodologies to ensure complete traceability throughout the food chain; scale-up, implementation and validation of methods in whole food chains; assurance of authenticity; validity of labelling; application of HACCP to the whole food chain.

- Methods of analysis, detection and control: The objective is to contribute to the development, improvement, validation and harmonisation of reliable and cost-effective sampling and measurement strategies for chemical contaminants and existing or emerging pathogenic micro-organisms (such as viruses, bacteria, yeasts, fungi, parasites, and new agents of the prion type including development of ante mortem diagnostic tests for BSE and scrapie) so as to control the safety of the food and feed supply and ensure accurate data for risk analysis.

Research will focus on: methods and standards for analysing and detecting food-borne pathogens and chemical contaminants, including pre-normative aspects; modelling and approaches to improve existing prevention and control strategies; detection tests and geographical mapping of prions; transfer and longevity of prions.



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- Safer and production methods and healthier foodstuffs including those based on and on organic farming processes: The objective is to develop lower input farming systems and improved transformation processes aimed at producing safer and health-promoting and feed, and improving the quality of food and feed through innovative technologies.

Research will focus on: development of improved integrated production systems, lower-input farming, organic farming and GMO-based production as well as processing and distribution methods and innovative technologies for safer, nutritious and higher quality food and feed; individual and comparative assessment of safety, quality, environmental impact and competitiveness aspects of different production methods and foodstuffs; improvement of animal husbandry, waste-management and animal welfare from housing to slaughter; application of plant and animal sciences and biotechnologies, including the application of genomics, for the development of higher quality food raw materials and nutritious foods.

- Impact of animal feed, on human health: The objective is to improve understanding of the role of animal feed, and the use of sub-products of different origins for that feed, in food safety, to reduce the use of undesirable raw materials and to develop alternative new animal feed sources.

Research will focus on: epidemiological studies of animal-feed induced food-borne diseases; influence of raw materials, including waste and by-products of different origins, processing methods, additives and veterinary drugs used in animal feed on animal and human health; improved waste management, to ensure exclusion of specified high-risk and condemned materials from the feed chain; novel protein, fat and energy sources other than meat and bone meal for optimal animal growth, reproductive potential and food product quality.

- Environmental health risks The objectives are to identify the environmental factors that are detrimental to health, understand the mechanisms involved and determine how to prevent or minimise these effects and risks.

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- Safer and environmentally friendly production methods and healthier foodstuffs: The objective is to develop lower input farming systems (agriculture and aquaculture) based on systems such as integrated production, lower-input methods including organic agriculture and the use of plant and animal sciences and biotechnologies and improved transformation processes aimed at producing safer healthier nutritious, functional and varied foodstuffs, and animal feed, and improving the quality of food and feed through innovative technologies.

Unchanged

- Impact of animal feed, on human health: The objective is to improve understanding of the role of animal feed, including products containing genetically modified organisms and the use of sub-products of different origins for that feed, in food safety, to reduce the use of undesirable raw materials and to develop alternative new animal feed sources.

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- (a) Risks linked to the food-chain (chemical, biological and physical)

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Research will focus on: identification of causal agents including contaminants, and physiological mechanisms, of environmental-linked health impacts; understanding of exposure pathways, estimation of cumulative, low dose and combined exposures; long-term effects; definition and protection of susceptible sub-groups; environmental causes and mechanisms responsible for the increase in allergies; impact of endocrine disrupters; chronic chemical pollution and combined environmental exposures, transmission of illnesses linked to water (parasites, viruses, bacteria, etc.).

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- (b) Combined exposures of authorised substances, including impact of local environmental disasters and pollution on the safety of foodstuffs, with emphasis being placed on cumulative risks, transmission routes to human beings, long-term effects and exposure to small doses, as well as the impact on particularly sensitive groups, and especially children

Research will focus on: identification of causal agents including contaminants, and physiological mechanisms, of environmental, and food-linked environmental hazards; understanding of exposure pathways, estimation of cumulative, low dose and combined exposures; long-term effects; definition and protection of susceptible sub-groups; environmental causes and mechanisms responsible for the increase in allergies; impact of endocrine disrupters; chronic chemical pollution and combined environmental exposures, transmission of illnesses linked to water (parasites, viruses, bacteria, etc.).

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

#### 1.1.6. Sustainable development and global change

The Treaty confirms Sustainable Development as a central objective of the European Community; Climate change, energy security, sustainable transport, protection of nature, and their interaction with human activities motivate this research action. The activities carried out within this priority area aim to strengthen the scientific and technological capacities needed for Europe to be able to implement a sustainable development model and make a significant contribution to the international efforts to understand and control global change and preserve the equilibrium of ecosystems.

#### Development

Strategic objectives address the reduction of greenhouse gases and pollutant emissions, the security of energy supply, the balanced use of the various transport modes, as well as to achieve an enhanced competitiveness of European industry. Achieving these objectives in the short term requires a large-scale research effort to encourage the deployment of

#### 1.1.6. Sustainable development, global change and ecosystems

The Treaty confirms Sustainable Development as a central objective of the European Community; this was emphasised by the recent European Council in Göteborg. In this context, global change, energy security, sustainable transport, sustainable management of Europe's natural resources, and their interaction with human activities motivate this research priority theme. The activities carried out within this priority aim at strengthening the scientific and technological capacities needed for Europe to be able to implement a sustainable development model in the short and in the long term, integrating its social, economic and environmental dimensions, and make a significant contribution to the international efforts to mitigate or even to reverse current adverse trends, to understand and control global change and preserve the equilibrium of ecosystems.

#### 1.1.6.1. Sustainable energy systems

Strategic objectives address the reduction of greenhouse gases and pollutant emissions, the security of energy supply, the increased use of renewable energy as well as to achieve an enhanced competitiveness of European industry. Achieving these objectives in the short term requires a large-scale research effort to encourage the deployment of technologies

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technologies already under development and to help promote changes in energy consumption behaviour and transport demand patterns. The longer term implementation of sustainable development requires an equally strong RTD effort to assure the economically attractive availability and overcome the potential barriers to adoption of renewable energy sources hydrogen and fuel cells that are intrinsically clean.

## Research priorities

(i) *Research activities having an impact in the short and medium term*

Community RTD activity is one of the main instruments which can serve to change significantly current unsustainable patterns of development, characterised by growing dependence on imported fossil fuels, continually rising energy demand, increasing congestion of the transport system, and growing CO<sub>2</sub> emissions, by offering new technological solution which could positively influence consumer/user behaviour in the short and medium term.

Proposed technological solutions are expected to emerge from, and to be demonstrated in, consumer/user pilot-environments, addressing technical but also organisational, institutional, financial and social issues.

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already under development and to help promote changes in energy demand patterns and consumption behaviour by improving energy efficiency and integrating renewable energy into the energy system. The longer term implementation of sustainable development requires also an important RTD effort to assure the economically attractive availability, of energy, and overcome the potential barriers to adoption of renewable energy sources and new carriers and technologies such as hydrogen and fuel cells that are intrinsically clean.

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Community RTD activity is one of the main instruments which can serve to support the implementation of new legislative instruments in the field of energy and to change significantly current unsustainable patterns of development, which are characterised by growing dependence on imported fossil fuels, continually rising energy demand, increasing congestion of the transport systems, and growing CO<sub>2</sub> emissions, by offering new technological solution which could positively influence consumer/user behaviour, especially in the urban environment.

The goal is to bring innovative and cost competitive technological solutions to the market as quickly as possible through demonstration and other research actions aiming at the market, which involve consumers/users in pilot environments, and which address not only technical but also organisational, institutional, financial and social issues.

- Clean energy, in particular renewable energy sources and their integration in the energy system, including storage, distribution and use.

The aim is to bring to the market improved renewable energy technologies and to integrate renewable energy into networks and supply chains, for example by supporting stakeholders who are committed to establishing 'Sustainable Communities' employing a high percentage of renewable energy supplies. Such actions will adopt innovative or improved technical and/or socio-economic approaches to 'green electricity', heat, or biofuels and their integration into energy distribution networks or supply chains, including combinations with conventional large-scale energy distribution.

Research will focus on: increased cost effectiveness, performance and reliability of the main new and renewable energy sources; integration of renewable energy and effective combination of decentralised

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sources, with cleaner conventional large-scale generation; validation of new concepts for energy storage, distribution and use.

- Energy savings and energy efficiency, including those to be achieved through the use of renewable raw materials.

The overall objective is to reduce the demand for energy by 18 % by the year 2010 in order to contribute to meeting the EU's commitments to combat climate change and to improve the security of energy supply. Research activities will focus in particular on Eco-Buildings to generate energy savings and improve environmental quality as well as quality of life for occupants. 'Polygeneration' activities will contribute to the Community target of doubling the share of cogeneration (CHP) in EU electricity generation from 9 % to 18 % by 2010, and improve the efficiency of combined production of electricity, heating and cooling services, by using new technologies such as fuel cells and integrate renewable energy sources.

Research will focus on: improving savings and efficiency mainly in the urban context, in particular in buildings, through the optimisation and validation of new concepts and technologies, including combined heat and power and district heating/cooling systems; opportunities offered by on-site production and use of renewable energy to improve energy efficiency in buildings.

- Alternative motor fuels.

The Commission has set an ambitious target of 20 % substitution of diesel and gasoline fuels by alternative fuels in the road transport sector by the year 2020. The aim is to improve the security of energy supply through reduced dependence on imported liquid hydrocarbons and to address the problem of greenhouse gas emissions from transport. In line with the Communication on alternative fuels for road transportation, short term RTD will concentrate on three types of alternative motor fuels that potentially could reach a significant market share: biofuels, natural gas and hydrogen.

Research will focus on: the integration of alternative motor fuels into the transport system, particularly into clean urban transport; the cost-effective and safe production, storage, and distribution (including fuelling infrastructure) of alternative motor fuels; the optimal utilisation of alternative fuels in new concepts of energy efficient vehicles; strategies and tools to manage the market transformation process for alternative motor fuels.

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- Renewable energy sources, more efficient and clean use of energy, especially in urban areas, new concepts of energy efficient and cleaner transport: the objective is to develop energy efficient technologies that reduce demand for fossil fuels by stimulating energy efficient behaviour in disparate user communities and bring about energy savings of 12 % by 2010, as well as to tilt the energy balance towards more sustainable energy systems, which combine heat and power as well as new and renewable sources and thereby increase the share of renewable energy systems from 6 % to 12 % by 2010.

Research will focus on: increased cost efficiency and reliability of the main new and renewable sources, and their combination with conventional large-scale and distributed generation; efficiency in building, district heating systems and CHP; demand side action for reducing gas and electricity consumption; new forms of clean urban transport; rationalisation of the use of the private vehicle; integration of new concepts for energy efficient vehicles and new/alternative fuels.

- (ii) *Research activities having an impact in the medium and longer term*

In the longer term the objective is to develop renewable energy sources, hydrogen technologies and fuel cells which are intrinsically clean and which can be well integrated in a sustainable energy supply mix both for stationary and for transport applications. This to bring about further reduction in greenhouse gas emissions beyond the Kyoto deadline of 2010. The future large-scale development of these technologies will depend on significant improvement in their cost and other aspects of competitiveness against conventional energy sources.

- Fuel cells: these represent an emerging technology which is expected, in the longer term, to replace a large part of the current combustion systems in industry, buildings and road transport, as they have a higher efficiency, lower pollution levels and a potential for lower cost. The long term cost target is 50 euro/kW for road transport and 300 euro/kW for high-durability stationary applications and fuel cell/electrolysers.

Research will focus on: cost reduction in fuel cell production and in applications for buildings, transport and de-centralised electricity production; advanced materials related to low and high temperature fuel cells for the above applications.

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In the medium and longer term the objective is to develop new and renewable energy sources, and new carriers such as hydrogen which are both affordable and clean and which can be well integrated in a long term sustainable energy supply and demand context both for stationary and for transport applications. Furthermore the continuing use of fossil fuels in the foreseeable future requires cost-effective solutions to the disposal of CO<sub>2</sub>. The goal is to bring about further reduction in greenhouse gas emissions beyond the Kyoto deadline of 2010. The future large-scale development of these technologies will depend on significant improvement in their cost and other aspects of competitiveness against conventional energy sources, within the overall socio-economic and institutional context in which they are deployed.

- Fuel cells, including their applications: these represent an emerging technology which is expected, in the longer term, to replace a large part of the current combustion systems in industry, buildings and road transport, as they have a higher efficiency, lower pollution levels and a potential for lower cost. The long term cost target is 50 euro/kW for road transport and 300 euro/kW for high-durability stationary applications and fuel cell/electrolysers.

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## INITIAL PROPOSAL

- The objective to establish hydrogen as an energy carrier is key in a future sustainable energy economy. The long term aim is to achieve an energy cost which is equivalent to that of conventional fuels without tax.

Research will focus on: cost-effective production of hydrogen from fossil fuels (including CO<sub>2</sub> capture and underground storage); hydrogen production e.g. by electrolysis from renewable and nuclear energy; hydrogen infrastructure including transport, distribution, storage and utilisation;

- Solar photovoltaic technologies and biomass: photovoltaics have, in the long term, the potential to make a large contribution to the world and EU energy supply. The objective is to overcome the major bottleneck of high investment costs, which, should be reduced by a factor of 4. The overall objective for biomass is to make bioenergy competitive with conventional fuels.

Research will focus on (photovoltaics): the whole production chain from basic material to the PV system, as well as integration of PV in habitat and large scale MW-size PV systems for production of electricity. biomass barriers in the biomass supply-use chain in the following areas: combustion technologies, gasification technologies for electricity and H<sub>2</sub>/syngas production and biofuels for transport.

## AMENDED PROPOSAL

- New technologies for energy carriers/transport and storage, in particular hydrogen: The aim is to develop new concepts for long term sustainable energy supply where hydrogen and clean electricity are seen as major energy carriers. For H<sub>2</sub>, the means must be developed to ensure its safe use at an equivalent cost to that of conventional fuels. For electricity, decentralised new and in particular renewable energy resources, must be optimally integrated, within inter-connected European, regional and local distribution networks to provide secure and reliable high quality supply.

Research will focus on: Clean cost-effective production of hydrogen; hydrogen infrastructure including transport, distribution, storage and utilisation; For electricity the focus will be on new concepts, for analysis, planning, control and supervision of electricity supply and distribution and on enabling technologies, for storage, interactive transmission and distribution networks.

- New and advanced concepts in renewable energy technologies: Renewable energy technologies have, in the long term, the potential to make a large contribution to the world and EU energy supply. The focus will be on technologies with a significant future energy potential and requiring long-term research, by means of actions with high European added value in particular to overcome the major bottleneck of high investment costs, and to make these technologies competitive with conventional fuels.

Research will focus on: for photovoltaics: the whole production chain from basic material to the PV system, as well as on the integration of PV in habitat and large scale MW-size PV systems for production of electricity. For biomass barriers in the biomass supply-use chain will be addressed in the following areas: production, combustion technologies, gasification technologies for electricity and H<sub>2</sub>/syngas production and biofuels for transport. For other areas the effort will be focused on integrating at European level specific aspects of RTD activities which require long term research.

- Capture and sequestration of CO<sub>2</sub>, associated with cleaner fossil fuel plants: Cost effective capture and sequestration of CO<sub>2</sub> is essential to include the use of fossil fuels in a sustainable energy supply scenario, reducing costs to the order of EUR 30 in the medium term and EUR 20 or less in the longer term per tonne of CO<sub>2</sub> for capture rates above 90 %.

## INITIAL PROPOSAL

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Research will focus on: developing holistic approaches to near zero emission fossil fuel based energy conversion systems, low cost CO<sub>2</sub> separation systems, both pre-combustion and post-combustion as well as oxyfuel and novel concepts: development of safe, cost efficient and environmentally compatible CO<sub>2</sub> disposal options, in particular geological storage, and exploratory actions for assessing the potential of chemical storage.

1.1.6.2. ***Sustainable surface transport***

The Common Transport Policy forecasts a transport demand growth by 2010 in the European Union of 38 % for freight and 24 % for passenger transport (base-year 1998). The already congested transport networks will have to absorb the additional traffic, and the trend suggests that the proportion absorbed by the less sustainable modes is likely to grow. The objective is consequently both to fight against congestion and to decelerate or even reverse this unsustainable trend by rebalancing transport modes. Short and medium term actions will develop and integrate new concepts and technologies into the transport system.

The White Paper: 'European transport policy for 2010: time to decide' forecasts a transport demand growth by 2010 in the European Union of 38 % for freight and 24 % for passenger transport (base-year 1998). The already congested transport networks will have to absorb the additional traffic, and the trend suggests that the proportion absorbed by the less sustainable modes is likely to grow. The objective is consequently both to fight against congestion and to decelerate or even reverse these trends regarding the modal split by better integrating and rebalancing the different transport modes, improving their safety, performance and efficiency, minimising their impact on the environment and ensuring the development of a genuinely sustainable European transport system, while supporting European industry's competitiveness in the production and operation of transport means and systems.

## Research priorities:

- (i) *Developing environmentally friendly transport systems and means of transport.*

The objective is to reduce the contribution of surface transport (rail, road, waterborne) to CO<sub>2</sub> production and other emissions including noise, while increasing safety, comfort, quality, cost-effectiveness and energy-efficiency of vehicles and vessels. Emphasis will be given to clean urban transport and rational use of the car in the city.

- New technologies and concepts for all surface transport modes (road, rail and waterborne).

Research will focus on: high efficiency propulsion systems and their components, based on alternative and renewable fuels, taking into account the fuelling infrastructure; development of zero or near zero emission propulsion systems and components, in particular those integrating fuel cells, hydrogen combustion and their fuelling infrastructure into the transport system; integrated concepts for clean urban transport and rational use of the car in urban locations.

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- Advanced design and production techniques.

Research will focus on: 'transport-specific' advanced design and production techniques, in particular for one-of-a-kind production environments, leading to improved quality, safety, recycling, comfort and cost-effectiveness of environmentally friendly vehicles (cars and trains) and vessels.

- (ii) *Making surface transport safer, more effective and more competitive.*

The objectives are to assure transport of passengers and freight, taking into account transport demand and the need for rebalancing transport modes, while increasing transport safety in line with the 2010 objectives for European transport policy (e.g. for road transport the objective would be to halve the number of fatalities).

- Rebalancing and integrating different transport modes.

Research will focus on: interoperable transport systems, to enable the inter-connectivity of the transport networks, in particular enabling a competitive European railway system and the integration of a European vessel traffic information system; intermodal transport services, technologies (e.g. harmonisation of unit loads) and systems, and advanced logistics;

- Increasing road, rail and waterborne safety and avoiding traffic congestion.

Research will focus on: strategies and technologies to increase road safety and to improve maritime safety; concepts and systems for advanced human-vehicle, vehicle-vehicle and vehicle-infrastructure interaction; large-scale integration and validation platforms for intelligent transport systems (e.g. transport pricing, transport and traffic management and transport information), including satellite navigation applications, new vehicle types and operational procedures to increase capacity and safety, while respecting the environment (in particular in urban and sensitive areas).

Research will focus on: safer and more environmentally friendly transport, in particular for the road and maritime sectors; integration of intelligent transport systems for the efficient management of infrastructure; enabling railway interoperability; development of inter-modality for passengers and freight, in particular through better management of the logistic chain and standardisation of loading units.

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## INITIAL PROPOSAL

**Global change**

Global change encompasses the complex dynamic changes over different time-scales in the physical, chemical and biological components of the Earth system (i.e. atmosphere, oceans and land) in particular those influenced by human activities. The objective of this priority area is to strengthen the capacity to understand, detect and predict global change and develop strategies for prevention, mitigation and adaptation, in particular in relation to all types of greenhouse gases, in close liaison with the relevant international research programmes and in the context of relevant conventions such as the Kyoto Protocol. Such an objective will be best achieved through activities aiming at the development of common and integrated approaches necessary to implement sustainable development, taking into account its environmental, economic and social aspects, as well as the impact of global change on all countries and regions of the world. It will foster the convergence of European and national research efforts for a consensual definition of the scientific thresholds of sustainability and estimation methods, and encourage international co-operation in order to achieve common strategies to respond to global change issues.

**Research priorities**

- Impact and mechanisms of greenhouse gas emissions The objective is to detect and describe global change processes, to improve prediction of their global and regional impacts, evaluate mitigation options and improve the access of European researchers to facilities and platforms for global change research.

Research will focus on: understanding and quantification of changes in the carbon and nitrogen cycles and the role of sources of all greenhouse gases and sinks in the terrestrial and ocean biosphere; influence of and effects on climate dynamics and variability, ocean and atmospheric chemistry, and their interactions; understanding and prediction of global climatic change; associated phenomena (e.g. El Niño, stratospheric ozone depletion, changes in sea level and ocean circulation); and impacts

## AMENDED PROPOSAL

**1.1.6.3. Global change and ecosystems**

Global change encompasses the complex dynamic changes over different time-scales in the physical, chemical and biological components of the Earth system (i.e. atmosphere, oceans and land) in particular those influenced by human activities. The objectives of this priority area are: (i) to strengthen the capacity to understand, detect and predict global change and develop strategies for prevention, mitigation and adaptation, in close liaison with the relevant international research programmes and in the context of relevant conventions such as the Kyoto Protocol and the Montreal Protocol; (ii) to preserve the ecosystems and protect biodiversity which would also contribute to the sustainable use of land and marine resources. In the context of global change, strategies for integrated, sustainable management of agricultural and forest ecosystems are of particular importance for the preservation of these ecosystems and will contribute substantially to the sustainable development of Europe. These objectives will be best achieved through activities aiming at the development of common and integrated approaches necessary to implement sustainable development, taking into account its environmental, economic and social aspects, as well as the impact of global change on all countries and regions of the world. It will foster the convergence of European and national research efforts for common definitions of thresholds of sustainability and estimation methods, and encourage international co-operation in order to achieve common strategies to respond to global change issues.

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- Impact and mechanisms of greenhouse gas emissions and atmospheric pollutants on climate, ozone depletion and carbon sinks (oceans, forests and soil). The objective is to detect and describe global change processes, associated with greenhouse gas emissions and atmospheric pollutants from all sources, including those resulting from energy supplies, transport and agriculture, to improve prediction and assessment of their global and regional impacts, evaluate mitigation options and improve the access of European researchers to facilities and platforms for global change research.

Research will focus on: understanding and quantification of changes in the carbon and nitrogen cycles; the role of all sources of greenhouse gases and atmospheric pollutants and their sinks in the biosphere; their effects on climate dynamics and variability, ocean and atmospheric chemistry, and their interactions; future stratospheric ozone levels and ultraviolet radiation; prediction of global climatic change and impacts; associated phenomena (e.g. El Niño, changes in sea level and ocean circulation); and mitigation and adaptation strategies.

## INITIAL PROPOSAL

- Water cycle: the objective is to assess the impact of global change and in particular climate change on the water cycle, water quality and availability, to provide the bases for management to mitigate the impacts.

Research will focus on: impact and feedback of climate change on hydrological variables, groundwater/surface water distribution, freshwater and wetland ecosystems and water quality; the driving role of oceans in the global water cycle; management strategies and their impacts; scenarios of water demand and availability.

- Biodiversity, protection of genetic resources, functioning of terrestrial and marine ecosystems and interactions between human activities and the latter: the objectives are to develop a better understanding of marine and terrestrial biodiversity and of ecosystem functioning, understand and minimise the impacts of human activities on them and ensure sustainability of natural resources.

Research will focus on: assessing and forecasting changes in biodiversity, structure, function and dynamics of ecosystems and their services; with emphasis on relationships between society, economy, biodiversity and habitats; integrated assessment of drivers affecting biodiversity, and mitigation of biodiversity loss; risk assessment, management, conservation and rehabilitation options

- Mechanisms of desertification and natural disasters connected with climate change: the objective is to elucidate the links between climatic change and the mechanisms of desertification and natural disasters, so as to improve risk and impact assessment and forecasting, decision support methodologies, and strategies for sustainable land and coastal management.

Research will focus on: large scale integrated assessment of land/soil degradation and desertification in Europe and related prevention and mitigation strategies; long term forecasting of hydro-geological hazards associated with global climate change; natural hazard monitoring, mapping and management strategies; improved disaster preparedness and mitigation.

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- Water cycle, including soil-related aspects: the objective is to understand the mechanisms and assess the impact of global change and in particular climate change on the water cycle, water quality and availability, as well as soil functions and quality to provide the bases for management tools for water systems to mitigate the impacts.

Research will focus on: impact of climate change on the components of the hydrological cycle — land/ocean/atmosphere interactions, groundwater/surface water distribution, freshwater and wetland ecosystems, soil functioning and water quality; assessment of vulnerability of water/soil systems to global change; management strategies and their impacts; scenarios of water demand and availability.

- Biodiversity and ecosystems: the objectives are to develop a better understanding of marine and terrestrial biodiversity and of ecosystem functioning, understand and minimise the impacts of human activities on them and ensure sustainable management of natural resources and terrestrial and marine ecosystems and the protection of genetic resources.

Research will focus on: assessing and forecasting changes in biodiversity, structure, function and dynamics of ecosystems and their services; with emphasis on marine ecosystems' functioning; relationships between society, economy, biodiversity and habitats; integrated assessment of drivers affecting ecosystems' functioning and biodiversity, and mitigation options; risk assessment, management, conservation and rehabilitation options in relation to terrestrial and marine ecosystems.

- Mechanisms of desertification and natural disasters: the objective is to understand the mechanisms of desertification and natural disasters, including their links with climatic change so as to improve risk and impact assessment and forecasting, and decision support methodologies.

Research will focus on: large scale integrated assessment of land/soil degradation and desertification in Europe and related prevention and mitigation strategies; long term forecasting of hydro-geological hazards; natural hazard monitoring, mapping and management strategies; improved disaster preparedness and mitigation.

## INITIAL PROPOSAL

- Global climate changing systems: the objective is to make systematic observations of climate parameters so as to strengthen climate change research, consolidate long-term observations for the modelling improve forecasting of the marine, terrestrial and atmospheric environment, establish common European data bases and contribute to international programmes.

Research will focus on: observations of basic marine, terrestrial and atmospheric parameters necessary for global climate change research and management strategies, and of extreme events; large observing/monitoring/surveying/modelling networks (taking into account the developments of GMES and providing the European dimension to G3OS).

## AMENDED PROPOSAL

- Strategies for sustainable land management, including coastal zones, agricultural land and forests. The objective is to contribute to the development of strategies and tools for sustainable use of land, with emphasis on the coastal zones, agricultural lands and forests, including integrated concepts for the multipurpose utilisation of agricultural and forest resources, and the integrated forestry/wood chain in order to ensure sustainable development at economic, social, and at environmental levels.

Research will focus on: development of the necessary tools for integrated management of coastal zones (ICZM); evaluation of positive and negative externalities under different production systems for agriculture and forestry; development of strategies for sustainable forest management considering regional specificity; strategies/concepts for sustainable management and multipurpose utilisation of forest and agriculture resources; cost-efficiency of new environmental-friendly processes and recycling technologies within the integrated forestry/wood chain.

- Operational forecasting and modelling, including global climate change observation systems: the objective is to make systematic observations of atmospheric, terrestrial and oceanic parameters including those of climate so as to improve forecasting of the marine, terrestrial and atmospheric environment, consolidate long-term observations for the modelling and in particular prediction, establish common European data bases and contribute to international programmes.

Research will focus on: observations of basic marine, terrestrial and atmospheric parameters necessary for global change research and management strategies, and of extreme events; large observing/monitoring/surveying/operational forecasting/modelling networks (taking into account the developments of GMES and providing the European dimension to G3OS).

- Complementary research will focus on: development of advanced methods for risk assessment and methods for appraising environmental quality, including relevant prenormative research on measurements and testing for these purposes.

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

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**1.1.7. Citizens and governance in the European knowledge-based society**

The Lisbon European Council recognised that the transition towards a European knowledge-based society will affect every aspect of people's lives. The overall objective is to provide a sound knowledge base for the management of this transition, which will be conditioned by national, regional and local policies, programmes and actions, as well as informed decision-making by individual citizens, families and other societal units.

Given the complexity, breadth and interdependence of these challenges and the issues involved, the research approach adopted must be based on greatly enhanced research integration, multi and transdisciplinary cooperation, and on the mobilisation of the social sciences and humanities research communities in Europe in addressing them. Activities will also facilitate the identification of medium to long term societal challenges arising from research in social sciences and humanities and will ensure the active participation of key societal stakeholders and the targeted dissemination of the work carried out. In order to support the development of comparative transnational and interdisciplinary research, while at the same time preserving the diversity of research methodologies throughout Europe, the collection and analysis of better and more genuinely comparable data and the coordinated development of statistics and qualitative and quantitative indicators in particular in the context of the emerging knowledge society at the European level is essential.

Appropriate coordination of socio-economic research and foresight elements across all the Priorities of this programme will be assured.

**Research priorities****(i) Knowledge-based European society**

The building of a European knowledge society is a clear political objective for the European Community. The research aims to provide the basis of understanding needed to ensure this takes place in a manner which accords with specific European conditions and aspirations.

- Improving the generation, distribution and use of knowledge and its impact on economic and social development. The objective is to improve significantly understanding of the characteristics of knowledge and its functioning as a public and private good, and to provide the bases for policy formulation and decision-making.

Research will focus on: characteristics of knowledge and its functioning in relation to the economy society and innovation; and the transformation of economic and social institutions; the dynamics of knowledge production, distribution and use, role of knowledge codification and impact of ICTs; the importance of territorial structures and social networks in these processes.

**1.1.7. Citizens and governance in a knowledge-based society**

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Appropriate coordination of socio-economic research and foresight elements across all the Priorities of the Specific Programmes will be assured.

**Unchanged****(i) Knowledge-based society and social cohesion**

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Research will focus on: characteristics of knowledge and its functioning in relation to the economy and society, as well as for innovation and for entrepreneurial activities; and the transformation of economic and social institutions; the dynamics of knowledge production, distribution and use, role of knowledge codification and impact of ICTs; the importance of territorial structures and social networks in these processes.

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- Options and choices for the development of a knowledge-based society serving the EU objectives set at the Lisbon summit. The objective is to develop an integrated understanding of how a knowledge-based society can promote the societal objectives of sustainable development, social and territorial cohesion and improved quality of life, with due consideration to the variety of social models in Europe.

Research will focus on: features of a knowledge based society in line with European social models and the need to improve the quality of life; social and territorial cohesion, gender and intergenerational relations and social networks; implications of changes to work and employment; access to education and training, and life-long learning.

- The variety of paths towards a knowledge society. The objective is to provide comparative perspectives across Europe and thus provide an improved basis for the formulation and implementation of transition strategies towards a knowledge society at the national and regional levels.

Research will focus on: globalisation in relation to pressures for convergence; the implications for regional variation; challenges to European societies from a diversity of cultures and increased sources of knowledge; the role of the media in this context.

(ii) *Citizens, democracy and new forms of governance*

The work will identify the main factors influencing changes in governance and citizenship, as well as the impacts of these changes and the possible options to enhance democratic governance, resolve conflicts, protect human rights and take account of cultural diversity and multiple identities.

- The implications of European integration and enlargement for governance and the citizen: The objective is to clarify the key interactions between European integration and enlargement, and issues of democracy, institutional arrangements and citizens' well-being.

Research will focus on: relationships between integration, enlargement and institutional change within a historical and comparative perspective; the implications of a changing global context and the role of Europe; the consequences of an enlarged European Union for the well-being of its citizens.

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- Options and choices for the development of a knowledge-based society: The objective is to develop an integrated understanding of how a knowledge-based society can promote the societal objectives of the EU set at the Lisbon summit and subsequent European Councils of sustainable development, social and territorial cohesion and improved quality of life, with due consideration to the variety of social models in Europe.

Research will focus on: features of a knowledge-based society in line with European social models and the need to improve the quality of life; social and territorial cohesion, gender and intergenerational relations and social networks; implications of changes to work and employment, and the labour market; access to education and training, and life-long learning.

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(ii) *Citizenship, democracy and new forms of governance.*

The work will identify the main factors influencing changes in governance and citizenship, in particular in the context of increased integration and globalisation and from the perspectives of history and cultural heritage as well as the impacts of these changes and the possible options to enhance democratic governance, resolve conflicts, protect human rights and take account of cultural diversity and multiple identities.

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Research will focus on: relationships between integration, enlargement and institutional change within the context of their historical evolution and with a comparative perspective; the implications of a changing global context and the role of Europe; the consequences of an enlarged European Union for the well-being of its citizens.

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- Articulation of areas of responsibility and new forms of governance: The objective are to support the development of forms of multi-level governance which are accountable, legitimate, and sufficiently robust and flexible to address societal change including integration and enlargement, and to assure the effectiveness and legitimacy of policy-making.

Research will focus on: the articulation of responsibilities between various territorial levels and between public and private sectors; democratic governance, representative institutions and roles of civil society organisations; privatisation, the public interest, new regulatory approaches, corporate governance; implications for legal systems.

- Security issues connected with the resolution of conflicts and restoration of peace and justice: the objectives are to support the development of institutional and social capacity in the field of conflict resolution, identify factors leading to success or failure in preventing conflict, and develop improved options for conflict mediation.

Research will focus on: early identification of factors leading to conflict within and between countries; comparative analysis of procedures for prevention and mediation of conflicts and achievement of justice in different fields; Europe's role in regional and international arenas in these respects.

- New forms of citizenship and identities: The objectives are to promote citizens' involvement and participation in European policy making, as well as to understand perceptions and impacts of European citizenship and human rights provisions, and factors that allow mobility and coexistence of multiple identities.

Research will focus on: relations between new forms of citizenship including rights of non-citizens; tolerance, human rights, racism and xenophobia; the role of the media in the development of a European public sphere; evolution of citizenship and identities in a context of cultural, and other diversities and increasing population flows; implications for the development of a European knowledge-based society.

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- Issues connected with the resolution of conflicts and restoration of peace and justice: the objectives are to support the development of institutional and social capacity in the field of conflict resolution, identify factors leading to success or failure in preventing conflict, and develop improved options for conflict mediation.

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- New forms of citizenship and cultural identities: the objectives are to promote citizens' involvement and participation in European policy-making, to understand perceptions and impacts of citizenship and human rights provisions in Europe and to identify factors that allow mobility and coexistence of multiple identities.

Research will focus on: relations between new forms of citizenship including rights of non-citizens; tolerance, human rights, racism and xenophobia; the role of the media in the development of a European public sphere; evolution of citizenship and identities in a context of cultural, and other diversities in Europe, taking into account population flows; social and cultural dialogue within Europe and with other world regions; implications for the development of a European knowledge-based society.

The research activities carried out within this thematic priority area will include exploratory research at the leading edge of knowledge on subjects closely related to one or more topics within it. Two complementary approaches will be utilised: one receptive and open — the other proactive.

## INITIAL PROPOSAL

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**1.2. Specific activities covering a wider field of research**

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Activities under this heading will complement research within the thematic priority areas and comprise the following:

- Anticipating the EU's scientific and technological needs
- Specific research activities for SMEs
- Specific international co-operation activities

**1.2.1. Anticipating the EU's scientific and technological needs****1.2.1. Supporting policies and anticipating scientific and technological needs**

These activities have a distinct role within the overall architecture of the Framework Programme 2002-2006. They involve common implementation arrangements, and the necessary critical mass, to assure efficient and flexible conduct of research which is essential to the fundamental objectives of Community research and which covers a wide range of needs that cannot be satisfied within the thematic priorities. They will have the following specific objectives:

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- To underpin the formulation and implementation of Community policies, bearing on the interests of possible future members of the Union as well as the existing Member States, and monitor their effects;
- To explore new and emerging scientific and technological problems and opportunities, including in particular interdisciplinary and multidisciplinary research areas, where European action is appropriate in view of the potential to develop strategic positions at the leading edge of knowledge and in new markets, or to anticipate major issues facing European society.

A feature common to these activities is that they will be implemented within a multi-annual perspective which takes direct account of the needs and viewpoints of the main associated actors (as appropriate: policymakers, industrial user groups, leading edge research groups, etc.). They will be implemented in conjunction with an annual programming mechanism, by which specific priorities, corresponding to identified needs and falling within the objectives indicated above, will be determined.

A feature common to these activities is that they will be implemented within a multi-annual perspective which takes direct account of the needs and viewpoints of the main associated actors (as appropriate: policymakers, industrial user groups, leading edge research groups, etc.). They will be implemented in conjunction with a flexible programming mechanism to be implemented during the course of the programme, by which specific priorities, corresponding to identified needs and falling within the objectives indicated above, will be determined.

Priorities thus determined will then be inscribed in the work-programme for the specific programme, alongside the priorities deriving from objectives in other parts of the programme, and updated regularly. This will result in a progressive allocation of the budget relating to these activities to the specific priorities identified, throughout the period of execution.

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## INITIAL PROPOSAL

The programming will be carried out by the Commission, and will be based on suggestions received in response to a wide-ranging consultation of interested circles in the EU and the countries associated with the framework programme, regarding the topics to be included.

A budget of EUR 440 million will be allocated to the research activities specified below, which have been determined on the basis of needs which can be identified now; This represents 50 % of the amount destined for all activities under this heading; the remaining 50 % will be allocated to research activities to be defined during the course of implementation of the specific programme.

(i) *Policy-orientated research*

The activities under this heading will provide, in particular, support for:

- the implementation of common policies, in particular the common agricultural policy, and the common fisheries policy;
- the achievement of Community policy objectives including in particular those set out in the 6th Environment Action Programme<sup>(1)</sup> the Green Paper 'Towards a European strategy for the security of energy supply'<sup>(2)</sup>; and the White Paper on European transport policy<sup>(3)</sup>;
- as well as those in such fields as public health and, gender equality, regional development, trade, enlargement external relations and development aid, and justice and internal affairs.
- the achievement of other important objectives of the Community, such as those set by the European Commission for the five years of its mandate and those derived from the political orientations given by the European Council, including the Lisbon strategy, with regard to economic policy, in the fields of the Information Society and e-Europe, enterprise, internal market and competitiveness, social policy and employment, and education and culture, including the requisite statistical methods and tools.

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A first allocation of EUR 350 million will be made to the research activities specified below, which have been determined on the basis of needs which can be identified now; the remaining EUR 220 million will be allocated during the course of implementation of the specific programme.

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- the common agricultural policy (CAP), and the common fisheries policy (CFP);
- sustainable development, in particular the Community policy objectives relating to environment (including those set out in the 6th Environment Action Programme<sup>(1)</sup>); energy (the Green Paper 'Towards a European strategy for the security of energy supply'<sup>(2)</sup>); and transport (the White Paper on European transport policy<sup>(3)</sup>);
- other Community policies, namely health (in particular public health), regional development, trade, development aid, internal market and competitiveness, social policy and employment, education training and culture, gender equality, consumer protection, the creation of an area of freedom, security and justice, external relations including those policies in support of enlargement, and including the requisite statistical methods and tools;
- Community policy objectives deriving from the political orientations given by the European Council, with regard to, for instance, economic policy, the Information Society, as well as e-Europe, and enterprise.

They may include pre-normative research, measurement and testing where necessary for the needs of Community policies.

<sup>(1)</sup> COM(2001) 31.

<sup>(2)</sup> COM(2000) 769.

<sup>(3)</sup> COM(2001) 370.

<sup>(1)</sup> COM(2001) 31.

<sup>(2)</sup> COM(2000) 769.

<sup>(3)</sup> COM(2001) 370.



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## Multi-annual programming

Unchanged

The multi-annual programming of these activities will take into account the opinions of the relevant Scientific Committees associated with the policies concerned. The programming will be conducted with the help of a User Group composed of different Commission Services, who will also have recourse, where appropriate, to an independent consultation structure composed of high-level scientific and industrial experts. The User Group will assess suggestions put forward regarding the topics to be included on the basis of the following criteria:

- their contribution to policy formulation and development (e.g. links with legislative proposals in preparation or with major deadlines in the area);
- their potential contribution to the EU's competitiveness, the strengthening of its scientific and technological bases and the achievement of the European Research Area, including the effective integration of the candidate countries.
- European added value, taking account in particular of research carried out in the Member States in the relevant fields;
- the scientific relevance and feasibility of the research themes and approaches proposed;
- assurance of an appropriate division of tasks, and synergy, between these activities and the Direct Actions of the Joint Research Centre in support of Community policies.

The programming may be altered by means of an emergency procedure based on the same evaluation criteria in the event of a crisis giving rise to urgent and unforeseen research needs.

## Initial research priorities

The programming method described above has been applied to define Policy-orientated research priorities responding to needs that can already be anticipated. In this first application, it has been based on suggestions for topics made by the Commission's policy services, drawing on the advice, as appropriate, of the relevant Scientific Committees, as well as the broader objectives of the Union as set out in successive conclusions of the meetings of the European Council. The priorities so defined will be incorporated in the workprogramme at the start of the programme.

Policy-orientated research priorities responding to immediate needs are based on suggestions for topics made by the Commission's policy services, drawing on the advice, as appropriate, of the relevant Scientific Committees, as well as the broader objectives of the Union as set out in successive conclusions of the meetings of the European Council.

They have been grouped within the following lines of action, in a structure which optimises synergies between different policy requirements and scientific inputs, and which cuts across and complements the thematic priorities:

Unchanged

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- Sustainable management of Europe's natural resources. Research under this heading responds to policy requirements relating, in particular, to the modernisation and sustainability of the common agriculture and fisheries policies and the promotion of rural development, including forestry. It will focus on:

Development of bases for policies to promote sustainable, quality-based agriculture; definition of multifunctional models of sustainable agriculture and forestry management, benefits and trade-impact assessment; improved tools for forecasting and assessment of international agriculture policies and markets and related agreements, and the common agriculture policy; environmental implications of agriculture, fisheries and aquaculture-based production systems, including non-food agriculture, and their interactions; characterisation of spatial entities, and related drivers of change for assessment of rural development and to provide tools to support environmental impact assessment; development of evaluation and monitoring tools for animal health and welfare.

Development of alternative approaches to fisheries management, through better understanding of key biological and selectivity parameters within an eco-system based approach; integration of multi-annual, multi-species and socio-economic aspects, and assessment of uncertainties; improvement of monitoring control and surveillance methods; development of bases for policies to promote sustainable aquaculture through, disease prevention, production systems diversification and

Better understanding of the structure and functioning of terrestrial and marine ecosystems, including the assessment of soil functions and degradation processes; tools for assessing water quality status, contaminant concentrations and improvement options; integrated air pollution assessment; strategic noise mapping.

- Providing health, security and opportunity to the people of Europe. Research in this category responds to policy requirements relating, in particular, to the implementation of the European Social Agenda, public health and consumer protection and the creation of an Area of Freedom, Security and Justice. It will focus on:

Methods to evaluate the need for, and performance and efficiency of, social and consumer policy measures, including aspects related to consumer satisfaction, unfair practices and impacts of other EU policies; the transformation of the labour market, and the cost of 'non-social

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the modernisation and sustainability of agriculture and forestry, including their multifunctional role in order to ensure the sustainable development and promotion of rural areas;

tools and assessment methods for sustainable agriculture and forestry management;

the modernisation and sustainability of fisheries policy, including aquaculture-based production systems;

new and more environment friendly production methods to improve animal health and welfare;

environmental assessment (soil, water, air, noise, including the effects of chemical substances).

Deleted

- Providing health, security and opportunity to the people of Europe. Research in this category responds to policy requirements relating, in particular, to the implementation of the European Social Agenda including future social policy issues, public health and consumer protection and the creation of an Area of Freedom, Security and Justice. It will focus on:

health determinants and the provision of high quality and sustainable health care services and pension systems (in particular in the context of ageing and demographic change);

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Europe', development of co-ordinated approaches and a comparative European knowledge base for policies to ensure sustainable pension and health care systems, in particular with respect to the impact of demographic change and ageing; development of improved methods for risk assessment, including non-animal test methods for chemical substances, measures related to product safety, and communication of emerging threats to consumers' and workers' health and safety.

Comparative assessment of health determinants, including nutrition, gender-related and socio-economic factors, of health services and e-health systems, and methods for intervention quality assessment; development of improved incidence measurement and understanding of transmission paths for emerging, rare and communicable diseases, including in the international context; development of safe and secure procedures for blood and organ donation, storage and use; methods to assess the distribution, and socio-economic impact, of disabilities.

Comparative research on factors underlying migration and refugee flows, including illegal immigration and trafficking in human beings, improved means to anticipate crime trends and causes, and to assess the effectiveness of crime-prevention policies; assessment of new challenges related to illicit drug use.

- Underpinning the economic potential and cohesion of a larger and more integrated European Union. Research in this category responds, in particular, to the needs of a series of policies concerned with the competitiveness, dynamism and integration of the European economy, in the context of enlargement, globalisation and Europe's commercial relations with the rest of the world. It will focus on:

Improved means to assess economic effectiveness and social impacts of monetary and fiscal policies, the contribution of financial market integration to economic development in the Euro area; the impact of cohesion policies on sustainable regional development; efficiency of sustainable development policies on key business sectors, to assess the economic/industrial impact of biotechnologies; methods of standardisation as tools to support internal market policies and to underpin Community trade policy positions and mutual recognition agreements.

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public health issues, including epidemiology contributing to disease prevention and responses to emerging rare and communicable diseases, allergies, procedures for secure blood and organ donations, non-animal test methods;

the impact of environmental issues on health (including methods for risk assessment and the mitigation of risks of natural disasters to people);

issues relating to handicapped/disabled people (including equal access facilities);

understanding of migration and refugee flows;

understanding crime trends in the context of public safety;

issues related to civil protection, including biosecurity, and crisis management.

Unchanged

underpinning European integration, sustainable development, competitiveness and trade policies (including improved means to assess economic development and cohesion);

the development of tools, indicators and operational parameters for assessing sustainable transport and energy systems performance (economic, environmental and social);

global security analysis and validation systems for transport and research relating to accident risks and safety in mobility systems;

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Development of bases for a comprehensive approach to transport security (in particular for air transport); development of tools, indicators and operational parameters to assess sustainable transport and energy system performance (economic, environmental, social), and monitor achievement of targets, in the enlarged Europe; forecasting tools, incorporating socio-economic and technological aspects, and cost-effective data sourcing, for energy and transport, to enable validation of proposed measures, including technological and market-based measures, and to assist in the development of innovative policies and policy packages to assure sustainability in the medium and long term.

Assessment of means for management and protection of digital identities and digital assets; assessment of policies, policy tools and best practice for promoting inclusive and secure access to the information society, benchmarking of government process re-engineering best practices to improve public services; e-education and associated contexts of learning, including lifelong learning; consumer protection in relation to information and communications services; damage assessment methods and conservation strategies to protect cultural heritage; development of advanced methods and techniques to improve the quality, accessibility and dissemination of statistics produced by the European statistical system.

A co-ordinated approach will be ensured when addressing research questions that are common to different policy areas, in particular with respect to the measurement and impact assessment of demographic changes and more broadly in the development of policy-relevant statistics and indicators.

(ii) *Research to explore new and emerging scientific and technological problems and opportunities*

Research under this heading will respond to needs in new interdisciplinary and multidisciplinary areas or areas at the leading edge of knowledge, and which fall within the legitimate scope of Community research, as well as to unexpected major developments. By bringing together resources from across the EU, it will aim to put European research in a leading position, opening the way or creating new scientific and technological developments. It will stimulate the flow of ideas between academia and industry, and allow Europe better to exploit its research assets in the drive towards a dynamic knowledge-based society.

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forecasting and developing innovative policies for sustainability in the medium and long term;

Information Society issues (such as management and protection of digital assets, and inclusive access to the information society);

the protection of cultural heritage;

improved quality, accessibility and dissemination of European statistics

Deleted

Unchanged

Research under this heading will respond to needs in new areas which fall within the legitimate scope of Community research and which cut across or lie outside the thematic priority areas, in particular because they are highly interdisciplinary and/or multidisciplinary. The research will also respond to unexpected major developments. By bringing together resources from across the EU, it will aim to put European research in a leading position, opening the way or creating new scientific and technological developments. It will stimulate the flow of ideas between academia and industry, and allow Europe better to exploit its research assets in the drive towards a dynamic knowledge-based society.

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The following areas of activity will be supported initially:

Unchanged

- Research to assess rapidly new discoveries, or newly-observed phenomena, which may indicate emerging risks or problems of high importance to European society, and identify appropriate responses to them.
- Research in emerging areas of knowledge and on future technologies, in particular in transdisciplinary fields, which is highly innovative and involves correspondingly high (technical) risks. It will be open to any new idea that has significant potential for major industrial and/or social impact, or for the development of Europe's research capabilities in the longer term.

Proposals will be evaluated on the basis of research excellence, potential for future impact, and, in the first of these areas particularly, innovativeness.

#### Multi-annual programming

Specific topics within the above categories on which research will be focused during the implementation of the programme will be selected by means of the multi-annual programming on the basis of their urgency or potential for future societal, industrial, or economic relevance, taking account of the ongoing research activities under this heading. The assessment of topics will be carried out with the support of an independent consultation structure composed of high-level scientific and industrial experts and will also incorporate the following criteria:

- the potential contribution of the research topics proposed for innovation and the EU's competitiveness, the strengthening of its scientific and technological bases and the achievement of the European Research Area, including the effective integration of the candidate countries;
- the scientific relevance and timeliness of the research themes and approaches proposed.

The programming may be altered by means of an emergency procedure based on the same evaluation criteria in the event of a crisis giving rise to urgent and unforeseen research needs.

#### (iii) Implementation

The activities programmed will be carried out by means of calls for proposals. They will essentially take the form of:

- Targeted Specific projects generally of a limited scale, carried out by means of partnerships of a size adapted to the needs to be covered.

- Specific targeted research projects generally of a limited scale, carried out by means of partnerships of a size adapted to the needs to be covered.

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- the networking of research activities carried out at national level where the objectives can be achieved by mobilising capacities existing in the Member States, candidate countries and other associated states.

In certain duly justified cases, where the objectives pursued can be better attained in this way, limited use may be made of the instruments used in the priority thematic areas.

The proposals will be selected by the Commission following evaluation by independent experts.

(ii) *Specific research activities for SMEs*

#### Objectives

Small and medium-sized enterprises (SMEs) play a crucial role in European competitiveness and job creation, not only because they represent the overwhelming majority of enterprises in Europe, but also because they are the source of dynamism and change in new markets, particularly those at the leading edge of technology. Although a heterogeneous community, they are all confronted by increased competition resulting from the completion of the European internal market and the need to innovate constantly and accommodate advances in technology. Besides this, an increasing number of SMEs both need and want to internationalise in search of new markets and business opportunities.

SMEs will participate, for the most part, in the activities implemented under the priority thematic areas of research within networks of excellence and integrated projects. In addition, specific schemes for SMEs in the form of actions on collective and cooperative research will be set up. These will be addressing primarily the large community of SMEs with a capacity to innovate but with limited research capability. However, the co-operative research scheme will be extended to provide support for new, high-tech SMEs through arrangements catering specifically for their needs.

Overall, at least 15 % of the budget relating to the 'integrating research' part of this programme will be allocated to SMEs.

#### Collective research

Collective research is a form of research undertaken by RTD performers on behalf of industrial associations or industry groupings in order to expand the knowledge base of large communities of SMEs and thus improve their general standard of competitiveness. Conducted on a European basis, through substantial projects of several years duration, this is an efficient way of addressing technological needs of significant sections of the industrial community.

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- Co-ordination actions, and the networking of research activities carried out at national level where the objectives can be achieved by mobilising capacities existing in the Member States, candidate countries and other associated States.

In certain duly justified cases, where the objectives pursued can be better attained in this way, limited use may be made of networks of excellence and integrated projects.

Unchanged

Specific support actions may also be used to implement these activities.

Deleted

#### 1.2.2. **Horizontal research activities involving SMEs**

Unchanged

SMEs will participate, for the most part, in the activities implemented under the priority thematic areas of research within networks of excellence, integrated projects and specific targeted research projects. In addition, specific schemes for SMEs in the form of actions on collective and cooperative research will be set up. These will be addressing primarily the large community of SMEs with a capacity to innovate but with limited research capability. However, the co-operative research scheme will also allow innovative SMEs to co-operate with universities and research centres

Overall, in addition to the horizontal activities for SMEs, at least 15 % of the budget relating to the seven thematic priorities under this programme will be allocated to SMEs.

Unchanged

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Based on schemes existing in many Member States, this measure aims at allowing industrial groupings to identify and express research needs that are common to large numbers of SMEs at European level. It should allow to improve the overall European technological basis of whole industrial sectors. By inter-linking industrial groupings in different countries and in financing larger projects with an increased responsibility for project co-ordinators, it will contribute to structuring the landscape of collective research in line with the objectives of the European Research Area.

Collective research projects could cover, for example:

- Research aimed at addressing common problems/challenges (e.g. to meet regulatory requirements, environmental performance)
- Pre-normative research (research to provide a scientific base for European norms and standards)
- Research aimed at reinforcing the technological basis of particular sector(s)
- Development of 'technological tools' (e.g. diagnosis, safety equipment)

Projects will be managed, on the basis of well-defined guidelines, by industrial associations or other groupings established at European level, or at least 2 national industrial associations/groupings established in different European countries. European Economic Interest Groups representing the interests of SMEs are also eligible. A 'core group' of SMEs associated to each project will monitor progress from the definition phase of the research to the dissemination of the results obtained.

A 2-step approach is envisaged in identifying topics and selecting proposals (call for outline proposals and, after those selected in a first round evaluation have been developed into complete proposal(s), evaluation and selection from amongst these). The level of funding and contractual arrangements of collective research projects will depend on their objectives:

- projects aimed at strengthening the competitiveness of a specific industrial sector would benefit from a maximum Community contribution of 50 % of the total eligible costs. In such cases the contracting party (the industrial groupings) would own the results,
- projects having a strong legislative or 'public well-being' content (e.g. environmental protection, enhancement of public health), could obtain a higher funding. In such cases, the main emphasis will be on a Europe-wide dissemination of the research results.

In all cases, dissemination of the results amongst the SMEs would be foreseen through, for example, special training and demonstration ('take-up') actions.

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Projects will be managed, on the basis of well-defined guidelines, by industrial associations or other groupings established at European level, or by at least 2 national industrial associations/groupings established in different European countries. European Economic Interest Groups representing the interests of SMEs are also eligible. A 'core group' of SMEs associated to each project will monitor progress from the definition phase of the research to the dissemination of the results obtained.

Unchanged

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## Co-operative research

Co-operative research is a scheme whereby a limited number of SMEs from different countries having specific problems or needs, outsource the required research to an RTD performer, while retaining ownership of the results. Projects are relatively short term and may address any research topic or field, being based on the specific needs and problems of the SMEs concerned. Other (non-SME) enterprises and end-users will be able to participate in co-operative research projects, under conditions ensuring they do not assume a dominant role, and have restricted access to the results.

These activities may also be carried out by innovative and high-tech SMEs in co-operation with research centres and universities.

Young high-technology SMEs, including 'start-ups', may need to outsource specific basic research requirements to extend or renew the knowledge base underpinning their own research activities. In this case, the co-operative research scheme can be used by a single SME which needs to co-operate with an RTD performer from another country having the required specialised complementary research skills. Special provisions regarding access to the results will apply for such cases.

Deleted

Co-operative research will be implemented via an open call for proposals. This activity will also be responsible for the co-ordination of a dedicated network of SME National Contact Points in the Member States and Associated States, providing SMEs at regional and national level with information and assistance on their participation in the Framework Programme, including in Networks of Excellence and Integrated Projects. Close co-ordination with the Economic and Technological Intelligence Actions and with the innovation support services, implemented under the heading 'Research and Innovation', will ensure that SMEs benefit from all the foreseen instruments and activities.

Co-operative research will be implemented via an open call for proposals. Information and advice about the possibilities of SME involvement will be ensured via entry points set up by the Commission, and by making use of the national contact point scheme. This activity will also be responsible for the co-ordination of a dedicated network of SME National Contact Points in the Member States and Associated States, providing SMEs at regional and national level with information and assistance on their participation in the Framework Programme, including in Networks of Excellence and Integrated Projects. Close co-ordination with the Economic and Technological Intelligence Actions and with the innovation support services, implemented under the heading 'Research and Innovation', will ensure that SMEs benefit from all the foreseen instruments and activities.

(iii) *Specific international co-operation activities*

Deleted

### 1.2.3. *Specific measures in support of international co-operation*

The general objective of the international cooperation activities carried out under the Framework Programme is to help open up the European Research Area to the rest of the world. These activities represent the particular contribution of the Framework Programme to this opening-up process, which will require a joint effort by the Community and the Member States.

Unchanged

Under this heading, the activities in question have the following particular objectives:



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- To help European researchers, businesses and research organisations in the EU and the countries associated with the Framework Programme to have access to knowledge and expertise existing elsewhere in the world.
- To help ensure Europe's strong and coherent participation in the research initiatives conducted at international level in order to push back the boundaries of knowledge or help to resolve the major global issues, for example as regards health and environment.
- To lend support, in the scientific and technological field, to the implementation of the Community's foreign policy and development aid policy.

Apart from opening up the networks of excellence and the integrated projects to participation by third-country researchers and institutions, international cooperation activities will take the form of specific activities.

Carried out in support of the Community's foreign policy and development aid policy, these specific activities will concern three groups of countries: the Mediterranean third countries, Russia and the CIS countries, and the developing countries.

They will be carried out in such a way as to complement the participation of researchers and entities in those countries in the networks of excellence and integrated projects which are open to them and in which they will participate in a variable way depending on the themes and countries.

The research priorities in this category of activities are defined on the basis of the interests and objectives of the Community's political partnership with the different groups of countries, as well as their particular economic and social needs.

They will therefore cover more particularly:

- In the case of the Mediterranean third countries, in support of the development of the Euro-Mediterranean partnership, issues relating to environment, health and water issues, as well as protection of the cultural heritage.
- In the case of Russia and the CIS countries, stabilisation of R & D potential, issues relating to changes in the industrial production system, environment and health protection and various safety aspects.
- In the case of the developing countries, the problems of health and public health, food safety, and the rational exploitation of resources.

These activities will be carried out by means of research, technological development and demonstration projects of a limited scale, actions to coordinate national efforts and, where necessary, specific support measures.

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Apart from opening up the activities of the seven thematic priorities to participation by third-country researchers and institutions, international cooperation activities will take the form of specific activities.

Unchanged

- In the case of the developing countries, the problems of health and public health, food security, and the rational exploitation of resources.

Unchanged

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Cooperation activities with Russia and the CIS will be carried out in particular through the INTAS structure set up jointly by the Community and the Member States.

In all three cases, one of the major objectives is to help strengthen, stabilise, develop or adapt the local research systems.

Accordingly, the Framework Programme activities will endeavour to strengthen coordination and complementarity with activities carried out by means of financial instruments such as, in the case of the Mediterranean third countries, the MEDA Programme, in the case of Russia and the CIS countries the Tacis Programme and in the case of the developing countries the EDF (European Development Fund) and the ALA (Latin America/Asia) Fund. These activities can help to promote the development in those countries of human resources for research, research infrastructures and capabilities relating to innovation and exploitation of results.

## 2. STRENGTHENING THE FOUNDATIONS OF THE EUROPEAN RESEARCH AREA

The establishment of the European Research Area depends on improving the coherence and co-ordination of research and innovation activities and policies conducted at national, regional and European level.

The objectives of Community action in this field are to stimulate and support programme coordination and joint actions among Member States and among European organisations as well as to develop the common knowledge base necessary for the coherent development of policies. The activities may be implemented in any scientific and technological area, including in the thematic priority domains.

### 2.1. Co-ordination of research activities

#### *Coordination of national activities*

The objective is to encourage and support initiatives undertaken by several countries, in areas of common strategic interest, to develop synergy between their existing activities through co-ordination of their implementation, mutual opening and mutual access to research results, as well as to define and implement joint activities.

The activities concerned must be understood as programmes or parts of programmes, instruments, plans or other initiatives undertaken at national or regional levels and involving public funding to support RTD work, the development of research capabilities, and the promotion of innovation. The activities may be undertaken directly by public authorities or research agencies at national or regional levels or through European co-operation frameworks such as the European Science Foundation (e.g. the collaborative scheme. EUROCORES).

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The objectives of Community action in this field are to stimulate and support programme coordination and joint actions conducted at national or regional level as well as among European organisations and thus help to develop the common knowledge base necessary for the coherent development of policies. The activities may be implemented in any scientific and technological area, including in the thematic priority domains.

### 2.1. Support for the co-ordination of activities

Unchanged

The activities concerned must be understood as programmes or parts of programmes, instruments, plans or other initiatives undertaken at national or regional levels and involving public funding to support RTD work, the development of research capabilities, and the promotion of innovation. The activities may be undertaken directly by public authorities or research agencies at national or regional levels or through European co-operation frameworks, in particular the EUROCORES collaborative scheme of the European Science Foundation.

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The Community will encourage and support initiatives aimed at networking national and regional activities and programmes, by supporting:

- the coordination of independent activities including their mutual opening;
- the preparation and the management of joint activities.

For this purpose, the Community will:

- support proposals selected following their submission in response to an open call for proposals (2 evaluations per year). Where appropriate, calls for expressions of interest, followed by targeted calls may be published.

Proposals may cover for instance strategic studies and planning, consultation of the research and innovation community, joint calls for proposals and peer review panels, exchange and dissemination of information and results, programme monitoring and evaluation, exchange of personnel.

Proposals will be evaluated taking into account in particular the following aspects: the scope of the resources mobilised, the scientific and technological relevance and impact, the expected improvement in the use of research resources at European level and where appropriate their contribution to promoting innovation.

- Develop an integrated information system, which will be easily accessible, user-friendly and updated regularly, to provide relevant information to:

Efforts to encourage co-ordination activities, using a bottom-up approach, will be carried out in the whole field of science and technology in areas such as:

- health: health of key population groups; major diseases and disorders (e.g. cancer, diabetes, cardiovascular diseases, hepatitis, visual impairment), rare diseases and major diseases linked to poverty in developing countries; activities involved will be implemented, for instance, through co-ordination of research and comparative studies, development of European databases and interdisciplinary networks, exchange of clinical practice and coordination of clinical trials;
- biotechnology: non-health and non-food applications;
- environment: urban environment (including sustainable urban development and cultural heritage, including, for example, ecosite concepts); marine environment and land/soil management; seismic risk;
- energy: new generation power plants ('near-zero-emission'), energy storage, transport and distribution.

Unchanged

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- policy makers and programme managers: information on national research programmes, instruments, research activities undertaken and planned to help identify opportunities for co-ordination, networking or joint initiatives;
- the research community: information on national or joint programmes in which they can participate.

*Co-ordination at European level*

The objective is to enhance the complementarity and synergy between Community actions undertaken under the Framework Programme and those of other European scientific co-operation organisations as well as among these organisations themselves. Through increased co-ordination and collaboration the various European co-operation frameworks will contribute more effectively to the overall coherence of European research efforts and the establishment of a European Research Area. Community participation in international activities can be supported in duly justified cases.

- Scientific and technological co-operation activities carried out in other European co-operation frameworks

COST is a long-standing bottom-up mechanism that facilitates co-ordination and exchanges between nationally funded scientists and research teams in a variety of areas. In order for COST to continue to ensure a cost-effective contribution to research co-ordination within the European research area, its management arrangements must be adapted to the new context. This will entail the establishment by COST member states of an appropriate organisation to which financial support may then be granted under this programme.

Coordination with EUREKA will be strengthened to improve strategic coherence and complementarity of funding, in particular in the thematic priority areas. Joint information and communication actions will also be organised where appropriate.

- Collaboration and joint initiatives of specialised European scientific cooperation organisations

With regard to thematic European organisations, such as CERN, ESA, ESO, EMBL, ESRF, ILL, the Community will encourage and support specific initiatives aiming at strengthening the coherence and synergies between their activities and between them and Community actions, in particular through the development of joint approaches and actions on issues of common interest.

## AMENDED PROPOSAL

- policy makers and programme managers: information on national and regional research programmes, instruments, research activities undertaken and planned to help identify opportunities for co-ordination, networking or joint initiatives;
- the research community: information on national, regional or joint programmes in which they can participate.

## Unchanged

Reinforced co-ordination among the activities of the European Science Foundation, COST and the Framework Programme will also be sought in areas of common interest.

## Unchanged

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**2.2. Coherent development of research and innovation policies**

The objective of the activities to be carried out in this area is to encourage the coherent development of research and innovation policies in Europe thanks to the early identification of challenges and areas of common interest as well as by providing national and Community policymakers with knowledge and decision-aiding tools that can help them formulate policy.

The objective of the activities to be carried out in this area is to encourage the coherent development of research and innovation policies in Europe thanks to the early identification of challenges and areas of common interest as well as by providing national, regional and Community policymakers with knowledge and decision-aiding tools that can help them formulate policy.

The activities to be carried out to this end will take place in the following areas:

Unchanged

- Analyses and studies; work relating to foresight, statistics and science and technology indicators

These activities will include studies, analyses and foresight activities relating to scientific and technological activities and research and innovation policies in the context of the implementation of the European Research Area.

The activities relating to foresight will include in particular the development of thematic dialogue platforms and a knowledge base for users and producers of prospective analyses, the exploitation of good practices with regard to methodology, as well as the preparation of medium and long-term scenarios for science and technology in Europe.

Work on indicators will involve the further development of relevant and harmonised indicators, taking into account the different dimensions of research and innovation and their impact on economy and society, for example for comparing the scientific and technological performance of the Member States and regions.

- Benchmarking of research and innovation policies at national, regional and European level

The first exercise to benchmark national RTD policies, which began in 2000, will be completed by mid 2002. In the light of this exercise, the methodology of the next benchmarking cycles, including the indicators, will be adapted and the exercises will be enlarged geographically by opening them up to the countries in the process of acceding to the EU and the associated countries, and will be extended to include other themes. Special attention will be paid to the dissemination and monitoring of the application of best practices in close collaboration with the Member States and the research actors.

The benchmarking work in progress in the field of innovation (gathering of information about innovation policies in Europe, development of the 'innovation scoreboard' and organisation of 'peer reviews' of innovation policies by 'thematic clubs' of policymakers) will be extended so as to open them up geographically, in social terms as a result of involving the innovation stakeholders, and in regional terms.

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## — Mapping scientific and technological excellence in Europe

The activities on mapping excellence will be expanded according to two guidelines, increasing the number of themes covered and regularly updating the results.

Special attention will be paid to the very broad dissemination of the information available as well as to the coordination of mapping with the activities aimed at promoting the integration of research efforts in Europe.

## — Improving the regulatory and administrative environment for research and innovation in Europe

The objective here is to examine and analyse regulatory and administrative obstacles, to identify and disseminate good management practices and to help formulate new approaches. The following are some of the areas that will be concerned: intellectual and industrial property; public-private relations with regard to research and innovation; the exploitation and dissemination of knowledge; the rules governing access to new products or services on the market; mechanisms for funding research and innovation and encouraging investment, in particular by the private sector.

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## ANNEX II

## INDICATIVE BREAKDOWN OF THE AMOUNT

Types of activities	Amount (EUR million)
INTEGRATING RESEARCH	
<b>Priority thematic areas of research</b>	
Genomics and biotechnology for health	
Information Society technologies	
Nanotechnologies intelligent materials, new production processes	
Aeronautics and space	
Food safety and health risks	
Sustainable development and global change	
Citizens and governance in the European knowledge-based society	
<b>Anticipating the EU's scientific and technological needs</b>	
Policy orientated research and leading edge topics	
Specific research activities for SMEs	
Specific international cooperation activities	
STRENGTHENING THE FOUNDATIONS OF THE EUROPEAN RESEARCH AREA	
Support for the co-ordination of activities	
Support for the coherent development of policies	
Total	

Types of activities	Amount (EUR million)
FOCUSING AND INTEGRATING COMMUNITY RESEARCH	<b>12 525 <sup>(1)</sup></b>
<b>Priority thematic areas of research <sup>(2)</sup></b>	<b>11 205</b>
Genomics and biotechnology for health	2 200
— Advanced genomics and its applications for health	1 150
— Combating major diseases	1 050
Information Society technologies	3 600 <sup>(3)</sup>
Nanotechnologies and nanosciences, knowledge-based multifunctional materials, and new production processes and devices	1 300
Aeronautics and space	1 075
Food quality and safety	685
Sustainable development global change and ecosystems	2 120
— Sustainable energy systems	810
— Sustainable surface transport	610
— Global change and ecosystems	700
Citizens and governance in a knowledge-based society	225
<b>Specific activities covering a wider field of research</b>	<b>1 320</b>
Supporting policies and anticipating scientific and technological needs	570
Horizontal research activities involving SMEs	450
Specific measures in support of international co-operation	300
STRENGTHENING THE FOUNDATIONS OF THE EUROPEAN RESEARCH AREA	<b>330</b>
Support for the co-ordination of activities	280
Support for the coherent development of policies	50
Total	<b>12 855</b>

<sup>(1)</sup> Including EUR 600 million for international co-operation activities, and including any amounts provided for under decisions of the European Parliament and Council pursuant to Article 169 of the Treaty.

<sup>(2)</sup> The aim is to allocate at least 15 % of the total financial resources assigned to this heading to SMEs.

<sup>(3)</sup> Including up to EUR 100 million for the further development of Géant and GRID.

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## ANNEX III

## MEANS FOR IMPLEMENTING THE PROGRAMME

In order to implement the specific programme, and in accordance with the Decisions of the European Parliament and of the Council concerning the multiannual Framework Programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (2002/. . /EC) and with the rules for the participation of undertakings, research centres and universities and for the dissemination of research results (2002/. . /EC), the Commission will use various instruments.

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions in order to verify their relevance with regard to the objectives of the programme, their scientific and technological excellence, their Community added value and the participants' management capacity.

The Community contribution will be granted in accordance with the abovementioned decisions. In the case of participation of bodies from regions lagging in development, it may be possible to obtain complementary funding from the Structural Funds within the limits specified by the Community framework for state aid for research

Unchanged

As regards the thematic priority areas, the importance of the new instruments (Integrated Projects and Networks of Excellence) is recognised as being an overall priority means to attain the objectives of critical mass, management simplification and European added value contributed by Community research in relation to what is already undertaken at national level, and of the integration of the research capacities. However, the size of projects is not a criterion for exclusion, and access to new instruments is ensured for SMEs and other small entities.

The new instruments will be used from the start of the Sixth Framework Programme in each theme and, where deemed appropriate, as a priority means, while maintaining the use of specific targeted projects and coordination actions.

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions.

The Community contribution will be granted in accordance with the abovementioned decisions and in compliance with the Community framework for state aid for research. In the case of participation of bodies from regions lagging in development, when a project receives the maximum intensity of co-financing authorised under the framework programme or an overall grant, an additional contribution from the Structural Funds, pursuant to Council Regulation (EC) No 1260/99 <sup>(1)</sup>, could be granted.

In the case of participation of entities from the associated candidate countries, an additional contribution from the pre-accession financial instruments could be granted under similar conditions.

In the case of participation of organisations from Mediterranean or developing countries, a contribution of the MEDA programme and of the financial instruments of the Community's aid to development could be envisaged.

In carrying out the programme, the Commission may have recourse to technical assistance.

In 2004 an evaluation will be undertaken by independent experts of the efficiency of each of these three types of instruments in the execution of the Sixth Framework Programme.

<sup>(1)</sup> OJ L 161, 26.6.1999.



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Actions under Articles 169 and 171 of the Treaty which contribute to the scientific and technological objectives set out in Annex I may be supported financially by the specific programme, in accordance with the relevant decisions under Article 172 of the Treaty.

A. **New instruments**

Unchanged

A.1. *Networks of excellence*

Networks of excellence are implemented in the seven priority thematic areas of the Framework Programme and, in duly justified cases, in research areas meeting the needs of Community policies and as well as in new and emerging areas

Networks of excellence are implemented in the seven priority thematic areas of the Framework Programme and, in duly justified cases, in research areas supporting policies and anticipating scientific and technological needs.

The objective of this instrument is to strengthen European scientific and technological excellence by means of a progressive and lasting integration of research capacities existing or emerging in Europe at both national and regional level. Each network will aim at advancing knowledge in a particular area by assembling a critical mass of skills.

The purpose of networks of excellence is to strengthen and develop Community scientific and technological excellence by means of the integration, at European level, of research capacities currently existing or emerging at both national and regional level. Each network will also aim at advancing knowledge in a particular area by assembling a critical mass of expertise. They will foster cooperation between capacities of excellence in universities, research centres, enterprises, including SMEs, and science and technology organisations. The activities concerned will be generally targeted towards long-term, multidisciplinary objectives, rather than predefined results in terms of products, processes or services.

In general, the network will be organised around a core group of participants to which others may be added. In order to create a virtual centre of excellence, they will integrate a considerable part or even the totality of their research activities in the area concerned. These activities will often be multidisciplinary, and oriented towards long-term objectives and not precise predefined results in terms of products, processes or services.

A network of excellence will be implemented by a joint programme of activities involving some or, where appropriate, all of the research capacities and activities of the participants in the relevant area to attain a critical mass of expertise and European added value. A joint programme of activities could aim at the creation of a self-standing virtual centre of excellence that may result in developing the necessary means for achieving a durable integration of the research capacities. A joint programme of activities will necessarily include those aimed at integration, as well as activities related to the spreading of excellence and dissemination of results outside the network.

In addition to these integrated research activities, the network's joint programme of activities will also comprise integration activities as well as activities related to spreading of excellence outside the network.

In pursuing its objectives, the network will therefore carry out:

Unchanged

— Research activities integrated by its participants

— Integration activities which will comprise in particular:

- adaptation of the participants' research activities in order to strengthen their complementarity;
- development and utilisation of electronic information and communication means, and development of virtual and interactive working methods;

## INITIAL PROPOSAL

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- short-, medium- and long-term exchanges of personnel, the opening of positions to researchers from other members of the network, or their training;
  - development and use of joint research infrastructures, and adaptation of the existing facilities with a view to a shared use;
  - joint management and exploitation of the knowledge generated, and actions to promote innovation.
- Activities of spreading of excellence which will comprise, as appropriate:
- training of researchers;
  - communication concerning the achievements of the network and the dissemination of knowledge;
  - services in support of technological innovation in SMEs, aimed in particular at the take-up of new technologies;
  - analyses of science/society issues related to the research carried out by the network.

In carrying out some of its activities (such as training of researchers), the network will endeavour to ensure publicity by publishing calls for applications.

The size of the network may vary according to the areas and subjects involved. As an indication, the number of participants should not be less than half a dozen. On average, in financial terms, the Community contribution to a network of excellence may represent several million euros per year.

The network proposals should comprise the following elements:

- a general outline of the joint programme of activities, and its content for the first year, broken down into research activities, integration activities, and activities for spreading excellence;
- the role of the participants, identifying the activities and resources that they will integrate;
- the operation of the network (coordination and management of activities);
- the plan for the dissemination of knowledge and the perspectives as regards exploitation of the results.

- a general outline of the joint programme of activities, and its content for the first period, broken down into research activities, integration activities, and activities for spreading excellence;

Unchanged

## INITIAL PROPOSAL

The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a call for applications.

The programme of activities would be updated yearly and would entail a reorientation of certain activities or launching of new ones not initially foreseen, which could involve new participants. The Commission may launch calls for proposals with a view to the allocation of additional contribution in order to cover, for example, an extension of the integrated activities of the existing network or the integration of new participants.

The Community's financial contribution will be a specified amount linked to the implementation of a set of work, initially calculated on the basis of the resources dedicated to carrying out the joint programme of activity and paid on an annual basis, taking into account activities and financial reports. As a complement to the resources of the participants. It should be sufficient to act as an incentive for integration, but without creating a financial dependence that might jeopardise the lasting association of the network.

*A.2. Integrated projects*

Integrated projects will be implemented in the seven priority thematic areas of the Framework Programme and, in duly justified cases, in, in research areas meeting the needs arising from the implementation of Community policies as well as in new and emerging

The objective of this instrument is to strengthen European competitiveness or contribute to resolve major societal problems by mobilising a critical mass of research and technological development resources and skills existing in Europe.

Accordingly, each integrated project will have the aim of obtaining identifiable scientific and technological results applicable to products, processes or services. The activities carried out in the context of an integrated project will have by definition clearly defined objectives even in the case of risky research.

In general, the participants in the projects will be organised around a core group made up of the main participants.

## AMENDED PROPOSAL

The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a competitive call.

Unchanged

The Community's financial contribution shall take the form of a grant for integration, the amount of which is determined in relation to the value of the capacities and resources which all the participants propose to integrate. It shall complement the resources deployed by the participants in order to carry out the joint programme of activities. It should be sufficient to act as an incentive for integration, but without creating a financial dependence that might jeopardise the lasting association of the network.

Unchanged

Integrated projects will be implemented in the seven priority thematic areas of the Framework Programme and, in duly justified cases, in, in research areas supporting policies and anticipating scientific and technological needs.

Integrated projects are designed to give increased impetus to the Community's competitiveness or to address major societal needs by mobilising a critical mass of research and technological development resources and competence. Each integrated project will be assigned clearly defined scientific and technological objectives and should be directed at obtaining specific results applicable in terms of, for instance, products, processes or services. Under these objectives they may include more long-term or 'risky' research.

Integrated projects will comprise a coherent set of component actions which may vary in size and structure according to the tasks to be carried out, each dealing with different aspects of the research needed to achieve common overall objectives, and forming a coherent whole and implemented in close coordination.

They will be carried out on the basis of overall financing plans preferably involving significant mobilisation of public and private sector funding, including funding from EIB and collaboration schemes such as Eureka.

## INITIAL PROPOSAL

All the activities carried out in the context of an integrated project will be defined in the general framework of an 'execution plan' comprising activities relating to:

- research, technological development and/or demonstration;
- management, dissemination and transfer of knowledge with a view to promoting innovation;
- analysis and assessment of the technologies concerned, as well as the factors relating to their exploitation.

In pursuit of its objectives, it may also comprise activities relating to:

- training researchers, students, engineers and industrial executives, in particular for SMEs;
- support for the take-up of new technologies, in particular by SMEs;
- information and communication, and dialogue with the public concerning the science/society aspects of the research carried out within the project.

The size of an integrated project may vary according to the themes and subjects, depending on the critical mass necessary in order to obtain the expected results under the best possible conditions.

The combined activities of an integrated project may represent a financial size ranging from several million euros to several tens of millions of euros.

In most cases an integrated project will comprise a set of specific actions, relating to certain aspects of the research needed to achieve the objectives pursued, of variable sizes and structures according to the tasks to be executed, implemented in a closely coordinated manner. In some cases, however, an integrated project may take the form of a single large project with a single component.

Integrated project proposals should comprise the following elements:

- the scientific and technological objectives of the project;
- the main lines and timetable of the execution plan, highlighting the articulation of the various components;

## AMENDED PROPOSAL

All the activities carried out in the context of an integrated project will be defined in the general framework of an 'implementation plan' comprising activities relating to:

- research, and as appropriate technological development and/or demonstration;

Unchanged

Deleted

The combined activities of an integrated project may represent a financial size ranging from several million euros to several tens of millions of euros. However, the size of projects is not a criterion for exclusion, and access to new instruments is ensured for SMEs and other small entities.

Deleted

Unchanged

## INITIAL PROPOSAL

- the stages of implementation and the results expected in each one of them;
- the role of the participants within the consortium and the specific skills of each of them;
- the organisation and management of the project;
- the plan for the dissemination of knowledge and the exploitation of results;
- the global budget estimate and the budget for the different activities, including a financial plan identifying the various contributions and their origin.

The partnership may evolve when necessary, within the limits of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a call for applications.

The execution plan will be updated yearly. This updating may entail the reorientation of certain activities and the launching of new ones. In the latter case, and where an additional Community contribution is needed, the Commission will identify these activities and the participants who will carry them out, by means of a call for proposals.

The Community contribution will be part of a financing plan which may involve recourse to other financing schemes, in particular Eureka or the instruments of the EIB or the EIF. It may amount to up to 50 % of the total project budget, broken down into budgets per activity. It will be paid annually on the basis of the proposed execution plan, and adjusted according to the activities and the financial reports.

A.3. *Collective research projects*

Implemented across the whole field of science and technology, these projects will be carried out by research entities for the benefit of industrial associations or groupings, in areas and on subjects of interest to a large number of SMEs confronted with common problems.

B. **Other instruments**

In order to implement the programme, the Commission may also have recourse to

- specific targeted projects in order to carry out research or demonstration activities in areas meeting the needs of Community policies, new or emerging needs, and specific international cooperation activities.

## AMENDED PROPOSAL

The partnership may evolve when necessary, within the limits of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a competitive call.

The implementation plan will be updated yearly. This updating may entail the reorientation of certain activities and the launching of new ones. In the latter case, and where an additional Community contribution is needed, the Commission will identify these activities and the participants who will carry them out, by means of a call for proposals.

The Community contribution shall take the form of a grant to the budget, calculated as a percentage of the budget allocated by the participants to carry out the project, adapted according to the type of activity.

A.3. *Collective research projects for SMEs*

Unchanged

In order to implement the programme, other instruments may also be used:

Deleted

## INITIAL PROPOSAL

- cooperative research projects across the whole field of science and technology, to enable SMEs to have access to entities with appropriate research capacities to carry out specific research activities.
- coordination and specific support actions in order to achieve the objectives identified in the programme and relating to the needs of Community policies, new or emerging needs, specific international cooperation activities, and the strengthening of the foundations of the European Research Area.
- accompanying actions by way of additional measures to achieve the objectives of the programme or prepare future activities in the context of the Community's research and technological development policy.

## AMENDED PROPOSAL

*B.1. Specific targeted research projects*

Specific targeted research projects will aim at improving European competitiveness. They will be sharply focussed and will take either of the following two forms, or a combination of the two:

- (a) a research and technological development project designed to gain new knowledge either to improve considerably or to develop new products, processes or services or to meet other needs of society and Community policies;
- (b) a demonstration project designed to prove the viability of new technologies offering potential economic advantage but which cannot be commercialised directly.

*B.2. Cooperative research projects for SMEs*

Implemented across the whole field of science and technology, these projects will be undertaken for the benefit of a number of SMEs on themes of common interest.

*B.3. Coordination actions*

Coordination actions are intended to promote and support the coordinated initiatives of a range of research and innovation operators aiming at improved integration. They will cover activities such as the organisation of conferences, meetings, the performance of studies, exchanges of personnel, the exchange and dissemination of good practices, setting up information systems and expert groups, and may, if necessary, include support for the definition, organisation and management of joint or common initiatives.

*B.4. Specific support actions*

Specific support actions will complement the implementation of the Framework Programme and may be used to help in preparations for future Community research and technological development policy activities including monitoring and assessment activities. In particular, they will involve conferences, seminars, studies and analyses, high level scientific awards and competitions, working groups and expert groups, operational support and dissemination, information and communication activities, or a combination of these, as appropriate in each case.

**Amended proposal for a Council Decision adopting a specific programme for research, technological development and demonstration: 'structuring the European Research Area' (2002-2006) <sup>(1)</sup>**

(2002/C 181 E/02)

(Text with EEA relevance)

COM(2002) 43 final — 2001/0123(CNS)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 31 January 2002)

<sup>(1)</sup> OJ C 240 E, 28.8.2001, p. 227.

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INITIAL PROPOSAL

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 166 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas:

- (1) In accordance with Article 166(3) of the Treaty Decision No ... of [...] of the European Parliament and the Council concerning the multi-annual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.
- (2) The framework-programme 2002-2006 is organised in three main blocks of activities, 'integrating research', 'structuring the European Research Area' and 'strengthening the foundations of the European Research Area', the second of which should be implemented by this specific programme.
- (3) The rules for the participation of undertakings, research centres and universities and for the dissemination of research results, for the framework programme, adopted by the European Parliament and Council in Decision No ... (hereinafter referred to as 'the rules for participation and dissemination') should apply to this programme.

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AMENDED PROPOSAL

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Unchanged

- (1) In accordance with Article 166(3) of the Treaty Decision No ... of [...] of the European Parliament and the Council concerning the sixth multi-annual framework programme of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.

- (2) The framework-programme is organised in three main blocks of activities, 'Focusing and integrating Community research', 'structuring the European Research Area' and 'strengthening the foundations of the European Research Area', the second of which should be implemented by this specific programme.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

(4) New instruments, involving simplified and decentralised management, and the exploitation of external technical support should, if fully exploited in this programme enable personnel and administrative expenses to be reduced to a maximum of 5,5 % of the overall amount deemed necessary for its implementation.

(4) The importance of the new instruments (Integrated Projects and Networks of Excellence) is recognised as being an overall priority means to attain the objectives of critical mass, management simplification and European added value contributed by Community research in relation to what is already undertaken at national level, and of the integration of the research capacities. They should enable personnel and administrative expenses to be reduced to a maximum of 6,0 % of the overall amount deemed necessary for the implementation of the programme.

(5) In implementing this programme, emphasis should be given to the participation of SMEs, and it may be appropriate to engage in international co-operation activities with third countries and international organisations. Special attention should be paid to the Accession countries.

(5) As provided for under Article 170 of the Treaty, this programme is open to the participation of countries having concluded the necessary agreements to this effect, and is also open on the project level, and on the basis of mutual benefit, to the participation of entities from third countries and of international organisations for scientific co-operation.

(6) Research activities carried out within this programme should respect fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union.

(6) In implementing this programme, emphasis should be given to the needs of SMEs and encouraging their participation.

(7) Research activities carried out within this programme should respect fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union.

(7) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research.

(8) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research, and further enhanced action is needed.

(9) Participation in the activities of this programme will be encouraged through publication of the necessary information on content, conditions and procedures, to be made available in a timely and thorough manner to potential participants, including those from the associated candidate countries and other associated countries. Specific activities will be undertaken in support of participation of scientists and institutions from developing countries, Mediterranean countries including the Western Balkans as well as Russia and the NIS.

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.



## INITIAL PROPOSAL

- (8) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities; the research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.
- (9) Since the measures for the implementation of this Decision are management measures within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(1)</sup>, they should be adopted by the use of the management procedure provided for in Article 4 of that Decision.
- (10) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme,

HAS ADOPTED THIS DECISION:

*Article 1*

1. In accordance with the framework programme, a specific programme on structuring the research area (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.
2. The objectives and scientific and technological priorities for the specific programme are set out in Annex I.

*Article 2*

In accordance with Annex II to the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 3 050 million, including a maximum of 5,5 % for the Commission's administrative expenditure. An indicative breakdown of this amount is given in Annex II.

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

## AMENDED PROPOSAL

- (10) This programme will be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities; the research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.
- (11) Since the measures for the implementation of this Decision are management measures within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(1)</sup>, they should be adopted by the use of the management procedure provided for in Article 4 of that Decision.
- (12) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme, which will be done in a spirit of openness with respect to all the relevant actors,

Unchanged

*Article 3*

All research activities carried out under the specific programme must be carried out in compliance with fundamental ethical principles.

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

## INITIAL PROPOSAL

*Article 3*

1. The detailed rules for financial participation by the Community in the specific programme shall be those referred to in Article 2(2) of the framework programme.

2. Instruments for implementing the specific programme are defined in Annexes I and III to the framework programme and described in Annex III.

3. The rules for participation and dissemination shall apply to the specific programme.

*Article 4*

1. The Commission shall draw up a work programme for the implementation of the specific programme, setting out in greater detail the objectives and scientific and technological priorities set out in Annex I, and the timetable for implementation.

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States and European and international organisations. It shall be updated where appropriate.

*Article 5*

1. The Commission shall be responsible for the implementation of the specific programme.

2. The procedure laid down in Article 6 shall apply for the adoption of the following measures:

— the drawing up and updating of the work programme referred to in Article (1),

— any adjustment to the indicative breakdown of the amount as set out in Annex II.

*Article 6*

1. The Commission shall be assisted by a committee, composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the management procedure laid down in Article 4 of Decision 1999/468/EC <sup>(1)</sup> shall apply, in compliance with Article 7(3) thereof.

## AMENDED PROPOSAL

*Article 4*

Unchanged

*Article 5*

Unchanged

*Article 6*

Unchanged

2. The procedure laid down in Article 7 shall apply for the adoption of the following measures:

— the drawing up and updating of the work programme referred to in Article 5(1), including the instruments to be used on a priority basis, and any subsequent adjustment to their use;

Unchanged

*Article 7*

Unchanged

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

## INITIAL PROPOSAL

3. The period provided for in Article 4(3) of Decision 1999/468/EC shall be two months.

*Article 7*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme.

2. The Commission shall arrange for the independent assessment provided for in Article 5 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 8*

This decision is addressed to the Member States.

## AMENDED PROPOSAL

*Article 8*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme; information on financial aspects shall be included.

2. The Commission shall arrange for the independent monitoring and assessment provided for in Article 6 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 9*

Unchanged

## ANNEX I

## SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND BROAD LINES OF THE ACTIVITIES

**Introduction**

Unchanged

This programme will attack a number of key structural weaknesses that are manifested across all fields of European research and which are likely to have progressively more important effects on the EU's capacity to meet the aspirations of its citizens as its economies and societies become more knowledge-based. It will:

- enhance the propensity, at all levels, to turn research into useful and commercially valuable innovations;
- promote the development of human resources which constitute the underlying raw material on which research capabilities must be built, as well as the mobility of researchers — and of their knowledge and expertise — between European countries and to Europe from outside;
- stimulate the development and upgrading of research infrastructures of the highest quality on a more rational and cost-effective basis, and make facilities and associated resources more universally available to researchers throughout Europe who are able to benefit from them;
- develop the means for more constructive and effective communication and dialogue between research and citizens in general, so as to enable society at large to have a better-informed and more constructive influence on the future development and governance of science, technology and innovation.

## INITIAL PROPOSAL

By their nature and means of implementation, the activities carried out within this programme are applicable to all fields of research and technology. They have specific vocations, distinct from, and complementary to, the activities implemented within other parts of the framework programme, notably those within the 'Integrating and strengthening the European Research Area' programme in the priority thematic areas defined for EU research in that programme, and attention will be given to ensure coherence with them.

This complementary relationship will be reflected in:

- improved provisions for human resource development and knowledge transfer arising from the implementation of the activities covered by this programme, which would apply, inter alia, to the thematic priority areas of research, as well as research infrastructures of broad application, including those crossing the boundaries between priority areas;
- the use, as appropriate, of consistent methods and tools to promote innovation through research and to reconcile better research with the concerns of society, as well as consistent frameworks for the implementation of actions on human resources, infrastructure support and ensuring the ethical conduct of research, which may be implemented, inter alia, within the context of integrated projects and networks of excellence.

Participation of the candidate countries in this programme will be encouraged.

## AMENDED PROPOSAL

During the implementation of this programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include the principles set out in the Charter of Fundamental Rights of the EU, including the following: protection of human dignity and human life, protection of personal data and privacy, as well as animals and the environment in accordance with Community law and relevant international conventions and codes of conduct, e.g. the Helsinki Declaration in its latest version, the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998, the UN Convention on the Rights of the Child, the Universal Declaration on the human genome and human rights adopted by UNESCO, and the relevant World Health Organisation (WHO) resolutions.

Account will also be taken to the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New Technologies (as from 1998).

Participants in research projects must conform to current legislation and regulations in the countries where the research will be carried out. Where appropriate, participants in research projects must seek the approval of the relevant ethics committees prior to the start of the RTD activities. An ethical review will be implemented systematically for proposals dealing with sensitive issues. In specific cases, an ethical review may take place during the implementation of a project.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

The following fields of research shall not be financed under this programme:

- research activity aiming at human cloning for reproductive purposes;
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable <sup>(1)</sup>;
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In accordance with the Amsterdam protocol on animal protection and welfare, animal experiments must be replaced with alternatives wherever possible. Suffering by animals must be avoided or kept to a minimum. This particularly applies (pursuant to Directive 86/609/EEC) to animal experiments involving species which are closest to human beings. Altering the genetic heritage of animals and cloning of animals may be considered only if the aims are ethically justified and the conditions are such that the animals' welfare is guaranteed and the principles of biodiversity are respected.

Where appropriate, participants in research projects must seek the approval of the relevant ethics committees prior to the start of the RTD activities. An ethical review at EC level will be implemented systematically for proposals dealing with sensitive issues. In specific cases, an ethical review may take place during the implementation of a project.

## 1. Research and innovation

Unchanged

### Objectives

The overall aim is to make a tangible improvement in Europe's innovation performance, in the short, medium and long term, by stimulating a better integration between research and innovation, and by working towards a more coherent and innovation-friendly policy and regulatory environment across the European Union.

To this end, and in accordance with the objectives of the communication <sup>(1)</sup> 'Innovation in a knowledge-driven economy', activities will be implemented in a number of specific areas that are complementary and mutually supportive, within themselves and with the actions carried out under the heading 'integrating and strengthening the European Research Area'. They will focus on improving the knowledge, understanding and capabilities of the actors involved — researchers, industrialists, investors, public authorities at European, national and regional levels, and others — by encouraging more intensive and fruitful interactions between them, and by providing strategic information and services, as well as developing new methodologies and tools, to assist them in their particular endeavours. A general principle underlying all these actions is that innovation cannot be separated from research; the actions serve to reinforce the links between research and innovation, from the point of the conception of research activities, right through the period of their realisation.

<sup>(1)</sup> COM(2000) 567 of 20.9.2000.

<sup>(1)</sup> Research relating to cancer treatment of the gonads can be financed.

## INITIAL PROPOSAL

To strengthen their structuring effect in Europe, these activities will, where appropriate, be carried out in cooperation with other forums or organisations at regional, national or European level, such as the Structural Funds or the EIB and the EIF in the context of the 'Innovation 2000 Initiative'.

## Activities envisaged

(i) *Networking the players and encouraging interaction between them*

The effectiveness of innovation systems depends on the intensity of interactions and exchanges between the players concerned. The European networks involved in this activity will, among other things, have the aim of encouraging interfaces between research and industry and between business and funding. The activities will concern the encouragement and validation of local and regional initiatives to promote the creation and development of innovative businesses; exchanges of good practice and the implementation of transnational cooperation involving universities, incubators, risk capital funds, etc.; and the optimisation of practices with regard to communication, training, transfer and sharing of knowledge between universities, businesses and the financial world.

(ii) *Encouraging transregional cooperation*

The regional level is the most appropriate for putting in place innovation strategies and programmes involving the main local players. The purpose of this activity, to be carried out in close cooperation with activities in the context of regional policy and the Structural Funds, will be to promote exchanges of information on specific innovation-related themes; facilitate transfers of good practice and put in place innovation strategies in the regions in countries due to join the EU; and encourage the carrying out at regional level of schemes or measures that have proved successful at European level.

(iii) *Experimenting with new tools and approaches*

The purpose of these activities is to experiment with new innovation concepts and methods. These activities will concern experimenting on a European scale with new concepts applied in a national or regional environment to promote innovation and the setting-up of innovative businesses; analysis of the potential, for reproducing and/or exploiting proven methods, tools or results in new contexts; and putting into place integrated platforms making it possible to input and disseminate knowledge and know-how concerning the socio-technical processes of innovation.

## AMENDED PROPOSAL

To strengthen their structuring effect in Europe, these activities will, where appropriate, be carried out in cooperation with other forums or organisations at regional, national or European level, such as the EIB and the EIF in the context of the 'Innovation 2000 Initiative', as well as in co-ordination with Structural Funds measures in this field.

## Unchanged

(i) *Networking the players and users and encouraging interaction between them*

The effectiveness of innovation systems depends on the intensity of interactions and exchanges between the players concerned. The European networks involved in this activity will, among other things, have the aim of encouraging interfaces between research and industry and between business and funding. The activities will concern the encouragement and validation of local and regional initiatives to promote the creation and development of innovative businesses; the involvement of users in the innovation process; exchanges of good practice and the implementation of transnational cooperation involving universities, incubators, risk capital funds, etc.; and the optimisation of practices with regard to communication, training, transfer and sharing of knowledge between universities, businesses and the financial world.

## Unchanged

The regional level is the most appropriate for putting in place innovation strategies and programmes involving the main local players. The purpose of this activity, to be carried out in close cooperation with activities in the context of regional policy and the Structural Funds, will be to promote exchanges of information on specific innovation-related themes; facilitate transfers of good practice and put in place innovation strategies in the regions in countries due to join the EU; and encourage the carrying out at regional and trans-regional level of schemes or measures that have proved successful at European level.

## Unchanged

The purpose of these activities is to experiment with new innovation concepts and methods addressing in particular critical points in the innovation process. These activities will concern experimenting on a European scale with new concepts applied in a national or regional environment to promote innovation and the setting-up of innovative businesses; analysis of the potential, for reproducing and/or exploiting proven methods, tools or results in new contexts; and putting into place integrated platforms making it possible to input and disseminate knowledge and know-how concerning the socio-technical processes of innovation.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

(iv) *Putting services in place and consolidating them*

Unchanged

The establishment of the European Research Area and the gradual integration of innovation systems in Europe will require a supply of information and services transcending the existing national fragmentation. The activities to be carried out will concern the CORDIS research and innovation information service, which will be supplemented by other media in order to reach the various target populations; the network of innovation relay centres, the geographical coverage of which will continue to be extended, and which will be supplemented by instruments to encourage the transnational transfer of knowledge and technologies; and information and support services in fields such as intellectual or industrial property and access to innovation funding.

(v) *Stepping up economic and technological intelligence*

In the knowledge-based economy, economic and technological intelligence is a vital component of competitive research and innovation strategies. The activities to be carried out will centre on the innovation players: SMEs, researcher-entrepreneurs and investors. They will mainly involve intermediaries working with/for these players as well as organisations with economic and technological intelligence expertise. They will concentrate on specific S&T themes or industrial sectors and may concern: innovation promotion in SMEs, in particular by means of activities aimed at facilitating their participation in the Community research programmes; support for activities concerning the gathering, analysis and dissemination of information on S&T developments, applications and markets which may be of assistance to the stakeholders; and identification and dissemination of best practice with regard to economic and technological intelligence.

(vi) *Analysing and evaluating innovation in Community research projects*

The research and innovation activities carried out in the context of Community projects, in particular within the networks of excellence and the integrated projects, represent a plentiful source of information about obstacles to innovation and the practices to be deployed in order to overcome them. The ex-post analysis of these practices will concern the gathering and analysis of information about measures taken to promote innovation in Community projects, as well as the obstacles encountered and the actions needed to remove them; the comparison of experience derived from Community projects with the lessons learnt from other national or intergovernmental programmes and the validation of the information obtained; and the active dissemination of this information among businesses and other participants in the generation and exploitation of knowledge.

## 2. Human resources and mobility

Today's knowledge-based societies are heavily dependent on their capacity to produce, transfer and utilise knowledge. This requires mobilising cognitive resources, beginning with the research community. The overall strategic objective of the Human Resources and Mobility activity is to provide broad support for the development of abundant and dynamic world-class human resources in the European research system, taking into account the inherent international dimension of research.

## INITIAL PROPOSAL

This will involve a coherent set of actions, largely based on the financing of structured mobility schemes for researchers. These will essentially be geared at the development and transfer of research competencies, the consolidation and widening of researchers' career prospects, and the promotion of excellence in European research. The widely-recognised Marie Curie name will apply to all the actions concerned.

The activity will be open to all fields of scientific and technological research that contribute to the Community's RTD objectives. However, the possibility of refining priorities, as regards for example, scientific disciplines, participating regions, types of research organisations, and the level of experience of the targeted researcher populations, will be retained, in order to respond to the evolution of Europe's requirements in the area.

Attention will be paid to:

- the participation of women within all actions, and appropriate measures to promote a more equitable balance between men and women in research,
- the personal circumstances relating to mobility, particularly with respect to the family, career development and languages,
- the development of research activity in the less-favoured regions of the EU and Associated Countries, and to the need for increased and more effective co-operation between research disciplines and between academia and industry, including SMEs.

With a view to further reinforcing the human potential for European research, this activity will also aim to attract the best and most promising researchers from third countries <sup>(1)</sup>, promote the training of European researchers abroad and stimulate the return of European scientists established outside Europe.

## AMENDED PROPOSAL

The mobility of researchers will be promoted with a view to the successful creation of the European Research area. This will involve a coherent set of actions, largely based on the financing of structured mobility schemes for researchers. These will essentially be geared at the development and transfer of research competencies, the consolidation and widening of researchers' career prospects, and the promotion of excellence in European research. The widely-recognised Marie Curie name will apply to all the actions concerned.

The activity will be open to all fields of scientific and technological research that contribute to the Community's RTD objectives. However, in order to respond to the evolution of Europe's requirements in this area, the possibility of refining priorities, as regards for example, scientific disciplines, participating regions, types of research organisations, and the potential of the targeted researcher populations, especially women and younger researchers will be retained, and will take into account measures taken towards creating synergies in the area of higher education in Europe.

Unchanged

<sup>(1)</sup> Participation and funding of researchers from third countries is foreseen in all of the host-driven mobility schemes (section (i)), as well as in one of the individual-driven schemes (section (ii)). In such cases, account will be taken of any relevant arrangements between the EU and those countries — or groups of countries, as well as of the relevant Framework Programme participation and financing rules



## INITIAL PROPOSAL

## AMENDED PROPOSAL

## Actions to be pursued

Three main strands of actions will be implemented.

(i) *Host-driven actions*

This first strand is aimed at supporting research networks, research organisations and enterprises, including in the provision of structured global schemes for the training and mobility of researchers, and the development and transfer of competencies in research. The actions concerned are intended to have a strong structuring effect on the European research system, in particular by encouraging junior researchers to pursue a research career. Training elements in this strand will be directed at researchers at the early stages (typically the first 4 years) of their research careers, such as those who are undertaking a doctoral degree, while the transfer of competencies and knowledge will involve more experienced researchers.

— Marie Curie Research Training Networks — These provide the means for research teams of recognised international stature to link up, in the context of a well-defined collaborative research project, in order to formulate and implement a structured training programme for researchers in a particular field of research. Networks will provide a cohesive, but flexible framework for the training and professional development of researchers, especially in the early stages of their research career. Networks also aim to achieve a critical mass of qualified researchers, especially in areas that are highly-specialised and/or fragmented; and to contribute to overcoming institutional and disciplinary boundaries, notably through the promotion of multidisciplinary research. They will also provide a straightforward and effective means to involve the less-favoured regions of the EU and Associated Countries in internationally-recognised European research co-operation. Partners will be given significant autonomy and flexibility in the detailed operation of the networks. The duration of a network will typically be 4 years, with associated fellowships of up to 3 years, including short-term stays.

— Marie Curie Host Fellowships for Early Stage Research Training — These will be targeted at higher education and research institutions, training centres and enterprises, with a view to reinforcing their training capability. The scheme will be directed at researchers in the early stages of their professional career. It will focus on the acquisition of specific scientific and technological competencies in research, as well as of complementary skills. Hosts will be selected on the basis of their area of specialisation in research training. The associated fellowships will allow for fellows' stays for up to a maximum duration of 3 years. The scheme will also work towards more co-ordinated approaches to training among the organisations concerned, particularly between those involved in international doctoral studies.

This first strand is aimed at supporting research networks, research organisations and enterprises, (in particular SMEs), in the provision of structured global schemes for the transnational training and mobility of researchers, and the development and transfer of competencies in research. The actions concerned are intended to have a strong structuring effect on the European research system, in particular by encouraging junior researchers to pursue a research career. Training elements in this strand will be directed at researchers at the early stages (typically the first 4 years) of their research careers, such as those who are undertaking a doctoral degree, while the transfer of competencies and knowledge will involve more experienced researchers. These actions are also intended to encourage mobility between different sectors.

Unchanged

— Marie Curie Host Fellowships for Early Stage Research Training — These will be targeted at higher education and research institutions, training centres and enterprises, with a view to reinforcing their training capability. The scheme will be directed at researchers in the early stages of their professional career. It will focus on the acquisition of specific scientific and technological competencies in research, as well as of complementary skills such as those relating to research management and ethics. Hosts will be selected on the basis of their area of specialisation in research training. The associated fellowships will allow for fellows' stays for up to a maximum duration of 3 years. The scheme will also work towards more co-ordinated approaches to training among the organisations concerned, particularly between those involved in international doctoral studies.

## INITIAL PROPOSAL

- Marie Curie Host Fellowships for the Transfer of Knowledge — These will be directed at European organisations (universities, research centres, enterprises, etc.) in need of developing new areas of competence, as well as at furthering the development of research capabilities in the less-favoured regions of the EU and Associated countries. Knowledge transfer fellowships will allow experienced researchers to be hosted at such organisations for the transfer of knowledge, research competencies and technology. Fellowships will have a maximum duration of 2 years.

- Marie Curie Conferences and Training Courses — These will enable junior researchers to benefit from the experience of leading researchers. Support will be given to specific training activities (including virtual ones) that highlight particular European achievements and interests. Two categories of measures are foreseen: the first concerns support for a coherent series of high-level conferences and/or training courses (summer schools, laboratory courses etc.) proposed by a single organiser, and covering a specific themes or several linked themes; the second involves support for the participation of junior researchers in large conferences selected for their specific training interest. Such activities would typically be for a few days, but could extend to a few weeks, for example in the case of summer schools.

(ii) *Individual-driven actions*

This second strand of actions concerns the support to individual researchers, in response to Europe's particular needs in terms of acquisition and transfer of competencies in research. It also addresses the professional re-integration of European researchers who have benefited from the Marie Curie scheme, as well as the return to Europe of European researchers who have been abroad for longer periods. It involves a number of schemes organised according to the geographical origin and destination of the researcher. Participation in these schemes will be open to researchers with at least 4 years of research experience, including those in possession of a doctorate degree.

- Marie Curie Intra-European Fellowships — these will allow the most promising researchers from EU and Associated countries to undertake training through research in the European organisations most appropriate to their individual needs. The application will be made by the fellow in conjunction with the host organisation. The topic will be freely chosen by the researcher in collaboration with the host, with a view to completing or diversifying his/her expertise. These fellowships will have a duration of 1 to 2 years.

## AMENDED PROPOSAL

Unchanged

- Marie Curie Conferences and Training Courses — These will enable junior researchers to benefit from the experience of leading researchers. Support will be given to specific training activities (including virtual ones) that highlight particular European achievements and interests. Two categories of measures are foreseen: the first concerns support for a coherent series of high-level conferences and/or training courses (summer schools, laboratory courses etc.) proposed by a single organiser, and covering one or several specific themes; the second involves support for the participation of junior researchers in large conferences selected for their specific training interest. Such activities would typically be for a few days, but could extend to a few weeks, for example in the case of summer schools.

Unchanged

This second strand of actions concerns the support to individual researchers, in response to their particular needs with a view to complement individual competencies in particular in terms of multidisciplinary and research management, in the process of reaching a position of professional maturity and independence. It also addresses the linkages between European and third countries' researchers. It involves a number of schemes organised according to the geographical origin and destination of the researcher. Participation in these schemes will be open to researchers with at least 4 years of research experience, including those in possession of a doctorate degree.

Unchanged

## INITIAL PROPOSAL

— Marie Curie Outgoing International Fellowships — These will be awarded to researchers from EU and Associated countries to work in established third country research centres, thereby widening their international experience in research. This scheme will require the submission of a coherent individual training programme, involving a first phase abroad, followed by a mandatory second phase in Europe. This support should allow for a sufficiently long training period.

— Marie Curie Incoming International Fellowships — These will aim at attracting high-level researchers and promising young researchers from third countries to work and undertake research training in Europe, with the view to developing mutually-beneficial research co-operation between Europe and third countries. In the case of emerging economies and developing countries, the scheme may include provision to assist fellows to return to their country of origin.

— Marie Curie Re-integration Grants — These will be directed at researchers from the EU and Associated countries who have just completed a Marie Curie fellowship of at least two years. It will consist of a lump sum in the form of a personal grant to be used within one year. It will be allocated to the fellow on the basis of the submission of a defined project, which will be evaluated on its own merits. The re-integration would not be restricted to the researcher's country of origin. A similar mechanism (but covering a period of re-integration of up to two years) will apply to European researchers who have carried out research outside Europe for at least 5 years.

(iii) *Excellence Promotion and Recognition*

This third strand of actions will focus on the promotion and recognition of excellence in European research, thereby increasing its visibility and attractiveness. It will aim at promoting European research teams, especially in new and/or emerging areas of research, and at highlighting personal achievements of European researchers, with a view to supporting their further development and international recognition, while also promoting the diffusion of their work for the benefit of the scientific community.

— Marie Curie Excellence Grants — These aim at providing support to individual researchers or research teams of the highest level of excellence for the establishment or expansion of their teams, more particularly for leading edge or interdisciplinary research activities. The grant will cover a period of up to 4 years and will be awarded on the basis of a well-defined research programme.

## AMENDED PROPOSAL

— Marie Curie Incoming International Fellowships — These will aim at attracting top-class researchers from third countries to work and undertake research training in Europe, with the view to developing mutually-beneficial research co-operation between Europe and third countries. In the case of emerging economies and developing countries, the scheme may include provision to assist fellows to return to their country of origin.

Deleted

Unchanged

— Marie Curie Excellence Grants — These aim at providing support for the creation and development of European research teams which are considered to have the potential to reach a high level of excellence, more particularly for leading edge or interdisciplinary research activities. The grant will cover a period of up to 4 years and will be awarded on the basis of a well-defined research programme.

## INITIAL PROPOSAL

- Marie Curie Excellence Awards — These aim at the public recognition of the excellence achieved by researchers who have in the past benefited from training and mobility support by the Community. Prize money will be awarded as a grant to be used for professional advancement, with the obligation to report within two years about the use made of the grant. Beneficiaries may propose themselves or be proposed by others.
  
- Marie Curie Chairs — These will be awarded for the purpose of making top-level appointments, in particular to attract world-class researchers and encourage them to resume their careers in Europe. Awards will normally have a duration of three years. This scheme may be developed in synergy with the host-driven actions.

## AMENDED PROPOSAL

- Marie Curie Excellence Awards — These are scientific prizes to give public recognition to excellence achieved by researchers who have in the past benefited from training and mobility support by the Community. Prize money will be awarded as a grant to be used for professional advancement, with the obligation to report within two years about the use made of the grant. Beneficiaries may propose themselves or be proposed by others.

Unchanged

(iv) *Return and Reintegration Mechanisms*

A further mechanism Marie Curie Return and Reintegration Grants will be directed at researchers from the EU and associated countries who have just completed a Marie Curie fellowship of at least two years. It will consist of a lump sum, in the form of a grant to be used within one year following the term of the Marie Curie action. It will be allocated to the fellows on the basis of a defined project, which will be evaluated on its own merits. The mechanism will assist the professional reintegration of the researcher, the priority being given to reintegration in his or her country or region of origin.

A similar mechanism, but covering a longer period, up to two years, will apply to European researchers who have carried out research outside Europe for at least 5 years, with or without having benefited from a Marie Curie action.

Co-operation with Member States and Associated Countries

The Human Resources and Mobility activity will seek to co-finance initiatives which foster co-operation and create synergies with national and regional programmes where these coincide with the specific objectives of the schemes outlined above. Such co-operation will be established on the basis of relevant Community criteria, with a view to creating genuine access to these initiatives for all EU and Associated Country researchers, as well as promoting the adoption of mutually-recognised research training standards.

In terms of management of the activity, beyond the increased importance of host-driven actions, Initiatives will be undertaken to reinforce co-operation with Member States and Associated Countries in the provision of 'proximity support' to researchers, which is a key element of any mobility scheme for researchers moving within or returning to Europe. This could be undertaken through the co-financing of existing and new structures, at national or regional level, with the aim of providing practical assistance to foreign researchers in matters (legal, administrative, familial or cultural) relating to their mobility.

Unchanged

The Human Resources and Mobility activity will seek to co-finance initiatives which foster co-operation and create synergies with and within national and regional programmes where these coincide with the specific objectives of the schemes outlined above. Such co-operation will be established on the basis of relevant Community criteria, with a view to creating genuine access to these initiatives for all EU and Associated Country researchers, as well as promoting the adoption of mutually-recognised research training standards.

Initiatives will be undertaken to reinforce co-operation with Member States and Associated Countries in the provision of 'proximity support' to researchers, which is a key element of any mobility scheme for researchers moving within or returning to Europe. In particular, this could be undertaken through the support to the networking of existing and new structures, at national or regional level, with the aim of providing practical assistance to foreign researchers in matters (legal, administrative, familial or cultural) relating to their mobility.

## INITIAL PROPOSAL

A further aspect of this co-operation might concern a number of tasks associated with the management and follow up of individual fellowship contracts. This would require prior establishment of a clear demarcation of tasks and responsibilities in accordance with Community financial regulations and rules, and the undertaking of relevant cost/benefit analyses.

## Internal, Framework Programme Co-operation

The role of the Human Resources and Mobility activity is to support research training and the development of research competencies. This does not preclude other activities within the new Framework Programme from incorporating similar elements. The Human Resources and Mobility activity will provide assistance with regard to the adoption of consistent criteria in relation to the evaluation, selection and monitoring of such actions, as well as the promotion of common approaches among the activities, with a view to ensuring coherence and developing possible synergies, and an equitable balance in the participation of men and women.

## 3. Research infrastructures

The ability of Europe's research teams to remain at the forefront of all fields of science and technology depends on their being supported by state-of-the-art infrastructures. The term 'research infrastructures' refers to facilities and resources that provide essential services to the research community in both academic and industrial domains. Research infrastructures may be 'single-sited' (single resource at a single location), 'distributed' (a network of distributed resources, including infrastructures based on Grid-type architectures), or 'virtual' (the service being provided electronically).

The overall objective of this activity is to promote the development of a fabric of research infrastructures of the highest quality and performance in Europe, and their optimum use on a European scale based on the needs expressed by the research community. Specifically this will aim at:

- ensuring that European researchers may have access to the infrastructures they require to conduct their research, irrespective of the location of the infrastructure;
- providing support for a co-ordinated approach for the development of new research infrastructures and for the operation and enhancement of existing infrastructures, including where appropriate facilities of world-wide relevance not existing in Europe.

Where relevant, support for research infrastructures in this programme will be implemented in association with the thematic priorities of the Framework Programme and with the other available forms of support.

## AMENDED PROPOSAL

A further aspect of this co-operation might concern a number of tasks associated with the management of the activity, beyond the increased importance of host-driven actions. In that context, envisaging alternative ways of management and follow up of individual fellowship contracts would require prior establishment of a clear demarcation of tasks and responsibilities in accordance with Community financial regulations and rules, and the undertaking of relevant cost/benefit analyses.

## Unchanged

- providing support for a co-ordinated approach for the development of new research infrastructures, also at the regional and transregional level, and for the operation and enhancement of existing infrastructures, including where appropriate facilities of world-wide relevance not existing in Europe.

## Unchanged

## INITIAL PROPOSAL

Five schemes for support will be implemented:

- Transnational Access. The objective is to sponsor new opportunities for research teams (including individual researchers) to obtain access to individual major research infrastructures most appropriate for their work. Community financing will cover the necessary operating costs of providing access to such infrastructures for research teams working in Member States and Associated States other than the State where the operator of a given infrastructure is located.
- Integrating Activities. The objective is to support the provision of essential services to the research community at European level. For this purpose the initiatives combine co-operation networks with one or more other specific activities, including for example transnational access and research activities to improve the performance of the infrastructure. The scheme will also encourage the bridging of gaps that may limit the potential for exploitation of research results by industry, including SME's. Integrated initiatives will be selected on the basis of a wide-scale but flexible scientific and technological programme of European dimension aiming, where appropriate, at the long-term sustainability of the programme.
- Communication Network Development. The objective of this scheme in support existing research infrastructures is to create a denser network between related initiatives, in particular by establishing a broadband communications network for all researchers in Europe and specific high performance Grids and test-beds
- Design studies. The objective is to contribute, on a case-by-case basis, to feasibility studies and technical preparatory work for those new infrastructures to be undertaken by one or a number of Member States, which have a clear European dimension and interest,
- Development of new infrastructures. In appropriate circumstances, this scheme could contribute towards the development of a new infrastructure alongside with other funding agencies

## AMENDED PROPOSAL

- Integrating Activities. The objective is to support the provision of essential services to the research community at European level. This may cover, in addition to transnational access, the establishment and operation of co-operation networks, and the execution of joint research projects, raising the level of the performance of the infrastructures concerned. The scheme will also encourage the bridging of gaps that may limit the potential for exploitation of research results by industry, including SMEs. Integrating activities will be selected on the basis of a wide-scale but flexible scientific and technological programme of European dimension aiming, where appropriate, at the long-term sustainability of the programme. This scheme may be implemented through Integrated Infrastructure Initiatives and Co-ordination Actions.
- Communication Network Development. The objective of this scheme in support of existing research infrastructures is to create, in conjunction with the priority thematic research area on Information Society Technologies, a denser network between related initiatives, in particular by establishing a high-capacity and high-speed communications network for all researchers in Europe (GEANT) and specific high performance grids and test-beds (GRIDs), as well as electronic publishing services.
- Design studies. The objective is to contribute, on a case-by-case basis, to feasibility studies and technical preparatory work for those new infrastructures to be undertaken by one or a number of Member States, which have a clear European dimension and interest, taking into account the needs of all potential users and systematically exploring the possibilities of contributions from other sources, including the EIB or the Structural Funds for the funding of these infrastructures.
- Development of new infrastructures. Optimising of European infrastructures by providing limited support for the development of a restricted number of projects for new infrastructures in duly justified cases where such support could have a critical catalysing effect in terms of European added value. This support, taking due account of Member States' opinion, may supplement contributions from the EIB or the Structural Funds to the funding of these infrastructures.

## INITIAL PROPOSAL

In general, funding provided for new or enhanced infrastructures will be limited to the minimum necessary to catalyse the activity; the major part of construction and operation, and the long-term sustainability of the infrastructures in question being assured by national and/or other sources of finance. Such funding would only be provided on the basis of a detailed justification, based on European added value, addressing the scientific, legal and financial dimensions of the proposed development. Feasibility studies and technical preparatory work should investigate the possibilities of combining funding with other sources of finance from the European Union (e.g. the European Investment Bank and the Structural Funds).

Broadband communication networks, which are highly relevant to the political goals set out by the European Research Area and the *e-Europe* initiative, should also be used as a means to enhance scientific co-operation with third countries.

Support for research infrastructures in this programme should, where relevant, take into account existing or future mechanisms for a co-ordinated approach to research infrastructures in Europe, as well as the scientific advice of existing European and international organisations (e.g. ESF). Accompanying measures under this programme may be implemented, where appropriate, to sustain these mechanisms.

#### 4. Science and Society

Today, and even more in the knowledge-based society of tomorrow, science and technology have a ubiquitous presence throughout the economy and in everyday life. If they are to realise their full potential in securing a continually-increasing quality of life — in the broadest sense — to Europe's citizens, new relations and a more productive dialogue between the scientific community, industrialists, policy-makers and society at large will be needed.

Such a dialogue cannot be confined to the EU alone. It must be international in scope, taking full account of the enlargement perspective and the global context. Given the very broad range of issues and interactions that are implied in the relations between science and technology, on one hand, and the broader community, on the other, these considerations must be integrated within all areas of activity of the framework programme. The role of this specific activity is to develop the structural links between the institutions and activities concerned and provide a central focus, through common reference frameworks and the development of appropriate tools and approaches, to guide activities in this domain covered by the different parts of the framework programme.

## AMENDED PROPOSAL

In general, funding provided for new or enhanced infrastructures will be limited to the minimum necessary to catalyse the activity; the major part of construction and operation, and the long-term sustainability of the infrastructures in question being assured by national and/or other sources of finance. Such funding would only be provided on the basis of a detailed justification, based on European added value, addressing the scientific, legal and financial dimensions of the proposed development.

Unchanged

Support for research infrastructures in this programme should, where relevant, take into account existing or future mechanisms for a co-ordinated approach to research infrastructures in Europe (e.g. National Research and Education Networks — NRENS), as well as the scientific advice of existing European and international organisations (e.g. European Science Foundation — ESF). Accompanying measures under this programme may be implemented, where appropriate, to sustain these mechanisms.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

It will be implemented by means of networks, benchmarking, exchange of best practices, developing and promoting awareness of methodologies, studies and the bringing together of national efforts. In specific cases, where appropriate, dedicated research will be supported.

(i) *Bringing research closer to society*

The aim is to examine systematically the various components of 'science and governance' in order to create conditions under which policy decisions are more effective in meeting society's needs, more soundly based in science and at the same time take account of the concerns of civil society. This requires consideration of effective processes of dialogue on emerging scientific and technological issues ultimately having consequences for prospective policy development; developing appropriate means for creating scientific references and channelling scientific advice to policy makers; and equipping the latter with tools to assess and manage scientific uncertainty, risk and precaution.

- Science and governance: analysing and support to best practice; developing new consultation mechanisms to promote more productive involvement of civil society and relevant stakeholders in policy formulation and implementation, including the communication of scientific outputs necessary to decision-taking in terms readily understandable to civil society and other stakeholders; monitoring activities concerning the functioning of policy-making processes to assess the interaction between experts, industry, civil society and policy-makers.
- Scientific advice and reference systems: exchange of experience and good practice; monitoring the production of scientific advice world-wide and how this advice is provided as input to decision; developing new and better methodologies for reliable and recognised reference systems; ensuring the smooth operation and effective use of the European Research Advisory Body and its sub-committees in order to provide scientific advice for the development of the European research area.

(ii) *Responsible research and application of science and technology*

The aim is to ensure that rapidly advancing progress in science is in harmony with the ethical values of all Europeans. Activities will promote 'responsible research' in Europe, in which the requirements for investigative freedom are better reconciled with social and environmental responsibilities in the development and application of science and technology, as well as the public dialogue, monitoring, and early warning, of ethical and social issues, and risks arising from new technological developments, for the benefit of national and international policy makers and other interested groups.



## INITIAL PROPOSAL

- Ethics: networking between existing ethics bodies and activities in Europe, and promotion of dialogue on ethics in research with other regions in the global context; awareness raising and training activities in ethics; co-ordination and development of codes of conduct for research activities and technological developments; research on ethics in relation to science, technology developments and their applications, for example, in relation to information society, nanotechnologies, human genetics and biomedical research and in food technologies.
- Uncertainty, risk, and implementing the precautionary principle: analysis and support to best practice in the application of the precautionary principle in different areas of policy making and in the assessment, management and communication of uncertainty and risk.

(iii) *Stepping up the science/society dialogue and women in science*

Support for the responsible development of science and technology requires not only a continued dialogue between the relevant stakeholder, but also better public awareness of scientific and technological advances and their possible implications, and a wider understanding of scientific and innovation culture. There are also particular needs to stimulate young peoples' interest in science, to increase the attractiveness of scientific careers, and to make progress towards gender equality in research, which will also enhance human resources and improve levels of excellence in European research.

- Public understanding: supporting awareness-raising events and the recognition of achievements in European research; analysis of the factors influencing public opinion, including the role of the media and science communicators; developing new ways of raising public awareness and knowledge; encourage comprehensive 'stakeholder' debates and stimulate awareness for innovation in society.
  - Young peoples' interest in scientific careers: initiatives to attract the younger generation to participate in the discussion on science and technology and their societal impact and to raise the S&T awareness among youth; support for the development of better approaches to science for girls and boys within and outside the formal education system, and for actions concerning a better understanding of the relative attractiveness and social aspects of taking science as a career.
  - Women and Science: actions to stimulate the policy debate at national and regional level to mobilise woman scientists and boost the participation of the private sector; promoting the enhancement of the Gender Watch System and associated activities to promote gender equality throughout the framework programme; specific actions to develop a better understanding of the gender issue in science.
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## AMENDED PROPOSAL

## INITIAL PROPOSAL

## AMENDED PROPOSAL

## ANNEX II

## INDICATIVE BREAKDOWN OF THE AMOUNT

Types of activities	Amount (EUR million)
Research and Innovation	
Human Resources	
Research infrastructures	
Science/society	
Total	

Types of activities	Amount (EUR million)
Research and Innovation	300
Human Resources	1 630
Research infrastructures	665 <sup>(1)</sup>
Science/society	60
Total	2 655

<sup>(1)</sup> Including up to EUR 200 million for the further development of Géant and GRID.

## ANNEX III

## MEANS FOR IMPLEMENTING THE PROGRAMME

In order to implement the specific programme, and in accordance with the Decisions of the European Parliament and of the Council concerning the multiannual Framework Programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (2002/.../EC) and with the rules for the participation of undertakings, research centres and universities and for the dissemination of research results (2002/.../EC), the Commission may use, across the whole field of science and technology:

Unchanged

— experimental projects relating to innovation aimed at experimenting with, validating and disseminating on a European scale new innovation concepts and methods in the area of 'Research and innovation'.

— Specific targeted innovation projects implemented in the area of 'Research and innovation'. They are designed to test, validate and disseminate new innovation concepts and methods at the European level.

— specific targeted projects in order to carry out research or demonstration activities in the area of 'Science and society'.

— Specific targeted research projects implemented in the area of 'Science and society'. They shall be sharply focussed and will take either of the following two forms, or a combination of the two:

(a) a research and technological development project designed to gain new knowledge either to improve considerably or to develop new products, processes or services or to meet other needs of society and Community policies;

(b) a demonstration project designed to prove the viability of new technologies offering potential economic advantage but which cannot be commercialised directly.

## INITIAL PROPOSAL

- integrated initiatives relating to infrastructure, combining activities that are essential for strengthening and developing research infrastructures for the provision of services on a European scale, in the area of 'Research infrastructures'.
- mobility and training actions implementing certain Marie Curie activities such as research training networks, conferences and training courses and individual training fellowships in the area of 'Human resources and mobility'.
- specific coordination and support actions in order to achieve the objectives identified in all the areas of the programme.
- accompanying actions by way of additional measures to achieve the objectives of the programme or to prepare future activities in the context of the Community's research and technological development policy.

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions in order to verify their relevance with regard to the objectives of the programme, their scientific and technological excellence, their Community added value and the participants' management capacity.

The Community contribution will be granted in accordance with the abovementioned decisions. In the case of participation of bodies from regions lagging in development, it may be possible to obtain complementary funding from the Structural Funds within the limits specified by the Community framework for State aid for research.

## AMENDED PROPOSAL

- Integrated infrastructure initiatives implemented in the area of 'Research infrastructure'. They shall combine in a single action several activities essential to reinforce and develop research infrastructures, in order to provide services at the European level. To this end, they shall combine networking activities with a support activity (such as relating to transnational access) or research activities needed to improve infrastructure performance, excluding, however, the financing of investment for new infrastructures, which can only be financed as specific support actions. They will include a component of dissemination of knowledge to potential users, including industry and in particular to SMEs.
- Actions to promote and develop human resources and mobility implemented in the area of 'Human resources and mobility'. They will be targeted at training, development of expertise or transfer of knowledge. They will involve support to actions carried out by natural persons, host structures, including training networks, and also by European research teams.
- Coordination actions implemented in all the areas of the programme. They are intended to promote and support the coordinated initiatives of a range of research and innovation operators aiming at improved integration. They will cover activities such as the organisation of conferences, meetings, the performance of studies, exchanges of personnel, the exchange and dissemination of good practices, setting up information systems and expert groups, and may, if necessary, include support for the definition, organisation and management of joint or common initiatives.
- Specific support actions implemented in all the areas of the programme. They will complement the implementation of the Framework Programme and may be used to help in preparations for future Community research and technological development policy activities including monitoring and assessment activities. In particular, they will involve conferences, seminars, studies and analyses, high level scientific awards and competitions, working groups and expert groups, operational support and dissemination, information and communication activities, or a combination of these, as appropriate in each case. They may also include actions in support of research infrastructure relating to, for instance, transnational access or preparatory technical work (including feasibility studies) and the development of new infrastructure.

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions.

The Community contribution will be granted in accordance with the abovementioned decisions and in compliance with the Community framework for State aid for research. In the case of participation of bodies from regions lagging in development, when a project receives the maximum intensity of co-financing authorised under the framework programme or an overall grant, an additional contribution from the Structural Funds, pursuant to Council Regulation (EC) No 1260/1999, could be granted.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

In the case of participation of entities from the candidate countries, an additional contribution from the pre-accession financial instruments could be granted under similar conditions.

In the case of participation of organisations from Mediterranean or developing countries, a contribution of the MEDA programme and of the financial instruments of the Community's aid to development could be envisaged.

Actions under Articles 169 and 171 of the Treaty which contribute to the scientific and technological objectives set out in Annex I may be supported financially by the specific programme, in accordance with the relevant decisions under Article 172 of the Treaty.

In carrying out the programme, the Commission may have recourse to technical assistance.

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**Amended proposal for a Council Decision adopting a specific programme for research, technological development and demonstration to be carried out by means of direct actions by the Joint Research Centre (2002-2006) <sup>(1)</sup>**

(2002/C 181 E/03)

(Text with EEA relevance)

COM(2002) 43 final — 2001/0124(CNS)

*(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 31 January 2002)*

<sup>(1)</sup> OJ C 240 E, 28.8.2001, p. 238.

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INITIAL PROPOSAL

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 166(4) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Having regard to the opinion of the Committee of the Regions,

Whereas:

- (1) In accordance with Article 166(3) of the Treaty, Decision No .../.../EC of [...] of the European Parliament and the Council concerning the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as the 'framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.
- (2) The framework programme is structured in three main blocks of activities, 'integrating research', 'structuring the European Research Area', and 'strengthening the foundations of the European Research Area', within the first of which the direct actions conducted by the Joint Research Centre should be implemented by this specific programme, while contributing in part to the aims of the other two.
- (3) The rules for the participation of undertakings, research centres and universities and for the dissemination of research results, for the framework programme, adopted by the European Parliament and Council in Decision No .../.../EC (hereafter referred to as 'the rules for participation and dissemination') should apply to this programme as regards dissemination of research results.

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AMENDED PROPOSAL

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Unchanged

- (1) In accordance with Article 166(3) of the Treaty, Decision No .../.../EC of [...] of the European Parliament and the Council concerning the sixth multiannual framework programme of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as the 'framework programme') is to be implemented through specific programmes that define detailed rules for their implementation, fix their duration and provide for the means deemed necessary.

- (2) The framework programme is structured in three main blocks of activities, 'Focusing and integrating Community research', 'structuring the European Research Area', and 'strengthening the foundations of the European Research Area', within the first of which the direct actions conducted by the Joint Research Centre should be implemented by this specific programme, while contributing in part to the aims of the other two.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

- (4) In implementing this programme, emphasis should be given to promoting mobility and training of researchers, and innovation, in the Community.
- (5) For the purpose of implementing this programme, in addition to cooperation covered by the Agreement on the European Economic Area or by an Association Agreement, it may be appropriate to engage in international cooperation activities, in particular on the basis of Article 170 of the Treaty, with third countries and international organisations. Special attention should be paid to Accession Countries.
- (6) Research activities carried out within this programme should respect the fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union.
- (7) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this scheme, an action plan is being implemented in order to reinforce and increase the place of women in science and research.
- (8) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant needs of JRC's user and Community policies, as well as respecting the objective and protecting the communities financial interests. The research activities carried out under it should be adapted where appropriate to these needs and to scientific and technological developments.
- (9) The JRC should actively pursue activities in innovation and technology transfer.
- (10) In the implementation of this programme, the Board of Governors of the JRC should be consulted by the Commission in accordance with the relevant provisions of Commission Decision 96/282/Euratom of 10 April 1996 on the reorganisation of the Joint Research Centre <sup>(4)</sup>.
- (11) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme.

- (5) For the purpose of implementing this programme, in addition to cooperation covered by the Agreement on the European Economic Area or by an Association Agreement, it may be appropriate to engage in international cooperation activities, in particular on the basis of Article 170 of the Treaty, with third countries and international organisations. Special attention should be paid to Candidate Countries.
- Unchanged
- (7) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolutions of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this scheme, an action plan is being implemented in order to reinforce and increase the place of women in science and research, and further enhanced action is needed.

Unchanged

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

<sup>(4)</sup> OJ L 107, 30.4.1996, p. 12.

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

## INITIAL PROPOSAL

- (12) The Board of Governors of the JRC has been consulted on the scientific and technological content of this specific programme,

HAS ADOPTED THIS DECISION:

*Article 1*

1. In accordance with Decision [...] on the framework programme 2002-2006 (hereinafter referred to as 'the framework programme'), a specific programme related to direct actions of research, technological development and demonstration to be carried out by the Joint Research Centre (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.

2. The objectives and scientific and technological priorities for the specific programme are set out in Annex I.

*Article 2*

In accordance with Annex II to Decision [...] the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 715 million. An indicative breakdown of this amount is given in Annex II to this Decision.

*Article 3*

1. The Commission shall be responsible for the implementation of the specific programme.

2. The specific programme shall be implemented by means of the instruments defined in Annexes I and III to the framework programme and in Annex III to this Decision.

3. The rules for the participation of undertakings, research centres and universities and for the dissemination of research results (hereinafter referred to as 'the rules for participation and dissemination') set out in Decision [...] shall apply to the specific programme, as regards dissemination of research results.

*Article 4*

1. The Commission shall draw up a work programme for the implementation of the specific programme, which shall be made available to all interested parties, setting out in greater detail the objectives and scientific and technological priorities, set out in Annex I, and the timetable for implementation, and the implementation arrangements.

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States, European and international organisations. It shall be updated where appropriate.

## AMENDED PROPOSAL

In accordance with Annex II to Decision [...] the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 760 million. An indicative breakdown of this amount is given in Annex II to this Decision.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Article 5*

For the purposes of implementing the specific programme, the Board of Governors of the JRC shall be consulted by the Commission in accordance with Commission Decision 96/282/Euratom.

The Commission shall regularly inform the Board of Governors of the implementation of this specific programme.

*Article 6*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme.

2. The Commission shall arrange for the independent assessment provided for in Article 5 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

2. The Commission shall arrange for the independent assessment provided for in Article 6 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 7*

Unchanged

This decision is addressed to the Member States.

## ANNEX I

**SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND BROAD OUTLINES OF THE ACTIVITIES****1. INTRODUCTION**

Unchanged

The Joint Research Centre carries out its work programme with the mission to provide customer-driven scientific and technical support for the conception, implementation and monitoring of European Union policies. The JRC serves the common interest of the Member States while being independent of special interests, private or national, and as such provides support when there is a need for European intervention.

The JRC's contribution to the Framework Programme incorporates recommendations of recent evaluations of the JRC <sup>(1)</sup> and requirements necessitated by the Reform of the Commission. In particular, it includes:

- A strengthened user-orientation
- Networking activities to create a broad knowledge base and, in the spirit of the European Research Area (ERA), more closely associate Member and Accession State laboratories, industry and regulators in the S & T support provided to the EU policies.
- The concentration of activities on selected themes;

<sup>(1)</sup> Davignon Report (2000), 5-year assessment of JRC (2000), 1999 JRC Scientific Audit, 2001 Prioritisation Audit.



## INITIAL PROPOSAL

- including training of researchers

It responds to clearly expressed needs and requirements, notably from the Commission services, which have been identified and are updated through systematic and regular contacts <sup>(1)</sup>.

In its domains of competence, the JRC's contribution will aim at establishing synergies with the relevant thematic priorities in the other specific programmes, notably through participation in the indirect action, with a view to add value, when appropriate, to the work carried out therein (e.g. through the comparison and validation of tests and methods or the integration of results for policy-making purposes).

The political and institutional context in which the JRC operates has evolved significantly in recent years. Rapid technological developments especially in biotechnology and the information society are changing our society with new demands on policy makers to simultaneously protect the citizen and ensure competitiveness in a global economy. Crises in consumer confidence and the growing impact of technology on day to day life have placed the onus on policy-makers throughout Europe and the world to secure reliable scientific input throughout the whole policy process. This encompasses the ability to respond rapidly in the event of unforeseen circumstances and to taking a more responsible view of potential longer-term impact of science and technology developments. The development of common European systems of scientific and technical reference, as foreseen in the ERA, is an important step in this direction.

With the implementation of the JRC's refocused mission to support EU policies <sup>(2)</sup>, the Framework Programme 2002-2006 represents a new chapter in how the JRC will perform its activities. On its own the JRC cannot be expected to cover the whole spectrum of scientific and technical support needed in such context. Three characteristics permeate its proposed work programme: (i) concentration, (ii) openness and networking and (iii) customer-orientation. Appropriate instruments will be set up to meet those objectives with particular attention to the clustering of projects contributing to specific policy areas (see Annex III).

The JRC, as the in-house RTD service of the Commission, will

- Provide demand-led S & T support to European policy formulation, development, implementation and monitoring in its areas of competence,
- Contribute to the establishment of common scientific and technical reference systems within the European Research Area.

## AMENDED PROPOSAL

- the training of researchers using, in particular, large scale facilities and specialised laboratories.

It responds to clearly expressed needs and requirements, notably from the Commission services, which have been identified and are updated through systematic and regular contacts <sup>(1)</sup>.

Unchanged

With the implementation of the JRC's refocused mission to support EU policies <sup>(2)</sup>, the sixth Framework Programme represents a new chapter in how the JRC will perform its activities. On its own the JRC cannot be expected to cover the whole spectrum of scientific and technical support needed in such context. Three characteristics permeate its proposed work programme: (i) concentration, (ii) openness and networking and (iii) customer-orientation. Appropriate instruments will be set up to meet those objectives with particular attention to the clustering of projects contributing to specific policy areas (see Annex III).

Unchanged

<sup>(1)</sup> Annual users workshops, interservice group of users DGs, bilateral agreements, etc.

<sup>(2)</sup> Fulfilling the JRC's mission in the European Research Area. Communication from the Commission to the Council and European Parliament 215 of 22.4.2001.

<sup>(1)</sup> Annual users workshops, interservice group of users DGs, bilateral agreements, in association with the High Level Users Group.

<sup>(2)</sup> Fulfilling the JRC's mission in the European Research Area. Communication from the Commission to the Council and European Parliament COM(2001) 215 of 22.4.2001.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

The thrust of JRC's support to EU policies lies in the provision of technical support on issues related to environmental protection, safety and security of the citizens and sustainable development. This includes risk assessment, testing, validation and refinement of methods, materials and technologies to support a range of policies — safety of food products, chemicals, air quality, water quality, nuclear safety, to protection against fraud. Almost all this support will be carried out in close collaboration with laboratories and research centres in Member States and elsewhere. To achieve this, the JRC has refocused its non-nuclear activities into two core areas, supported by horizontal competencies:

- Food, chemical products and health
- Environment and sustainability.

The core areas will be complemented by horizontal activities:

- Technology foresight
- Reference materials and measurements
- Public security and anti-fraud.

## 2. PROGRAMME CONTENT

### 2.1. Food, chemical products and health

The health protection of consumers particularly from the potentially harmful effects of contaminants in food and of chemical products is a key European policy. This is evidenced by the creation of a European Food Authority and the development of a new Community policy on chemicals.

In the framework programme 2002-2006 the JRC will respond to a series of specific requirements associated with the rapidly evolving food and chemical Community policies. It will develop further as a scientific reference and validation centre in selected areas linked to the quality and safety of food, the safety of chemical products, the Community dimension of chemical measurement/metrology infrastructure and health-related information. JRC's strategy relies heavily on extensive networking with laboratories in the Member States, on the maintenance of advanced analytical facilities and reference measurement and material production and on expanded competencies in life sciences including proteomics and bioinformatics. Services like information systems, data banks (e.g. molecular register) will be provided in support to relevant EU policies. Given the novelty of many issues and the complexity of the regulatory environment, training will also be a priority. Work will be focused on the following priorities:

- Food safety and quality
- Genetically modified organisms (GMOs)
- Chemical products
- Biomedical applications

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Food safety and quality*

Emphasis will be on the development and validation of reliable methods and reference materials for the detection of contaminants (natural such as mycotoxins and man-made such as PCBs), residues (e.g. pesticides, growth hormones and veterinary drugs) and ingredients and additives in food as well as in animal feed. JRC's prime role will be the coordination of testing of methods and materials and the submission of approved results to support risk assessment and management (in close support to the European Community Reference Laboratories for Veterinary Residues). As most food-borne diseases derive from microbiological including virus contamination, emphasis will be placed on evaluation of new approaches for rapid identification and monitoring. Research on genomics and proteomics will identify the cause of many food-related problems such as allergenicity, and the nature of TSE diseases. The JRC will maintain flexibility to deal with new public health issues as they arise and will establish additional efforts in the area of microbiology.

Standardisation of tests and evaluation of new methods for sensitive detection of BSE and TSE will involve the implementation of quality control of large scale post-mortem testing in abattoirs in collaboration with relevant DGs, TSE Ad-hoc Scientific Committee and leading TSE research laboratories. The JRC will investigate the fate of specific risk material (monitoring of food products for presence of central nervous tissue, recycling and safe handling of animal meal). Special emphasis will be put on safety aspects of animal feed being the prime route to the food chain.

Food quality will grow in importance due to the relationship between health and food. Apart from assessment of compliance with labelling (detection of frauds and adulteration) there is a strong need to judge the efficacy and/or side effects of food supplements and functional food. The growing popularity of organic food requires the availability of suitable methods to assess authenticity. The JRC will focus its expertise in the area of food authenticity towards the emergence of 'nutraceuticals' and their effectiveness.

Technological prospective research will be conducted on the development of food products and processes, and on the impact of food safety policies on the agri-food sector.

*Genetically modified organisms (GMOs)*

Concerning the presence of GMOs in food and environment the JRC will provide considerable scientific and technical support in this field. This support will be carried out in the context of the European network of GMO laboratories, coordinated by JRC at the request of EU Member States. Tasks will include development and validation methods for GMO detection, identification and quantification, increasing the range of certified reference materials (new species, processed food), development of biomolecular databases, and training. Research activities (e.g. on sampling and traceability) focusing on novel varieties of food and feeds or on tackling the problem of species unauthorised for use in EU will be performed to underpin regulatory needs and to achieve pan-European harmonisation.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

The study of GMOs in the environment will require the building of new competencies to deal with the genetic, biodiversity and agronomic aspects of introducing new organisms in the environment.

*Chemical products*

The new Community policy on chemicals will impact strongly on the support required of JRC <sup>(1)</sup> throughout this Framework Programme. The role for JRC will encompass operating an expanded scheme to regulate chemicals; this will reinforce the already close links with relevant Member State authorities, industry and with international bodies e.g. OECD. The risk assessment experience and expertise of the ECB will also provide a solid foundation for significant research effort in this area.

The validation of alternative methods will increase in importance in support of the new testing programme of the new chemicals policy. Research will also take place on the safety of vaccines and on the challenging area of the long-term effects of repeated low doses of potentially hazardous substances.

Exchange of validated information through telematic means on health and medicines between regulatory bodies in EU Candidate Countries and diffusion to all user-groups including consumers and patients are pursued.

The JRC will contribute to risk assessment on existing dangerous substances with attention paid to the migration of harmful compounds from materials in contact with human and food, e.g. plasticisers in toys and the harmful effects of cosmetics. Prospective analyses of the relations between Community policies and innovation and competitiveness of the European chemical industry will also be undertaken.

*Biomedical applications*

An ageing population will inevitably change the profile of demand on EU health systems. The JRC plans to apply its expertise in materials and life sciences on the biocompatibility and long-term reliability of implants and on the use of optical techniques in minimally invasive medical systems. This work necessitates networking with research laboratories, hospitals, industry and regulatory authorities. It will also work towards a globally accepted system for clinical diagnostic measurement in collaboration with the International Federation of Clinical Chemistry (Directives on In-Vitro-diagnostics and Medical Devices).

JRC's nuclear and isotopic facilities and competencies in the production and use of radioactive and stable isotopes will also be used for medical purposes as in new types of cancer therapies ( $\alpha$ -immunotherapy, Boron Neutron Capture Therapy (BNCT)) as well as in clinical reference materials.

<sup>(1)</sup> Includes work of the European Chemicals Bureau (ECB) of the JRC.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

**2.2. Environment and sustainability**

The quality and use of water, air and soils, the sustainable use of energy and the threat of global warming are concerns of growing political attention. Community policy developments in those fields call for adequate knowledge of causes, processes, impacts and trends. The JRC defines its programme in a manner which takes direct account of those requirements. It will thereby consolidate its role as a centre of knowledge and reference in environmental matters of significant European dimension. It will do so by becoming increasingly involved in reference networks with Member States and internationally, particularly in the accession States. Service to the policy making process will be strengthened by developing a closer partnership with the relevant Commission Services and by pursuing cross-policy, techno-economic prospective research. Attention will also be given to reinforcing the synergy with the European Environment Agency with particular attention to the diffusion of scientific results. The programme will cover the following areas:

- assessing and preventing global change;
- protection of the European environment (air, water and terrestrial resources);
- contributions to sustainable development (new and renewable energies, environmental assessment);
- support to GMES (Global Monitoring for Environment and Security).

*Assessing and preventing adverse global change*

The JRC will provide support to the development of EU's strategy to combat global warming, making use of its combined technical, socio-economic, modelling and research skills. The implementation of the Kyoto Protocol necessitates the understanding of the causes and processes controlling greenhouse gas cycles. A priority for JRC will be the direct support of the EU Monitoring Mechanism of greenhouse gases (Council Decision 92/296/EEC). Closing gaps of knowledge by specific research contribution will be a critical part of the role of the JRC in this context. Work will focus on the establishment of a reference system which will enhance data quality and reduce uncertainty. A critical part of this is the monitoring of changes in land cover, land use and forestry at various scales (see also GMES). Energy scenarios for the future as well as carbon emission forecasts are also key to the implementation of relevant measures. Policy options to reduce emissions in a cost-effective way will also be investigated. To maximise its efforts, the JRC will conduct its global change activities in a dedicated cluster. Issues associated with climate policy implementation, carbon sequestration, atmospheric quality measurements, the dynamics of ozone and UV radiation over Europe could also be examined.

*Protection of the European environment*

- Preserving air quality

Air pollution is a key concern for the European citizen and is also the focus of a large body of regulatory instruments (e.g. CAFE).

## INITIAL PROPOSAL

## AMENDED PROPOSAL

The cornerstones of JRC's efforts will be (a) the assessment of emissions by vehicles and stationary sources (new emission directives, standards for diesel/gasoline, new fuels, particulate matter and dioxin emissions; harmonisation/standardisation of world-wide reference test cycles and of measuring methods for industrial emissions) and (b) the provision of reference for the implementation and the development of air quality directives (analysis quantification of air pollution, monitoring, techniques, pre-normative work, methods for evaluating the impact of air quality policies on human exposure and modelling tools for data analysis and comparisons of abatement scenarios).

Cross sectoral integrated analysis of the transport, energy, health and enterprise policies will be conducted to determine their effect on emissions and ambient pollution levels. The work will be conducted in the context of large networks of experts including representatives from the automotive and energy industries.

— Water quality

Water is a key resource issue of the future; maintaining natural water sources and securing good quality drinking water are of particular relevance. The Framework Directive on Water will oblige co-ordination and harmonisation of monitoring and reporting processes of all Community regulatory existing instruments during the next six years. Research leading to the harmonisation of a common database on reports by Member States on implementation of various water related directives (e.g. Residual urban water, Nitrates, Surface water, etc.) will be pursued. JRC will focus on the determination of ecological water quality parameters (also in the context of supporting existing generic European metrological infrastructure), identification of significant pollutants, indicators of quality in inland and coastal waters and on the identification of microbiological hazards, especially in waste waters as well as on socio-economic implications of the new regulatory framework. Impacts on health are addressed under the 'Food Safety and Quality' chapter of this programme. Integrated coastal zone management research will be pursued to provide community reference approaches.

— Terrestrial resources

The soils and the landscapes are the site of most human activities and their characteristics are determined by management practices. The environmental component of the agricultural policy as well as several pieces of EU legislation (e.g. Water Directive, Spatial Development Perspective, Urban Agenda, Climate Change and others) deal with a range of those issues. The JRC will provide support to the development of a common platform for integrated spatial analysis as a basis for policy making and evaluation. Catchment areas will be used as units of study for evaluating various processes and impacts. The extensive database managed by the European Soils Bureau will be expanded through networking; the ongoing collaboration with Eurostat will also be reinforced. Attention will be paid to the development of tools and to provide information on natural landscapes in the context of forestry, land use and biodiversity conservation. Support to the environmental component of the common agricultural policy will be provided in terms of landscape analysis and use of

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## AMENDED PROPOSAL

indicators. Information on the state and changes in urban and regional environment will be produced. Work will rely upon the use of advanced remote sensing techniques, geographical information systems and modelling of spatial processes.

*Contributions to sustainable development*

Work on sustainable development pervades the whole JRC programme and attention is paid to the integration of economic, social and environmental dimensions.

*— Energy*

The Kyoto protocol has given a critical dimension to the energy debate since energy use and transport, two cornerstones of economic life, have major impacts on the emission of greenhouse gases. The importance of new and renewable energies as well as of energy efficiency and technology for the security of supply has been underlined in a recent Green Paper and in a Communication on 'Renewables'.

The JRC experience in the field of renewables, energy policy and energy technology will be exploited to provide support to emerging Community issues in a deregulated market; a concentration on the following areas of work is foreseen:

- development of reference systems — through accredited laboratory and certification schemes — in renewable energy production (with priority on solar electricity), storage and energy use in buildings,
- technology assessment, validation and modelling activities of new and conventional energy technologies with particular reference to safety, efficiency, waste and biomass generated power technologies and waste incineration performances,
- energy scenarios and forecasting in the context of greenhouse gases emissions and market assessment for new and renewable energy technologies in a competitive energy economy.

*— Environmental assessment*

The need for an 'integrated' assessment of environment quality is increasingly recognised. The JRC will support the EU Sustainable Development strategy through the development of appropriate integrated policy assessment tools and through activities leading to the integration of environmental concerns in EU policies. The European Integrated Pollution Prevention and Control Bureau (IPPC) will continue its directive-linked work on assessing best available technologies in view of reducing pollution in selected industrial sectors. Complex emission scenarios are needed to link air pollution and global change. Waste management is an important area where an integrated analysis from waste generation to treatment and disposal is necessary. Environmental integrity and human health is another area of integrated studies to which the JRC will contribute. New assessment tools and approaches to eco-toxicology will be developed to address topics

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such as air pollution and contaminants in waters (endocrine disruptors, biocides and pharmaceuticals). The JRC will also provide methodological support to the integration of the environmental dimension in development assistance.

The JRC will contribute to the fulfilment of the EC legislation for exchanging environmental monitoring data (incl. radioactivity) and information (through model intercomparison) under routine and emergency conditions.

A focus on inter-policy linkages and impacts will be retained by JRC as a specific contribution to the implementation of sustainable development practices at Community level.

*Support to GMES*

The need for independent information on key issues affecting the world's environment and the security of the citizen is increasingly recognised. GMES is a European initiative towards the implementation of operational services for collecting, analysing and disseminating a range of information items related to changes in environmental quality, resource availability and management, natural risks and hazards. The GMES is being implemented under the dual concern of preserving the global environment and reducing or anticipating threats to the security of the citizen. It focuses primarily on the use of earth observation techniques for maintaining an adequate long-term watch on key landscape parameters (such as land cover, use, resource degradation or depletion etc.) at various geographical levels. It will also call for techniques to support the assessment of natural risks and the management of catastrophic events. The JRC will focus on the development of EU-policy relevant applications which feed into the GMES concept in three areas of work: support to international environmental agreements, assessing risks and hazards, and evaluating environmental stress.

**2.3. Technology foresight**

Increasingly, the definition of EU policies is dependent on the timely anticipation and understanding of developments in science and technology and the social and economic environment. JRC's expertise in analysing inter-relationships between technology and society, and its experience in coordinating cross-sectoral and multidisciplinary foresight research on an international scale will contribute to the implementation of the objectives of the European Research Area (ERA). Throughout the framework programme 2002-2006, the JRC's activities in this research area will be based on a close collaboration with DG RTD and other customer DGs. The activity will focus on:

- Techno-economic foresight
- International Foresight Cooperation forum.



## INITIAL PROPOSAL

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*Techno-economic foresight*

JRC will undertake medium to long-term prospective studies on crucial technological developments affecting the EU and the relevant impact on growth, sustainable development, employment, social cohesion and competitiveness. This activity will also provide background analysis and information that will be valuable in the implementation by the JRC of its work in its specific competence areas. It will include prospective analysis to identify technological bottlenecks and opportunities, including quantitative estimations; identification of promising technologies and the conditions required for their uptake.

*International foresight cooperation forum*

The JRC will strengthen its working relationships with international think-tanks and top level advisors, by following up existing successful experiences (e.g. the European science and technology observatory (ESTO) network, the High-Level Economists Group) and by pursuing the establishment of an International foresight cooperation framework. The availability of a mechanism to share analysis on the main emerging challenges will in particular prove useful in promoting Europe's role in the international debate on science and governance. A common reference system in policy-oriented foresight analysis will be established in the context of regional exercises with particular attention to Candidate Countries.

**2.4. Reference materials and measurements**

Recognition of standards and measurements in products is an important component for the implementation of Community policies related to consumer safety, free trade, competitiveness of European industry and external relations. JRC will further support the existing or developing European metrological infrastructure to produce results of demonstrated quality, develop specific reference measurements, produce certified reference materials (CRMs) to improve their global acceptance, organise international measurement evaluation programmes and will establish trans-national databases in support to EU policies. Throughout JRC's work programme agreed reference methods and materials are required, whether in environment, food safety, public health or the nuclear industry. In addition to work described in the previous sections, JRC plans to support the creation of a European Certified Reference Material system. This will put the Centre in position to provide sound advice to Commission services where applicable to EU legislation and practice.

— BCR <sup>(1)</sup> and industrial certified reference materials

— Metrology in chemistry.

<sup>(1)</sup> Bureau Communautaire de Référence.

## INITIAL PROPOSAL

*BCR and certified reference materials*

This activity concerns developing concepts and techniques for the production and certification of reference materials to improve their global acceptance under the EU-US Mutual Recognition Agreement, where JRC advises DG TRADE. JRC will concentrate on production of BCRs and new CRMs for control of industrial processes and products. As support to DG RTD, JRC will, where feasible, extend its responsibility for storage and distribution of BCR to the management of the production and certification of new CRMs from indirect actions. Nuclear reference materials used for safeguards and nuclear materials accountancy will be expanded to the environment.

*Metrology in chemistry*

The JRC will continue to represent the Commission in international bodies responsible for the development of a world-wide chemical measurement system. Strategic tasks will include the development of primary measurement techniques, the production and certification of isotopic reference materials and organisation of International Measurement Evaluation Programmes. Topics depend on EU policy requirements and evaluations rely heavily on the participation of numerous laboratories, especially those which have a reference role to play in their sector or region. Through the establishment of networks (PECOMet-Network and MetMED) support will be provided to EU-Candidate countries and Mediterranean countries to build up a structured measurement system in chemistry.

## AMENDED PROPOSAL

*Metrology in chemistry and physics*

The information generated by studying the interactions of neutrons with matter is fundamental to many applications areas. Infrastructures will be maintained to investigate basic metrology in physics in a systematic manner over a wide energy range, emphasising its relevance for training. The radionuclide metrology activity provides support to food, chemical and environmental safety. The JRC will continue to represent the Commission in international bodies responsible for the development of a world-wide chemical measurement system. Strategic tasks will include the development of primary measurement techniques, the production and certification of isotopic reference materials and organisation of International Measurement Evaluation Programmes. Topics depend on EU policy requirements and evaluations rely heavily on the participation of numerous laboratories, especially those which have a reference role to play in their sector or region. Through the establishment of networks (PECOMet-Network and MetMED) support will be provided to EU-Candidate countries and Mediterranean countries to build up a structured measurement system in chemistry.

**2.5. Public security and anti-fraud**

## Unchanged

Public security issues — proliferation of weapons of mass destruction, the globalisation of the economy, infringements to privacy and Internet vulnerabilities, risks from natural or technological disasters — require a coordinated international approach. The EU is providing a framework through a number of mechanisms and at the same time it has declared zero tolerance to fraud. These political initiatives and commitments need scientific and technical support and the JRC is shaping its programme to directly answer some of those specific requirements. JRC has, over the years, developed a broad-based and well-recognised expertise in the general domain of security and anti-fraud, in the handling of large information infrastructures and in dealing with complex systems. In the framework programme 2002-2006, such expertise will be provided to user European institutions according to their priorities and needs. Increased emphasis will be given to exploiting networks with other research institutions and stakeholders in order to deepen and widen the support. JRC will concentrate on the following issues:

## INITIAL PROPOSAL

- International humanitarian security
- Natural and technological hazards, risks and emergencies
- Cybersecurity
- Monitoring compliance with EU regulations and fraud control.

*International humanitarian security*

The JRC will maintain a focus on technical aspects of EU efforts in humanitarian demining, firstly to improve knowledge of existing technology for minefield survey and detection through testing and benchmarking, secondly to assess new technologies, and thirdly to increase the visibility, transparency and efficiency of EU mine action operations.

The JRC, through the GMES initiative, will also contribute to developing a European capability that allows integrated space-based data, environmental data and socio-economic data to be made available for European security policies on a timely basis. Based on its expertise in safeguarding nuclear materials, the JRC is prepared, if required, to deal with the technical issues raised in non-proliferation and disarmament of weapons of mass destruction.

*Natural and technological hazards, risks and emergencies*

JRC will continue to support efforts to develop a European framework for forecasting, assessing, managing and reducing risks in the Community. In the Framework Programme 2002-2006 the JRC will further develop a system approach to the management of natural and technological hazards. For technological risks — from aircraft incidents and industrial hazards — JRC's efforts will be centred round its operation and improvement of harmonised European monitoring systems (ECCAIRS <sup>(1)</sup> MAHB <sup>(2)</sup>, EPERC <sup>(3)</sup>) which will be further extended to the enlargement countries. For natural hazards, JRC will endeavour to provide Europe with a similar capability. At the same time, efforts to develop a common European approach towards floods and forest fires will continue through a focus on integration of advanced modelling, conventional and space-based data. A link to the GMES initiative will be developed. Various networks, such as the European network of earthquake engineering laboratories will be extended to international level. Similarly, JRC in collaboration with European partners will set up a network of experimental facilities to develop a common integrated initiative for structural safety.

## AMENDED PROPOSAL

The JRC, through the GMES initiative, will also contribute to developing a European capability that allows integrated space-based data, environmental data and socio-economic data to be made available for European security policies, including humanitarian aid, on a timely basis. Based on its expertise in safeguarding nuclear materials, the JRC is prepared, if required, to deal with the technical issues raised in non-proliferation and disarmament of weapons of mass destruction.

Unchanged

<sup>(1)</sup> European Coordination Centre for Aircraft mandatory accident Reporting Systems.

<sup>(2)</sup> Major Accidents Hazard Bureau.

<sup>(3)</sup> European Pressure Equipment Research Council.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Cybersecurity*

The JRC will build on experience gained in supporting the EU's dependability initiative, out-of-court dispute settlement systems as well as the observatory on electronic payment systems. Working closely with the responsible Commission Services and Member State organisations, it will support the development of an appropriate EU response to risks of cybercrime, privacy and Internet vulnerabilities. Efforts will concentrate on methods for better characterising these risks, on criteria for evaluating technical counter-measures and on testing them in JRC facilities and on developing appropriate and harmonised measures, indications and statistics in consultation with other interested parties, including Europol. The JRC will also maintain an Internet website on the issue of cybercrime and report its progress to the EU Forum established in the framework of the Commission Communication on 'Creating a safer information society by improving the security of information infrastructures and combating computer-related crime' (COM(2000) 890 final).

*Monitoring compliance with EU regulations and fraud control*

The JRC supports the Commission's efforts to increase the effectiveness of anti-fraud measures, both by providing advanced technologies to bodies that operate at the EU level and by supporting Member States in the use of the latest technologies. The JRC, working closely with the concerned Commission services, will maintain appropriate support to the common agricultural policy, the common fisheries policy and the European Anti-Fraud Office, OLAF. As well as exploring the application of new technologies — DNA analysis for livestock identification, satellite image interpretation for crop acreage monitoring or fishing vessel identification, cross-correlation of isotopic analysis of beverages and foodstuffs to determine contents and origin, intelligence gathering from open sources, language technology to analyse multilingual documents — the JRC will continue to provide customers with the integrated knowledge that includes the entire cycle from data capture, data fusion, data mining through to visualisation and estimation.

The JRC will also build on its methodological experience to provide timely, reliable and more socially-robust information to the policy process. This will be achieved for official statistics through the coordination, with Eurostat, of thematic research networks with emphasis on short-term indicators, business cycle and financial analysis and through the development of a quality assurance methodology for scientific input to governance.

Increased importance will be devoted to early warnings and trend detection, dissemination, awareness raising and knowledge-sharing with partner laboratories in the Member States. The fraud problem will not be tackled on an individual case basis but at a system level — developing procedures and regulations that involve less bureaucracy and that are intrinsically less prone to fraud.

## INITIAL PROPOSAL

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## ANNEX II

## INDICATIVE BREAKDOWN OF THE AMOUNT

(EUR million)	
Activity	Amount
Food, Chemical products and Health	207
Environment and Sustainability	286
Horizontal Activities	222
— Technology Foresight; Reference Materials and Measurements; Public Security and Antifraud	
Total	715 <sup>(1)</sup> <sup>(2)</sup>

<sup>(1)</sup> Of which approximately 6 % may be allocated to exploratory research and up to 2 % for exploitation of own JRC results and technology transfer.

<sup>(2)</sup> This total includes the JRC's budget contribution necessary for its participation in indirect actions.

(EUR million)	
Activity	Amount
Food, Chemical products and Health	212
Environment and Sustainability	286
Horizontal Activities	262
— Technology Foresight; Reference Materials and Measurements; Public Security and Antifraud (EUR 222 million)	
— Research Training; Access to Infrastructures (EUR 40 million)	
Total	760 <sup>(1)</sup> <sup>(2)</sup>

<sup>(1)</sup> Of which approximately 6 % may be allocated to exploratory research and up to 2 % for exploitation of own JRC results and technology transfer.

<sup>(2)</sup> This total includes the JRC's budget contribution necessary for its participation in indirect actions.

## ANNEX III

## SPECIFIC RULES FOR IMPLEMENTING THE PROGRAMME

1. The Commission, after consulting the Board of Governors of the JRC, shall implement the direct action on the basis of the scientific objectives and contents described in Annex I. The activities relating to this action shall be performed in the relevant institutes of the Joint Research Centre (JRC).
2. In the implementation of its activities, the JRC will, whenever appropriate and feasible, participate in or organise networks of public and private laboratories in the Member States or European research consortia supporting the European policy making process. Particular attention shall be paid to cooperation with industry, especially with small and medium-sized enterprises. Research bodies established in third countries may also cooperate on projects, in accordance with the relevant provisions of Article 6 of the Framework Programme and, where applicable, of agreements for scientific and technological cooperation between the Community and the third countries concerned. Particular attention will be paid to cooperation with research laboratories and institutes in the Candidate Countries and countries of central and eastern Europe and the former Soviet Union.

Unchanged

It will also use appropriate mechanisms to continuously identify the requirements and needs of its customers and users and to involve them in the related activities.

The knowledge gained through implementation of the projects will be disseminated by the JRC itself (taking into account possible limitations due to confidentiality issues).

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## 3. The accompanying measures shall include:

- organisation of the visits of JRC staff to national laboratories, industrial laboratories and universities,
  - the promotion of mobility of young scientists, particularly from the Candidate countries, with particular attention to encourage participation of women,
  - specialised training in support of the elaboration and/or implementation of the European policies with the emphasis on multidisciplinary,
  - the organisation of visits to JRC institutes of visiting scientists and seconded national experts, particularly from Candidate countries, with particular attention to encourage participation of women,
  - systematic exchange of information, through, *inter alia*, the organisation of scientific seminars, workshops and colloquiums and scientific publications,
  - the independent scientific and strategic evaluation of the performance of the projects and programmes.
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**Amended proposal for a Council Decision adopting a specific programme (Euratom) for research and training on nuclear energy (2002-2006) <sup>(1)</sup>**

(2002/C 181 E/04)

(Text with EEA relevance)

COM(2002) 43 final — 2001/0125(CNS)

*(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 31 January 2002)*

<sup>(1)</sup> OJ C 240 E, 28.8.2001, p. 249.

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INITIAL PROPOSAL

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the first paragraph of Article 7 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas:

(1) By Decision No .../Euratom the Council adopted the multiannual framework programme 2002-2006 of the European Atomic Energy Community for research and training activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') to be implemented by means of research and training programme(s) drawn up in accordance with Article 7 of the Treaty, which define the detailed rules for their implementation, fix their duration and provide for the means deemed necessary.

(2) The rules for the participation of undertakings, research centres and universities for the implementation of the framework programme, adopted by the Council in Decision No .../Euratom (hereinafter referred to as 'the rules for participation') should apply to this programme.

(3) The Commission's administrative expenditure for the implementation of this programme reflects the high number of staff seconded to laboratories in the Member States and to the ITER project.

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AMENDED PROPOSAL

Unchanged

(1) By Decision No .../Euratom the Council adopted the sixth multiannual framework programme 2002-2006 of the European Atomic Energy Community for research and training activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') to be implemented by means of research and training programme(s) drawn up in accordance with Article 7 of the Treaty, which define the detailed rules for their implementation, fix their duration and provide for the means deemed necessary.

Unchanged

## INITIAL PROPOSAL

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| <p>(4) In implementing this programme, emphasis should be given to promoting mobility of researchers, and innovation, in the Community as well as international co-operation activities with third countries and international organisations. Special attention should be paid to the Accession countries.</p> <p>(5) Research activities carried out within this programme should respect fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union</p> <p>(6) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolution of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research.</p> <p>(7) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities. The research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.</p> | <p>(4) This programme is open to the participation of countries having concluded the necessary agreements to this effect, and is also, except in the case of fusion research, open on the project level, and on the basis of mutual benefit, to the participation of entities from third countries and of international organisations for scientific co-operation.</p> <p>(5) In implementing this programme, emphasis should be given to promoting mobility of researchers, and innovation, in the Community as well as international co-operation activities with third countries and international organisations. Special attention should be paid to the candidate countries.</p> <p>(6) Research activities carried out within this programme should respect fundamental ethical principles, including those reflected in Article 6 of the Treaty on the European Union and in the Charter of Fundamental Rights of the European Union, as well as the need to take into account public acceptability of these activities.</p> <p>(7) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolution of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research, which should ensure the respect of equality of opportunity, irrespective of gender.</p> <p>(8) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant interests, in particular of the scientific, industrial, user and policy communities. The research activities carried out under it should be adapted where appropriate to the needs of Community policies and to scientific and technological developments.</p> <p>(9) Participation in the activities of this programme will be encouraged through publication of the necessary information on content, conditions and procedures, to be made available in a timely and thorough manner to potential participants, including those from the associated candidate countries and other associated countries.</p> |
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<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656



## INITIAL PROPOSAL

(8) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme.

(9) The Scientific and Technical Committee has been consulted,

HAS ADOPTED THIS DECISION:

*Article 1*

1. In accordance with the framework programme, a specific programme for research and training on nuclear energy (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.

2. The objectives and scientific and technological priorities for the specific programme are set out in Annex I.

*Article 2*

In accordance with Annex II to the framework programme], the amount deemed necessary for the execution of the specific programme is EUR 900 million, including a maximum of 16,5 % for the Commission's administrative expenditure. An indicative breakdown of this amount is given in Annex II to this decision.

*Article 3*

1. The detailed rules for financial participation by the Community in the specific programme shall be those referred to in Article 2(2) of the framework programme.

2. The specific programme shall be implemented by means of instruments defined in Annex III.

3. The rules for participation shall apply to the specific programme.

## AMENDED PROPOSAL

(10) The Commission will in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme, which will be done in a spirit of openness with respect to all the relevant actors.

(11) The Scientific and Technical Committee has been consulted,

Unchanged

1. In accordance with the sixth framework programme, a specific programme for research and training on nuclear energy (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.

Unchanged

In accordance with Annex II to the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 940 million, including a maximum of 16,5 % for the Commission's administrative expenditure. An indicative breakdown of this amount is given in Annex II to this decision.

*Article 3*

All research activities carried out under the specific programme shall be carried out in compliance with fundamental ethical principles.

*Article 4*

Unchanged

## INITIAL PROPOSAL

*Article 4*

1. The Commission shall draw up a work programme for the implementation of the specific programme, setting out in greater detail the objectives and scientific and technological priorities set out in Annex I, and the timetable for implementation.

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States, European and international organisations. It shall be updated where appropriate.

*Article 5*

1. The Commission shall be responsible for the implementation of the specific programme.

2. For the purposes of implementing the specific programme the Commission shall be assisted by a consultative committee. The members of this committee can vary according to the different subjects on the committee's agenda. For fission-related aspects, the composition of this committee and the detailed operational rules and procedures applicable to it shall be as laid down in Council Decision 84/338/Euratom, ECSC, EEC <sup>(1)</sup> dealing with management and co-ordination advisory committees. For the fusion-related aspects they shall be as laid down in the Council Decision of 16 December 1980 dealing with the consultative committee for the fusion programme.

*Article 6*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article of the framework programme.

2. The Commission shall arrange for the independent assessment provided for in Article 5 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 7*

This decision is addressed to the Member States.

## AMENDED PROPOSAL

*Article 5*

1. The Commission shall draw up a work programme for the implementation of the specific programme, setting out in greater detail the objectives and scientific and technological priorities set out in Annex I, including the instruments to be used on a priority basis, and the timetable for implementation.

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States, European and international organisations. It shall be updated where appropriate, including in relation to the use of instruments on a priority basis.

*Article 6*

Unchanged

*Article 7*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 5(2) of the framework programme, information on financial aspects shall be included.

2. The Commission shall arrange for the independent monitoring and assessment provided for in Articles 5 and 6 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 8*

Unchanged

<sup>(1)</sup> OJ L 177, 4.7.1984, p. 25.

## INITIAL PROPOSAL

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## ANNEX I

**SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND BROAD LINES OF THE ACTIVITIES****1. INTRODUCTION**

Unchanged

As the source of 35 % of the electricity produced in the European Union, nuclear energy is an element of the debate on how to combat climate change and reduce the energy dependency of the EU. But significant challenges need to be faced. Controlled thermonuclear fusion is one of the long term options for energy supply, in particular for the centralised supply of base-load electricity. The priority is to make progress towards demonstrating the scientific and technological feasibility of fusion energy and assessing its sustainable qualities. In the short term, ways of dealing with nuclear waste that are acceptable to society need to be found, and more particularly the implementation of technical solutions for the management of long-lived waste. Innovative concepts for the safer exploitation of nuclear fission should also be studied as possible contributions to meeting European energy needs in the decades ahead.

As the source of 35 % of the electricity produced in the European Union, nuclear energy is an element of the debate on how to combat climate change and reduce the energy dependency of the EU. But significant challenges need to be faced. Controlled thermonuclear fusion is one of the long term options for energy supply, in particular for the centralised supply of base-load electricity. The priority is to make progress towards demonstrating the scientific and technological feasibility of fusion energy and assessing its sustainable qualities. In the short term, ways of dealing with nuclear waste that are acceptable to society need to be found, and more particularly the implementation of technical solutions for the management of long-lived waste. Innovative concepts for the safer exploitation of nuclear fission should also be studied as possible contributions to meeting European energy needs in the decades ahead. The high standards of radiation protection in the Community must be maintained through focused and co-ordinated research, in particular into the effects of low levels of exposure.

Co-operation at European level, including the exchange of scientists and common research programmes, is already well established in this field. In respect of nuclear waste, and other activities, this will be intensified and deepened at programme and project level with the aim of better use of resources (both human resources and experimental facilities) and promoting a common European view on key problems and approaches, in accordance with the needs of the European research area. Links will be established with national programmes and networking will be promoted with third countries, in particular, USA, Canada and Japan. In the case of fusion, the Community and Member States will continue to work within the framework of an integrated programme of activities.

Co-operation at European level, including the exchange of scientists and common research programmes, is already well established in this field. In respect of nuclear waste, radiation protection and other activities, this will be intensified and deepened at programme and project level in order to make better use of resources (both human resources and experimental facilities) and promote a common European view on key problems and approaches, in accordance with the needs of the European research area. Links will be established with national programmes and networking will be promoted with third countries, in particular, USA, the Newly Independent States of the Former Soviet Union (NIS), Canada and Japan. In the case of fusion, the Community, the Member States and Countries Associated with the activities covered by the Euratom Framework Programme will continue to work within the framework of an integrated programme of activities.

Co-ordination will be assured with the JRC programme on 'nuclear safety and safeguards'.

Unchanged

**2. PRIORITY THEMATIC AREAS****2.1. Fusion energy research****Objectives**

Fusion energy could contribute in the second half of the century to the emission-free large-scale production of base-load electricity. The advances made in fusion energy research justify to further pursue a vigorous effort towards the long-term objective of a fusion power plant. Theoretical work and experimental studies on the existing devices world-wide, in particular on JET, have established the scientific and technical readiness for the construction of a project of the next generation after JET with

## INITIAL PROPOSAL

the objective of demonstrating the scientific and technological feasibility of fusion energy. World wide collaboration on fusion energy research has progressed to the detailed engineering design of such a Next Step device, ITER, with the objectives of extended burn in inductive operation with power amplification  $Q > 10$ , demonstrating generation of 400 MW of fusion power over about 400 seconds, that could allow burning plasmas to be studied in conditions relevant to energy production.

The successful completion of the ITER Engineering Design Activities makes it possible, in line with the reactor orientation of the Community activities on fusion energy research, to take a decision about the realisation of the Next Step. Subject to a positive outcome of the international negotiations on the juridical and institutional conditions of the establishment of an ITER Legal Entity and negotiations for its joint implementation (construction, operation, exploitation and decommissioning), a specific decision could be sought in the period 2003-2004, so that construction could effectively start during the period 2005-2006. The period 2003-2006 has therefore to be seen as a transition period marked by the need to rationalise European activities due to the strong orientation of the programme towards the Next Step. The budgetary proposition for research in the field of fusion energy over the period 2003-2006 provides that out of a total appropriation of 700 Mio EUR, 200 Mio EUR are foreseen for the realisation of ITER.

If and when decided, the realisation of the Next Step will mobilise significant human and financial resources. Once a decision is taken to go ahead with the project, adaptations to the current efforts of the European partners of Euratom in the field of fusion and organisational changes will be required, in particular to jointly steer the European contribution to ITER. The amount of 500 Mio EUR is proposed to allow the continuation of a meaningful R & D programme, including the transition between the activities currently carried out in the framework of the Associations<sup>(1)</sup> and JET, and what would become the 'accompanying programme' in physics and technology for fusion once construction of the Next Step/ITER device has reached its steady state after 2006.

## Priorities

(i) *Associations' programme in physics and technology*

The Associations' programme will include:

- R & D in fusion physics and plasma engineering, focusing on the study and evaluation of magnetic confinement formulas, with in particular the continuation of the construction of the Wendelstein 7-X 'stellarator' and operation of the existing installations in the Euratom Associations.

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The successful completion of the ITER Engineering Design Activities makes it possible, in line with the reactor orientation of the Community activities on fusion energy research, to take a decision about the realisation of the Next Step. Subject to a positive outcome of the international negotiations on the juridical and institutional conditions of the establishment of an ITER Legal Entity and negotiations for its joint implementation (construction, operation, exploitation and decommissioning), a specific decision could be sought in the period 2003-2004, so that construction could effectively start during the period 2005-2006. The period 2003-2006 has therefore to be seen as a transition period marked by the need to rationalise European activities due to the strong orientation of the programme towards the Next Step. The budgetary proposition for research in the field of fusion energy over the period 2003-2006 provides that out of a total appropriation of 750 Mio EUR, up to a maximum of 200 Mio EUR is foreseen for the realisation of ITER.

If and when decided, the realisation of the Next Step will mobilise significant human and financial resources. Once a decision is taken to go ahead with the project, adaptations to the current efforts of the European partners of Euratom in the field of fusion and organisational changes will be required, in particular to jointly steer the European contribution to ITER. The amount of 550 Mio EUR is proposed to allow the continuation of a meaningful R & D programme, including the transition between the activities currently carried out in the framework of the Associations<sup>(1)</sup> and JET, and what would become the 'accompanying programme' in physics and technology for fusion once construction of the Next Step/ITER device has reached its steady state after 2006.

## Unchanged

<sup>(1)</sup> Established under contracts of associations between the Community and entities in the Members States.

<sup>(1)</sup> Established under contracts of associations between the Community and entities in the Members States.

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- Structured R & D activities in fusion technology in particular research on fusion materials and participation in the R & D activities for the decommissioning of JET, which is foreseen at the end of its operations.
- Investigations of socio-economic aspects, focusing on evaluation of economic costs and social acceptability of fusion energy, in complement to the further studies on safety and environmental aspects; co-ordination, in the context of a keep-in-touch activity, of the Member States' civil research activities on inertial confinement and possible alternative concepts; dissemination of results and the diffusion of information to the public; mobility and training.

In contributing to the Associations' programme, priority will be given to multilateral actions to focalise activities on common projects such as those directly related to operation on JET and to the Next Step/ITER and/or staff training. Depending on a decision on the realisation of ITER and its timing, the current Community support to the Associations activities will be adjusted, and the phasing out of the exploitation of a number of facilities will be considered. Adequate means shall be ensured to maintain a strong European co-ordination of the fusion activities, which has demonstrated its usefulness over the years.

The extent of the accompanying domestic programme in fusion physics and technology which is required in the Associations and European industry to take full benefit from ITER, will depend (a) on the level of the European share in ITER and (b) on where it would be sited. This could entail investments aiming at maintaining experimentation on fusion devices at world-class level in Europe beyond the start of operation of ITER and an adequate programme of technological development.

(ii) *Exploitation of the JET facilities*

The JET facilities will continue to be exploited in the framework of the European Fusion Development Agreement (EFDA), in view of completing the exploitation of the performance enhancements currently under way. The use of the JET facilities will have to be suspended at an appropriate time to enable the corresponding resources to be redirected to the Next Step/ITER.

(iii) *Next Step/ITER*

The Proposal for the Euratom framework programme (2002-2006) includes the continuation of Next Step activities with a view to participate in its construction in the second half of the period. However, since decisions on ITER do not depend only upon EU Institutions but also on the EU international partners, the proposed programme of activities must be open regarding the eventual siting and framework of the Next Step/ITER and the precise content of the accompanying domestic programme.

## AMENDED PROPOSAL

The Proposal for the Euratom framework programme (2002-2006) includes the continuation of Next Step activities with a view to participate in its construction in the second half of the period. However, since decisions on ITER do not depend only upon EU Institutions but also on the EU international partners, the proposed programme of activities must be open regarding the eventual siting and framework of the Next Step/ITER and the precise content of the accompanying domestic programme. The studies performed in preparation of possible European site(s) will be completed.

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The EU participation in ITER would include contributions to the construction of equipment and installations, which are within the perimeter of the ITER site and necessary for its exploitation, as well as to the costs associated with the staffing and management of, and the support to be given to, the project during construction. The level and nature of this participation will depend on the outcome of the negotiations with the EU international partners, and in turn on the location of the ITER site. If ITER was located in Europe, the EU participation would also include contribution to the costs to be borne by Europe as a Host Party.

**2.2. Treatment and disposal of radioactive waste****Objectives**

The absence of a broadly agreed approach to waste management and disposal is one of the main impediments to the continued and future use of nuclear energy. In particular, this applies to the disposal of long-lived waste components in geological repositories, which will be required no matter what treatment method is chosen for the spent fuel and high level waste. Research alone cannot ensure societal acceptance; however, it is needed in order to develop and test the repository technologies, investigate suitable sites, promote basic scientific understanding relating to safety and safety assessment methods, and to develop decision processes that are perceived as fair and equitable by the stakeholders involved.

Research is also needed to explore the potential offered by new reactor types and/or fuel cycles to make better use of fissile material and generate less waste, while meeting appropriate cost expectations, and to clarify the prospects for conducting partitioning and transmutation, which have a theoretical potential to reduce the hazard of the waste, on an industrial scale with adequate safety and at reasonable cost.

**Research Priorities***(i) Research on geological disposal*

The aims are to establish a sound technical basis for demonstrating the safety of disposing high level radioactive wastes in geological formations and underpin the development of a common European view on the main issues related to the disposal of waste.

- Improvement of fundamental knowledge, developing and testing technologies: research will focus on key physical, chemical and biological processes; interaction between the different natural and engineered barriers, their long-term stability and means of implementing disposal technologies in underground research laboratories.

## AMENDED PROPOSAL

Unchanged

**2.2. Management of radioactive waste**

Unchanged

Research is also needed to explore the technical and economic potential of concepts for nuclear energy generation able to make better use of fissile material and generate less waste and of partitioning and transmutation to reduce the hazard of the waste on an industrial scale.

Unchanged

The aims are to establish a sound technical basis for demonstrating the safety of disposing spent fuel and long lived radioactive wastes in geological formations and underpin the development of a common European view on the main issues related to the disposal of waste.

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- New and improved tools: research will focus on models for performance, safety assessment and methodologies to demonstrate long term safety, including sensitivity and uncertainty analyses, evaluation of alternative measures of performance and processes to the public concerns on waste disposal.

(ii) *Partitioning and transmutation and reactor nuclear energy*

The aims are to determine practical ways of reducing the amount and/or hazard of the waste to be disposed of by partitioning and transmutation and to explore the potential of new reactor concepts.

- Partitioning and transmutation: research will focus on fundamental assessments of the overall concept; demonstration at pilot scale of the most promising partitioning technologies; further development of technologies for transmutation; and evaluation of their industrial practicality.

- New reactor to produce less waste: research will focus primarily on The High Temperature Reactor (HTR), in particular, in particular with regard to power conversion system for direct cycle, material properties in a high temperature helium environment, innovative fuel coatings, process heat applications and safety and licensing issues.

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- New and improved tools: research will focus on models for performance and safety assessment, and methodologies to demonstrate long term safety, including sensitivity and uncertainty analyses, and development and evaluation of alternative measures of performance and of better governance processes that properly address public concerns on waste disposal.

(ii) *Partitioning and transmutation and other concepts to produce less waste in nuclear energy generation*

The aims are to determine practical ways of reducing the amount and/or hazard of the waste to be disposed of by partitioning and transmutation and to explore the potential of concepts for nuclear energy to produce less waste.

Unchanged

- Concepts to produce less waste: research will focus on exploring the potential for the more efficient use of fissile material in existing reactors and of other concepts to produce less waste in nuclear energy generation.

### 2.3. Radiation protection

#### Objectives

Radiation is used extensively in medicine and industry (including the generation of nuclear energy) and its safety is predicated on a sound radiation protection policy and its effective implementation. Community research underpins European policy and has contributed to the high levels of protection achieved in practice. These standards must be maintained and, in some cases, improved and research has a key role in this process. The main objective is to resolve uncertainties in the risk from exposures to radiation at low and protracted doses (i.e. at levels typically encountered by the population and in workplaces) which remains a controversial scientific and policy issue, and has important implications for the use of radiation in both medicine and industry. Community research in other areas will focus on making better use of national efforts, principally through their more effective integration by networking and targeted research where this would either be complementary to, or provide synergy with, national programmes.

#### Research priorities:

- Quantification of risks associated with low and protracted exposures: research will focus on epidemiological studies of suitable exposed populations, complemented by cellular and molecular biology research on the interaction between radiation and the DNA, cells, organs and the body.

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## 3. OTHER ACTIVITIES IN THE FIELD OF NUCLEAR SAFETY

## Objectives

The objectives are to support EU policies in the fields of health, safety energy and the environment, and better integrate European research on nuclear fission and the other uses of ionising radiation.

## Research priorities

(i) *Radiation protection*

The aims are to underpin Community standards on radiation protection and how they are applied, to respond flexibly and rapidly to emerging needs and to enhance European capability through better integration of the research effort. Research will focus on:

- quantification of risks at low and protracted doses typical of those encountered in the environment and the workplace, through epidemiological studies of suitable exposed populations complemented by cellular and molecular biology research. Collaboration with Russia and other CIS countries will be essential for gaining access to data on exposed populations of interest.
- better integration of European research, in particular in the areas of health and environmental protection, radioecology, emergency and environmental management, medical uses of radiation and exposure to natural sources of radiation.

- Medical exposures and natural sources of radiation: enhancing the safety and efficacy of medical uses of radiation; better assessment and management of natural sources, in particular, naturally occurring radioactive materials.
- Protection of the environment and radioecology: conceptual and methodological basis for protection of the environment; better assessment and management of the impact of natural and artificial sources of radiation on man and the environment.
- Risk and emergency management: better approaches for risk governance; more effective and coherent emergency management in Europe, including rehabilitation of contaminated areas.
- Protection of the workplace: improved monitoring and management of occupational exposures in industries involving exposure to radiation.

## 3. OTHER ACTIVITIES IN THE FIELD OF NUCLEAR TECHNOLOGIES AND SAFETY

## Unchanged

The objectives are to support EU policies in the fields of health, energy and the environment, to ensure that European capability is maintained at a high level in relevant fields not covered by the thematic priorities and to contribute towards the creation of the European Research Area.

## Unchanged

## Deleted



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(ii) *Innovative concepts ways of producing nuclear energy*

The aim is to investigate possible evaluate innovative concepts for nuclear energy. Research will focus on:

- further development of innovative concepts and for nuclear energy that have been identified as offering longer term benefits such as in terms of cost, safety, waste management, costs and sustainability.

(iii) *Education and training*

The aim is to better integrate European education and training in the nuclear sciences to combat the decline in both student numbers and teaching establishments, thus providing the necessary competence and expertise for the continued safe use of nuclear energy and other uses of radiation in industry and medicine. Support will focus on:

- development of a more harmonised approach for education in the nuclear sciences and engineering in Europe and its implementation, including and the better integration of national resources and capabilities.

This will be complemented by support for individual fellowships, special training courses, training networks, and grants for young research workers from former Soviet Union.

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(i) *Innovative concepts*

The aims are to evaluate innovative concepts and develop improved and safer processes in the field of nuclear energy. Research will focus on:

- Evaluation of innovative concepts and development of improved and safer processes for the generation and exploitation of nuclear energy that have been identified as offering longer term benefits in terms of, cost, safety, environmental impact, resource utilisation, proliferation resistance, or diversity of application.

(ii) *Education and training*

The aim is to better integrate European education and training in nuclear safety and radiation protection to combat the decline in both student numbers and teaching establishments, thus providing the necessary competence and expertise for the continued safe use of nuclear energy and other uses of radiation in industry and medicine. Support will focus on:

Unchanged

This will be complemented by support for fellowships, special training courses, training networks, grants for young research workers from the NIS and CEE countries, and transnational access to infrastructure.

(iii) *Safety of existing nuclear installations*

The aim is to improve safety in existing nuclear installations in Member States and candidate countries during their remaining operational lifetimes and subsequent decommissioning, making use of the considerable knowledge and experience gained internationally from experimental and theoretical research. Research will focus on:

- plant management including effects of ageing and fuel performance; severe accident management, in particular the development of advanced numerical simulation codes; integration of European capabilities and knowledge from practical decommissioning; developing harmonised approaches to safety and best practice, both operational and regulatory, at a European level.

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## ANNEX II

## INDICATIVE BREAKDOWN OF THE AMOUNT

Types of activities	Amount (EUR million)
1. Priority thematic areas of research	890
1.1. Controlled thermonuclear fusion	750
1.2. Management of radioactive waste	90
1.3. Radiation protection	50
2. Other activities in the field of nuclear technologies and safety	50
Total	940

## ANNEX III

## MEANS FOR IMPLEMENTING THE PROGRAMME

In order to implement the specific programme, and in accordance with the Decisions of the European Parliament and of the Council concerning the multiannual Framework Programme 2002-2006 of the European Atomic Energy Community for research and training activities aimed at contributing towards the creation of the European Research Area (2002/.../Euratom) and with the rules for the participation of undertakings, research centres and universities for the implementation of the framework programme (2002/.../Euratom), the Commission will use various instruments.

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions in order to verify their relevance with regard to the objectives of the programme, their scientific and technological excellence, their Community added value and the participants' management capacity.

Unchanged

The Commission will evaluate the proposals in accordance with the evaluation criteria set out in the abovementioned Decisions.

As regards the thematic priority areas, management of radioactive waste and radiation protection, the importance of the new instruments (Integrated Projects and Networks of Excellence) is recognised as being an overall priority means to attain the objectives of critical mass, management simplification and European added value contributed by Community research in relation to what is already undertaken at national level, and of the integration of the research capacities. However, the size of projects is not a criterion for exclusion, and access to new instruments is ensured for SMEs and other small entities.

The new instruments will be used from the start of the sixth framework programme in each theme and, where deemed appropriate, as a priority means, while maintaining the use of specific targeted projects and coordination actions.

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The indirect RTD actions implemented in the area of thermonuclear fusion and in the framework of contracts, agreements or legal entities to which the Community is a party or of which it is a member, conform to the rules which have been established for them, in conformity with the Decision on the rules of participation.

In carrying out the programme, the Commission may have recourse to technical assistance.

In 2004 an evaluation will be undertaken by independent experts of the efficiency of each of these two types of instruments in the execution of the sixth framework programme.

## A. New instruments

Unchanged

A.1. *Networks of excellence*

In general, the network will be organised around a core group of participants to which others may be added. In order to create a virtual centre of excellence, they will integrate a considerable part or even the totality of their research activities in the area concerned. These activities will often be multidisciplinary, and oriented towards long-term objectives and not precise predefined results in terms of products, processes or services.

The purpose of networks of excellence is to strengthen and develop Community scientific and technological excellence by means of the integration, at European level, of research and training capacities currently existing or emerging at both national and regional level. Each network will also aim at advancing knowledge in a particular area by assembling a critical mass of expertise. They will foster cooperation between capacities of excellence in universities, research centres, enterprises, including SMEs, and science and technology organisations. The activities concerned will be generally targeted towards long-term, multidisciplinary objectives, rather than predefined results in terms of products, processes or services.

In addition to these integrated research activities, the network's joint programme of activities will also comprise integration activities as well as activities related to spreading of excellence outside the network.

A network of excellence will be implemented by a joint programme of activities involving some or, where appropriate, all of the research and training capacities and activities of the participants in the relevant area to attain a critical mass of expertise and European added value. A joint programme of activities could aim at the creation of a self-standing virtual centre of excellence that may result in developing the necessary means for achieving a durable integration of the research and training capacities. A joint programme of activities will necessarily include those aimed at integration, as well as activities related to the spreading of excellence and dissemination of results outside the network.

In pursuing its objectives, the network will therefore carry out:

Unchanged

— Research activities integrated by its participants

— Research and training activities integrated by its participants

— Integration activities which will comprise in particular:

Unchanged

— adaptation of the participants' research activities in order to strengthen their complementarity;

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- development and utilisation of electronic information and communication means, and development of virtual and interactive working methods;
  - short-, medium- and long-term exchanges of personnel, the opening of positions to researchers from other members of the network, or their training;
  - development and use of joint research infrastructures, and adaptation of the existing facilities with a view to a shared use;
  - joint management and exploitation of the knowledge generated, and actions to promote innovation.
- Activities of spreading of excellence which will comprise, as appropriate:
- training of researchers;
  - communication concerning the achievements of the network and the dissemination of knowledge;
  - services in support of technological innovation, aimed in particular at the take-up of new technologies;
  - analyses of science/society issues related to the research carried out by the network.

In carrying out some of its activities (such as training of researchers), the network will endeavour to ensure publicity by publishing calls for applications.

The size of the network may vary according to the areas and subjects involved. As an indication, the number of participants should not be less than half a dozen. On average, in financial terms, the Community contribution to a network of excellence may represent several million euros per year.

The network proposals should comprise the following elements:

- a general outline of the joint programme of activities, and its content for the first year, broken down into research activities, integration activities, and activities for spreading excellence;
- the role of the participants, identifying the activities and resources that they will integrate;
- the operation of the network (co-ordination and management of activities);

- a general outline of the joint programme of activities, and its content for the first period, broken down into research activities, integration activities, and activities for spreading excellence;

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- the plan for the dissemination of knowledge and the perspectives as regards exploitation of the results.

The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a call for applications.

The programme of activities would be updated yearly and would entail a reorientation of certain activities or launching of new ones not initially foreseen, which could involve new participants. The Commission may launch calls for proposals with a view to the allocation of additional contribution in order to cover, for example, an extension of the integrated activities of the existing network or the integration of new participants.

The Community's financial contribution will be a specified amount linked to the implementation of a set of work, initially calculated on the basis of the resources dedicated to carrying out the joint programme of activity and paid on an annual basis, taking into account activities and financial reports. As a complement to the resources of the participants should be sufficient to act as an incentive for integration, but without creating a financial dependence that might jeopardise the lasting association of the network.

A.2. *Integrated projects*

The objective of this instrument is to strengthen European competitiveness or contribute to resolve major societal problems by mobilising a critical mass of research and technological development resources and skills existing in Europe.

Accordingly, each integrated project will have the aim of obtaining identifiable scientific and technological results applicable to products, processes or services. The activities carried out in the context of an integrated project will have by definition clearly defined objectives even in the case of risky research.

In general, the participants in the projects will be organised around a core group made up of the main participants.

All the activities carried out in the context of an integrated project will be defined in the general framework of an 'execution plan' comprising activities relating to:

- research, technological development and/or demonstration;
- management, dissemination and transfer of knowledge with a view to promoting innovation;
- analysis and assessment of the technologies concerned, as well as the factors relating to their exploitation.

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The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a competitive call.

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The Community's financial contribution shall take the form of a grant for integration, the amount of which is determined in relation to the value of the capacities and resources which all the participants propose to integrate. It shall complement the resources deployed by the participants in order to carry out the joint programme of activities. It should be sufficient to act as an incentive for integration, but without creating a financial dependence that might jeopardise the lasting association of the network.

Unchanged

Integrated projects are designed to give increased impetus to the Community's competitiveness or to address major societal needs by mobilising a critical mass of research and training resources and competence. Each integrated project will be assigned clearly defined scientific and technological objectives and should be directed at obtaining specific results applicable in terms of, for instance, products, processes or services. Under these objectives they may include more long-term or 'risky' research.

Integrated projects will comprise a coherent set of component actions which may vary in size and structure according to the tasks to be carried out, each dealing with different aspects of the research needed to achieve common overall objectives, and forming a coherent whole and implemented in close coordination.

They will be carried out on the basis of overall financing plans preferably involving significant mobilisation of public and private sector funding, including funding from EIB and collaboration schemes such as Eureka.

All the activities carried out in the context of an integrated project will be defined in the general framework of an 'implementation plan' comprising activities relating to:

Unchanged

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In pursuit of its objectives, it may also comprise activities relating to:

- training researchers, students, engineers and industrial executives;
- support for the take-up of new technologies;
- information and communication, and dialogue with the public concerning the science/society aspects of the research carried out within the project.

The size of an integrated project may vary according to the themes and subjects, depending critical mass necessary in order to obtain the expected results under the best possible conditions.

Deleted

The combined activities of an integrated project may represent a financial size ranging from several million euros to several tens of millions of euros.

Unchanged

In most cases an integrated project will comprise a set of specific actions, relating to certain aspects of the research needed to achieve the objectives pursued, of variable sizes and structures according to the tasks to be achieved, executed in a closely co-ordinated manner. In some cases, however, an integrated project may take the form of a single large project with a single component.

Deleted

Integrated project proposals should contain the following elements:

Unchanged

- the scientific and technological objectives of the project;
- the main lines and timetable of the execution plan, highlighting the articulation of the various components;
- the stages of implementation and the results expected in each one of them;
- the role of the participants within the consortium and the specific skills of each of them;
- the organisation and management of the project;
- the plan for the dissemination of knowledge and the exploitation of results;
- the global budget estimate and the budget for the different activities, including a financial plan identifying the various contributions and their origin.

The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a call for applications.

The partnership may evolve when necessary, within the limit of the initial Community contribution, by replacing participants or adding new ones. In most cases, this will be done through publication of a competitive call.

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The execution plan will be updated yearly. This updating may entail the reorientation of certain activities and the launching of new ones. In the latter case, and where an additional Community contribution is needed, the Commission will identify these activities and the participants who will carry them out, by means of a call for proposals.

The Community contribution will be part of a financing plan which may involve recourse to other financing schemes, in particular Eureka or the instruments of the EIB or the EIF. It may amount to up to 50 % of the total project budget, broken down into budgets per activity. It will be paid annually on the basis of the proposed execution plan, and adjusted according to the activities and the financial reports.

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The implementation plan will be updated yearly. This updating may entail the reorientation of certain activities and the launching of new ones. In the latter case, and where an additional Community contribution is needed, the Commission will identify these activities and the participants who will carry them out, by means of a call for proposals.

The Community contribution shall take the form of a grant to the budget, calculated as a percentage of the budget allocated by the participants to carry out the project, adapted according to the type of activity.

A.3. *Integrated infrastructure initiatives*

Integrated infrastructure initiatives shall combine in a single action several activities essential to reinforce and develop research infrastructures, in order to provide services at the European level. To this end, they shall combine networking activities with a support activity (such as relating to transnational access) or research activities needed to improve infrastructure performance, excluding, however, the financing of investment for new infrastructures, which can only be financed as specific support actions. They will include a component of dissemination of knowledge to potential users, including industry and in particular to SMEs.

B. **Other instruments**

In order to implement the programme, the Commission can have recourse to

- specific targeted projects in order to carry out research or demonstration activities
- integrated initiatives relating to infrastructure, combining activities that are essential to strengthening and developing research infrastructures for the provision of services on a European scale
- mobility and training actions
- specific co-ordination and support actions in order to achieve the objectives identified in all the areas of the programme.
- accompanying actions by way of additional measures to achieve the objectives of the programme or prepare future activities in the context of the Community's research and technological development policy.

Unchanged

In order to implement the programme, other instruments may also be used:

Deleted

B.1. *Specific targeted research or training projects*

- I. Specific targeted research projects will aim at improving European competitiveness. They will be sharply focussed and will take either of the following two forms, or a combination of the two:

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- (a) a research and technological development project designed to gain new knowledge either to improve considerably or to develop new products, processes or services or to meet other needs of society and Community policies;
- (b) a demonstration project designed to prove the viability of new technologies offering potential economic advantage but which cannot be commercialised directly.

II. Specific targeted projects on training are designed to facilitate the timely diffusion of new knowledge on a European scale and better integrate national activities.

*B.2. Actions to promote and develop human resources and mobility*

These actions will be targeted at training, development of expertise or transfer of knowledge. They will involve support to actions carried out by natural persons, host structures, including training networks, and also by European research teams.

*B.3. Coordination actions*

Coordination actions are intended to promote and support the coordinated initiatives of a range of research and innovation operators aiming at improved integration. They will cover activities such as the organisation of conferences, meetings, the performance of studies, exchanges of personnel, the exchange and dissemination of good practices, setting up information systems and expert groups, and may, if necessary, include support for the definition, organisation and management of joint or common initiatives.

*B.4. Specific support actions*

Specific support actions will complement the implementation of the framework programme and may be used to help in preparations for future Community research and technological development policy activities including monitoring and assessment activities. In particular, they will involve transnational access to infrastructures, conferences, seminars, studies and analyses, working groups and expert groups, operational support and dissemination, information and communication activities, or a combination of these, as appropriate in each case.

**C. Specific implementation rules in the area of research into thermonuclear fusion**

Deleted

In the implementation of activities in the research area on controlled thermonuclear fusion, the following rules will be applied.

**I. Procedures**

The projects undertaken in the context of shared-cost of research and technological development actions will be carried out on the basis of procedures set out in:



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- the contracts of association with the Member States and the Associated States or organisations in those States,
- the European Fusion Development Agreement (EFDA),
- any other multilateral agreement concluded between the Community and associated organisations (such as the agreement on the promotion of mobility) or legal entities which may be set up after the competent consultative committee has given its opinion,
- other contracts of limited duration, in particular with organisations in the Member States or the associated states without an association,
- international agreements covering projects carried out in the framework of co-operation with third countries, such as ITER, and by legal entities which may be set up in the framework of such agreements.

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**II. Financial contribution**

The Framework programme financial contribution to the current expenditure of the Associations and to contracts of limited duration will be progressively and substantially reduced from its current annual rate, over the duration of the framework programme.

The modalities of participation of the Community in the activities related to the joint implementation of projects carried out within the framework of international co-operations such as ITER are defined in the relevant international co-operations and by the legal entities which can be established in the frame of these agreements. Appropriate legal entities, or any other appropriate forms, may be created by Euratom and the associated organisations in order to manage this Community participation.

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RTDT activities and Community financial contribution according to type of instrument

Type of instrument	RTD activities	Community contribution <sup>(1)</sup>
Networks of Excellence	Priority thematic areas Other activities in the field of nuclear technology and safety <sup>(2)</sup>	Grant for integration: maximum of 25 % of the value of the capacity and resources proposed for integration by participants as a fixed amount to support the joint programme of activities <sup>(3)</sup>
Integrated Projects	Priority thematic areas Other activities in the field of nuclear technology and safety <sup>(2)</sup>	Grant to the budget of a maximum of: 50 % for research 35 % for demonstration 100 % for certain other activities such as training of researchers and consortium management <sup>(4)</sup> <sup>(5)</sup>
Specific targeted research or training projects	Priority thematic areas <sup>(2)</sup> Other activities in the field of nuclear technology and safety	Grant to the budget of a maximum of 50 % of the budget <sup>(4)</sup> <sup>(5)</sup>
Actions to promote and develop human resources and mobility	Priority thematic areas Other activities in the field of nuclear technology and safety	Grant to the budget of a maximum of 100 % of the budget <sup>(4)</sup> , if necessary as a lump sum
Coordination actions	Priority thematic areas Other activities in the field of nuclear technology and safety	Grant to the budget of a maximum of 100 % of the budget <sup>(4)</sup>
Specific support actions	Priority thematic areas Other activities in the field of nuclear technology and safety	Grant to the budget of a maximum of 100 % of the budget <sup>(4)</sup> <sup>(7)</sup> , if necessary as a lump sum
Integrated initiatives relating to infrastructure	Priority thematic areas Other activities in the field of nuclear technology and safety	Grant to the budget: depending on the type of activity, of 50 to 100 % of the budget <sup>(4)</sup> <sup>(5)</sup> <sup>(6)</sup>

<sup>(1)</sup> As a general principle, the Community financial contribution cannot cover 100 % of the expenditure of an indirect action with the exception of proposals covering a purchase price governed by the terms applicable to public procurement procedures or taking the form of a pre-defined lump sum pre-set by the Commission.

However, the Community financial contribution may bear up to 100 % of the expenditure of an indirect action if they complement those otherwise borne by the participants. Also, in the specific case of coordination actions, it covers up to 100 % of the budget necessary for the coordination of activities funded by the participants themselves.

<sup>(2)</sup> In duly justified cases.

<sup>(3)</sup> This rate varies for different areas.

<sup>(4)</sup> Subject to specific conditions specific legal entities, particularly public bodies, will receive funding of up to 100 % of their marginal/additional cost.

<sup>(5)</sup> The rates of assistance may be differentiated in accordance with the rules of the Community framework for State aid for research and development depending on whether activities relate to research (maximum 50 %) or demonstration (maximum 35 %) or to other activities implemented, such as training of researchers (maximum 100 %) or the management of the consortium (maximum 100 %).

<sup>(6)</sup> The activities of an integrated initiative relating to infrastructure must include one networking activity (Coordination Action: maximum 100 % of the budget) and at least one of the following activities: research activities (maximum 50 % of the budget) or specific service activities (Specific Support Action, for example, transnational access to research infrastructures: maximum 100 % of the budget).

<sup>(7)</sup> For actions in support of research infrastructure relating to preparatory technical work (including feasibility studies) and the development of new infrastructure, 6th framework programme participation is restricted to maximum of 50 % and 10 % of the budget respectively.

**Amended proposal for a Council Decision adopting a specific programme 2002-2006 for research and training to be carried out by the Joint Research Centre by means of direct actions for the European Atomic Energy Community <sup>(1)</sup>**

(2002/C 181 E/05)

(Text with EEA relevance)

COM(2002) 43 final — 2001/0126(CNS)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 31 January 2002)

<sup>(1)</sup> OJ C 240 E, 28.8.2001, p. 259.

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INITIAL PROPOSAL

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AMENDED PROPOSAL

THE COUNCIL OF THE EUROPEAN UNION,

Unchanged

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the first paragraph of Article 7 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas:

- (1) By Decision No .../Euratom, the Council adopted the multiannual framework programme 2002-2006 of the European Atomic Energy Community for research and training activities aimed at contributing towards the creation of the European Research Area (hereinafter referred to as 'the framework programme') to be implemented by means of research and training programme(s) drawn up in accordance with Article 7 of the Treaty, which define the detailed rules for their implementation, fix their duration and provide for the means deemed necessary.
- (2) The rules for the participation of undertakings, research centres and universities and for the dissemination of research results, for the framework programme, adopted by the Council in Decision No .../Euratom should apply to this programme.
- (3) In implementing this programme, emphasis should be given to promoting the mobility and training of researchers, and innovation, in the Community.
- (4) For the purpose of implementing the framework programme, it may be appropriate to engage in international co-operation activities, in particular on the basis of Chapter X of the Treaty, with third countries and international organisations. Special attention should be paid to Accession Countries.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

- (5) Research activities carried out within this programme should respect the fundamental ethical principles, notably those which appear in the Charter of Fundamental Rights of the European Union.
- (6) Following the Commission Communication 'Women and Science' <sup>(1)</sup> and the Resolution of the Council <sup>(2)</sup> and the European Parliament <sup>(3)</sup> on this theme, an action plan is being implemented in order to reinforce and increase the place and role of women in science and research.
- (7) This programme should be implemented in a flexible, efficient and transparent manner, taking account of relevant needs of JRC's users and Community policies, as well as respecting the objective of protecting the communities financial interests. The research activities carried out under it should be adapted where appropriate to these needs and to scientific and technological developments.
- (8) The JRC should implement the research and training activities carried out by means of direct action, in particular the tasks entrusted to the Commission by the Treaty. The Commission should undertake the tasks incumbent upon it in the area of nuclear fission, making use of the technical expertise of the JRC.
- (9) The JRC should actively pursue activities in innovation and technology transfer.
- (10) In the implementation of this programme, the Board of Governors of the JRC should be consulted by the Commission in accordance with the relevant provisions of Commission Decision 96/282/Euratom of 10 April 1996 on the reorganisation of the JRC <sup>(4)</sup>.
- (11) The Commission should in due course arrange for an independent assessment to be conducted concerning the activities carried out in the fields covered by this programme.
- (12) The Scientific and Technical Committee has been consulted on the scientific and technological content of this specific programme.
- (13) The Board of Governors of the JRC has been consulted on the scientific and technological content of this specific programme,

<sup>(1)</sup> COM(1999) 76.

<sup>(2)</sup> Resolution of 20 May 1999 (OJ C 201, 16.7.1999).

<sup>(3)</sup> Resolution of 3 February 2000, PE 284.656.

<sup>(4)</sup> OJ L 107, 30.4.1996, p. 12.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

HAS ADOPTED THIS DECISION:

*Article 1*

1. In accordance with Decision [...] on the framework programme 2002-2006 (hereinafter referred to as 'the framework programme'), a specific programme related to direct action of research and training activities to be carried out by the Joint Research Centre (hereinafter referred to as 'the specific programme') is hereby adopted for the period from [...] to 31 December 2006.

2. The objectives and scientific and technological priorities for the specific programme are set out in Annex I.

*Article 2*

In accordance with Annex II to [Decision [...]]/the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 330 million. An indicative breakdown of this amount is given in Annex II to this Decision.

In accordance with Annex II to [Decision [...]]/the framework programme, the amount deemed necessary for the execution of the specific programme is EUR 290 million. An indicative breakdown of this amount is given in Annex II to this Decision.

*Article 3*

Unchanged

1. The Commission shall be responsible for the implementation of the specific programme.

2. The specific programme shall be implemented in accordance with the specific rules set out in Annex III.

*Article 4*

1. The Commission shall draw up a work programme for the implementation of the specific programme, which shall be made available to all interested parties, setting out in greater detail the objectives and priorities, the timetable for implementation and the implementation arrangements.

2. The work programme shall take account of relevant research activities carried out by the Member States, Associated States, European and international organisations. It shall be updated where appropriate.

*Article 5*

1. For the purposes of implementing the specific programme, the Board of Governors of the JRC shall be consulted by the Commission in accordance with Commission Decision 96/284/Euratom.

2. The Commission shall regularly inform the Board of Governors of the implementation of this specific programme.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Article 6*

1. The Commission shall regularly report on the overall progress of the implementation of the specific programme, in accordance with Article 4 of the framework programme.

2. The Commission shall arrange for the independent assessment provided for in Article 5 of the framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

*Article 7*

The Commission may request the JRC to execute, on the basis of the criterion of mutual benefit, projects with legal entities established in third countries when this contributes effectively to the execution of direct actions.

*Article 8*

This decision is addressed to the Member States.

## ANNEX I

**SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND BROAD OUTLINES OF THE ACTIVITIES**

## 1. INTRODUCTION

Unchanged

The Joint Research Centre carries out its mission to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of European Union policies. It serves the common interest of the Member States while being independent of special interests, private or national.

The JRC's contribution to the framework programme 2002-2006 incorporates recommendations of recent evaluations of the JRC <sup>(1)</sup> and requirements necessitated by the Reform of the Commission. In particular, it includes

- As strengthened user-orientation.
- Networking activities to create a broad knowledge base and, in the spirit of the European Research Area (ERA), more closely associate Member State laboratories, industry and regulators in the S&T support provided to the EU policies.
- The concentration of activities on selected themes, including training of researchers to maintain nuclear expertise in the EU and its associated Member States.

<sup>(1)</sup> Davignon Report (2000), 5-year assessment of JRC (2000), 1999 JRC Scientific Audit, Prioritisation Audit 2001.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

Co-ordination will be assured with the indirect actions under the Euratom specific programme.

It responds to clearly expressed needs and requirements, notably from the Commission services, which have been identified, are updated through systematic and regular contacts <sup>(1)</sup>.

In its domains of competence, the JRC's contribution will aim at establishing synergies with the relevant thematic priorities in the other specific programmes, notably through participation in the indirect action, with a view to add value, when appropriate, to the work carried out therein (e.g. through the comparison and validation of tests and methods or the integration of results for policy-making purpose).

## 2. PROGRAMME CONTENT

### 2.1. Motivation

JRC's activities in the nuclear area aim to support related Community policies and specific Treaty obligations entrusted to the Commission. Nuclear energy supplies about a third of the Community's electricity and vigilance is still required to ensure a continuation of the Community's outstanding safety record, to maintain efforts to avoid proliferation and to efficiently manage the processing and long-term storage of waste. The Enlargement of the Union together with the needs of safeguarding material arising from the disarmament process or the emergence of new technological developments introduce new challenges.

Focusing its activities in areas where Community involvement is appropriate, the JRC operates where its pan-European identity provides an added value and where its action is justified by the cross-border aspects of nuclear safety and security or by public concern about the issues: safeguards, non-proliferation, radioactive waste management, reactor safety and radiation monitoring will be the key areas.

The principal objective will be to further develop collaboration through networking, leading to broad consensus on a range of these issues at European and world-level. The application of Safeguards by the Euratom Safeguards Office (ESO) and the IAEA requires R & D support and direct assistance. Special attention will be given to co-operation with future EU Member States. Training activities will be an important component for JRC to help equip the EU with a future generation of scientists with necessary nuclear skills and expertise. Main areas of research activity will therefore be as follows:

<sup>(1)</sup> Annual user workshops, interservice group of user DGs, bilateral agreement, etc.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

— Radioactive waste management and safeguarding nuclear materials.

— Safety of present and innovative reactors, radiation monitoring and medical applications from nuclear research.

— Safety of the different types of reactors, radiation monitoring and metrology.

## 2.2. Radioactive waste management and safeguarding nuclear materials

Unchanged

### *Spent fuel and high level waste treatment and storage*

To address the issues of spent nuclear fuels and radio-active waste treatment and management, the JRC will further develop its understanding of fundamental physical, chemical and materials science data on actinides and actinide-containing products. The JRC will continue to provide basic nuclear data (such as elements cross sections, behaviour in extreme conditions) of importance for waste management studies as well as for material and medical sciences.

To address the issues of spent nuclear fuels and radio-active waste treatment and management, the JRC will further develop its understanding of fundamental physical, chemical and materials science data on actinides and actinide-containing products.

The basic processes governing the behaviour of irradiated fuel under conditions of interim storage or long-term geological disposal will be further investigated.

Unchanged

The JRC will continue to test and evaluate processes to improve the efficient separation (partitioning) of radio-toxic elements from spent fuel and the subsequent reprocessing of the resulting products. This will be carried out with European partners under the transmutation and partitioning programme. Besides this experimental and theoretical approach JRC will pursue and extend its participation in networks with a possible co-ordinating role like in the international working group on fuel design for the accelerator driven systems.

### *Nuclear safeguards*

The safeguards work will provide direct support to the inspectorates (ESO and IAEA) and to operators and will undertake related underpinning research to prepare for future demands including continuous improvements of safeguards activities to adapt to political context, in particular changes in verification regimes, and technological evolution. The activity includes the development and assessment of instrumentation in the areas of destructive and non-destructive assays; provision of certified reference materials, containment and surveillance, training of inspectors and the upgrading and operation of on-site laboratories. JRC will continue to be the focus point of the European Safeguards Research and Development Association (ESARDA) network.



## INITIAL PROPOSAL

The strengthening of the safeguard regime is increasingly reliant on information technologies to improve efficiency and to carry out new measures. JRC will pursue its efforts in developing environmental monitoring, satellite monitoring, and innovative data and information management systems as well as improved communications and remote surveillance techniques that enable certain safeguards activities to be performed remotely from headquarters. Synergy with the work performed by JRC in the area of anti-fraud will be further developed.

The JRC will continue to support the transfer of the technological 'acquis communautaire' in the safeguards area to the Applicant Countries.

The JRC is closely involved in the international efforts to detect clandestine activities and to combat the illicit trafficking of nuclear materials. Nuclear forensic science will be further developed.

*From nuclear safeguards to non-proliferation of weapons of mass destruction*

The JRC will support the non-proliferation by adapting specialised know-how and techniques used for nuclear safeguards that may also potentially support verification regimes of nuclear and other weapons for mass destruction.

### 2.3. Safety of present and innovative reactors, radiation monitoring and medical applications from nuclear research

*Safety of present and innovative reactors*

The high safety level of plants within the EU must be maintained, in particular for reactors to be operated for a further 10-50 years. The JRC will continue supporting safety authorities and nuclear plant operators by networking on ageing, damage detection, in-service inspection structural integrity assessment and production of fundamental neutron data. Accident analysis and management, validation of codes, systems' analysis, and risk-informed methods development are traditional JRC competencies, which are important both for EU harmonisation and in view of enlargement. Support to the PHEBUS programme will continue. Retrieval of experimental data and their archiving for easy availability will be supported.

Development of a common safety culture in central and eastern European countries is a further area for JRC support; this includes operational safety measures and plant upgrading, structural integrity, accident prevention and management.

## AMENDED PROPOSAL

### 2.3. Safety of the different types of reactors, radiation monitoring and metrology

*Safety of the different types of reactors*

The high safety level of plants within the EU must be maintained, in particular for reactors to be operated for a further 10-50 years. The JRC will continue supporting safety authorities and nuclear plant operators by networking on ageing, damage detection, in-service inspection and structural integrity assessment. Accident analysis and management, validation of codes, systems' analysis, and risk-informed methods development are traditional JRC competencies, which are important both for EU harmonisation and in view of enlargement. Support to the PHEBUS programme will continue. Retrieval of experimental data and their archiving for easy availability will be supported.

Unchanged

## INITIAL PROPOSAL

On the safety of nuclear fuel, JRC will concentrate on mechanical and chemical interactions at the fuel/cladding interface and on fuel behaviour at high burn-up. The TRANSURANUS fuel performance codes will continue to be extended with new data and training of users, including scientists from eastern European countries.

Together with industry and R & D institutions, the JRC will contribute to the analysis and evaluation of several safety features of new energy production systems, currently under investigation in several countries.

*Radiation monitoring*

Research into understanding how to protect the citizen and the environment against the effects of ionising radiation requires reliable dosimetry as a basis. The JRC's long-standing expertise in radio-protection and its reference laboratory for radionuclide metrology will be used to develop further skills and various nuclear measurements.

The radionuclide metrology activity includes new networks, which will provide support to nuclear safety together with food, chemical and environmental safety (with the detection of radioactivity traces and speciation). Efforts will focus on reference radionuclide metrology and on monitoring of low radiation levels.

*Medical applications from nuclear research*

A number of nuclear technologies of importance for medical applications have resulted from JRC's nuclear facilities and expertise. These emerge from research on new isotope production, development of clinical reference materials and support to diagnostic and therapeutic tools. The JRC will improve the co-ordination of such activities throughout Europe through networking with universities, nuclear research facilities, research centres, European medical associations and the pharmaceutical industry.

## AMENDED PROPOSAL

Together with industry and R & D institutions, the JRC will contribute to the analysis and evaluation of several safety features of the different types of energy production systems, currently under investigation in several countries.

*Radiation monitoring and metrology*

Research into understanding how to protect the citizen and the environment against the effects of ionising radiation requires reliable dosimetry as a basis. The JRC's long-standing expertise in radio-protection and metrology will be further oriented towards this subject.

Radionuclide metrology will focus on reference measurements and the development of international standards for reference radioactivity measurements. Additionally, support to nuclear safety and safeguards, radiation monitoring according to the Treaty, and the measurement of ultra low levels of radiation will be carried out.

JRC expertise in radioactivity trace analysis and speciation will be further developed in the context of environment protection.

Deleted

## INITIAL PROPOSAL

## AMENDED PROPOSAL

## ANNEX II

## INDICATIVE BREAKDOWN OF THE AMOUNT

Activity	Amount (Euro million)
Radioactive waste management and safeguarding nuclear materials	213
Safety of present and innovative reactors, radiation monitoring and medical applications from nuclear research	102
Staff necessary for the monitoring of the decommissioning of JRC obsolete installations	15
<b>Total</b>	<b>330 <sup>(1)</sup> <sup>(2)</sup></b>

<sup>(1)</sup> Of which approximately 6 % may be allocated to exploratory research and up to 2 % for exploitation of own JRC results and technology transfer.

<sup>(2)</sup> This total includes the JRC's budget contribution necessary for its participation in indirect actions.

Activity	Amount (Euro million)
Radioactive waste management and safeguarding nuclear materials	186
Safety of the different types of reactors, radiation monitoring and metrology	89
Staff necessary for the monitoring of the decommissioning of JRC obsolete installations	15
<b>Total</b>	<b>290 <sup>(1)</sup> <sup>(2)</sup></b>

<sup>(1)</sup> Of which approximately 6 % may be allocated to exploratory research and up to 2 % for exploitation of own JRC results and technology transfer.

<sup>(2)</sup> This total includes the JRC's budget contribution necessary for its participation in indirect actions.

## ANNEX III

## SPECIFIC RULES FOR IMPLEMENTING THE PROGRAMME

1. The Commission, after consulting the Board of Governors of the JRC, shall implement the direct action on the basis of the scientific objectives and contents described in Annex I. The activities relating to this action shall be performed in the relevant institutes of the Joint Research Centre (JRC).

Unchanged

2. In the implementation of its activities, the JRC will, whenever appropriate and feasible, participate in or organise networks of public and private laboratories in the Member States or European research consortia in the support of the European policy making process. Particular attention shall be paid to co-operation with industry, especially with small and medium-sized enterprises. Research bodies established in third countries may also co-operate on projects, in accordance with the relevant provisions of Article 6 and, where applicable, of agreements for scientific and technological co-operation between the Community and the third countries concerned. Particular attention will be paid to co-operation with research laboratories and institutes in the Candidate countries and countries of central and eastern Europe and the former Soviet Union.

It will also use appropriate mechanisms to continuously identify the requirements and needs of its customers and users and to involve them in the related activities.

3. The knowledge gained through implementation of the projects will be disseminated by the JRC itself (taking into account possible limitations due to confidentiality issues).

## INITIAL PROPOSAL

## AMENDED PROPOSAL

## 4. The accompanying measures shall include:

- the organisation of the visits of JRC staff to national laboratories, industrial laboratories and universities,
  - the promotion of mobility of young scientists, particularly from the Candidate countries,
  - specialised training with the emphasis on the nuclear expertise and the nuclear safety culture in the European Union,
  - the organisation of visits to JRC institutes of visiting scientists and seconded national experts, particularly from the Candidate countries,
  - systematic exchange of information, through, *inter alia*, the organisation of scientific seminars, workshops and colloquiums and scientific publications,
  - the independent scientific and strategic evaluation of the performance of the projects and programmes.
-

**Proposal for a Council Directive laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever**

(2002/C 181 E/06)

(Text with EEA relevance)

COM(2002) 51 final

(Submitted by the Commission on 1 February 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease <sup>(1)</sup>, and in particular Articles 15 and 24(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The general measures laid down in Directive 92/119/EEC have the aim of preventing the further spread of certain animal diseases of major economic importance and in particular of controlling the movement of animals and products liable to spread the infection.

(2) The International Office of Epizootics (OIE) is the technical reference body for animal health recognised by the World Trade Organization. It has drawn up a list of epidemic animal diseases of major economical importance (List A).

(3) It is necessary and appropriate that Directive 92/119/EEC should apply to all the epidemic diseases on List A, with the exception of those for which specific provision has already been made at Community level.

(4) Teschen disease is no longer included in List A. It is appropriate, therefore, to delete that disease from the list set out in Annex I to Directive 92/119/EEC.

(5) African swine fever is a disease of major economic importance, included in List A, which occurs in certain limited areas of the Community. It is therefore appropriate to establish Community measures for the control of that disease.

(6) African swine fever should be included in the list set out in Annex I to Directive 92/119/EEC and specific provisions for its control should be laid down in accordance with Article 15 of that Directive.

(7) Measures should be adopted to control the movement of pigs and their products from areas subject to restrictions arising from an outbreak of African swine fever. Such measures should be similar to those established at Community level for the control of other pig diseases such as swine vesicular disease and classical swine fever.

(8) In particular, Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever <sup>(2)</sup> should be used as a model for the establishment of specific measures for the control of African swine fever. However, adjustments should be made because of the differences between the two diseases and, in particular, account should be taken of the incubation period for African swine fever and the possibility that this disease is transmitted by vectors.

(9) A procedure for close cooperation between the Member States and the Commission should be introduced,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

**Subject-matter**

This Directive lays down the minimum Community measures for the control of African swine fever.

It removes Teschen disease from the group of diseases to which the general control measures laid down in Directive 92/119/EEC apply.

*Article 2*

**Definitions**

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

(a) 'pig' means any animal of the *Suidae* family, including feral pigs;

(b) 'feral pig' means a pig which is not kept or bred on a holding;

<sup>(1)</sup> OJ L 62, 15.3.1993, p. 69. Directive as amended by the 1994 Act of Accession.

<sup>(2)</sup> OJ L 316, 1.12.2001, p. 5.

- (c) 'holding' means any agricultural or other premises located in the territory of a Member State where pigs are being bred or kept on a permanent or temporary basis. This definition does not include slaughterhouses, means of transport and fenced areas where feral pigs are kept and may be hunted; these fenced areas must be of a size and structure that makes the measures laid down in Article 5(1) not applicable;
- (d) 'diagnostic manual' means the diagnostic manual referred to in Article 18(3);
- (e) 'pig suspected of being infected with African swine fever virus' means any pig or pig carcass exhibiting clinical symptoms or showing *post-mortem* lesions or reactions to laboratory tests carried out in accordance with the Diagnostic Manual which indicate the possible presence of African swine fever;
- (f) 'case of African swine fever' or 'pig infected with African swine fever' means any pig or pig carcass:
- in which clinical symptoms or *post-mortem* lesions of African swine fever have been officially confirmed, or
  - in which the presence of the disease has been officially confirmed as the result of a laboratory examination carried out in accordance with the diagnostic manual;
- (g) 'outbreak of African swine fever' means the holding where one or more cases of African swine fever has or have been detected;
- (h) 'primary outbreak' means the outbreak within the meaning of Article 2(d) of Council Directive 82/894/EEC <sup>(1)</sup>;
- (i) 'infected area' means the area of a Member State where, following the confirmation of one or more cases of African swine fever in feral pigs, disease eradication measures are in place in accordance with Article 15 or 16;
- (j) 'primary case of African swine fever in feral pigs' means any case of African swine fever which is detected in feral pigs in an area in which no measures are in place in accordance with Articles 15 or 16;
- (k) 'contact holding' means a holding where African swine fever may have been introduced, whether as a result of the location, movement of persons, pigs or vehicles or in any other way;
- (l) 'owner' means any person or persons, either natural or legal, having ownership of the pigs, or charged with keeping the said animals, whether or not for financial reward;
- (m) 'competent authority' means the competent authority within the meaning of Article 2(6) of Council Directive 90/425/EEC <sup>(2)</sup>;
- (n) 'official veterinarian' means the veterinarian designated by the competent authority of the Member State;
- (o) 'processing' means one of the treatments for high risk material laid down in Article 3 of Council Directive 90/667/EEC <sup>(3)</sup>, applied in such a way as to avoid the risk of spread of African swine fever virus;
- (p) 'killing' means the killing of pigs within the meaning of Article 2(6) of Council Directive 93/119/EEC <sup>(4)</sup>;
- (q) 'slaughter' means the slaughter of pigs within the meaning of Article 2(7) of Directive 93/119/EEC;
- (r) 'vector' means a tick of the species *Ornithodoros erraticus*.

### Article 3

#### African swine fever notification

1. Member States shall ensure that the presence or the suspected presence of African swine fever are compulsorily and immediately notifiable to the competent authority.
2. Without prejudice to existing Community provisions on notification of outbreaks of animal diseases, the Member State in whose territory African swine fever is confirmed shall:
  - (a) give notification of the disease and provide information to the Commission and the other Member States in accordance with Annex I on:
    - the outbreaks of African swine fever which are confirmed in holdings;
    - the cases of African swine fever which are confirmed in a slaughterhouse or in means of transport;
    - the primary cases of African swine fever which are confirmed in feral pigs;
    - the results of the epidemiological inquiry carried out in accordance with Article 8;

<sup>(1)</sup> OJ L 378, 31.12.1982, p. 58. Directive as last amended by Commission Decision 2000/556/EC (OJ L 235, 19.9.2000, p. 27).

<sup>(2)</sup> OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

<sup>(3)</sup> OJ L 363, 27.12.1990, p. 51. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

<sup>(4)</sup> OJ L 340, 31.12.1993, p. 21.

- (b) provide information to the Commission and the other Member States on the further cases confirmed in feral pigs in a African swine fever infected area in accordance with the provisions laid down in Article 16(3)(a) and (4).

#### Article 4

##### **Measures in cases where the presence of African swine fever on a holding is suspected**

1. Where a holding contains one or more pigs suspected of being infected with African swine fever virus, Member States shall ensure that the competent authority immediately sets in motion official means of investigation to confirm or rule out the presence of the said disease in accordance with the procedures laid down in the diagnostic manual.

When the holding is visited by an official veterinarian, a check of the register and of the pig identification marks referred to in Articles 4 and 5 of Council Directive 92/102/EEC <sup>(1)</sup> shall also be carried out.

2. When the competent authority considers that the presence of African swine fever in a holding cannot be ruled out, it shall have the holding placed under official surveillance and shall in particular order that:

- (a) all the pigs in the various categories on the holding are to be counted and a list compiled of the number of pigs already sick, dead or likely to be infected in each category; the list shall be updated to take account of pig births and deaths during the period of suspicion; the information on the list shall be produced upon request and may be checked at each visit;
- (b) all the pigs on the holding shall be restricted to their living quarters or be confined in some other place where they can be isolated;
- (c) no pigs may enter or leave the holding. The competent authority may, if necessary, extend the ban on leaving the holding to cover other species of animals and require the application of appropriate measures to destroy rodents or insects;
- (d) no pig carcasses may leave the holding without an authorisation issued by the competent authority;
- (e) no meat, pig products, semen, ova or embryos of pigs, animal feed, utensils, materials or waste likely to transmit African swine fever may leave the holding without an authorisation issued by the competent authority; meat, pig products, semen, ova or embryos shall not be moved from the holding for intra-Community trade;
- (f) the movement of persons to or from the holding shall be subject to written authorisation by the competent authority;

- (g) the movement of vehicles to or from the holding shall be subject to written authorisation by the competent authority;

- (h) appropriate means of disinfection shall be used at the entrances and exits of buildings housing pigs and of the holding itself; any person entering or leaving pig holdings shall fulfil appropriate hygienic measures necessary to reduce the risk of spread of African swine fever virus. Furthermore, all means of transport shall be carefully disinfected before leaving the holding;

- (i) an epidemiological inquiry shall be carried out in accordance with Article 8.

3. Where required by the epidemiological situation, the competent authority:

- (a) may apply the measures of Article 5(1) in the holding referred to in paragraph 2; however, the competent authority may, where it considers that conditions permit, limit the application of these measures only to the pigs suspected of being infected or contaminated with African swine fever virus and the part of the holding where they were kept, provided that these pigs have been housed, kept and fed completely separately from the other pigs in the holding. In any case, a sufficient number of samples shall be taken from the pigs when they are killed in order that the presence of African swine fever virus can be confirmed or ruled out, in accordance with the diagnostic manual;
- (b) may establish a temporary control zone around the holding referred to in paragraph 2; some or all the measures referred to in paragraphs 1 or 2 shall be applied in the pig holdings within this zone.

4. Once adopted, the measures provided for in paragraph 2 shall not be lifted until the presence of African swine fever has been officially ruled out.

#### Article 5

##### **Measures in cases where the presence of African swine fever on a holding is confirmed**

1. In cases where the presence of African swine fever is officially confirmed in a holding, Member States shall ensure that, in addition to the measures referred to in Article 4(2), the competent authority prescribes that:

- (a) all pigs on the holding are to be killed without delay under official supervision and in such a way as to avoid the risk of spread of African swine fever virus during transport or killing;

<sup>(1)</sup> OJ L 355, 5.12.1992, p. 32. Directive as amended by the 1994 Act of Accession.

- (b) a sufficient number of samples are to be taken, in accordance with the diagnostic manual, from the pigs when they are killed, in order that the manner of introduction of African swine fever virus into the holding and the length of time during which it may have existed on the holding before the disease was notified may be established;
- (c) the carcasses of pigs which have died or have been killed are to be processed under official supervision;
- (d) meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the taking of official measures is wherever possible to be traced and processed under official supervision;
- (e) semen, ova or embryos of pigs collected from the holding during the period between the probable introduction of disease into the holding and the taking of official measures are to be traced and destroyed under official supervision in such a way as to avoid the risk of spread of African swine fever virus;
- (f) all substances and waste likely to be contaminated, such as feedingstuffs, are to be subjected to a treatment ensuring the destruction of African swine fever virus; all materials for single use which may be contaminated and in particular those used for the killing operations are to be destroyed; these actions are to be carried out in accordance with the instructions of the official veterinarian;
- (g) after the pigs have been eliminated, the buildings used for housing the pigs, the vehicles used for transporting them or their carcasses and the equipment, bedding, manure and slurry likely to be contaminated are to be cleaned and disinfected or treated in accordance with Article 12;
- (h) in the case of a primary outbreak of disease, the African swine fever virus isolate is to be subject to the laboratory procedure laid down in the diagnostic manual to identify the genetic type;
- (i) an epidemiological inquiry is to be carried out in accordance with Article 8.

2. In cases where an outbreak has been confirmed in a laboratory, a zoo, a wild life park or a fenced area where pigs are kept for scientific purposes or purposes related to conservation of species or conservation of rare breeds, the Member State concerned may decide to derogate from the provisions laid down in paragraphs 1(a) and 1(e), provided that basic Community interests are not endangered.

Such a decision shall immediately be notified to the Commission.

The Commission shall in all cases immediately review the situation with the Member State concerned and in the Standing Veterinary Committee at the earliest possible opportunity. If necessary, measures to prevent the spreading of the

disease shall be adopted in accordance with the procedure referred to in Article 24(2).

#### Article 6

##### **Measures in cases where the presence of African swine fever is confirmed in holdings consisting of various production units**

1. Where the presence of African swine fever is confirmed in holdings which consist of two or more separate production units and in order that the fattening of pigs may be completed, the competent authority may decide to derogate from the provisions of Article 5(1)(a) as regards healthy pig production units on a holding which is infected provided that the official veterinarian confirms that the structure, size and distance of these production units and the operations carried out there are such that the production units provide completely separate facilities for housing, keeping and feeding, so that the virus cannot spread from one production unit to another.

2. If use is made of the derogation referred to in paragraph 1, the Member States shall draw up detailed rules for applying it in the light of the animal health guarantees which can be secured.

3. Member States which make use of this derogation shall immediately notify the Commission thereof. The Commission shall in all cases immediately review the situation with the Member State concerned and in the Standing Veterinary Committee at the earliest possible opportunity. If necessary, measures to prevent the spreading of the disease shall be adopted in accordance with the procedure laid down in Article 24(2).

#### Article 7

##### **Measures in contact holdings**

1. Holdings shall be recognised as contact holdings where the official veterinarian finds, or considers on the basis of the epidemiological inquiry carried out in accordance with Article 8, that African swine fever may have been introduced, either from other holdings to the holding referred to in Article 4 or Article 5, or from the latter holding to other holdings.

The provisions of Article 4 shall be applied in such holdings until the presence of African swine fever has been officially ruled out.

2. The competent authority shall apply the measures provided for in Article 5(1) in the contact holdings referred to in paragraph 1 if the epidemiological situation so requires.

A sufficient number of samples shall be taken from the pigs, in accordance with the diagnostic manual, when they are killed in order that the presence of African swine fever virus in these holdings can be confirmed or ruled out.



*Article 8***Epidemiological inquiry**

Member States shall ensure that the epidemiological inquiry in relation to suspected cases or outbreaks of African swine fever is carried out on the basis of questionnaires, prepared within the framework of the contingency plans referred to in Article 21.

Such inquiry shall deal at least with:

- (a) the length of time during which African swine fever virus may have existed on the holding before the disease was notified or suspected;
- (b) the possible origin of African swine fever on the holding and the identification of other holdings in which pigs may have become infected or contaminated from the same source;
- (c) the movement of persons, vehicles, pigs, carcasses, semen, vectors, meat or any material which could have carried the virus to or from the holdings in question.

If the results of this inquiry suggest that African swine fever may have spread from or to holdings located in other Member States, the Commission and the Member States concerned shall be immediately informed.

*Article 9***Establishment of protection and surveillance zones**

1. Immediately after the diagnosis of African swine fever has been officially confirmed in pigs on a holding, the competent authority shall establish a protection zone with a radius of at least three kilometres around the outbreak site, which shall itself be included in a surveillance zone of a radius of at least ten kilometres.

The measures referred to in Articles 10 and 11 shall be applied in the respective zones.

2. When establishing zones, the competent authority must take account of:

- (a) the results of the epidemiological inquiry carried out in accordance with Article 8;
- (b) the geographical situation, particularly natural or artificial boundaries;
- (c) the location and proximity of holdings;
- (d) patterns of movements and trade in pigs and the availability of slaughterhouses and facilities for processing carcasses;

- (e) the facilities and personnel available to control any movement of pigs within the zones, in particular if the pigs to be killed have to be moved away from their holding of origin.

3. If a zone includes parts of the territory of several Member States, the competent authorities of the Member States concerned shall collaborate to establish the zone.

4. The competent authority shall take all necessary measures, including the use of prominent signs and warning notices and the use of media resources, such as the press and television, to ensure that all persons in the protection and surveillance zones are fully aware of the restrictions in force in accordance with Articles 10 and 11, and shall take such measures as it considers appropriate to ensure the adequate enforcement of these measures.

*Article 10***Measures in the established protection zone**

1. Member States shall ensure that the following measures are applied in the protection zone:

- (a) a census of all the holdings shall be made as soon as possible; after the establishment of the protection zone these holdings shall be visited by an official veterinarian within not more than seven days for a clinical examination of the pigs and for a check of the register and of the pig identification marks referred to in Articles 4 and 5 of Directive 92/102/EEC;
- (b) the movement and transport of pigs on public or private roads, excluding when necessary the service roads of holdings, shall be prohibited unless approved by the competent authority when allowing the movements referred to in point (f). This prohibition need not be applied to the transit of pigs by road or rail without unloading or stopping. Furthermore, in accordance with the procedure referred to in Article 24(2), a derogation may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in the said zone for immediate slaughter;
- (c) trucks and other vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (such as carcasses, feedingstuff, manure, slurry and so forth) shall be cleaned, disinfected and treated as soon as possible after contamination, in accordance with the provisions and procedures laid down in Article 12. No truck or vehicle which has been used in connection with the transport of pigs may leave the zone without being cleaned and disinfected and then inspected and authorised by the competent authority;

(d) no other domestic animal may enter or leave a holding without the authorisation of the competent authority;

(e) all dead or diseased pigs on a holding shall be immediately notified to the competent authority, which shall carry out appropriate investigations in accordance with the procedures laid down in the diagnostic manual;

(f) pigs may not be removed from the holding in which they are kept for at least 40 days after the completion of the preliminary cleansing and disinfection of the infected holdings. After 40 days, subject to the conditions set out in paragraph 3, the competent authority may authorise the removal of pigs from the said holding to be directly transported to:

— a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter;

— a processing plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision;

— under exceptional circumstances, to other premises located within the protection zone. Member States availing themselves of this provision shall immediately inform the Commission thereof in the Standing Veterinary Committee;

(g) semen, ova or embryos of pigs shall not leave the holdings situated within the protection zone;

(h) any person entering or leaving pig holdings shall observe appropriate hygienic measures as necessary to reduce the risk of spread of African swine fever virus.

2. Where the prohibitions provided for in paragraph 1 are maintained beyond 40 days because of further outbreaks of the disease and as a result animal welfare or other problems arise in keeping the pigs, subject to the conditions set out in paragraph 3, the competent authority may, following a reasoned application by the owner, authorise the removal of pigs from a holding within the protection zone, to be directly transported to:

(a) a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter;

(b) a processing plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision;

(c) under exceptional circumstances, to other premises located within the protection zone. Member States availing them-

selves of this provision shall immediately inform the Commission thereof in the Standing Veterinary Committee.

3. Where reference is made to this paragraph, the competent authority may authorise the removal of pigs from the holding concerned, on condition that:

(a) an official veterinarian has carried out a clinical examination of the pigs in the holding and in particular of those to be moved, including the taking of the body temperature in accordance with the procedures laid down in the diagnostic manual and a check of the register and the pig identification marks referred to in Articles 4 and 5 of Directive 92/102/EEC;

(b) the checks and examinations have shown no evidence of African swine fever and compliance with the provisions of Directive 92/102/EEC;

(c) the pigs are transported in vehicles sealed by the competent authority;

(d) the vehicle and equipment which have been involved in the transport of the pigs are immediately cleaned and disinfected after the transport in accordance with the provisions referred to in Article 12;

(e) if the pigs are to be slaughtered or killed, a sufficient number of samples is then taken from the pigs in accordance with the diagnostic manual in order that the presence of African swine fever virus in these holdings can be confirmed or ruled out;

(f) if the pigs are to be transported to a slaughterhouse:

— the competent authority responsible for the slaughterhouse has been informed of the intention to send the pigs and notifies the dispatching competent authority of their arrival;

— on arrival at the slaughterhouse these pigs are kept and slaughtered separately from other pigs;

— during ante- and post-mortem inspection carried out at the designated slaughterhouse, the competent authority takes into account any signs relating to the presence of African swine fever;

— the fresh meat from these pigs is either processed or marked with the special mark referred to in Article 5a of Council Directive 72/461/EEC <sup>(1)</sup>, and is subsequently treated in accordance with the rules laid down in Article 4(1)(a)(i) of Council Directive 80/215/EEC <sup>(2)</sup>. This must be done at an establishment designated by the competent authority. The meat must be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport.

<sup>(1)</sup> OJ L 302, 31.12.1972, p. 24. Directive as last amended by the 1994 Act of Accession.

<sup>(2)</sup> OJ L 47, 21.2.1980, p. 4. Directive as last amended by the 1994 Act of Accession.

4. The measures in the protection zone shall continue to be applied at least until:

- (a) cleansing and disinfection in the infected holdings have been carried out;
- (b) pigs on all holdings have undergone clinical and laboratory examinations carried out in accordance with the diagnostic manual in order to detect the possible presence of African swine fever virus.

The examinations referred to in point (b) shall not take place until 45 days have elapsed since the completion of preliminary cleansing and disinfection measures on the infected holdings.

#### Article 11

##### Measures in the established surveillance zone

1. Member States shall ensure that the following measures are applied in the surveillance zone:

- (a) a census shall be taken of all pig holdings;
- (b) the movement and transport of pigs on public or private roads, excluding when necessary the service roads of holdings, shall be prohibited, unless approved by the competent authority. This prohibition need not be applied to the transit of pigs by road or rail, without unloading or stopping, or to slaughter pigs coming from outside the surveillance zone and on their way to a slaughterhouse situated in the said zone for immediate slaughter;
- (c) trucks and other vehicles and equipment which are used to transport pigs or other livestock or material which may be contaminated (such as carcasses, feedingstuff, manure, slurry and so forth) shall be cleaned, disinfected and treated as soon as possible after contamination, in accordance with the provisions and procedures laid down in Article 12. No truck or vehicle which has been used in the transport of pigs may leave the zone without having been cleaned and disinfected;
- (d) no other domestic animal may enter or leave a holding during the first seven days after establishment of the zone without the authorisation of the competent authority;
- (e) all dead or diseased pigs on a holding shall be immediately notified to the competent authority, which shall carry out appropriate investigations in accordance with the procedures laid down in the diagnostic manual;
- (f) pigs may not be removed from the holding in which they are kept for at least 30 days after the completion of the preliminary cleansing and disinfection of the infected holdings. After 30 days, subject to the conditions set out in Article 10(3), the competent authority may authorise the

removal of the pigs from the said holding to be directly transported to:

- a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, for the purpose of immediate slaughter;
- a processing plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision;
- under exceptional circumstances, other premises located within the protection or surveillance zone. Member States availing themselves of this provision shall immediately inform the Commission thereof in the Standing Veterinary Committee.

However, if the pigs are to be transported to a slaughterhouse, at the request of a Member State, accompanied by appropriate justification, and in accordance with the procedure referred to in Article 24(2), derogations from the provisions laid down in Article 10(3)(e) and (f), fourth indent, may be authorised, in particular with respect to the marking of the meat from these pigs and its subsequent use, and the destination of the treated products;

- (g) semen, ova or embryos of pigs shall not leave the holdings situated within the surveillance zone;
- (h) any person entering or leaving pig holdings shall observe appropriate hygienic measures as necessary to reduce the risk of spread of African swine fever virus.

2. Where the prohibitions provided for in paragraph 1 are maintained beyond 40 days because of further outbreaks of the disease, and where as a result animal welfare or other problems arise in keeping the pigs, subject to the conditions set out in Article 10(3), the competent authority may, following a reasoned application by the owner, authorise removal of pigs from a holding within the surveillance zone to be directly transported to:

- (a) a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, for the purpose of immediate slaughter;
- (b) a processing plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision;
- (c) under exceptional circumstances, other premises located within the protection or surveillance zone. Member States availing themselves of this provision shall immediately inform the Commission thereof in the Standing Veterinary Committee.

3. The measures in the surveillance zone shall continue to be applied at least until:

- (a) cleansing and disinfection in the infected holdings have been carried out;
- (b) pigs on all holdings have undergone clinical and, where necessary, laboratory examinations as laid down in the diagnostic manual in order to detect the eventual presence of African swine fever virus.

The examinations referred to in point (b) shall not take place until 40 days have elapsed since the completion of preliminary cleansing and disinfection measures on the infected holdings.

#### Article 12

##### Cleansing and disinfection

Member States shall ensure that:

- (a) the disinfectants to be used and their concentrations are officially approved by the competent authority;
- (b) the cleansing and disinfection operations are carried out under official supervision in accordance with:
  - the instructions given by the official veterinarian; and
  - the principles and procedures for cleansing, disinfecting and treatment laid down in Annex II.

#### Article 13

##### Repopulation of pig holdings following disease outbreaks

1. The reintroduction of pigs to holdings referred to in Article 5 shall not take place until at least 40 days after completion of the cleansing and disinfection operations in accordance with Article 12.

2. The reintroduction of pigs shall take account of the type of farming practised on the holding concerned, and shall conform to one of the procedures set out in paragraphs 3 and 4.

3. In the case of holdings where the occurrence of disease has not been linked to vectors, the following procedure shall apply:

- (a) as regards open-air holdings, the reintroduction of pigs shall start with the introduction of sentinel pigs which have been checked and found negative for the presence of antibodies against African swine fever virus or which come from holdings not subjected to any restrictions related to African swine fever. The sentinel pigs shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and shall be sampled 45 days later, and shall be tested for the

presence of antibodies, in accordance with the diagnostic manual. No pig may leave the holding before the negative results of the serological tests are available; if none of the pigs has developed antibodies against African swine fever virus, full re-population may then take place.

- (b) as regards all other forms of rearing, the reintroduction of pigs shall either take place in accordance with the measures provided for in point (a) or shall be based on total repopulation, provided that:

- all the pigs arrive within a period of twenty days and come from holdings not subjected to any restrictions related to African swine fever;

- pigs in the repopulated herd shall be subjected to a serological examination in accordance with the diagnostic manual. Sampling for that examination shall be carried out at the earliest 45 days after the arrival of the last pigs;

- no pig may leave the holding before the negative results of the serological examination are available.

4. In the case of holdings where the occurrence of disease has been linked to vectors, restocking shall not take place for at least 6 years, unless specific operations to eliminate the vector from the premises and places where the pigs are to be kept or can come in contact with the vector have been successfully carried out under official supervision. Thereafter, the measures laid down in paragraph 3(a) shall apply.

In addition to those measures, however, no pig may leave the holding in question after full repopulation until further serological examinations for African swine fever have been carried out with negative results on samples collected from the pigs in the holding at the earliest 60 days after full repopulation, in accordance with the diagnostic manual.

5. Where the occurrence of disease has not been linked to vectors, if more than 6 months have elapsed since the completion of the cleansing and disinfection operations in the holding, the competent authority may authorise derogation from the provisions laid down in paragraph 3, taking into account the epidemiological situation.

#### Article 14

##### Measures in cases where African swine fever is suspected or confirmed in a slaughterhouse or means of transport

1. Where there is a suspicion of African swine fever in a slaughterhouse or means of transport, Member States shall ensure that the competent authority immediately sets in motion official means of investigation to confirm or to rule out the presence of the disease in accordance with the procedures laid down in the diagnostic manual.

2. Should a case of African swine fever be detected in a slaughterhouse or means of transport, the competent authority shall ensure that:

- (a) all susceptible animals in the slaughterhouse or in the means of transport are killed without delay;
- (b) the carcasses, offal and animal waste of possibly infected and contaminated animals are processed under official supervision;
- (c) cleansing and disinfection of buildings and equipment, including vehicles, takes place under the supervision of the official veterinarian in accordance with Article 12;
- (d) an epidemiological inquiry is carried out as provided in Article 8 *mutatis mutandis*;
- (e) the African swine fever virus isolate is subject to the laboratory procedure laid down in the diagnostic manual, to identify the genetic type of virus;
- (f) the measures referred to in Article 7 are applied in the holding where the infected pigs or carcasses came from and in the other contact holdings. Unless otherwise indicated by the epidemiological inquiry, the measures laid down in Article 5(1) shall be applied in the holding of origin of the infected pigs or carcasses;
- (g) no animals are reintroduced for slaughter or transport until at least 24 hours after completion of the cleansing and disinfection operations conducted in accordance with Article 12.

#### Article 15

##### Measures in cases where African swine fever is suspected or confirmed in feral pigs

1. Immediately after the competent authority of a Member State has information that feral pigs are suspected of being infected, it shall take all appropriate measures to confirm or rule out the presence of the disease, by giving information to the owners of pigs and to hunters, and by investigations of all feral pigs shot or found dead, including laboratory testing.

2. As soon as confirmation of a primary case of African swine fever in feral pigs has taken place, in order to reduce the spread of disease, the competent authority of a Member State shall immediately:

- (a) establish an expert group including veterinarians, hunters, wild life biologists and epidemiologists. The expert group shall assist the competent authority in:

- studying the epidemiological situation and defining an infected area in accordance with the provisions laid down in Article 16(3)(b);

- establishing appropriate measures to be applied in the infected area in addition to the ones referred to in points (b) and (c); these measures may include suspension of hunting and a ban on feeding feral pigs;

- drawing up the eradication plan to be submitted to the Commission in accordance with Article 16;

- carrying out audits to verify the effectiveness of the measures adopted to eradicate African swine fever from the infected area;

(b) place under official surveillance pig holdings in the defined infected area, and shall in particular order that:

- an official census be carried out of all categories of pigs on all holdings; the census shall be kept up to date by the owner. The information in the census shall be produced on request and may be checked at each inspection. However, as regards open-air pig holdings, the first census carried out may be done on the basis of an estimate;

- all pigs on the holding be kept in their living quarters or some other place where they can be isolated from feral pigs. The feral pigs must not have access to any material which may subsequently come in contact with the pigs on the holding;

- no pigs enter or leave the holding, except where authorized by the competent authority having regard to the epidemiological situation;

- appropriate means of disinfection be used at the entrance and exits of buildings housing pigs and of the holding itself;

- appropriate hygienic measures be applied by all persons coming in contact with feral pigs, to reduce the risk of spread of African swine fever virus;

- all dead or diseased pigs with African swine fever symptoms on a holding be tested for the presence of African swine fever;

- no part of any feral pig, whether shot or found dead, nor any material or equipment which could be contaminated with African swine fever virus, shall be brought into a pig holding;

- pigs, their semen, embryos or ova shall not be moved from the infected area for intra-Community trade;

- (c) arrange that all feral pigs shot or found dead in the defined infected area are inspected by an official veterinarian and examined for African swine fever in accordance with the diagnostic manual. Carcasses of all animals found positive shall be processed under official supervision. Where such testing proves negative as regards African swine fever, Member States shall apply the measures laid down in Article 11(2) of Council Directive 92/45/EEC <sup>(1)</sup>. Parts not intended for human consumption shall be processed under official supervision;
- (d) ensure that the African swine fever virus isolate is subject to the laboratory procedure indicated in the diagnostic manual, to identify the genetic type of virus.

3. If a case of African swine fever has occurred in feral pigs in an area of a Member State close to the territory of another Member State, the Member States concerned shall collaborate in the establishment of disease control measures.

#### Article 16

#### Plans for the eradication of African swine fever from a feral pig population

1. Without prejudice to the measures laid down in Article 15, Member States shall submit to the Commission within 90 days from the confirmation of a primary case of African swine fever in feral pigs a written plan of the measures taken to eradicate the disease in the area defined as infected, and of the measures applied on the holdings in that area.

The Commission shall examine the plan in order to determine whether it permits the desired objective to be attained. The plan, if necessary with amendments, shall be approved in accordance with the procedure referred to in Article 24(2).

The plan may subsequently be amended or supplemented to take account of developments in the situation.

If these amendments concern the re-definition of the infected area, Member States shall ensure that the Commission and the other Member States are informed of these amendments without delay.

If the amendments concern other provisions of the plan, Member States shall submit the amended plan to the Commission for examination and eventual approval in accordance with the procedure referred to in Article 24(2).

2. After the measures provided for in the plan mentioned in paragraph 1 have been approved, they shall replace the initial measures laid down in Article 15, on a date which shall be decided upon when approval is given.

3. The plan mentioned in paragraph 1 shall contain information on:

- (a) the results of the epidemiological investigations and controls carried out in accordance with Article 15 and the geographical distribution of the disease;
- (b) the definition of the infected area within the territory of the Member State concerned. When defining the infected area, the competent authority shall take into account:
  - the results of the epidemiological investigations carried out and the geographical distribution of the disease;
  - the feral pig population in the area;
  - the existence of major natural or artificial obstacles to movements of feral pigs;
- (c) the organisation of close cooperation between biologists, hunters, hunting organisations, the wildlife services and veterinary services (animal health and public health);
- (d) the information campaign to be enforced to increase hunters' awareness of the measures they have to adopt in the framework of the eradication plan;
- (e) specific efforts made to determine the extent of the infection in the feral pig population, by investigating feral pigs shot by hunters or found dead, and by laboratory testing, including age-stratified epidemiological investigations;
- (f) the requirements to be complied with by hunters in order to avoid any spread of the disease;
- (g) the method of removal of feral pigs found dead or shot, which shall be based on:
  - processing under official supervision; or
  - inspection by an official veterinarian and laboratory tests as provided for in the diagnostic manual. Carcasses of all animals found positive shall be processed under official supervision. Where such testing proves negative as regards African swine fever, Member States shall apply the measures laid down in Article 11(2) of Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;
- (h) the epidemiological inquiry which is carried out on each feral pig, whether shot or found dead. This inquiry must include the completion of a questionnaire which supplies information about:
  - the geographical area where the animal was found dead or shot;
  - the date on which the animal was found dead or shot;
  - the person who found or shot the animal;

<sup>(1)</sup> OJ L 268, 14.9.1992, p. 35. Directive as last amended by Directive 97/79/EC (OJ L 24, 30.1.1998, p. 31).

- the age and sex of the pig;
  - if shot: symptoms before shooting;
  - if found dead: the state of the carcass;
  - laboratory findings;
- (i) surveillance programmes and prevention measures applicable to the holdings situated in the defined infected area, and, if necessary, in its surroundings, including the transport and movement of animals within, from and to the area; these measures shall at least include the ban on moving pigs, their semen, embryos or ova from the infected area for intra-Community trade;
- (j) other criteria to be applied for lifting the measures taken;
- (k) the authority with responsibility for supervising and co-ordinating the departments responsible for implementing the plan;
- (l) the information system established in order that the expert group appointed in accordance with Article 15(2)(a) can review on a regular basis the results of the eradication plan;
- (m) the disease monitoring measures that shall be enforced after a period of at least twelve months has elapsed from the last confirmed case of African swine fever in feral pigs in the defined infected area; these monitoring measures shall stay in place for at least twelve months and shall at least include the measures already enforced in accordance with points (e), (g) and (h).
4. A report concerning the epidemiological situation in the defined area and the results of the eradication plan shall be transmitted to the Commission and to the other Member States every six months.
- More detailed rules relating to the information that is to be provided by the Member States on this matter may be adopted in accordance with the procedure referred to in Article 23(2).

#### Article 17

##### **Measures to prevent the spread of African swine fever virus by means of vectors**

1. Should the presence of vectors be possible or suspected on a holding where African swine fever has been confirmed, the competent authority shall ensure that:
- (a) the infected building and its surroundings are checked for the presence of vectors, by means of physical inspection and, if necessary, the trapping of specimens;

- (b) where the presence of vectors is confirmed:
- appropriate laboratory tests are carried out to confirm or rule out the presence of African swine fever virus in the vectors;
  - further appropriate monitoring and control measures are established in the area around the holding;
- (c) where the presence of vectors is confirmed but its control is impracticable, pigs are not kept on the holding for at least 6 years.
2. Information on the implementation of the provisions laid down in paragraph 1 shall be provided by the Member State concerned to the Commission and to the other Member States in the framework of the Standing Veterinary Committee.
3. Further measures for the monitoring and control of vectors and for the prevention of African swine fever may be adopted in accordance with the procedure referred to in Article 24(2).

#### Article 18

##### **Diagnostic procedures and bio-safety requirements**

1. Member States shall ensure that:
- (a) diagnostic procedures, sampling and laboratory testing to detect the presence of African swine fever are carried out in accordance with the diagnostic manual;
- (b) a national laboratory is responsible for coordinating standards and methods of diagnosis in each Member State in accordance with the provisions of Annex III.
2. The national laboratories shall liaise with the Community reference laboratory as indicated in Annex IV. Without prejudice to the provisions of Council Decision 90/424/EEC<sup>(1)</sup>, and in particular Article 28 thereof, the powers and duties of the laboratory shall be those described in that Annex.
3. In order to ensure uniform procedures to diagnose African swine fever and an appropriate differential diagnosis with classical swine fever, within six months from the date when this Directive enters into force and in accordance with the procedure referred to in Article 23(2), the classical swine fever diagnostic manual adopted in accordance with Article 17(3) of Directive 2001/89/EC shall be amended to include at least:

- (a) minimum quality standards to be observed by the African swine fever diagnostic laboratories and for the transport of samples;

<sup>(1)</sup> OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2001/572/EC (OJ L 203, 28.7.2001, p. 16).

- (b) criteria and procedures to be followed when clinical or post-mortem examinations are carried out to confirm or exclude the presence of African swine fever;
- (c) criteria and procedures to be followed for the collection of samples from live pigs or their carcasses, to confirm or exclude African swine fever by laboratory examinations, including sampling methods for serological or virological screenings carried out in the framework of the application of the measures provided for in this Directive;
- (d) laboratory tests to be used for the diagnosis of African swine fever, including criteria for evaluating the results of the laboratory tests;
- (e) laboratory techniques for the genetic typing of the African swine fever virus isolate.

4. In order that appropriate bio-safety conditions are guaranteed to protect animal health, the African swine fever virus, its genome and antigens and vaccines for research, diagnosis or manufacture shall be manipulated or used only in places, establishments or laboratories approved by the competent authority.

The list of approved places, establishments or laboratories shall be transmitted to the Commission within six months of the date laid down in the second subparagraph of Article 27 and shall be kept updated thereafter.

#### Article 19

#### Use, manufacture and sale of African swine fever vaccines

Member States shall ensure that:

- (a) the use of African swine fever vaccines is prohibited;
- (b) the manipulation, manufacture, storage, supply, distribution or sale of African swine fever vaccines in the territory of the Community is carried out under official control.

#### Article 20

#### Community controls

Experts from the Commission may, in co-operation with the competent authorities of the Member State concerned, and in so far as it is necessary to ensure the uniform application of this Directive, make on-the spot checks in accordance with the procedures laid down in Commission Decision 98/139/EC <sup>(1)</sup>.

#### Article 21

#### Contingency plans

1. Each Member State shall draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of African swine fever.

This plan shall allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak.

2. The criteria and requirements to be applied *mutatis mutandis* for drawing up the contingency plan shall be those set out in Annex VII to Directive 2001/89/EC.

In accordance with the procedure referred to in Article 23(2), those criteria and requirements may be amended or supplemented to take into account the specific nature of African swine fever and the progress made in the development of disease control measures.

3. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that they are compatible with those of the other Member States.

The plans, if necessary amended, shall be approved in accordance with the procedure referred to in Article 23(2).

Whenever necessary, the plans shall subsequently be amended or supplemented, in accordance with the procedure referred to in Article 23(2), to take into account developments in the situation. In any case, every five years each Member State shall update the plan and submit it to the Commission for approval in accordance with the procedure referred to in Article 23(2).

#### Article 22

#### Disease control centres and expert groups

In order to ensure full coordination of the measures necessary for the swift eradication of African swine fever, the provisions laid down in Article 23 of Directive 2001/89/EC shall apply *mutatis mutandis*.

#### Article 23

#### Normal regulatory procedure

1. The Commission shall be assisted by the Standing Veterinary Committee established by Decision 68/361/EEC <sup>(2)</sup>.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC <sup>(3)</sup> shall apply, in compliance with Article 7 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be three months.

<sup>(2)</sup> OJ L 255, 18.10.1968, p. 23.

<sup>(3)</sup> OJ L 184, 17.7.1999, p. 23.

<sup>(1)</sup> OJ L 38, 12.2.1998, p. 10.



*Article 24***Accelerated regulatory procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee established by Decision 68/361/EEC.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be 15 days.

*Article 25***Amendment to Annex I to Directive 92/119/EEC**

In Annex I of Directive 92/119/EC the words 'Teschen disease' are replaced by the words 'African swine fever'.

*Article 26***Amendments to the annexes and adoption of further detailed rules**

1. The Annexes to this Directive may be amended as necessary in accordance with the procedure referred to in Article 23(2).
2. Any further detailed rules necessary for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 23(2).

*Article 27***Transposition into national law**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2002 at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 January 2003. When Member States adopt the provisions referred to in the first paragraph, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 28***Transitional provisions**

Pending the application of this Directive, transitional provisions on the control of African swine fever may be adopted in accordance with the procedure referred to in Article 23(2).

*Article 29***Entry into force**

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

*Article 30***Addressees**

This Directive is addressed to the Member States.

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## ANNEX I

**NOTIFICATION OF DISEASE AND FURTHER EPIDEMIOLOGICAL INFORMATION TO BE PROVIDED BY THE MEMBER STATE WHERE AFRICAN SWINE FEVER HAS BEEN CONFIRMED**

1. Within 24 hours of the confirmation of any primary outbreak, primary case in feral pigs or case in a slaughterhouse or means of transport, the Member State concerned must notify by means of the Animal Disease Notification System established in accordance with Article 5 of Council Directive 82/894/EEC:
  - (a) the date of dispatch;
  - (b) the time of dispatch;
  - (c) the name of Member State;
  - (d) the name of disease;
  - (e) the number of the outbreak or case;
  - (f) the date on which African swine fever was suspected;
  - (g) the date of confirmation;
  - (h) the methods used for confirmation;
  - (i) whether the disease has been confirmed in feral pigs or in pigs in a holding, slaughterhouse or means of transport;
  - (j) the geographical location where the outbreak or the case of African swine fever has been confirmed;
  - (k) the disease control measures applied.
2. In the case of primary outbreaks or cases in slaughterhouses or means of transport, the Member State concerned must forward the following information in addition to the data referred to in point 1:
  - (a) the number of susceptible pigs in the outbreak, slaughterhouse or means of transport;
  - (b) the number of dead pigs of each category in the holding, slaughterhouse or means of transport;
  - (c) for each category, the morbidity of the disease and the number of pigs in which African swine fever has been confirmed;
  - (d) the number of pigs killed in the outbreak, or in the slaughterhouse or means of transport;
  - (e) the number of carcasses processed;
  - (f) in the case of an outbreak, its distance from the nearest pig holding;
  - (g) if African swine fever was confirmed in a slaughterhouse or means of transport, the location of the holding or holdings of origin of the infected pigs or carcasses.
3. In the case of secondary outbreaks, the information referred to in points 1 and 2 must be forwarded within the time-limits laid down in Article 4 of Directive 82/894/EEC.
4. The Member State concerned shall ensure that the information to be provided in accordance with points 1, 2 and 3, in relation to any outbreak or case of African swine fever in a holding, slaughterhouse or means of transport is followed as soon as possible by a written report to the Commission and the other Member States including at least:
  - (a) the date on which the pigs in the holding, slaughterhouse or means of transport were killed and their carcasses processed;
  - (b) the results of the tests carried out on samples taken when pigs were killed;

- (c) where the derogation provided for in Article 6(1) has been applied, the number of pigs killed and processed, and the number of pigs which are to be slaughtered at a later date together with the time limit laid down for their slaughter;
- (d) any information relating to the possible origin of the disease or, if ascertained, its actual origin;
- (e) information on the control system established to ensure that the measures laid down in Article 10 and 11 for the control of animal movements are effectively implemented;
- (f) in the case of a primary outbreak or of a case of African swine fever in a slaughterhouse or means of transport, the genetic type of virus responsible for the outbreak or for the case;
- (g) where pigs have been killed in contact holdings or in holdings containing pigs suspected of being infected with African swine fever virus, information on:
  - the date of killing and the number of pigs of each category killed in each holding;
  - the epidemiological link between the outbreak or case of African swine fever and each contact holding or the other reasons that have induced the suspicion that African swine fever is present in each suspected holding;
  - the results of the laboratory tests carried out on the samples taken from the pigs in the holdings and when such pigs were killed;

where pigs in contact holdings have not been killed, information must be provided concerning the reasons for this decision.

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## ANNEX II

### PRINCIPLES AND PROCEDURES FOR CLEANSING AND DISINFECTION

#### 1. General principles and procedures:

- (a) the cleansing and disinfection operations and where necessary the measures to destroy rodents and insects must be carried out under official supervision and in accordance with the instructions given by the official veterinarian;
- (b) the disinfectants to be used and their concentrations must be officially approved by the competent authority to ensure destruction of African swine fever virus;
- (c) the efficacy of disinfectants must be checked before use, as the efficacy of certain disinfectants is diminished by prolonged storage;
- (d) the choice of disinfectants and of procedures for disinfection must be made taking into account the nature of the premises, vehicles and objects which are to be treated;
- (e) the conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular technical parameters indicated by the manufacturer, such as pressure, minimum temperature and required contact time must be observed;
- (f) irrespective of the disinfectant used, the following general rules apply:
  - thorough soaking of bedding and litter as well as faecal matter with the disinfectant,
  - washing and cleansing by careful brushing and scrubbing of the ground, floors, ramps and walls after the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures,
  - then, further application of disinfectant for a minimum contact time as stipulated in the manufacturer's recommendations;
- (g) where washing is carried out with liquids applied under pressure re-contamination of the previously cleansed parts must be avoided;
- (h) washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated must be included;

- (i) following the disinfection procedures re-contamination must be avoided;
  - (j) cleansing and disinfection required in the framework of this Directive must be documented in the holding or vehicle register and where official approval is required be certified by the supervising official veterinarian.
2. Special provisions on the cleansing and disinfection of infected holdings:
- (a) preliminary cleansing and disinfection:
    - during the killing of the animals all necessary measures must be taken to avoid or minimize the dispersion of African swine fever virus. Those measures include *inter alia* the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation,
    - carcasses of killed animals must be sprayed with disinfectant,
    - if the carcasses have to be removed from the holding for processing, covered and leak proof containers must be used,
    - as soon as the carcasses of the pigs have been removed for processing, those parts of the holding in which the animals were housed and any parts of other buildings, yards etc. contaminated during killing, or post-mortem examination must be sprayed with disinfectants approved in accordance with Article 12,
    - any tissue or blood spilled during slaughter or post-mortem or gross contamination of buildings, yards, utensils etc. must be carefully collected and processed with the carcasses,
    - the disinfectant must remain on the surface for at least 24 hours;
  - (b) final cleansing and disinfection:
    - manure and used beddings must be removed and treated as provided in point 3(a),
    - grease and dirt must be removed from all surfaces by the application of a degreasing agent and the surfaces washed with water,
    - after washing with cold water, further spraying with disinfectant must be applied,
    - after seven days the premises must be treated with a degreasing agent, rinsed with water, sprayed with disinfectant and rinsed again with water.
3. Disinfection of contaminated bedding, manure and slurry:
- (a) manure and used bedding must be stacked to heat, sprayed with disinfectant and left for at least 42 days or destroyed by burning or burying;
  - (b) slurry must be stored for at least 60 days after the last addition of infective material, unless the competent authorities authorise a reduced storage period for slurry which has been effectively treated in accordance with the instructions given by the official veterinarian so as to ensure the destruction of the virus.
4. However, by way of derogation from points 1 and 2, in the case of open-air holdings the competent authority may establish specific procedures for cleansing and disinfection, taking into account the type of holding and the climatic conditions.
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## ANNEX III

**NATIONAL AFRICAN SWINE FEVER LABORATORIES AND THEIR RESPONSIBILITIES**

1. The national African swine fever laboratories are as follows:

**BELGIUM**

Centre d'Etude et de Recherche Vétérinaires et Agrochimiques, 1180 Bruxelles

**DENMARK**

Statens veterinære Institut for Virusforskning, Lindholm, 4771 Kalvehave

**GERMANY**

Bundesforschungsanstalt für Viruserkrankungen der Tiere, Tübingen

**GREECE**

Veterinary Institute of Infectious and Parasitic Diseases, 15310 Ag. Paraskevi

**SPAIN**

Centro de Investigación en Sanidad Animal, 28130 Valdeolmos (Madrid)

**FRANCE**

AFSSA-Ploufragan, Zoopole des Côtes d'Armor, 22440 Ploufragan

**IRELAND**

Veterinary Research Laboratory, Abbotstown, Castleknock, Dublin 15

**ITALY**

Istituto Zooprofilattico Sperimentale dell'Umbria e delle Marche, 06100 Perugia

**LUXEMBOURG**

Laboratoire de Médecine Vétérinaire de l'Etat, 1020 Luxembourg

**THE NETHERLANDS**

Instituut voor Veehouderij en Diergezondheid (ID-Lelystad), 8200 AB Lelystad

**AUSTRIA**

Bundesanstalt für Veterinärmedizinische Untersuchungen in Mödling, Robert-Koch-Gasse 17, 2340 Mödling

**PORTUGAL**

Laboratório Nacional de Investigação Veterinária, 1500 Lisboa

**FINLAND**

Eläinlääkintä- ja elintarviketutkimuslaitos, 00231 Helsinki

**SWEDEN**

Statens veterinärmedicinska anstalt, 75189 Uppsala

**UNITED KINGDOM**

Institute for Animal Health, Pirbright, Woking, Surrey GU24 0NF

2. The national African swine fever laboratories are responsible for ensuring that in each Member State the laboratory testing to detect the presence of African swine fever and the identification of the genetic type of virus isolates are carried out in accordance with the diagnostic manual. To this end they may make special agreements with the Community Reference Laboratory or with other national laboratories.

3. The national African swine fever laboratory in each Member State is responsible for coordinating the standards and diagnostic methods in each African swine fever diagnostic laboratory within that State. To this end:
  - (a) they may provide diagnostic reagents to individual laboratories;
  - (b) they shall control the quality of all diagnostic reagents used in that Member State;
  - (c) they shall arrange comparative tests periodically;
  - (d) they shall hold isolates of African swine fever virus from cases and outbreaks confirmed in that Member State.

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#### ANNEX IV

##### COMMUNITY REFERENCE LABORATORY FOR AFRICAN SWINE FEVER

1. The Community Reference Laboratory for African swine fever is: Centro de Investigación en Sanidad Animal, 28130 Valdeolmos, Madrid, Spain.
2. The functions and duties of the Community Reference Laboratory for African swine fever are:
  - (a) To coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing African swine fever, specifically by:
    - storing and supplying cell cultures for use in diagnosis;
    - typing, storing and supplying strains of African swine fever virus for serological tests and the preparation of anti-sera;
    - supplying standardised sera, conjugate sera and other reference reagents to the national laboratories in order to standardise the tests and reagents employed in the Member States;
    - building up and holding an African swine fever virus collection;
    - organising periodic comparative tests of diagnostic procedures at Community level;
    - collecting and collating data and information on the methods of diagnosis used and the results of tests carried out;
    - characterising isolates of the virus by the most up-to-date methods available to allow greater understanding of the epizootiology of African swine fever;
    - keeping abreast of developments in African swine fever surveillance, epizootiology and prevention throughout the world;
    - retaining expertise on the virus causing African swine fever and other pertinent viruses to enable rapid differential diagnosis;
  - (b) to make the necessary arrangements for training or re-training experts in laboratory diagnosis with a view to harmonising diagnostic techniques;
  - (c) to have trained personnel available for emergency situations occurring within the Community;
  - (d) to perform research activities and whenever possible coordinate research activities directed towards an improved control of African swine fever.
3. The Community Reference Laboratories for classical swine fever and African swine fever shall organise their activities in such a way so as to ensure a proper co-ordination of the comparative tests organised at Community level for the diagnosis of these two diseases.

**Amended proposal for a Directive of the European Parliament and of the Council on Market Access to Port Services <sup>(1)</sup>**

(2002/C 181 E/07)

(Text with EEA relevance)

COM(2002) 101 final — 2001/0047(COD)

*(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 19 February 2002)*

<sup>(1)</sup> OJ C 154 E, 29.5.2001, p. 290.

INITIAL PROPOSAL

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF  
THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

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

Having regard to the opinion of the Committee of the Regions,

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

Whereas:

- (1) The objective of Article 49 of the Treaty is to eliminate the restrictions on freedom to provide services in the Community; in accordance with Article 51 of the Treaty, that objective must be achieved within the framework of the common transport policy
- (2) Through Council Regulations (EEC) No 4055/86 of 22 December 1986 applying the principle of freedom to provide services to maritime transport between Member States and between Member States and third countries <sup>(1)</sup> and (EEC) No 3577/92 of 7 December 1992 applying the principle of freedom to provide services to maritime transport within Member States (maritime cabotage) <sup>(2)</sup> that objective has been attained with regard to maritime transport services as such.
- (3) Port services are essential to the proper functioning of maritime transport since they make an essential contribution to the efficient use of maritime transport infrastructure.

AMENDED PROPOSAL

Unchanged

- (1) The objective of Article 49 of the Treaty is to eliminate the restrictions on freedom to provide services in the Community; in accordance with Article 51 of the Treaty, that objective must be achieved within the framework of the common transport policy, whilst respecting, inter alia, the Treaty's environmental protection rules.

Unchanged

<sup>(1)</sup> OJ L 378, 31.12.1986, p. 1. Last amended by Council regulation (EEC) No 3573/90 (OJ L 353, 17.12.1990, p. 16).

<sup>(2)</sup> OJ L 364, 12.12.1992, p. 7.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

- (4) In the Green Paper on Sea Ports and Maritime Infrastructure of December 1997 <sup>(1)</sup> the Commission indicated its intention of proposing a legislative framework in order to achieve access to the port services market in Community ports with international traffic. Therein, port services should be defined as those services of commercial value that are normally provided against payment in a port.
- (5) Facilitating access to the port services market at Community level should remove prevailing restrictions that hamper access for port service operators, improve the quality of service provided to users of the port, increase efficiency and flexibility, help reduce costs and thereby contribute to promoting short sea shipping and combined transport.
- (6) Where the authorisation under this Directive takes the form of a contract falling within the scope of Directives 92/50/EEC <sup>(2)</sup>, 93/36/EEC <sup>(3)</sup>, 93/37/EEC <sup>(4)</sup> and 93/38/EEC <sup>(5)</sup>, these latter Directives apply. Equally, where applicable, Directives 89/48/EEC <sup>(6)</sup>, 92/51/EEC <sup>(7)</sup> and 1999/42/EC <sup>(8)</sup> on the mutual recognition of professional education and training apply.
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- <sup>(1)</sup> COM(97) 678 final of 10 December 1997.
- <sup>(2)</sup> Directive 92/50/EEC of 18 June 1992 relating to the coordination of procedures for the award of public service contracts (OJ L 209, 24.7.1992, p. 1), last amended by Directive 97/52/EC (OJ L 328, 28.11.1997).
- <sup>(3)</sup> Directive 93/36/EEC of 14 June 1993 co-ordinating procedures for the award of public supply contracts (OJ L 199, 9.8.1993, p. 1), last amended by Directive 97/52/EC (OJ L 328, 28.11.1997).
- <sup>(4)</sup> Directive 93/37/EEC of 14 June 1993 concerning the co-ordination of procedures for the award of public works contracts (OJ L 199, 9.8.1993, p. 54), last amended by Directive 97/52/EC (OJ L 328, 28.11.1997).
- <sup>(5)</sup> Directive 93/38/EEC of 14 June 1993 co-ordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors (OJ L 199, 9.8.1993, p. 84), last amended by Directive 98/4/EC (OJ L 101, 1.4.1998).
- <sup>(6)</sup> Directive 89/48/EEC of 21 December 1989 on a general system for the recognition of higher education diplomas awarded on completion of professional education and training of at least three years' duration.
- <sup>(7)</sup> Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC.
- <sup>(8)</sup> Directive 1999/42/EC of 7 June 1999 establishing a mechanism for the recognition of qualifications in respect of the professional activities covered by the Directives on liberalisation and transitional measures and supplementing the general systems for the recognition of qualifications.



## INITIAL PROPOSAL

- (7) Diverse national legislations and practices have led to disparities in the procedures applied and have created legal uncertainty regarding the rights of providers of port services and the duties of competent authorities. It is in the Community's interest, therefore, to establish a Community legal framework which lays down basic rules on access to the port services market, the rights and obligations of current and prospective service providers, the managing bodies of the ports, as well as on the procedures accompanying the authorisations and selection processes.
- (8) In accordance with principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objectives of the proposed action, which is the access for any natural or legal person, established in the Community, to the market for port services, cannot be sufficiently achieved by the Member States because of the dimension of that action and can therefore be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve that objective and does not go beyond what is necessary for that purpose.
- (9) The Community legislation on access to port services does not exclude the application of other Community rules. Competition rules have already been applied to port services and are relevant in particular to monopoly situations.
- (10) In the interest of an efficient and safe port management, Member States may require that service providers obtain authorisations. The criteria for granting such authorisations must be objective, transparent, non-discriminatory, relevant and proportional. They must be made public.
- (11) Since ports are made up of limited geographical areas, access to the market may, in certain cases, meet capacity and available-space constraints and traffic-related safety constraints for technical-nautical services. In such cases it may therefore be necessary to limit the number of authorised providers of port services
- (12) The criteria for any limitation must be objective, transparent, non-discriminatory, relevant and proportional. In the case of cargo handling, and unless exceptional circumstances prevail, the number of service providers for each category of cargo handling must not be limited to fewer than two completely independent providers.

## AMENDED PROPOSAL

- (8) In accordance with principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objectives of the proposed action, which is the access for any natural or legal person, established in the Community, to the market for port services, can be better achieved by establishing common principles for all Member States. This Directive confines itself to the minimum required in order to achieve that objective and does not go beyond what is necessary for that purpose.
- (9) The Community legislation on access to port services does not exclude the application of other Community rules. Competition rules, including those relating to services of general economic interest, have already been applied to port services and are relevant in particular to monopoly situations.
- Unchanged
- (11) Since ports are made up of limited geographical areas, access to the market may, in certain cases, meet capacity and available-space and traffic-related safety constraints. In such cases and in order to ensure the ports' overall efficiency it may therefore be necessary to limit the number of authorised providers of port services whilst public service obligations of a service provider or the managing body of the port as well as environmental rules are respected.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

(13) Service providers should have the right to employ personnel of their own choice.

(13) Service providers should have the right to employ personnel of their own choice. They must comply with the rules on training, professional competence and working conditions.

(14) Where the number of providers of port services is limited, these will need to be selected by the competent authority, according to a transparent, objective, open and fair selection procedure with non-discriminatory rules.

Unchanged

(15) In order to ensure that decisions and procedural measures under this Directive are taken, and are seen to be taken, by neutral bodies, the position of the managing body of a port which is itself, or wishes to become, a provider of a port service should be defined. It must be subject to the same conditions and procedures as other service providers whilst remaining in a position to ensure the functioning of the port. Therefore any decision on limiting the number of service providers and the selection itself must be entrusted to a neutral body and the managing body of a port shall not discriminate between service providers and between port users.

(16) It is therefore necessary to ensure non-discrimination between the managing body of the port and independent operators, as well as between managing bodies of different ports.

(17) In the financial field it is necessary to impose the obligation for managing bodies of ports covered by this Directive, which are also acting as service providers, to keep accounts for activities carried out in their function as managing bodies separate from those carried out on a competitive basis.

(18) Commission Directive 2000/52/EC of 26 July 2000 lays down, for a certain number of undertakings, the obligation to maintain separate accounts which only applies to undertakings whose total annual turnover for each of the last two years exceeded EUR 40 million.

In the light of the introduction of the freedom to provide port services in the Community, it is necessary to ensure that the principle of separation of accounts applies to all ports falling within the scope of the present Directive and to impose on ports transparency rules that are not less strict than those laid down in the Commission Directive 2000/52/EC.

(19) The requirement to keep accounts for port service activities should apply to all undertakings which have been selected to provide such services.

## INITIAL PROPOSAL

- (20) Self-handling should be allowed and any criteria set for self-handlers should not be stricter than those set for providers of port services for the same or a comparable kind of service.
- (21) Authorisations granted through a selection procedure should be limited in time. It is reasonable to take into account, when determining the period of authorisation, whether the provider has had to invest in assets or not and, where this is the case, whether these assets are moveable or not. Although such procedure should lead to an adequate outcome, it is nevertheless necessary to set maximum periods of authorisation.
- (22) The current situation in the Community ports, with its multitude of authorisation and selection methods and periods, requires that clear transition periods be determined. These transition rules should distinguish between ports where the number of service providers is restricted and those ports where it is not.
- (23) Where the number of service providers is not restricted, there is no reason to change the existing authorisations, whilst future ones should be granted in accordance with the Directive's rules.
- (24) Where the number of service providers is restricted, the transitional periods should distinguish between authorisations granted in accordance with a public tender, or an equivalent procedure, or not; between situations where the service provider has made significant investments or not; and where these investments were made in moveable or immovable assets. The interests of legal certainty require that, in each case maximum periods be fixed, whilst leaving national authorities a substantial margin adequately to take into account the specificities of each case.
- (25) Member States should determine the competent authorities responsible for the implementation of this Directive.
- (26) Appeal procedures against decisions of the competent authorities should be in place.
- (27) Member States must ensure an adequate level of social protection for the staff of undertakings providing port services.

## AMENDED PROPOSAL

- (20) Self-handling should be allowed in accordance with the conditions laid down in this Directive, and any criteria set for self-handlers should be the same as those set for providers of port services for the same or a comparable kind of service.
- (21) Authorisations granted through a selection procedure should be limited in time. It is reasonable to take into account, when determining the period of authorisation, whether the provider has had to invest in assets or not and, where this is the case, whether these assets are moveable or not.
- Unchanged
- (27) Member States must ensure an adequate level of social protection for the staff of undertakings providing port services and ensure that an adequate level of professional skills is maintained especially where service providers change.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

- (28) The provisions of this Directive in no way affect the rights and obligations of Member States in respect of law and order, safety and security at ports as well as environmental protection.
- (29) This Directive does not affect the application of the rules of the Treaty; in particular the Commission will continue to ensure compliance with these rules by exercising, when necessary, all the powers granted to it by Article 86 of the Treaty.
- (30) On the basis of Member States' reports on the application of this directive, the Commission should make an assessment accompanied, if appropriate, by a proposal for the Directive's revision,

Unchanged

HAVE ADOPTED THIS DIRECTIVE:

*Article 1***Objective**

Freedom to provide port services shall apply to Community providers of port services under the provisions set out in this Directive. Providers of port services shall have access to port installations to the extent necessary for them to carry out their activities.

1. Freedom to provide port services shall apply to Community providers of port services under the provisions set out in this Directive. Providers of port services shall have access to port installations to the extent necessary for them to carry out their activities.

2. The provisions of this Directive set out that the freedom to provide port services may be subject to a port's or port system's constraints relating to available space or capacity or maritime traffic-related safety and must respect, where applicable, requirements in respect of safety, environmental protection and public service obligations.

*Article 2***Scope**

1. This Directive applies to those port services set out in the Annex which are provided inside the port area for users of the port.

1. This Directive applies to those port services set out in the Annex which are provided for users of the port, either inside the port area or on waterway access to and from the port or port system.

2. This Directive applies to any sea port or port system located in the territory of a Member State and open to general commercial maritime traffic, provided that the port's average annual throughput over the last 3 years has not been less than 3 million tonnes or 500 000 passenger movements.

Unchanged

## INITIAL PROPOSAL

3. Where a port reaches the freight traffic threshold referred to in paragraph 2 without reaching the corresponding passenger movement threshold, the provisions of this Directive shall not apply to port services reserved exclusively for passengers. Where the passenger movement but not the freight traffic threshold is reached, the provisions of this Directive shall not apply to port services reserved exclusively for freight. The Commission shall publish for information, in the *Official Journal of the European Communities* and on the basis of information provided by Member States, a list of the ports referred to in this Article. The list shall first be published within three months following the entry into force of this Directive, and thereafter annually.

4. Member States may require that the providers of port services be established within the Community and that vessels used exclusively for the provision of port services shall be registered in, and fly the flag of a Member State.

## Article 3

1. This Directive is without prejudice to the obligations for competent authorities which flow from Directive 92/50/EEC, Directive 93/36/EEC, Directive 93/37/EEC and Directive 93/38/EEC.

2. Where one of the Directives referred to in paragraph 1 makes the tendering of a service contract mandatory, Articles 8(1, 2, 3, 4 and 5), 12(1 and 2), and 13 of this Directive shall not apply to the award of that contract.

3. This Directive is without prejudice, where applicable, to the obligations of competent authorities which flow from Directives 89/48/EEC, 92/51/EEC and 99/42/EC on a mutual recognition among Member States of professional education and training.

## Article 4

**Definitions**

For the purposes of this Directive:

1. 'sea port' (in this Directive referred to as 'port') is an area of land and water made up of such improvement works and equipment as to permit, principally, the reception of ships, their loading and unloading, the storage of goods, the receipt and delivery of these goods by inland transport, the embarkation and disembarkation of passengers;

## AMENDED PROPOSAL

3. Where a port reaches the freight traffic threshold referred to in paragraph 2 without reaching the corresponding passenger movement threshold, the provisions of this Directive shall not apply to port services reserved exclusively for passengers. Where the passenger movement but not the freight traffic threshold is reached, the provisions of this Directive shall not apply to port services reserved exclusively for freight. The Commission shall publish for information, in the *Official Journal of the European Communities* and on the basis of information provided by Member States, a list of the ports and port systems referred to in this Article. The list shall first be published within three months following the entry into force of this Directive, and thereafter annually.

Unchanged

2. Where one of the Directives referred to in paragraph 1 makes the tendering of a service contract mandatory, Articles 8(1, 2, 3, 4 and 5), 12(1 and 2), and 13 of this Directive shall not apply to the award of that contract. However, Member States may include specificities with regard to their ports in the tendering process of such contracts.

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

2. 'port system' means two or more ports grouped together to serve the same city or conurbation

2. 'port system' means two or more ports in the same area and managed by a single managing body;

3. 'port authority' or 'managing body of the port' (hereafter referred to as 'managing body of the port') means a body which, whether or not in conjunction with other activities, has as its objective under national law or regulation the administration and management of the port infrastructures, and the co-ordination and control of the activities of the different operators present in the port or port system concerned. It may consist of several separate bodies or be responsible for more than one port;

Unchanged

4. 'port services' means the services of commercial value that are normally provided against payment in a port and which are listed in the Annex;

5. 'provider of port services' means any natural or legal person providing, or wishing to provide, one or more categories of port services;

6. 'public service requirement' is a requirement adopted by a competent authority in order to secure adequate provision of certain categories of port services;

7. 'self-handling' means a situation in which a port user provides for itself one or more categories of port services and where normally no contract of any description with a third party is concluded for the provision of such services;

7. 'self-handling' means a situation in which a port user using its own personnel and equipment provides for itself one or more categories of port services in accordance with the criteria laid down in this Directive and where normally no contract of any description with a third party is concluded for the provision of such services;

8. 'authorisation' means any permission, including a contract, allowing a natural or legal person to provide port services or to carry out self-handling.

Unchanged

#### Article 5

#### Competent authorities

Member States shall designate the competent authority or authorities for the purpose of implementing Articles 6, 7, 8, 10, 11, 12 and 19 of this Directive.

#### Article 6

#### Authorisation

1. Member States may require that a provider of port services obtains prior authorisation under the conditions set out in par. 2, 3, 4 and 5. Authorisation shall be automatically granted to service providers selected under Article 8.

## INITIAL PROPOSAL

2. The criteria for the granting of the authorisation by the competent authority must be transparent, non-discriminatory, objective, relevant and proportional. The criteria may only relate to the provider's professional qualifications, his sound financial situation and sufficient insurance cover maritime safety or the safety of installations, equipment

The authorisation may include public service requirements relating to safety, regularity, continuity, quality and price and the conditions under which the service may be provided.

3. Where the required professional qualifications include specific local knowledge or experience with local conditions, the competent authority must provide adequate training for applicant service providers.

4. Criteria referred to in paragraph 2 shall be made public and providers of port services shall be informed in advance of the procedure for obtaining the authorisation. This requirement applies equally to an authorisation linking the provision of service to an investment into immobile assets which will revert to the port upon expiry of the authorisation.

5. The provider of port services has the right to employ personnel of his own choice to carry out the service covered by the authorisation

*Article 7***Limitations**

1. Member States may only limit the number of providers of port services for reasons of constraints relating to available space or capacity or, for technical-nautical services, to maritime traffic-related safety. The competent authority must:

- (a) inform interested parties of the category or categories of port services and the specific part of the port to which the restrictions apply as well as the reasons for such restrictions;
- (b) allow the highest number of service providers possible under the circumstances.

## AMENDED PROPOSAL

2. The criteria for the granting of the authorisation by the competent authority must be transparent, non-discriminatory, objective, relevant and proportional. The criteria may only relate to

- (a) the professional qualifications of the provider, his sound financial situation and sufficient insurance cover;
- (b) maritime safety or the safety of the port or access to it, its installations, equipment and persons;
- (c) employment and social matters, where applicable;
- (d) environmental requirements, where applicable;
- (e) the development plans of the port.

Unchanged

5. The provider of port services carrying out the service covered by the authorisation has the right to employ personnel of his own choice provided he fulfils criteria set according to paragraph 2.

Unchanged

1. Member States may only limit the number of providers of port services for reasons of constraints relating to available space or capacity, to maritime traffic-related safety or in accordance with environmental regulations. The competent authority must:

Unchanged

## INITIAL PROPOSAL

2. Where constraints relating to available space or capacity exist and, for as long as there are no exceptional circumstances in relation to the volume of traffic and categories of cargoes, the competent authority shall authorise at least two service providers for each category of cargo, which shall be completely independent of each other.

3. Where the competent authority deciding on limitations in relation to the port in question is the managing body of that port and where the managing body itself or a service provider over which it has direct or indirect control or is involved in, is, or wishes to become, also a service provider in that port, Member States shall designate a different competent authority and entrust it with the decision, or approval of a decision, on limitations. This newly designated competent authority must be independent of the managing body of the port in question and must not:

- (a) provide port services similar to those provided by any of the service providers in the port in question; and
- (b) have any direct or indirect control over, or be involved in, any of the service providers in the port in question.

## Article 8

**Selection procedure**

1. Where the number of providers of port services has been limited in application of Article 7, the competent authority shall take the necessary measures to ensure a transparent and objective selection procedure, through tendering or an equivalent procedure, using proportionate, non-discriminatory and relevant criteria.

2. The competent authority shall publish in the *Official Journal of the European Communities* an invitation to interested parties to participate in the selection process.

This publication may refer to the competent authority's or the port's own internet web-site or, where there is no such web-site, any other appropriate manner which makes the necessary information available in a timely way to any person interested in the process.

3. The competent authority shall include in its publication

- (a) authorisation and selection criteria that define the authority's minimum requirements;
- (b) award criteria that define the grounds on which the authority will choose among offers meeting the selection criteria and

## AMENDED PROPOSAL

1. Where the number of providers of port services has been limited by the competent authority in application of Article 7, the latter shall take the necessary measures to ensure a transparent and objective selection procedure, through tendering or an equivalent procedure, using proportionate, non-discriminatory and relevant criteria.

Unchanged

- (a) authorisation criteria according to Article 6(2) as well as selection criteria that define the authority's minimum requirements;

- (b) award criteria that define the grounds on which the authority will choose among offers meeting the selection criteria;



## INITIAL PROPOSAL

- (c) conditions setting out the service requirements that the contract will cover and identifying any assets to be placed at the disposal of the successful tenderer together with the relevant terms and applicable rules

4. The procedure shall provide for an interval of at least 52 days between the dispatch of the call for proposals and the latest date for receipt of them.

5. The competent authority shall include in the information it supplies to potential providers all relevant information it holds.

6. Where the competent authority carrying out the selection procedure in relation to the port in question is the managing body of that port and where the managing body itself or a service provider over which it has direct or indirect control or is involved in, is, or wishes to become, a service provider in that port, Member States shall designate a different competent authority and entrust it with the selection procedure in question. This newly designated competent authority must be independent of the managing body of the port in question and must not:

- (a) provide port services similar to those provided by any of the service providers in the port in question; and
- (b) have any direct or indirect control over, or be involved in, any of the service providers in the port in question.

*Article 9***Duration**

Providers of port services shall be selected for a limited period of time to be determined in accordance with the following criteria:

1. In cases where the service provider will make no or insignificant investments in order to carry out the provision of services, the maximum duration of its authorisation shall be 5 years.
2. In cases where the service provider will make significant investments in
  - (a) moveable assets, the maximum period shall be 10 years;
  - (b) immovable assets, the maximum period shall be 25 years, irrespective of whether their ownership will revert to the port.

## AMENDED PROPOSAL

- (c) conditions setting out the service requirements that the contract will cover and identifying any infrastructure and equipment to be placed at the disposal of the successful tenderer together with the relevant terms and applicable rules;

- (d) penalties and the terms governing cancellation in the event of non-compliance; and

- (e) the authorisation period.

Unchanged

6. Where the competent authority carrying out the selection procedure of a specific port service in relation to the port in question is the managing body of that port and where the managing body itself or a service provider over which it has direct or indirect control or is involved in, is, or wishes to become, a provider of the same or a similar service in that port, Member States shall designate a different competent authority and entrust it with the selection procedure in question. This newly designated competent authority must be independent of the managing body of the port in question and must not:

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Article 10***Accounting provisions**

The competent authority shall oblige the selected service providers to keep separate accounts for each port service in question. The compilation of the accounts must accord with current commercial practice and generally recognised accounting principles.

*Article 11***Self-handling**

1. Member States shall take the necessary measures to allow self-handling to be carried out in accordance with this Directive.

2. Self-handling may be subject to an authorisation for which the criteria must not be stricter than those applying to providers of the same or a comparable port service.

2. Self-handling may be subject to an authorisation for which the criteria must be the same as those applying to providers of the same or a comparable port service.

*Article 12***Managing body of the port**

1. Where the managing body of the port provides port services, it must fulfil the criteria set out in Article 6 and separate the accounts of each of its port service activities from the accounts of its other activities. The compilation of the accounts must accord with current commercial practice and generally recognised accounting principles to ensure that:

- (a) the internal accounts corresponding to different activities are separate;
- (b) all costs and revenues are correctly assigned or allocated on the basis of consistently applied and objectively justifiable cost accounting principles;
- (c) the cost accounting principles according to which separate accounts are maintained are clearly identified.

2. The auditor's report on the annual accounts must indicate the existence of any financial flows between the port service activity of the managing body of the port and its other activities. The auditor's report must be kept by the Member States and made available to the Commission upon request.

3. Where as a result of a selection procedure under Article 8 no suitable service provider could be found for a specific port service, the competent authority may, under the conditions of paragraph 1 of this Article, reserve the provision of this service to the managing body of the port for a maximum period of 5 years.

Unchanged

## INITIAL PROPOSAL

4. The managing body of the port shall not discriminate between service providers. It shall in particular refrain from any discrimination in favour of an undertaking or body in which it holds an interest.

5. The provisions of this Directive in no way affect the rights and obligations of Member States in respect of the Transparency Directive 2000/52/EC.

*Article 13***Appeals**

1. Member States shall ensure that any party with a legitimate interest has the right to appeal against the decisions or individual measures taken, under this Directive, by competent authorities or the managing body of the port.

2. Where an application for access to provide port services under this Directive is rejected, the applicant(s) shall be informed of the reasons for not having been authorised or selected. Such reasons must be objective, non-discriminatory, well-founded and duly substantiated. Appeal procedures must be made available to the applicant. It must be possible to bring the appeal before a national court or a public authority that is independent in its organisation, funding, legal structure and decision-making of the competent authority or managing body of the port concerned and from any service provider.

3. Member States shall take the necessary measures to ensure that decisions taken by appeal bodies are subject to judicial review.

*Article 14***Safety, security and environmental protection**

The provisions of this Directive in no way affect the rights and obligations of Member States in respect of law and order, safety and security at ports as well as environmental protection.

*Article 15***Social protection**

Without prejudice to the application of this Directive, and subject to the other provisions of Community law, Member States shall take the necessary measures to ensure the application of their social legislation.

## AMENDED PROPOSAL

The provisions of this Directive in no way affect the rights and obligations of Member States, and of competent authorities appointed by them, in respect of law and order, safety and security at ports as well as environmental protection.

Unchanged

Without prejudice to the application of this Directive, and subject to the other provisions of Community law, Member States shall take the necessary measures to ensure the application of their social legislation. Social standards must not be below those laid down by applicable Community legislation.

## INITIAL PROPOSAL

## AMENDED PROPOSAL

*Article 16*

Unchanged

**Transitional measures**

1. Where the number of providers of port services in a port is not limited by constraints relating to available space or capacity or maritime safety, existing authorisations may remain in force unchanged until such time as the number becomes limited. New authorisations must comply with the provisions of this Directive.

2. Where the number of providers of port services in a port is limited, the rules of points (a) to (e) apply.

(a) Where an existing authorisation was granted after a public tender or an equivalent procedure and is otherwise in conformity with the rules of this Directive, the authorisation may remain in force unchanged.

(b) Where an existing authorisation was not granted in conformity with the rules of this Directive and where the service provider has made no or insignificant investments, a new authorisation procedure in conformity with the rules of this Directive must be carried out within 2 years of the date of transposition of this Directive in the case of a sole service provider and within 4 years in all other cases.

(c) Where in the context of an existing authorisation a service provider has made significant investments in moveable assets, the following shall apply:

(i) Where the authorisation was not granted in conformity with the rules of this Directive but was preceded by a public tender or an equivalent procedure, the maximum duration of the existing authorisation shall be 10 years;

(ii) Where the authorisation was not granted in conformity with the rules of this Directive and was not preceded by a public tender or an equivalent procedure, a new authorisation procedure in conformity with the rules of this Directive must be carried out within 3 years of the date of transposition of this Directive in the case of a sole service provider and within 5 years in all other cases.

## INITIAL PROPOSAL

- (d) Where in the context of an existing authorisation a service provider has made significant investments in immovable assets, the following shall apply:
- (i) Where the authorisation was not granted in conformity with the rules of this Directive but was preceded by a public tender or an equivalent procedure, the maximum duration of the existing authorisation shall be 25 years;
  - (ii) Where the authorisation was not granted in conformity with the rules of this Directive and was not preceded by a public tender or an equivalent procedure, a new authorisation procedure in conformity with the rules of this Directive must be carried out within 5 years of the date of transposition of this Directive in the case of a sole service provider and within 8 years in all other cases.
- (e) Where in the context of an existing authorisation a service provider has made significant investments in moveable and immovable assets, point (d) shall apply.

## AMENDED PROPOSAL

*Article 17***Compensation**

A selected service provider shall, where appropriate, pay compensation for immovable assets it takes over. The competent authority may establish their value prior to a selection procedure.

*Article 17***Information report and revision**

Member States shall send the Commission a report on the application of this Directive no later than 3 years after the date of transposition.

On the basis of the Member States' reports, the Commission will make an assessment of the implementation by Member States of the Directive accompanied, where appropriate, by a proposal for its revision.

*Article 18*

Unchanged

*Article 18***Implementation**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than one year from the date of its entrance into force. They shall forthwith inform the Commission thereof.

*Article 19*

Unchanged

## INITIAL PROPOSAL

## AMENDED PROPOSAL

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

## Article 19

## Article 20

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

Unchanged

## Article 20

## Article 21

Unchanged

**Addressees**

This Directive is addressed to the Member States.

## ANNEX

**LIST OF PORTS SERVICES CONCERNED BY THIS DIRECTIVE**

## 1. Technical-nautical services

Unchanged

(a) Pilotage

(b) Towage

(c) Mooring.

## 2. Cargo handling including

(a) Loading and unloading;

(b) stevedoring, stowage, transshipment and other intra-terminal transport;

Unchanged

(c) Storage, depot and warehousing, depending on cargo categories;

(d) Cargo consolidation.

## 3. Passenger services (including embarkation and disembarkation)

**Proposal for a Council Decision concerning the conclusion of the Agreement on maritime transport between the European Community and its Member States, on the one hand, and the People's Republic of China on the other hand**

(2002/C 181 E/08)

COM(2002) 97 *final* — 2002/0048(CNS)

(Submitted by the Commission on 22 February 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof, in conjunction with the first sentence of the first subparagraph of Article 300(2) and the first subparagraph of Article 300(3) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Whereas the European Community should approve the Agreement on maritime transport between the European Community and its Member States on the one hand, and the People's Republic of China on the other hand,

HAS DECIDED AS FOLLOWS:

*Article 1*

The Agreement on maritime transport between the European Community and its Member States, on the one hand, and the

People's Republic of China, on the other hand, is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

*Article 2*

The President of the Council is hereby authorised to designate the persons empowered to sign the Agreement in order to express the consent of the Community to be bound thereby.

*Article 3*

The President of the Council shall, on behalf of the Community, give the notification provided for in Article 15(2) of the Agreement.

*Article 4*

This Decision shall be published in the *Official Journal of the European Communities*.

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## ANNEX

**DRAFT AGREEMENT ON MARITIME TRANSPORT BETWEEN THE EUROPEAN COMMUNITY AND ITS MEMBER STATES, OF THE ONE PART, AND THE PEOPLE'S REPUBLIC OF CHINA, OF THE OTHER PART**

THE KINGDOM OF BELGIUM,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

IRELAND,

THE ITALIAN REPUBLIC,

THE GRAND DUCHY OF LUXEMBOURG,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE PORTUGUESE REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

Parties to the Treaty establishing the European Community and the Treaty on European Union, hereinafter referred to as the 'European Community Member States', and

THE EUROPEAN COMMUNITY,

of the one part, and

THE PEOPLE'S REPUBLIC OF CHINA

hereinafter referred to as 'China',

of the other part,

TAKING INTO ACCOUNT the Trade and Economic Co-operation Agreement between the European Economic Community and the People's Republic of China of May 1985;

TAKING INTO ACCOUNT the importance of the maritime relations existing between the European Community and its Member States and the People's Republic of China;

BELIEVING that the cooperation in the international maritime field between the Contracting Parties will be beneficial for the development of the trade and economic relations between the People's Republic of China and the European Community and its Member States;

WILLING to further strengthen and consolidate the relations, on the basis of equality and mutual benefit, in the field of international maritime transport;



RECOGNISING the importance of maritime transport services and wishing to promote even further multimodal transport involving a sea leg in order to increase efficiencies in the transport chain;

RECOGNISING the importance of further developing a flexible and market-oriented approach and the benefits to operators of both parties to control and operate their own international cargo transport services in the context of an efficient international maritime transport system;

TAKING INTO ACCOUNT the existing bilateral maritime agreements between the European Community Member States and the People's Republic of China;

SUPPORTING multilateral negotiations on maritime transport services in the World Trade Organisation;

HAVE DECIDED to conclude this Agreement and to this end have designated their plenipotentiaries:

THE KINGDOM OF BELGIUM,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

IRELAND,

THE ITALIAN REPUBLIC,

THE GRAND DUCHY OF LUXEMBOURG,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE PORTUGUESE REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

Parties to the Treaty establishing the European Community and the Treaty on European Union, hereinafter referred to as the 'European Community Member States', and

THE EUROPEAN COMMUNITY,

of the one part, and

THE PEOPLE'S REPUBLIC OF CHINA

WHO, having exchanged their full powers, found in good and due form,

HAVE AGREED AS FOLLOWS:

## Article 1

### Aim

This Agreement is aimed to improve the conditions under which maritime cargo transport operations are carried out to and from China, to and from the European Community, as well as to and from the European Community and China on the one hand and third countries on the other, for the benefit of economic operators. It is based on the principles of freedom to provide maritime transport services, free access to cargoes and cross trades, unrestricted access to and non-discriminatory treatment in the use of ports and auxiliary services as well as regarding commercial presence. It covers all aspects of door-to-door-services.

## Article 2

### Scope

1. This Agreement applies to the international maritime cargo transport and logistic services, including multimodal operations involving a sea leg, between the ports of China and of the Member States of the European Community as well as to the international maritime cargo transport between the ports of the Member States of the European Community. It also applies to cross trades and to the movement of equipment such as empty containers — not being carried as cargo against payment — between ports of China or between ports of a Member State of the European Community.

If vessels of one Contracting Party sail from one port of the other Contracting Party to another or from one port of a Member State of the European Community to another to load cargo for foreign countries or discharge cargo from abroad, it shall be regarded as a part of the international maritime transport.

This Agreement shall not apply to domestic transport purely between the ports of China or between the ports of any particular Member State of the European Community.

2. This Agreement shall not affect the application of the bilateral maritime agreements concluded between China and the Member States of the European Community for issues falling outside the scope of this Agreement.

3. This Agreement shall not affect the right of vessels of third parties to engage in cargo and passenger transport between the ports of the Contracting Parties or between the ports of either Contracting Party and a third party.

## Article 3

### Definitions

For the purpose of this Agreement:

(a) 'International maritime cargo transport and logistic services' cover the supply of services of international maritime

transport of cargo, and the related cargo handling, storage and warehousing services, customs clearance services, container station and depot services, port and inland located, shipping agency services and freight forwarding services;

(b) 'Multimodal transport operations' is the carriage of goods using more than one mode of transport including a sea-leg under a single document;

(c) 'Shipping agency services' means activities consisting in representing, within a given geographic area, as an agent, the business interests of one or more shipping lines or shipping companies, for the following purposes:

— marketing and sales of maritime transport and related services, from quotation to invoicing, and issuance of bills of lading on behalf of the companies, contracting of the necessary related services, preparation of documentation, and provision of business information;

— acting on behalf of the companies organising the call of the ship or taking over cargoes when required;

(d) 'Freight forwarding services' means the activity consisting of organising and monitoring shipment operations on behalf of shippers, through contracting related services, preparation of documentation and provision of business information;

(e) 'Shipping company' means a company which meets the following conditions:

1. to be constituted in accordance with the public or private laws of China, or the European Community or a Member State of the European Community,

2. to have its registered office or central administration or principal place of business in China or the European Community respectively,

3. to engage in international shipping service with its owned or operated vessels.

Shipping companies established outside the European Community or China and controlled by nationals of a Member State of the European Community or of China respectively, shall also be beneficiaries of the provisions of this Agreement, if their vessels are registered in that Member State or in China in accordance with their legislation;

(f) 'Subsidiary' means a company owned by a shipping company and having legal personality;

(g) 'Branch office' means a place of business owned by a shipping company and not having legal personality;

(h) 'Representative office' means a representative office of a shipping company of one Contracting Party established in the other Contracting Party;

(i) 'Vessel' means any merchant ship registered in accordance with the laws of China, or the European Community or its Member States in the vessel registration office of either Contracting Party under the national flag of that Contracting Party and engaged in international maritime transport, including vessels flying the flag of a third country but owned or operated by a shipping company of China or a Member State of the European Community. However, this term does not include warships and any other non-commercial ships.

#### Article 4

##### Supply of services

1. Each Contracting Party shall continue to grant non-discriminatory treatment to vessels flying the flag of the other party or operated by nationals or companies of the other Party, as compared to the treatment accorded to its own vessels, with regard to access to ports, the use of infrastructure and auxiliary maritime services of those ports, as well as related fees and charges, customs formalities and assignment of berths and facilities for loading and unloading.

2. The Contracting Parties undertake to apply effectively the principle of unrestricted access to the international maritime market and traffic on a non-discriminatory and commercial basis.

3. In applying the principles of paragraphs 1 and 2, the Contracting Parties shall:

(a) not introduce cargo sharing clauses in future agreements with third countries concerning maritime transport services and terminate such provisions in the case they exist in previous bilateral agreements within a reasonable period of time;

(b) abolish, upon entry into force of this Agreement, all unilateral administrative, technical, or other measures, which could constitute an indirect restriction and have discriminatory effects on the free supply of services in international maritime transport;

(c) abstain from implementing on entry into force of this Agreement administrative, technical or legislative measures which could have the effect of discriminating against nationals or companies of the other Party in the supply of services in international maritime transport.

4. One Contracting Party shall allow shipping companies of the other Contracting Party to have access to and use of, on a non-discriminatory basis and on agreed terms between the companies concerned, feeder services provided by shipping companies registered in the former Contracting Party for the

international cargo between the ports of China or between the ports of a Member State of the European Community.

#### Article 5

##### Commercial presence

In respect of activities for the provision of international maritime cargo transport and logistic services, including door-to-door multimodal operations, each Contracting Party shall permit the shipping companies of the other Party, to establish wholly-owned or jointly-invested subsidiaries, branches or representative offices and, as regards subsidiaries and branches to engage in economic activities, in accordance with its laws and regulations. Such activities include, but are not limited to:

1. cargo soliciting and booking of space;
2. making, confirming, handling and issuing of the bill of lading, including the commonly accepted through bill of lading in the international maritime transport; preparation of documentation concerning transport documents and customs documents;
3. fixing, collecting and remitting freight and other charges incurred on the basis of the service contracts or tariff rates;
4. negotiating and signing service contracts;
5. signing contracts for trucking, railway transport, cargo dealing and other related auxiliary services;
6. quoting and publishing tariff rates;
7. engaging in marketing activities related to their service;
8. owning the equipment necessary for the economic activities;
9. provision of business information by any means, including computerised information systems and electronic data interchange (subject to any non-discriminatory restrictions concerning telecommunications);
10. setting up joint ventures with any locally established shipping agency to engage in agency related businesses, such as organising the call of the vessels or taking delivery of cargoes for shipment.

#### Article 6

##### Transparency

1. Each Contracting Party shall, after prior consultation and appropriate pre-notice, publish promptly all relevant measures of general application, which pertain to or affect the operation of this Agreement.

2. Where publication as referred to in paragraph 1 is not practicable, such information shall be made otherwise publicly available.

3. Each Contracting Party shall respond promptly to all requests by the other Party for specific information on any of its measures of general application within the meaning of paragraph 1.

#### *Article 7*

##### **Domestic regulation**

1. The Contracting Parties shall ensure that all measures of general application affecting trade in international maritime transport services are administered in a reasonable, objective and impartial manner.

2. In those cases where authorisation is required, the competent authorities of a Contracting Party shall, within a reasonable period of time after the submission of an application considered complete under domestic laws and regulations, inform the applicant of the decision concerning the application. At the request of the applicant, the competent authorities of a Contracting Party shall provide, without undue delay, information concerning the status of the application.

3. To ensure that measures relating to technical standards and licensing requirements and procedures do not constitute unnecessary barriers to trade, requirements shall be based on objective, non-discriminatory, pre-established and transparent criteria, such as the ability to supply the service; and in the case of licensing procedures, not in themselves be a restriction on or a barrier to the supply of the service.

#### *Article 8*

##### **Key personnel**

The wholly-owned or jointly-invested subsidiaries, branches or representative offices of the shipping companies of one Contracting Party established in the other Contracting Party shall be entitled to employ key personnel, in accordance with the legislation in force in the host country, irrespective of their nationality. Each Contracting Party shall facilitate the acquisition of work permits and visas for foreign employees.

#### *Article 9*

##### **Payments and capital movements**

1. Revenues of nationals or companies of one Contracting Party derived from international maritime transport and multimodal operations in the other Contracting Party may be settled in freely convertible currencies.

2. The revenues and expenses of the economic activities of the subsidiaries, branches and representative offices of the shipping companies of a Contracting Party established in the other Contracting Party may be settled in the currency of the

host country. The balance after the payment of the local fees by the abovementioned shipping companies, subsidiaries, branches or representative offices may be freely remitted abroad at the exchange rate of the bank on the date of remittance.

#### *Article 10*

##### **Maritime cooperation**

The Contracting Parties shall, for the purpose of promoting the development of the maritime industry of the Contracting Parties, encourage their competent authorities, shipping companies, ports, relevant research institutions, universities and colleges to co-operate, including in, but not limited to, the following fields:

1. to exchange views related to their activities in the framework of international maritime organisations;
2. to formulate and perfect the legislation relating to maritime transport and market administration;
3. to promote efficient transport service for international sea trade by the effective exploitation of the ports and fleets of the Contracting Parties;
4. to guarantee shipping safety and to prevent marine pollution;
5. to promote maritime education and training, especially the training of seafarers;
6. to exchange personnel, scientific information and technology;
7. to enhance their efforts to combat piracy and terrorism.

#### *Article 11*

##### **Consultations and settlement of disputes**

1. The Contracting Parties shall establish appropriate procedures to ensure the proper implementation of the Agreement.
2. Should any dispute between the Contracting Parties arise from the interpretation or application of this Agreement, the competent authorities of the Contracting Parties shall seek to resolve the dispute through friendly consultation. In the event that no agreement is reached, it shall be settled through the diplomatic channel.

#### *Article 12*

##### **Amendment**

This Agreement may be amended by a written agreement between the Contracting Parties and the amendment will come into force in accordance with the procedures specified in paragraph 2 of Article 15 of this Agreement.

*Article 13***Territorial application**

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of China.

*Article 14***Authentic text**

This Agreement is drawn up in duplicate in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Chinese languages, each of these texts being equally authentic.

*Article 15***Duration and entry into force**

1. The Agreement is concluded for a period of five years. It shall be tacitly renewed on a yearly basis unless one of the Contracting Parties denounces it in writing six months before the date of expiry.

2. This Agreement will be approved by the Contracting Parties in accordance with their own procedures.

This Agreement shall enter into force on the first day of the second month following the date on which the Contracting Parties notify each other that the procedures referred to in the first paragraph have been completed.

3. If this Agreement is less favorable on certain issues than existing bilateral agreements between individual European Community Member States and China, the more favorable provisions shall prevail without prejudice to Community obligations and taking into account the Treaty. The provisions of this Agreement replace those of previous bilateral agreements concluded between European Community Member States and China, if the latter provisions are either inconsistent with the former, save for the situation referred to in the preceding sentence, or identical to them. Provisions of existing bilateral agreements not covered by this Agreement shall continue to apply.

IN WITNESS WHEREOF the undersigned Plenipotentiaries have signed this Agreement.

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**Proposal for a Directive of the European Parliament and of the Council on the recognition of professional qualifications**

(2002/C 181 E/09)

(Text with EEA relevance)

COM(2002) 119 final — 2002/0061(COD)

*(Submitted by the Commission on 7 March 2002)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 40, Article 47(1), the first and third sentences of Article 47(2), and Article 55 thereof,

Having regard to the proposal from the Commission,

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

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

Whereas:

(1) Pursuant to Article 3(1)(c) of the Treaty, the abolition, as between Member States, of obstacles to the free movement of persons and services is one of the objectives of the Community. For nationals of the Member States, this includes, in particular, the right to exercise a profession, in a self-employed or employed capacity, in a Member State other than the one in which they have obtained their professional qualifications. In addition, Article 47(1) of the Treaty lays down that directives shall be issued for the mutual recognition of diplomas, certificates and other evidence of formal qualifications.

(2) Following the European Council of Lisbon on 23 and 24 March 2000, the Commission adopted a Communication on 'An Internal Market Strategy for Services'<sup>(1)</sup>, aimed in particular at making the free provision of services within the Community as simple as within an individual Member State. Further to the Communication from the Commission entitled 'New European Labour Markets, Open to All, with Access to All'<sup>(2)</sup>, the

European Council of Stockholm on 23 and 24 March 2001 entrusted the Commission with presenting 'for the 2002 Spring European Council [...] specific proposals for a more uniform, transparent and flexible regime of recognition of qualifications [...]'.

(3) The guarantee conferred by this Directive on persons having acquired their professional qualifications in a Member State to have access to the same profession and pursue it in another Member State with the same rights as nationals is without prejudice to compliance by the migrant professional with any non-discriminatory conditions of access which might be laid down by the latter Member State, provided that these are objectively justified and proportionate.

(4) In order to facilitate the free provision of services, there should be specific rules aimed at extending the exercise of professional activities under the original professional title. In the case of information society services provided at a distance, the provisions of 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<sup>(3)</sup> also apply.

(5) In view of the different systems established for the provision of services on the one hand, and for establishment on the other, the criteria for distinguishing between these two concepts in the event of the movement of the service provider to the territory of the host Member State must be clarified by establishing a simple presumption based on a time criterion.

(6) While maintaining, for the freedom of establishment, the principles and safeguards underlying the different systems for recognition in force, their rules must be improved in the light of experience. Moreover, the relevant directives have been amended on several occasions, and their provisions must be reorganised and rationalised by standardising the principles applicable. It is therefore

<sup>(1)</sup> Document COM(2000) 888.

<sup>(2)</sup> Document COM(2001) 116.

<sup>(3)</sup> OJ L 178, 17.7.2000, p. 1.

necessary to replace Council Directives 89/48/EEC <sup>(1)</sup> and 92/51/EEC <sup>(2)</sup>, as well as Directive 1999/42/EC of the European Parliament and of the Council <sup>(3)</sup> on the general system for the recognition of professional qualifications, and Council Directives 77/452/EEC <sup>(4)</sup>, 77/453/EEC <sup>(5)</sup>, 78/686/EEC <sup>(6)</sup>, 78/687/EEC <sup>(7)</sup>, 78/1026/EEC <sup>(8)</sup>, 78/1027/EEC <sup>(9)</sup>, 80/154/EEC <sup>(10)</sup>, 80/155/EEC <sup>(11)</sup>, 85/384/EEC <sup>(12)</sup>, 85/432/EEC <sup>(13)</sup>, 85/433/EEC <sup>(14)</sup> and 93/16/EEC <sup>(15)</sup> concerning the professions of nurse responsible for general care, dental practitioner, veterinary surgeon, midwife, architect, pharmacist and doctor, as last amended by Directive 2001/19/EC of the European Parliament and of the Council <sup>(16)</sup>, by combining them in a single text.

(7) In the case of the professions covered by the general system for the recognition of qualifications, hereinafter referred to as 'the general system', the Member States retain the right to lay down the minimum level of qualification required to ensure the quality of the services provided on their territory. However, pursuant to Articles 10, 39 and 43 of the EC Treaty, they may not require a national of a Member State to obtain qualifications, which they generally lay down only in terms of the diplomas awarded under their national educational system, where the person concerned has already obtained all or part of their qualifications in another Member State. As a result, it should be laid down that any host Member State in which a profession is regulated must take account of the qualifications obtained in another Member State and assess whether they correspond to those which it requires.

(8) Absent harmonisation of the minimum training conditions for access to the professions governed by the general system, it must be possible for the host Member States to impose a compensation measure. This measure must be proportionate and, in particular, take account of the applicant's professional experience. Experience shows that requiring the migrant to choose between an aptitude test or an adaptation period offers adequate safeguards as

regards the latter's level of qualification, so that any derogation from that choice should in each case be justified by an imperative requirement in the general interest.

(9) In order to promote the free movement of workers, freedom of establishment and the free provision of services, while ensuring an adequate level of qualification, various professional associations and organisations have established common platforms at European level under which professionals meeting a number of criteria relating to professional qualifications are awarded the right to bear the professional title awarded by those associations or organisations. The Directive should take account, under certain conditions and in compliance with Community law, and in particular Community law on competition, of those initiatives, while promoting, in this context, a more automatic character of recognition under the general system.

(10) In order to take into account all situations for which there was still no provision relating to the recognition of professional qualifications, the general system must be extended to those cases which are not covered by a specific system, either where the profession is not covered by one of those systems or where, although the profession is covered by such a specific system, the applicant does not meet the conditions to benefit from it.

(11) There is a need to simplify the rules allowing access to a number of industrial, commercial and craft activities, in Member States where those professions are regulated, in so far as those activities have been pursued for a reasonable and sufficiently recent period of time in another Member State, while maintaining for those activities a system of automatic recognition based on professional experience.

(12) Freedom of movement and the mutual recognition of the evidence of formal training of doctors, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives, pharmacists and architects must be based on the fundamental principle of automatic recognition of the evidence of formal qualifications on the basis of coordinated minimum conditions for training. In addition, access in the Member States to the professions of doctor, nurse responsible for general care, dental practitioner, veterinary surgeon, midwife and pharmacist must be made conditional upon the possession of a given qualification ensuring that the person concerned has undergone training which meets the minimum conditions laid down. This system must be supplemented by a number of acquired rights from which qualified professionals benefit under certain conditions.

<sup>(1)</sup> OJ L 19, 24.1.1989, p. 16.

<sup>(2)</sup> OJ L 209, 24.7.1992, p. 25.

<sup>(3)</sup> OJ L 201, 31.7.1999, p. 77.

<sup>(4)</sup> OJ L 176, 15.7.1977, p. 1.

<sup>(5)</sup> OJ L 176, 15.7.1977, p. 8.

<sup>(6)</sup> OJ L 233, 24.8.1978, p. 1.

<sup>(7)</sup> OJ L 233, 24.8.1978, p. 10.

<sup>(8)</sup> OJ L 362, 23.12.1978, p. 1.

<sup>(9)</sup> OJ L 362, 23.12.1978, p. 7.

<sup>(10)</sup> OJ L 33, 11.2.1980, p. 1.

<sup>(11)</sup> OJ L 33, 11.2.1980, p. 8.

<sup>(12)</sup> OJ L 223, 21.8.1985, p. 15.

<sup>(13)</sup> OJ L 253, 24.9.1985, p. 34.

<sup>(14)</sup> OJ L 253, 24.9.1985, p. 37.

<sup>(15)</sup> OJ L 165, 7.7.1993, p. 1.

<sup>(16)</sup> OJ L 206, 31.7.2001, p. 1.

- (13) The professional activities of general practitioners are covered by a specific system which differs from that for basic practitioners and specialised medical practitioners. The Member States cannot therefore recognise any medical specialism which has a field of professional activity similar to that of general practitioners.
- (14) In an effort to simplify the system, particularly with a view to enlargement, the principle of automatic recognition must apply only to those medical specialisms which are common to and obligatory for all the Member States. Those medical specialisms which are common to a limited number of Member States must be incorporated into the general system for recognition without prejudice to the established rights. In practice, the effects of this amendment should be limited for the migrant, in so far as these situations should not be subject to compensation measures. Moreover, this Directive is without prejudice to the possibility for Member States to establish, amongst themselves, automatic recognition for certain medical and dental specialisms common to them according to their own rules.
- (15) All Member States must recognise the profession of dental practitioner as a specific profession distinct from that of medical practitioner, whether or not specialised in odontostomatology. The Member States must ensure that the training given to dental practitioners equips them with the skills needed for prevention, diagnosis and treatment relating to anomalies and illnesses of the teeth, mouth, jaws and associated tissues. The professional activity of the dental practitioner must be carried out by holders of a qualification as dental practitioner set out in this Directive.
- (16) It did not appear desirable to lay down standardised training for midwives for all the Member States. Rather, the latter should have the greatest possible freedom to organise their training.
- (17) With a view to simplifying this Directive, reference should be made to the concept of 'pharmacist' in order to delimit the scope of the provisions relating to the automatic recognition of the qualifications, without prejudice to the special features of the national regulations governing those activities.
- (18) Holders of qualifications as a pharmacist are specialists in the field of medicines and must, in principle, have access in all Member States to a minimum range of activities in this field. In defining this minimum range, this Directive must neither have the effect of limiting the activities accessible to pharmacists in the Member States — in particular as regards medical biology analyses — nor create a monopoly for those professionals, as this remains a matter solely for the Member States. The provisions of this Directive are without prejudice to the possibility for the Member States to impose supplementary training conditions for access to activities not included in the coordinated minimum range of activities. This means that the host Member State must be able to impose these conditions on the nationals who hold qualifications which are covered by automatic recognition within the meaning of this Directive.
- (19) This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the exercise of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from exercising certain pharmacist's activities or subjecting them to certain conditions.
- (20) Architectural design, the quality of buildings, their harmonious incorporation into their surroundings, respect for natural and urban landscapes and for the public and private heritage are a matter of public interest. Mutual recognition of qualifications must therefore be based on qualitative and quantitative criteria which ensure that the holders of recognised qualifications are in a position to understand and translate the needs of individuals, social groups and authorities as regards spatial planning, the design, organisation and realisation of structures, conservation and the exploitation of the architectural heritage, and protection of natural balances.
- (21) National regulations in the field of architecture and on access to and the exercise of the professional activities of an architect vary widely in scope. In most Member States, activities in the field of architecture are exercised, de jure or de facto, by persons bearing the title of architect alone or accompanied by another title, without those persons having a monopoly on the exercise of such activities, unless there are legislative provisions to the contrary. These activities, or some of them, may also be exercised by other professionals, in particular by engineers who have undergone special training in the field of construction or the art of building. With a view to simplifying this Directive, reference should be made to the concept of 'architect' in order to delimit the scope of the provisions relating to the automatic recognition of the qualifications, without prejudice to the special features of the national regulations governing those activities.
- (22) In order to ensure the effectiveness of the system for the recognition of professional qualifications, uniform formalities and rules of procedure must be defined for its implementation, as well as certain details of the exercise of the profession.



- (23) Since collaboration among the Member States and between them and the Commission is likely to facilitate the implementation of this Directive and compliance with the obligations deriving from it, the means of collaboration must be organised.
- (24) Administering the various systems of recognition set up by the sectoral directives and the general system has proved cumbersome and complex. There is therefore a need to simplify the administration and updating of this Directive to take account of scientific and technical progress, in particular where the minimum conditions of training are coordinated with a view to automatic recognition of qualifications. A single committee for the recognition of professional qualifications must be set up for this purpose.
- (25) Pursuant to Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>, the measures needed to implement this Directive should be adopted according to the procedure laid down in Article 5 of that Decision.
- (26) The preparation by the Member States of a periodic report on the implementation of this Directive, containing statistical data, will make it possible to determine the impact of the system for the recognition of professional qualifications.
- (27) There should be a suitable procedure for adopting temporary measures if the application of any provision of this Directive were to encounter major difficulties in a Member State.
- (28) The provisions of this Directive do not affect the powers of the Member States as regards the organisation of their national social security system and determining the activities which must be exercised under that system.
- (29) In view of the speed of technological change and scientific progress, life-long learning is of particular importance for a large number of professions. In this context, it is for the Member States to adopt the detailed arrangements under which, through suitable ongoing training, professionals will keep abreast of technical and scientific progress.
- (30) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, the objectives of the proposed measure, that is the rationalisation, simplification and improvement of the rules for the recognition of professional qualifications, cannot be sufficiently achieved by the Member States and can therefore be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.

- (31) This Directive is without prejudice to the application of Article 39(4) and Article 45 of the Treaty, nor of the measures necessary to ensure a high level of health and consumer protection,

HAVE ADOPTED THIS DIRECTIVE:

## TITLE I

### GENERAL PROVISIONS

#### Article 1

##### Purpose

This Directive establishes rules according to which a Member State which makes access to or pursuit of a regulated profession in its territory contingent upon possession of specific professional qualifications (referred to hereafter as the 'host Member State') shall accept professional qualifications obtained in one or more other Member States (referred to hereafter as the 'home Member State') and which allow the holder of the said qualifications to pursue the same profession there, as a sufficient condition for access to and pursuit of that profession.

#### Article 2

##### Scope

1. This Directive shall apply to all nationals of a Member State wishing to practise a regulated profession in a Member State other than that in which they obtained their professional qualifications, on either a self-employed or employed basis.

2. Each Member State may permit persons in possession of evidence of formal qualifications not obtained in a Member State to perform regulated professional activities on its territory, in accordance with its rules. In the case of professions covered by Title III, Chapter III, this initial recognition must respect the minimum training conditions laid down in that Chapter.

#### Article 3

##### Definitions

1. For the purposes of this Directive, the following terms are defined as follows:

- (a) regulated profession: a professional activity or group of professional activities, access to which, the practice of which, or one of the modes of pursuit is subject, directly or indirectly, to legislative, regulatory or administrative provisions concerning possession of specific professional qualifications;
- (b) professional qualifications: qualifications attested by evidence of formal training, an attestation of competence referred to in Article 11(2)(a) and/or professional experience;

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

(c) evidence of formal qualifications: diplomas, certificates and other evidence issued by an authority in a Member State and certifying successful completion of professional training obtained mainly in the Community.

2. A profession practised by the members of an association or organisation listed in Annex I is treated as a regulated profession.

On each occasion that a Member State grants recognition to an association or organisation referred to in the first paragraph, it shall inform the Commission, which shall issue an appropriate notification in the *Official Journal of the European Communities*.

3. Evidence of formal training issued by a non-member country shall be regarded as evidence of formal qualifications if the holder has three years' professional experience, certified by the Member State which recognised that evidence of formal qualifications in accordance with Article 2(2).

#### Article 4

##### Effects of recognition

1. The recognition of professional qualifications by the host Member State allows the beneficiary to gain access in that Member State to the same profession to that for which he is qualified in the home Member State and to practise it in the host Member State with the same rights as its nationals.

2. For the purposes of this Directive, the profession which the applicant wishes to pursue in the host Member State is the same as that for which he is qualified in his home Member State if the activities covered are similar.

3. Where the profession for which the applicant is qualified in the home Member State constitutes an autonomous activity a profession covering a wider field of activities in the host Member State and where the difference cannot be made up by a compensatory measure referred to in Article 14, the recognition of the applicant's qualifications gives him access to that activity alone in the host Member State.

#### TITLE II

##### FREE MOVEMENT OF SERVICES

#### Article 5

##### Principle of the free provision of services

1. Without prejudice to Article 6(2), Member States shall not restrict, for any reason relating to professional qualifications, the free provision of services in another Member State:

(a) if the service provider is legally established in a Member State for the purpose of practising the same professional activity there, and

(b) where the service provider moves, if he has practised that activity for at least two years in the Member State of establishment when the profession is not regulated in that Member State.

2. For the purposes of this Directive, where the service provider moves to the territory of the host Member State, the pursuit of a professional activity for a period of not more than sixteen weeks per year in a Member State by a professional established in another Member State shall be presumed to constitute a 'provision of services'.

The presumption referred to in the previous paragraph shall not preclude assessment on a case-by-case basis, for example, in the light of the duration of the provision, its frequency, regularity and continuity.

3. The service shall be provided under the professional title of the Member State in which the service provider is legally established, insofar as such a title exists in that Member State for the professional activity in question.

That title shall be indicated in the official language or one of the official languages of the Member State of establishment in such a way as to avoid any confusion with the professional qualification of the host Member State.

#### Article 6

##### Exemptions

Pursuant to Article 5(1), the host Member State shall exempt service providers established in another Member State from the requirements which it places on professionals established in its territory relating to:

- (a) authorisation by, registration with or membership of a professional organisation or body;
- (b) registration with a public social security body for the purpose of settling accounts with an insurer relating to activities pursued for the benefit of insured persons.

The service provider shall, however, inform in advance or, in an urgent case, afterwards, the body referred to in point (b) of the first paragraph of the services which he has provided.

#### Article 7

##### Information to be provided in advance if the service provider moves

Where the service provider moves in order to provide services, he shall, in advance, inform the contact point of the Member State of establishment, referred to in Article 53. In urgent cases, the service provider shall inform the contact point of that Member State as soon as possible after the services have been provided.

## Article 8

**Administrative cooperation**

The competent authorities of the host Member State may ask the competent authorities of the Member State of establishment to provide proof of the service provider's nationality and proof that he is legally practising the activities in question in that Member State. The competent authorities of the Member State of establishment shall provide this information in accordance with the provisions of Article 52.

Furthermore, in the cases referred to in Article 5.1(b), the competent authorities of the host Member State may ask the contact point of the Member State of establishment, referred to in Article 53, to provide proof that the service provider has practised the activities in question in the Member State of establishment for at least two years. Such proof may take any form.

## Article 9

**Information to be given to the recipients of the service**

In addition to the other requirements relating to information contained in Community law, the Member States shall ensure that the service provider furnishes the recipient of the services with the following information:

- (a) if the service provider is registered in a commercial register or similar public register, the commercial register in which he is registered, his registration number, or equivalent means of identification contained in that register;
- (b) if the activity is subject to authorisation in the Member State of establishment, the name and address of the competent supervisory authority;
- (c) any professional association or similar body with which the service provider is registered;
- (d) the professional qualification and the Member State in which it was awarded;
- (e) a reference to the professional rules applicable in the Member State of establishment and to the means of gaining access to those rules;
- (f) if the service provider performs an activity which is subject to VAT, the VAT identification number referred to in Article 22(1) of the Sixth Council Directive 77/388/EEC <sup>(1)</sup>.

<sup>(1)</sup> OJ L 145, 13.6.1977, p. 1. Directive last amended by Directive 1999/85/EC (OJ L 277, 28.10.1999, p. 34).

## TITLE III

**FREEDOM OF ESTABLISHMENT**

## CHAPTER I

**GENERAL SYSTEM FOR THE RECOGNITION OF EVIDENCE OF TRAINING**

## Article 10

**Scope**

This Chapter applies to all professions which are not covered by Chapters II and III of this Title and to all cases in which the applicant does not satisfy the conditions laid down in those Chapters.

## Article 11

**Levels of qualification**

1. For the purpose of applying Article 13, the following five levels of professional qualification are established:

- (a) level 1, 'attestation of competence';
- (b) level 2, 'certificate';
- (c) level 3, 'diploma certifying successful completion of a short training course';
- (d) level 4, 'diploma certifying successful completion of an intermediate training course';
- (e) level 5, 'diploma certifying successful completion of a higher training course'.

2. Level 1 corresponds to:

- (a) an attestation of competence issued by a competent authority in the home Member State on the basis of a very short training course, a specific examination without prior training or full-time practice of the profession in a Member State for three consecutive years or for an equivalent duration on a part-time basis during the previous 10 years;
- (b) general primary or secondary education, attesting that the holder has acquired general knowledge.

3. Level 2 corresponds to training at secondary level, of a professional nature or general in character, supplemented by a professional course.

4. Level 3 corresponds to training at post-secondary level and of a duration of at least one year and less than three years.

The following shall be treated as level-3 training courses:

- (a) training courses with a special structure which provide a comparable professional standard and which prepare the trainee for a comparable level of responsibilities and functions. The courses listed in Annex II are specific examples;

(b) regulated training which is specifically directed to the practice of a particular profession and which consists of a course of education supplemented, where appropriate, by professional training, probationary or professional practice, for which the structure and level are laid down in the legislative, regulatory or administrative provisions of the Member State in question, or which are subject to control or approval by the authority designated for that purpose. The regulated training courses listed in Annex III are specific examples.

5. Level 4 corresponds to a course of training at higher or university level and of a duration of at least three years and less than four years.

The following shall be treated as level-4 training: Regulated training which is directly aimed at the practice of a particular profession and which consist of a three-year programme of post-secondary study or a part-time programme of post-secondary study of equivalent duration, carried out in a university or an institution providing an equivalent level of training, and, possibly, professional training, probationary or professional practice required in addition to the programme of post-secondary study.

The structure and level of the professional training, probationary or professional practice shall be laid down in the legislative, regulatory or administrative provisions of the Member State in question or be subject to control or approval by the authority designated for that purpose.

6. Level 5 corresponds to training at higher education level and of a minimum duration of four years.

The following shall be treated as level-5 training: regulated training aimed specifically at the pursuit of a particular profession and which consists of a programme of post-secondary study of at least four years' duration or a programme of part-time post-secondary study of equivalent duration, carried out in a university or an institution providing an equivalent level of training and, possibly, professional training, probationary or professional practice required in addition to a programme of post-secondary study.

The structure and level of the professional training, probationary or professional practice shall be laid down in the legislative, regulatory or administrative provisions of the Member State in question or be subject to supervision or approval by the authority designated for that purpose.

#### Article 12

##### Conditions for recognition

Any document or set of documents issued by a competent authority in a Member State, certifying successful completion of training in the Community, recognised by that Member State as being of an equivalent level and conferring on the holder the same rights of access to or pursuit of a profession, shall be treated as proof of training of the type covered by Article 11, including the level in question.

Any professional qualification which, although not satisfying the requirements contained in the legislative, regulatory or administrative provisions in force in the home Member State for access to or the practice of a profession, confers on the holder acquired rights by virtue of these provisions, shall be treated as a professional qualification under the first paragraph and under the same conditions.

#### Article 13

##### Conditions for recognition

1. If access to or pursuit of a regulated profession in a host Member State is contingent upon possession of specific professional qualifications, the competent authority of that Member State shall permit access to and pursuit of that profession, under the same conditions as apply to its nationals, to applicants possessing the attestation of competence or evidence of formal training required by another Member State in order to gain access to and pursue that profession on its territory.

Attestations of competence or evidence of formal training shall satisfy the following conditions:

- (a) they shall have been obtained in another Member State;
- (b) they shall attest a level of professional qualification at least equivalent to the level immediately below that which is required in the host Member State, as described in Article 11.

2. Access to and pursuit of the profession, as described in paragraph 1, shall also be granted to applicants who have practised the profession referred to in that paragraph on a full-time basis for two years during the previous 10 years in another Member State which does not regulate that profession, providing they possess one or more attestations of competence or documents providing evidence of formal training.

Attestations of competence and evidence of formal training shall satisfy the following conditions:

- (a) they shall have been issued by a competent authority in a Member State, designated in accordance with the legislative, regulatory or administrative provisions of that Member State;
- (b) they shall attest a level of professional qualification at least equivalent to the level immediately below that required in the host Member State, as described in Article 11;
- (c) they shall attest that the holder has been prepared for the practice of the profession in question.

The two years' professional experience referred to in the first subparagraph may not, however, be required if the evidence of formal training which the applicant possesses, and which is referred to in that subparagraph, certifies regulated training within the meaning of Article 11.4(b), 11.5, second subparagraph and 11.6, second subparagraph.

#### Article 14

##### Compensation measures

1. Article 13 does not preclude the host Member State from requiring the applicant to complete an adaptation period of up to three years or to take an aptitude test if:

- (a) the duration of the training of which he provides evidence under the terms of Article 13, paragraph 1 or 2, is at least one year shorter than that required by the host Member State;
- (b) the training he has received covers substantially different matters than those covered by the evidence of formal training required in the host Member State;
- (c) the regulated profession in the host Member State comprises one or more regulated professional activities which do not exist in the corresponding profession in the applicant's home Member State within the meaning of Article 4(2), and that difference consists in specific training which is required in the host Member State and which covers substantially different matters from those covered by the applicant's attestation of competence or evidence of formal training.

2. If the host Member State makes use of the option provided for in paragraph 1, it must offer the applicant the choice between an adaptation period and an aptitude test.

Where a Member State considers, with respect to a given profession, that it is necessary to derogate from the requirement, set out in the previous subparagraph, that it give the applicant a choice between an adaptation period and an aptitude test, it shall inform the other Member States and the Commission in advance and provide sufficient justification for the derogation.

If, after receiving all necessary information, the Commission considers that the derogation referred to in the second subparagraph is inappropriate or that it is not in accordance with Community law, it shall, within three months, ask the Member State in question to refrain from taking the envisaged measure. In the absence of a response from the Commission within the abovementioned deadline, the derogation may be applied.

3. For the purpose of applying paragraph 1(b) and (c), 'substantially different matters' means matters of which knowledge is essential for practising the profession and with regard to which the training received by the migrant shows important differences in terms of duration or content from the training required by the host Member State.

4. Paragraph 1 shall be applied with due regard to the principle of proportionality. In particular, if the host Member State intends to require the applicant to complete an adaptation period or take an aptitude test, it must first ascertain whether the knowledge acquired by the applicant in the course

of his professional experience in a Member State or in a non-member country, is of a nature to cover, in full or in part, the substantial difference referred to in paragraph 3.

#### Article 15

##### Waiving of compensation measures on the basis of common platforms

1. Professional associations may notify the Commission of common platforms which they establish at European level. For the purposes of this Article, 'common platform' means a set of criteria of professional qualifications which attest to a sufficient level of competence for the pursuit of a given profession and on the basis of which those associations accredit the qualifications obtained in the Member States.

If the Commission is of the opinion that the platform in question facilitates the mutual recognition of professional qualifications, it shall inform the Member States thereof and shall take a decision in accordance with the procedure referred to in Article 54(2).

2. Where the applicant's qualifications satisfy the criteria established by a decision within the meaning of paragraph 1, the host Member State shall waive application of Article 14.

3. If a Member State considers that a common platform no longer offers adequate guarantees with regard to professional qualifications, it shall inform the Commission accordingly, which shall, if appropriate, take a decision in accordance with the procedure referred to in Article 54(2).

## CHAPTER II

### RECOGNITION OF PROFESSIONAL EXPERIENCE

#### Article 16

##### Requirements regarding professional experience

If, in a Member State, access to or pursuit of one of the activities listed in Annex IV is contingent upon possession of general, commercial or professional knowledge and aptitudes, that Member State shall recognise previous pursuit of the activity in another Member State as sufficient proof of such knowledge and aptitudes. The activity must have been pursued in accordance with Articles 17 and 18.

#### Article 17

##### Activities referred to in list I of Annex IV

1. For the activities in list I of Annex IV, the activity in question must have been previously pursued:

- (a) either for five consecutive years on a self-employed basis or as a company director,

- (b) or for three consecutive years on a self-employed basis or as a company director, where the beneficiary proves that he has received previous training of at least three years for the activity in question, evidenced by a certificate recognised by that Member State or judged by a competent professional body to be fully valid,
- (c) or for four consecutive years on a self-employed basis or as a company director, where the beneficiary can prove that he has received, for the activity in question, previous training of at least two years' duration, attested by a certificate recognised by the Member State or judged by a competent professional body to be fully valid,
- (d) or for three consecutive years on a self-employed basis or as a company director, if the beneficiary can prove that he has performed the activity in question on an employed basis for at least five years,
- (e) either five consecutive years on an employed basis, if the beneficiary can prove that he has received, for the activity in question, previous training of at least three years' duration, as attested by a certificate recognised by that Member State or judged by a competent professional body to be fully valid,
- (f) or for six consecutive years on an employed basis, if the beneficiary can prove that he has received previous training in the activity in question of at least two years' duration, as attested by a certificate recognised by that Member State or judged by a competent professional body to be fully valid.

2. In cases (a) and (d), the activity must not have finished more than 10 years before the date on which the complete application was submitted by the person concerned to the competent authority referred to in Article 52.

#### Article 18

##### Activities referred to in list II of Annex IV

1. For the activities in list II of Annex IV, the activity in question must have been previously pursued:
  - (a) for three consecutive years, either on a self-employed basis or as a company director,
  - (b) or for two consecutive years, either on a self-employed basis or as a company director, if the beneficiary can prove that he has received previous training for the activity in question, as attested by a certificate recognised by that Member States or judged by a competent professional body to be fully valid,
  - (c) or for two consecutive years, either on a self-employed basis or as a company director, if the beneficiary can prove that he has pursued the activity in question on an employed basis for at least three years,

- (d) or for three consecutive years, on an employed basis, if the beneficiary can prove that he has received previous training for the activity in question, as attested by a certificate recognised by that Member State or judged by a competent professional body to be fully valid.

2. In cases (a) and (c), the activity must not have ended more than ten years prior to the date on which the complete application is presented by the person concerned to the competent authority referred to in Article 52.

#### Article 19

##### Amendment of the list of activities in Annex IV

The lists of activities in Annex IV which are the subject of recognition of professional experience pursuant to Article 16 may be amended in accordance with the procedure referred to in Article 54(2).

#### CHAPTER III

#### RECOGNITION ON THE BASIS OF COORDINATION OF MINIMUM TRAINING CONDITIONS

##### Section 1

##### General provisions

#### Article 20

##### Principle of automatic recognition

1. Each Member State shall recognise evidence of training giving access to the professional activities of general practitioner and specialised doctor, nurse responsible for general care, dental practitioner, veterinary surgeon, pharmacist and architect, listed in Annex V, points 5.1.2, 5.1.3, 5.2.3, 5.3.3, 5.4.3, 5.6.4 and 5.7.2 respectively, which satisfy the minimum training conditions referred to in Articles 22, 23, 29, 32, 35, 40 and 42 respectively, and shall, for the purposes of access to and pursuit of the professional activities, give such evidence the same effect on its territory as the evidence of formal training which it itself issues.

Such evidence of formal qualifications must be issued by the competent bodies in the Member States and accompanied, where appropriate, by the certificates listed in Annex V, points 5.1.2, 5.1.3, 5.2.3, 5.3.3, 5.4.3, 5.6.4 and 5.7.2 respectively.

The provisions of subparagraphs 1 and 2 do not affect the acquired rights referred to in Articles 21, 25, 31, 34 and 45.

2. Each Member State shall recognise, for the purpose of pursuing general medical activities in the framework of its national social security system, evidence of formal training listed in Annex V, point 5.1.5 and issued to nationals of the Member States by the other Member States in accordance with the minimum training conditions laid down in Article 26.

The provisions of the previous subparagraph do not affect the acquired rights referred to in Article 28.

3. Each Member State shall recognise evidence of formal training as a midwife, awarded to nationals of Member States by the other Member States, listed in Annex V, point 5.5.4, which complies with the minimum training conditions referred to in Article 36 and satisfies the criteria set out in Article 37, and shall, for the purposes of access to and pursuit of the professional activities, give such evidence the same effect on its territory as the evidence of formal training which it itself issues. This provision does not affect the acquired rights referred to in Articles 21 and 39.

4. Evidence of formal training as an architect referred to in Annex V, point 5.7.2, which is subject to automatic recognition pursuant to paragraph 1, proves completion of a course of training which began not earlier than during the academic reference year referred to in that Annex.

5. Each Member State shall make access to and pursuit of the professional activities of doctors, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists subject to possession of evidence of formal training referred to in Annex V, points 5.1.2, 5.1.3, 5.1.5, 5.2.3, 5.3.3, 5.4.3, 5.5.4 and 5.6.4 respectively, attesting that the person concerned has acquired, over the duration of his training, and where appropriate, the knowledge and aptitudes referred to in Annex V, points 5.1.1, 5.2.1, 5.3.1, 5.4.1, 5.5.1 and 5.6.1.

The knowledge and aptitudes referred to in Annex V, points 5.1.1, 5.2.1, 5.3.1, 5.4.1, 5.5.1 and 5.6.1, may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting them to scientific and technical progress.

Such updates shall not entail, for any Member State, an amendment of its existing legislative principles regarding the structure of professions as regards training and conditions of access by natural persons.

6. Each Member State shall notify the Commission of the legislative, regulatory and administrative provisions which it adopts with regard to the issuing of evidence of formal training in the area covered by this Chapter.

The Commission shall publish an appropriate communication in the *Official Journal of the European Communities*, indicating the

titles adopted by the Member States for evidence of formal training and, where appropriate, the body which issues the evidence of formal training, the certificate which accompanies it and the corresponding professional title referred to in Annex V, points 5.1.2, 5.1.3, 5.1.5, 5.2.3, 5.3.3, 5.4.3, 5.5.4, 5.6.4 and 5.7.2 respectively.

#### Article 21

##### Acquired rights

1. Without prejudice to the acquired rights specific to the professions concerned, in cases where the evidence of medical training provides access to the professional activities of general practitioners and specialised doctors, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists held by nationals of Member States do not satisfy all the training requirements referred to in Articles 22, 23, 29, 32, 35, 36 and 40, each Member State shall recognise as sufficient proof certificates of training issued by those Member States insofar as they attest successful completion of training which began before the reference dates laid down in Annex V, points 5.1.2, 5.1.3, 5.2.3, 5.3.3, 5.4.3, 5.5.4 and 5.6.4 and are accompanied by a certificate stating that the holders have been effectively and lawfully engaged in the activities in question for at least three consecutive years during the five years preceding the award of the certificate.

2. The same provisions shall apply to evidence of medical training providing access to the professional activities of general practitioners, specialised doctors, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists obtained in the territory of the former German Democratic Republic and which do not satisfy all the minimum training requirements laid down in Articles 22, 23, 29, 32, 35, 36 and 40 if they certify successful completion of training which began before:

(a) 3 October 1989 for general practitioners, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists, and

(b) 3 April 1992 for specialised doctors.

The evidence of training referred to in the first subparagraph confers on the holder the right to pursue professional activities throughout German territory under the same conditions as evidence of formal training issued by the competent German authorities referred to in Annex V, points 5.1.2, 5.1.3, 5.2.3, 5.3.3, 5.4.3, 5.5.4 and 5.6.4.

3. Each Member State shall recognise as sufficient proof for nationals of Member States whose evidence of formal training as a doctor, nurse responsible for general care, dental practitioner, veterinary surgeon, midwife and pharmacist does not correspond to the titles given for that Member State in Annex V, points 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.2.3, 5.3.3, 5.4.3, 5.5.4 and 5.6.4, evidence of formal training issued by those Member States accompanied by a certificate issued by the competent authorities or bodies.

The certificate referred to in the first subparagraph shall state that the evidence of formal training certifies successful completion of training in accordance with Articles 22, 23, 26, 29, 32, 35, 36 and 40 respectively of this Directive and is treated by the Member State which issued it in the same way as the qualifications whose titles are listed in Annex V, points 5.1.2., 5.1.3, 5.1.4, 5.1.5, 5.2.3, 5.3.3, 5.4.3, 5.5.4 and 5.6.4.

## Section 2

### *Doctors of medicine*

#### *Article 22*

#### **Basic medical training**

1. Admission to basic medical training shall be contingent upon possession of a diploma or certificate providing access, for the studies in question, to universities or institutes of a Member State which provide higher education of a level recognised as being of an equivalent level, for the studies in question, of a Member State.

2. Basic medical training shall comprise a total of at least six years of study or 5 500 hours of theoretical and practical training provided by, or under the supervision of, a university.

For persons who began their studies before 1 January 1972, the course of training referred to in paragraph 1 may comprise six months of full-time practical training at university level under the supervision of the competent authorities.

3. Continuous training shall ensure, in accordance with the procedures specific to each Member State, that persons who have completed their studies are able to keep abreast of medical progress.

#### *Article 23*

#### **Specialist medical training**

1. Admission to specialist medical training shall be contingent upon completion and validation of six years of study as part of a training programme referred to in Article 22 in the course of which the trainee has acquired the relevant knowledge of general medicine.

2. Specialist medical training shall comprise theoretical and practical training at a university or medical teaching hospital or, where appropriate, a medical care establishment approved for that purpose by the competent authorities or bodies.

The Member States shall ensure that the minimum duration of specialist medical training courses referred to in Annex V, point 5.1.4 is not less than the duration provided for in that point.

Training shall be given under the supervision of the competent authorities or bodies. It shall include personal participation of the trainee specialised doctor in the activity and responsibilities entailed by the services in question.

3. Training shall be given on a full-time basis at specific establishments which are recognised by the competent authorities. It shall entail participation in the full range of medical activities of the department where the training is given, including duty on call, in such a way that the trainee specialist devotes all his professional activity to his practical and theoretical training throughout the entire working week and throughout the year, in accordance with the procedures laid down by the competent authorities. Accordingly, these posts shall be the subject of appropriate remuneration.

This training may be interrupted for reasons such as military service, scientific missions, pregnancy or illness. Such interruptions may not result in a reduction in the overall duration of the training.

4. By way of exception, the Member States may authorise part-time specialist training, under conditions allowed by the competent national authorities, if, in the light of individual justified circumstances, full-time training is not feasible. The competent authorities shall ensure that the overall duration and quality of part-time specialist training shall not be lower than that of full-time training. This level may not be compromised by the part-time nature of the training, nor by the pursuit of paid professional activity.

The part-time training of specialised doctors shall satisfy the same requirements as full-time training, from which it is distinguished only by the possibility of limiting the participation in medical activities to a duration of at least half of that provided for with full-time training.

Such part-time training shall therefore be the subject of appropriate remuneration.

5. The Member States shall make the issuance of evidence of specialist medical training contingent upon possession of evidence of basic medical training referred to in Annex V, point 5.1.2.

6. The minimum periods of training referred to in Annex V, point 5.1.4 may be amended in accordance with the procedure referred to in Article 54(2).



*Article 24***Types of specialist medical training**

Evidence of formal training as a specialised doctor referred to in Article 20 is such evidence awarded by the competent authorities or bodies referred to in Annex V, point 5.1.3 as corresponds, for the specialised training in question, to the titles in use in the various Member States and referred to in Annex V, point 5.1.4.

The inclusion in Annex V, point 5.1.4 of new medical specialties common to all the Member States may be decided on in accordance with the procedure referred to in Article 54(2).

*Article 25***Acquired rights specific to specialised doctors**

1. A host Member State may require of specialised doctors whose part-time specialist medical training was governed by legislative, regulatory and administrative provisions in force as of 20 June 1975 and who began their specialist training no later than 31 December 1983 that their evidence of formal training be accompanied by a certificate stating that they have been effectively and lawfully engaged in the relevant activities for at least three consecutive years during the five years preceding the award of that certificate.

2. Every Member State shall recognise the qualification of specialised doctors awarded in Spain to doctors who completed their specialist training before 1 January 1995, even if that training does not satisfy the minimum training requirements provided for in Article 23, insofar as that qualification is accompanied by a certificate issued by the competent Spanish authorities and attesting that the person concerned has passed the examination in specific professional competence held in the context of exceptional measures concerning recognition laid down in Royal Decree 1497/99, with a view to ascertaining that the person concerned possesses a level of knowledge and aptitude comparable to that of doctors who possess a qualification as a specialised doctor defined for Spain in Annex V, points 5.1.3 and 5.1.4.

3. Every Member State which applies relevant legislative, regulatory or administrative provisions shall accept as sufficient proof evidence of formal training as a specialised doctor issued by other Member States which correspond, for the specialist training in question, to the titles listed in Annex VI, point 6.1, insofar as they attest a course of training which began before the reference date referred to in Annex V, point 5.1.3 and are accompanied by a certificate stating that the holders have been effectively and lawfully engaged in the activities in question for at least three consecutive years during the five years preceding the award of the certificate.

The same provisions shall apply to evidence of specialist medical training obtained in the territory of the former German Democratic Republic if they attest a course of

training which began before 3 April 1992 and confer on the holder the right to pursue the professional activities throughout German territory under the same conditions as evidence of formal training awarded by the competent German authorities referred to in Annex VI, point 6.1.

4. Every Member State which applies relevant legislative, regulatory or administrative provisions shall accept evidence of specialist medical training corresponding, for the specialist training in question, to the titles listed in Annex VI, point 6.1, awarded by the Member States listed therein and attesting a course of training which began after the reference date laid down in Annex V, point 5.1.3 and before the deadline laid down in Article 58, and shall, for the purposes of access to and pursuit of the professional activities of specialised doctor, give such evidence the same effect on its territory as certificates of training which it itself issues.

5. Every Member State which has repealed its legislative, regulatory or administrative provisions relating to the award of certificates of specialist medical training referred to in Annex VI, point 6.1 and which has adopted measures relating to acquired rights benefiting its nationals, shall grant nationals of other Member States the right to benefit from those measures, insofar as these certificates were issued before the date on which the host Member State ceased to issue certificates of training for the specialty in question.

The dates on which these provisions were repealed are set out in Annex VI, point 6.1.

*Article 26***Training of general practitioners**

1. Admission to general medical training shall be contingent on the completion and validation of six years of study as part of a training programme referred to in Article 22.

2. The training of general practitioners leading to the award of evidence of formal qualifications issued before 1 January 2006 shall be of a duration of at least two years on a full-time basis. In the case of certificates of training issued after that date, the training shall be of a duration of at least three years on a full-time basis.

Where the training programme referred to in Article 22 comprises practical training given by an approved hospital possessing appropriate general medical equipment and services or as part of an approved general medical practice or an approved centre in which doctors provide primary medical care, the duration of that practical training may, up to a maximum of one year, be included in the duration provided for in the first subparagraph for certificates of training issued on or after 1 January 2006.

The option provided for in the second subparagraph is only available for Member States in which the training of general practitioners lasted two years as of 1 January 2001.

3. The training of general practitioners shall be carried out on a full-time basis, under the supervision of the competent authorities or bodies. It shall be more practical than theoretical.

The practical training shall be given, on the one hand, for at least six months in an approved hospital possessing appropriate equipment and services and, on the other hand, for at least six months as part of an approved general medical practice or an approved centre at which doctors provide primary health care.

The practical training shall take place in conjunction with other health establishments or structures concerned with general medicine. Without prejudice to the minimum periods laid down in the second subparagraph, however, the practical training may be given during a period of not more than six months in other approved establishments or health structures concerned with general medicine.

The training shall require the personal participation of the trainee in the professional activity and responsibilities of the persons with whom he is working.

4. By way of exception, Member States may authorise specific courses of general medical training on a part-time basis, of a level qualitatively equivalent to full-time training, insofar as the following conditions are met:

- (a) the fact that the training is followed on a part-time basis does not reduce the total duration of the training;
- (b) the weekly duration of part-time training is not less than half of the weekly duration of full-time training;
- (c) part-time training includes a certain number of periods of full-time training, both for the part given in a hospital environment and the part given in an approved general medical practice or an approved centre in which doctors provide primary health care. The number and duration of these periods of full-time training must be such as to provide adequate preparation for the practice of general medicine.

5. Member States shall make the issuance of evidence of general medical training subject to possession of one of the certificates of general medical training referred to in Annex V, point 5.1.2.

6. Member States may issue certificates of training referred to in Annex V, point 5.1.5 to a doctor who has not completed

the training provided for in this Article but who has completed a different, supplementary training, as attested by evidence of formal training issued by the competent authorities in a Member State. They may not, however, award evidence of formal training unless it attests knowledge of a level equivalent to the knowledge acquired from the training provided for in this Article.

Member States shall determine, *inter alia*, the extent to which the complementary training and professional experience already acquired by the applicant may replace the training provided for in this Article.

The Member States may only issue the evidence of formal training referred to in Annex V, point 5.1.5 if the applicant has acquired at least six months' experience of general medicine in a general medical practice or a centre in which doctors provide primary health care of the types referred to in paragraph 3 of this Article.

#### Article 27

##### **Pursuit of the professional activities of general practitioners**

Each Member State shall, subject to the provisions relating to acquired rights, make the pursuit of the activities of a general practitioner in the framework of its national social security system contingent upon possession of evidence of formal training referred to in Annex V, point 5.1.5.

Member States may exempt persons who are currently undergoing specific training in general medicine from this condition.

#### Article 28

##### **Acquired rights specific to general practitioners**

1. Each Member State shall determine the acquired rights. It shall, however, confer as an acquired right the right to perform the activities of a general practitioner in the framework of its national social security system, without the evidence of formal qualifications referred to in Annex V, point 5.1.5, on all doctors who enjoy this right as of the reference date stated in that point by virtue of provisions applicable to the medical profession giving access to the professional activities of general practitioner and who are established as of that date on its territory, having benefited from the provisions of Article 20 or Article 21.

The competent authorities of each Member State shall, on demand, issue a certificate stating the holder's right to pursue the activities of general practitioner in the framework of their national social security systems, without the evidence of formal qualifications referred to in Annex V, point 5.1.5, to doctors who enjoy acquired rights pursuant to the first subparagraph.

2. Every Member State shall recognise the certificates referred to in paragraph 1, second subparagraph, awarded to nationals of Member States by the other Member States, and shall give such evidence the same effect on its territory as evidence of formal training which it awards and which permit the pursuit of the activities of a general practitioner in the framework of its national social security system.

### Section 3

#### *Nurses responsible for general care*

##### Article 29

#### **Training of nurses responsible for general care**

1. Admission to training for nurses responsible for general care shall be contingent upon completion of general education of 10 years, as attested by a diploma, certificate or other evidence issued by the competent authorities or bodies in a Member State or by a certificate attesting success in an examination, of an equivalent level, for admission to a school of nursing.

2. Training of nurses responsible for general care shall be given on a full-time basis and shall include at least the programme described in Annex V, point 5.2.2.

The content listed in Annex V, point 5.2.2 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting it to scientific and technical progress.

Such updates may not entail, for any Member State, any amendment of its existing legislative principles relating to the structure of professions as regards training and the conditions of access by natural persons.

3. The training of nurses responsible for general care shall comprise at least three years of study or 4 600 hours of theoretical and clinical training, the duration of the theoretical training representing at least one-third and the duration of the clinical training at least one-half of the minimum duration of the training. Member States may grant partial exemptions to persons who have received part of their training on courses which are of at least an equivalent level.

The Member States shall ensure that institutions providing nurse training are responsible for the coordination of theo-

retical and clinical training throughout the entire study programme.

By way of exception, the Member States may authorise part-time training under conditions allowed by the competent national authorities. The total duration of part-time training may not be less than that of full-time training, and the level of training may not be compromised by the fact that it is given on a part-time basis.

4. Theoretical training is that part of nurse training from which trainee nurses acquire the professional knowledge, insights and aptitudes necessary for organising, dispensing and evaluating overall health care. The training shall be given by teachers of nursing care and by other competent persons, in nursing schools and other training establishments selected by the training institution.

5. Clinical training is that part of nurse training in which trainee nurses learn, as part of a team and in direct contact with a healthy or sick individual and/or community, to organise, dispense and evaluate the required comprehensive nursing care, on the basis of the knowledge and aptitudes which they have acquired. The trainee nurse shall learn not only how to work in a team, but also how to lead a team and organise overall nursing care, including health education for individuals and small groups, within the health institute or in the community.

This training shall take place in hospitals and other health institutions and in the community, under the responsibility of nursing teachers, in cooperation with and assisted by other qualified nurses. Other qualified personnel may also take part in the teaching process.

Trainee nurses shall participate in the activities of the department in question insofar as those activities are appropriate to their training, enabling them to learn to assume the responsibilities involved in nursing care.

##### Article 30

#### **Performance of the professional activities of nurses responsible for general care**

For the purposes of this Directive, the professional activities of nurses responsible for general care are the activities performed on a professional basis and referred to in Annex V, point 5.2.3.

*Article 31***Acquired rights specific to nurses responsible for general care**

Where the general rules of acquired rights apply to nurses responsible for general care, the activities referred to in Article 21 must have included full responsibility for the planning, organisation and administration of nursing care delivered to the patient.

*Section 4***Dental practitioners***Article 32***Dental training**

1. Admission to training as a dental practitioner presupposes possession of a diploma or certificate giving access, for the studies in question, to universities or higher institutes of a level recognised as equivalent, in a Member State.

2. Dental training shall comprise a total of at least five years of full-time theoretical and practical study, comprising at least the programme described in Annex 5.3.2 and given in a university, in a higher institute providing training recognised as being of an equivalent level or under the supervision of a university.

The content listed in Annex V, point 5.3.2 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting it to scientific and technical progress.

Such updates may not entail, for any Member State, any amendment of its existing legislative principles relating to the system of professions as regards training and the conditions of access by natural persons.

*Article 33***Performance of the professional activities of dental practitioners**

1. For the purposes of this Directive, the professional activities of dental practitioners are the activities defined in paragraph 3 and pursued under the professional qualifications listed in Annex V, point 5.3.3.

2. The profession of dental practitioner is based on dental training referred to in Article 32 and shall constitute a specific profession which is distinct from other general or specialised medical professions. Pursuit of the activities of a dental practitioner requires the possession of evidence of formal qualifications referred to in Annex V, point 5.3.3. Holders of such evidence of formal qualifications shall be treated in the same way as those to whom Articles 21 or 34 apply.

3. The Member States shall ensure that dental practitioners are generally able to gain access to and pursue the activities of prevention, diagnosis and treatment of anomalies and diseases affecting the teeth, mouth, jaws and adjoining tissue, having due regard to the regulatory provisions and rules of professional ethics on the reference dates referred to in Annex V, point 5.3.3.

*Article 34***Acquired rights specific to dental practitioners**

1. Every Member State shall, for the purposes of the pursuit of the professional activities of dental practitioners under the qualifications listed in Annex V, point 5.3.3, recognise evidence of medical training issued in Italy, Spain and Austria to persons who began their medical training on or before the reference date stated in that Annex for the Member State concerned, accompanied by a certificate issued by the competent authorities of that Member State.

The certificate must show that the two following conditions are met:

- (a) that the persons in question have been effectively, lawfully and principally engaged in that Member State in the activities referred to in Article 33 for at least three consecutive years during the five years preceding the award of the certificate,
- (b) that those persons are authorised to pursue the said activities under the same conditions as holders of evidence of formal qualifications listed for that Member State in Annex V, point 5.3.3.

Persons who have successfully completed at least three years of study, certified by the competent authorities in the Member State concerned as being equivalent to the training referred to in Article 32, shall be exempted from the three-year practical work experience referred to in the second indent, point (a).

2. Each Member State shall recognise evidence of medical training issued in Italy to persons who began their university medical training after 28 January 1980 and no later than 31 December 1984, accompanied by a certificate issued by the competent Italian authorities.

The certificate must show that the three following conditions are met:

- (a) that the persons in questions passed the relevant aptitude test held by the competent Italian authorities with a view to establishing that those persons possess a level of knowledge and aptitudes comparable to that of persons possessing evidence of formal qualifications listed for Italy in Annex V, point 5.3.3,

- (b) that they have been effectively, lawfully and principally engaged in the activities referred to in Article 33 in Italy for at least three consecutive years during the five years preceding the award of the certificate,
- (c) that they are authorised to engage in or are effectively, lawfully and principally engaged in the activities referred to in Article 33, under the same conditions as the holders of evidence of formal training listed for Italy in Annex V, point 5.3.3.

Persons who have successfully completed at least three years of study certified by the competent authorities as being equivalent to the training referred to in Article 32 shall be exempt from the aptitude test referred to in the second subparagraph, point (a).

3. Every Member State which applies relevant legislative, regulatory or administrative provisions shall accept evidence of dental training issued by the other Member States and referred to in Annex VI, point 6.2 as sufficient proof, insofar as they attest a course of training which began before the reference date referred to in that Annex and if they are accompanied by a certificate stating that the holder has been effectively and lawfully engaged in the activities in question for at least three consecutive years during the five years previous to the date of issue of the attestation.

The same provisions shall apply to evidence of formal training as a specialised dental practitioner acquired in the territory of the former German Democratic Republic, insofar as they attest a course of training which began before 3 October 1989 and confer on the holder the right to pursue the professional activities throughout German territory under the same conditions as evidence of formal training issued by the competent German authorities referred to in Annex VI, point 6.2.

4. Every Member State which applies relevant legislative, regulatory or administrative provisions shall accept evidence of dental training referred to in Annex VI, point 6.2, awarded by the Member States listed therein and which attests a course of training which began after the reference date referred to in that Annex and before the deadline laid down in Article 58, and shall, for the purposes of access to the professional activities of specialised dental practitioners and the performance of those activities, give such evidence the same effect on its territory as the evidence of training which it itself issues.

## Section 5

### **Veterinary surgeons**

#### *Article 35*

#### **The training of veterinary surgeons**

1. The training of veterinary surgeons shall comprise a total of at least five years of full-time theoretical and practical study

at a university or at a higher institute providing training recognised as being of an equivalent level, or under the supervision of a university, covering at least the study programme referred to in Annex V, point 5.4.2.

The content listed in Annex V, point 5.4.2 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting it to scientific and technical progress.

Such updates may not entail, for any Member State, any amendment of its existing legislative principles relating to the structure of professions as regards training and conditions of access by natural persons.

2. Admission to veterinary training shall be contingent upon possession of a diploma or certificate entitling the holder to enter, for the studies in question, university establishments or institutes of higher education recognised by a Member State to be of an equivalent level for the purpose of the relevant study.

## Section 6

### **Midwives**

#### *Article 36*

#### **The training of midwives**

1. The training of midwives shall comprise a total of at least:

- (a) specific full-time training as a midwife comprising at least three years of theoretical and practical study (route I) comprising at least the programme described in Annex V, point 5.5.2, or
- (b) specific full-time training as a midwife of 18 months' duration (route II) comprising at least the study programme described in Annex V, point 5.5.2, which was not the subject of equivalent training of nurses responsible for general care.

The Member States shall ensure that institutions providing midwife training are responsible for coordinating theory and practice throughout the programme of study.

The content listed in Annex V, point 5.5.2 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting it to scientific and technical progress.

Such updates must not entail, for any Member State, any amendment of existing legislative principles relating to the structure of professions as regards training and the conditions of access by natural persons.

2. Access to training as a midwife shall be contingent upon one of the following conditions:

- (a) completion of at least the first ten years of general school education for route I, or
- (b) possession of evidence of formal qualifications as a nurse responsible for general care referred to in Annex V, point 5.2.3 for route II.

3. By way of exception, the Member States may authorise part-time training, under the conditions allowed by the competent national authorities. The total duration of part-time training may not be less than that of full-time training, and the level of training may not be compromised by its part-time character.

#### Article 37

##### **Procedures for the recognition of evidence of formal qualifications as a midwife**

1. The certificates of training as a midwife referred to in Annex V, point 5.5.4 shall be subject to automatic recognition pursuant to Article 20 insofar as they satisfy one of the following criteria:

- (a) Full-time training of at least three years as a midwife:
  - (i) either made contingent upon possession of a diploma, certificate or other evidence of qualification giving access to universities or higher education institutes, or otherwise guaranteeing an equivalent level of knowledge; or
  - (ii) is followed by a two-year practical work experience for which a certificate has been issued in accordance with paragraph 2.
- (b) Full-time training as a midwife of at least two years or 3 600 hours, contingent upon possession of evidence of formal training as a nurse responsible for general care referred to in Annex V, point 5.2.3.
- (c) Full-time training as a midwife of at least 18 months or 3 000 hours, contingent upon possession of evidence of formal training as a nurse responsible for general care referred to in Annex V, point 5.2.3 and followed by one year's professional practice for which a certificate has been issued in accordance with paragraph 2.

2. The certificate referred to in paragraph 1 shall be issued by the competent authorities in the home Member State. It shall certify that the holder, after obtaining evidence of formal training as a midwife, has satisfactorily performed all the activities of a midwife for a corresponding period in a hospital or a health care establishment approved for that purpose.

#### Article 38

##### **Pursuit of the professional activities of a midwife**

1. The provisions of this sub-section shall apply to the activities of midwives as defined by each Member State, without prejudice to paragraph 2, and pursued under the professional qualifications set out in Annex V, point 5.5.4.

2. The Member States shall ensure that midwives are able to gain access to and pursue at least the activities listed in Annex V, point 5.5.3.

#### Article 39

##### **Acquired rights specific to midwives**

1. Every Member State shall, in the case of nationals of Member States whose evidence of formal qualifications as a midwife satisfies all the minimum training requirements laid down in Article 36 but which, by virtue of Article 37, is not recognised unless it is accompanied by a certificate of practical work experience referred to in Article 37(2), recognise as sufficient proof certificates of training issued by those Member States before the reference date referred to in Annex V, point 5.5.4, accompanied by a certificate stating that those nationals have been effectively and lawfully engaged in the activities in question for at least two consecutive years during the five years preceding the award of the certificate.

2. The conditions laid down in paragraph 1 shall apply to the nationals of Member States whose evidence of formal training as a midwife certifies completion of training received in the territory of the former German Democratic Republic and which satisfies all the minimum training requirements laid down in Article 36 but which, by virtue of Article 37, must not be recognised unless they are accompanied by the attestation of professional experience referred to in Article 37(2), insofar as they attest a course of training which began before 3 October 1989.

#### Section 7

##### **Pharmacist**

#### Article 40

##### **Training as a pharmacist**

1. Admission to a course of training as a pharmacist shall be contingent upon possession of a diploma or certificate giving access, in a Member State, to the studies in question, at universities or higher institutes of a level recognised as equivalent.

2. Evidence of formal qualifications as a pharmacist attesting training of at least five years' duration, including at least:

- (a) four years of full-time theoretical and practical training at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university;
- (b) six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department.

That training cycle shall include at least the programme described in Annex V, point 5.6.2.

The contents listed in Annex V, point 5.6.2 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting them to scientific and technical progress.

Such updates must not entail, for any Member State, any amendment of existing legislative principles relating to the structure of professions as regards training and the conditions of access by natural persons.

#### Article 41

##### **Pursuit of the professional activities of a pharmacist**

1. For the purposes of this Directive, the activities of a pharmacist are those, access to which and pursuit of which are contingent, in one or more Member States, upon professional qualifications and which are open to holders of evidence of formal training of the types listed in Annex V, point 5.6.4.

2. The Member States shall ensure that the holders of evidence of university training in pharmacy or of a level deemed to be equivalent, which satisfies the provisions of Article 40, are able to gain access to and pursue at least the activities listed in Annex V, point 5.6.3, subject to the requirement, where appropriate, of supplementary professional experience.

3. If a Member State makes access to or pursuit of one of the activities of a pharmacist contingent upon supplementary professional experience, in addition to possession of evidence of formal qualifications referred to in Annex V, point 5.6.4, that Member State shall recognise as sufficient proof in this regard a certificate issued by the competent authorities in the home Member State stating that the person concerned has been engaged in those activities in the home Member State for a similar period.

4. If, on 16 September 1985, a Member State has a competitive examination in place designed to select from among the holders referred to in paragraph 1, those who are to be authorised to become owners of new pharmacies whose creation has been decided on as part of a national system of geographical division, that Member State may, by way of derogation from paragraph 1, proceed with that examination and require nationals of Member States who possess evidence of

formal qualifications as a pharmacist referred to in Annex V, point 5.6.4 or who benefit from the provisions of Article 21 to take part in it.

#### Section 8

##### **Architect**

##### *Article 42*

##### **Training of architects**

1. Training as an architect shall comprise a total of at least four years of full-time study or six years of study, at least three years of which on a full-time basis, at a university or comparable teaching institution. The training must lead to successful completion of a university-level examination.

That training, which must be of university level, and of which architecture is the principal component, must maintain a balance between theoretical and practical aspects of architectural training and guarantee the acquisition of the knowledge and aptitudes listed in Annex V, point 5.7.1.

2. The knowledge and aptitudes listed in Annex V, point 5.7.1 may be amended in accordance with the procedure referred to in Article 54(2) with a view to adapting them to scientific and technical progress.

Such updates must not entail, for any Member State, any amendment of existing legislative principles relating to the structure of professions as regards training and the conditions of access by natural persons.

#### Article 43

##### **Derogations from the conditions for the training of architects**

1. By way of derogation from Article 42, the following shall also be recognised as satisfying Article 20: training existing as of 5 August 1985, provided by 'Fachhochschulen' in the Federal Republic of Germany over a period of three years, satisfying the requirements referred to in Article 42 and giving access to the activities referred to in Article 44 in that Member State under the professional title of 'architect', insofar as the training was followed by a four-year period of professional experience in the Federal Republic of Germany, as attested by a certificate issued by the professional association in whose roll the name of the architect wishing to benefit from the provisions of this Directive appears.

The professional association must first ascertain that the work performed by the architect concerned in the field of architecture represents convincing application of the full range of knowledge and aptitudes listed in Annex V, point 5.7.1. That certificate shall be awarded in line with the same procedure as that applying to registration in the professional association's roll.

2. By way of derogation from Article 42, the following shall also be recognised as satisfying Article 20: training as part of social promotion schemes or part-time university studies, training which satisfies the requirements referred to in Article 42, as attested by an examination in architecture passed by a person who has been working for six years or more in the field of architecture under the supervision of an architect or architectural bureau. The examination must be of university level and be equivalent to the final examination referred to in Article 42(1), subparagraph 1.

#### Article 44

##### **Performance of the professional activities of architects**

1. For the purposes of this Directive, the professional activities of an architect are the activities regularly carried out under the professional title of 'architect'.

2. Nationals of a Member State who are authorised to use that title pursuant to a law which gives the competent authority of a Member State the power to award that title to nationals of Member States who are especially distinguished by the quality of their work in the field of architecture shall be deemed to satisfy the conditions required for the pursuit of the activities of an architect, in the professional capacity of an architect. The architectural qualifications of the persons concerned shall be attested by a certificate awarded by their home Member State.

#### Article 45

##### **Acquired rights specific to architects**

1. Each Member State shall accept certificates of training as an architect listed in Annex VI, point 6.3, awarded by the other Member States, and attesting a course of training which began no later than the academic reference year referred to in the abovementioned Annex, even if they do not satisfy the minimum requirements laid down in Article 42, and shall, for the purposes of access to and pursuit of the professional activities of an architect, give such evidence the same effect on its territory as certificates of training as an architect which it itself issues.

Under these circumstances, certificates issued by the competent authorities of the Federal Republic of Germany attesting that evidence of formal qualifications issued on or after 8 May 1945 by the competent authorities of the German Democratic Republic is equivalent to such evidence listed in the said Annex, shall be recognised.

2. Without prejudice to paragraph 1, every Member State shall recognise the following evidence of formal training and shall, for the purposes of access to and pursuit of the professional activities of an architect performed, give them the same effect on its territory as evidence of formal training which it itself issues: certificates issued to nationals of Member States by the Member States which have enacted regulations governing the access to and pursuit of the activities of an architect as of the following dates:

— 1 January 1995 for Austria, Finland and Sweden

— 5 August 1987 for the other Member States,

The certificates referred to in paragraph 1 shall certify that the holder was authorised, no later than the respective date, to use the professional title of architect, and that he has been effectively engaged, in the context of this legislation, in the activities in question for at least three consecutive years during the five years preceding the award of the certificate.

#### CHAPTER IV

##### **COMMON PROVISIONS ON ESTABLISHMENT**

#### Article 46

##### **Documentation and formalities**

1. Where the competent authorities of the host Member State decide on an application to pursue the regulated profession in question by virtue of this Title, those authorities may demand the documents and certificates listed in Annex VII.

The documents referred to in Annex VII, point 1, shall not be more than three months old by the date on which they are submitted.

The Member States, bodies and other legal persons shall guarantee the confidentiality of the information which they receive.

2. The host Member State may, if it knows of any serious, specific circumstances which have arisen prior to that person's establishment in that Member State outside its territory, and which are liable to have consequences in that Member State for the pursuit of the activities in question, inform the home Member State accordingly.

The home Member State shall examine the veracity of the circumstances and its authorities shall decide on the nature and scope of the investigations which need to be carried out and shall inform the host Member State of the conclusions which it draws from the information available to it.

3. Where a host Member State requires its nationals to swear a solemn oath or make a sworn statement in order to gain access to a regulated profession, and where the wording of that oath or statement cannot be used by nationals of the other Member States, the host Member State shall ensure that the persons concerned can use an appropriate equivalent wording.

#### Article 47

##### **Procedure for the mutual recognition of professional qualifications**

1. The competent authority of the host Member State shall acknowledge receipt of the application within one month of receipt and inform the applicant of any missing document.



2. The procedure for examining an application to practise a regulated profession must be completed as quickly as possible and lead to a duly substantiated decision by the competent authority in the host Member State no later than three months after the date on which the applicant's complete file was submitted.

3. The decision, or failure to reach a decision within the deadline, shall be subject to appeal under national law.

#### Article 48

##### Use of professional titles

1. If, in a host Member State, the use of a professional title relating to one of the activities of the profession in question is regulated, nationals of the other Member States who are authorised to practise a regulated profession on the basis of Title III shall use the professional qualification of the host Member State, which corresponds to that profession in that Member State, and make use of any associated initials.

If, however, pursuant to Article 4(3), access to a profession in the host Member State is partial, that Member State may add a reference to that effect to the professional qualification.

2. Where a profession is regulated in the host Member State by an association or organisation listed in Annex I, nationals of Member States shall not be authorised to use the professional title issued by that organisation or association, or its abbreviated form, unless they furnish proof that they are members of that association or organisation.

If the association or organisation makes membership contingent upon certain qualifications, it may only do so in respect of nationals of other Member States who possess professional qualifications within the meaning of Article 3, second indent, under the conditions laid down in this Directive.

#### Article 49

##### Knowledge of languages

1. Persons benefiting from the recognition of professional qualifications shall have a knowledge of languages necessary for practising the profession in the host Member State.

2. The Member States shall ensure that, where appropriate, the beneficiaries acquire the language knowledge necessary for performing their professional activity in the host Member State.

#### TITLE IV

##### DETAILED RULES FOR PURSUING THE PROFESSION

#### Article 50

##### Use of titles

Without prejudice to Articles 5(3) and 48, the host Member State shall ensure that the right shall be conferred on the persons concerned to use titles conferred on them in the

home Member State, and possibly an abbreviated form thereof, in the language of that Member State. The host Member State may require that title to be followed by the name and address of the establishment or examining board which awarded it.

Where a qualification issued by the home Member State is liable to be confused in the host Member State with a qualification which, in the latter Member State, requires supplementary training not acquired by the beneficiary, the host Member State may require the beneficiary to use the title acquired in the home Member State in an appropriate form, to be laid down by the host Member State.

#### Article 51

##### Approval by health insurance funds

Without prejudice to Articles 5.1 and 6, subparagraph 1, point (b), Member States which require persons who acquired their professional qualifications in their territory to complete a preparatory period of in-service training and/or a period of professional experience in order to be approved by a health insurance fund, shall waive this obligation for the holders of evidence of professional qualifications acquired in other Member States.

#### TITLE V

##### ADMINISTRATIVE COOPERATION AND RESPONSIBILITY FOR IMPLEMENTATION

#### Article 52

##### Competent authorities

1. The competent authorities of the host Member State and of the home Member State shall work in close collaboration and shall provide mutual assistance in order to facilitate application of this Directive. They shall ensure the confidentiality of the information which they exchange.

2. Every Member State shall, no later than the deadline laid down in Article 54, designate the authorities and bodies competent to award or receive certificates of training and other documents or information, and those competent to receive applications and take the decisions referred to in this Directive, and shall inform the other Member States and the Commission thereof immediately.

3. Every Member State shall designate a coordinator for the activities of the authorities referred to in paragraph 1 and shall inform the other Member States and the Commission thereof.

The coordinators' remit shall be:

(a) to promote uniform application of this Directive;

(b) to collect all the information which is relevant for application of this Directive, such as on the conditions for access to regulated professions in the Member States.

For the purpose of fulfilling the remit described in subparagraph 2, point (b), the coordinators may solicit the help of the contact points referred to in Article 53.

#### Article 53

##### **Contact points**

Each Member State shall designate, no later than the deadline laid down in Article 58, a contact point whose remit shall be:

- (a) to provide the citizens and contact points of the other Member States with such information as is necessary concerning the recognition of professional qualifications provided for in this Directive, such as information on the national legislation governing the professions and the practice of those professions, including social legislation, and, where appropriate, the rules of ethics;
- (b) to assist citizens in realising the rights conferred on them by this Directive, in cooperation, where appropriate, with the other contact points and the competent authorities in the host Member State.

The contact points shall inform the Commission of the enquiries with which they are dealing pursuant to the provisions of the first subparagraph, point (b) within two months of receiving them.

#### Article 54

##### **Committee on the recognition of professional qualifications**

1. The Commission shall be assisted by a Committee on the recognition of professional qualifications, referred to hereafter as 'the Committee', comprising representatives of the Member States and chaired by the representative of the Commission.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having due regard to the provisions of Article 8 of that Decision.

The period provided for in Article 5(6) of Decision 1999/468/EC is fixed at two months.

3. The Committee may be asked to give its opinion on any other matter relating to implementation of this Directive.
4. The Committee shall adopt its rules of procedure.

#### TITLE VI

##### **OTHER PROVISIONS**

#### Article 55

##### **Reports**

As from the deadline laid down in Article 58, the Member States shall, every two years, send a report to the Commission

on the application of the system. In addition to general observations, the report shall contain a statistical summary of decisions taken and a description of the main problems arising from the application of the Directive.

#### Article 56

##### **Derogation clause**

If, for the application of one of the provisions of this Directive, a Member State encounters major difficulties in a particular area, the Commission shall examine those difficulties in collaboration with the Member State concerned.

Where appropriate, the Commission shall decide, in accordance with the procedure referred to in Article 54(2), to permit the Member State in question to derogate from the provision in question for a limited period.

#### Article 57

##### **Abrogation**

Directives 77/452/EEC, 77/453/EEC, 78/686/EEC, 78/687/EEC, 78/1026/EEC, 78/1027/EEC, 80/154/EEC, 80/155/EEC, 85/384/EEC, 85/432/EEC, 85/433/EEC, 89/48/EEC, 92/51/EEC, 93/16/EEC and 1999/42/EEC are repealed with effect from the date laid down in Article 58.

References to repealed Directives shall be understood as references to this Directive

#### Article 58

##### **Transposition**

The Member States shall implement the legislative, regulatory and administrative provisions necessary to comply with this Directive by [two years from the publication in the OJ] at the latest. They shall inform the Commission thereof immediately.

When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

#### Article 59

##### **Entry into force**

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Communities*.

#### Article 60

This Directive is addressed to the Member States.

## ANNEX I

**LIST OF PROFESSIONAL ASSOCIATIONS OR ORGANISATIONS FULFILLING THE CONDITIONS OF  
ARTICLE 3(2)****Ireland <sup>(1)</sup>**

1. The Institute of Chartered Accountants in Ireland <sup>(2)</sup>
2. The Institute of Certified Public Accountants in Ireland <sup>(2)</sup>
3. The Association of Certified Accountants <sup>(2)</sup>
4. Institution of Engineers of Ireland
5. Irish Planning Institute

**United Kingdom**

1. Institute of Chartered Accountants in England and Wales
2. Institute of Chartered Accountants of Scotland
3. Institute of Chartered Accountants in Ireland
4. Chartered Association of Certified Accountants
5. Chartered Institute of Loss Adjusters
6. Chartered Institute of Management Accountants
7. Institute of Chartered Secretaries and Administrators
8. Chartered Insurance Institute
9. Institute of Actuaries
10. Faculty of Actuaries
11. Chartered Institute of Bankers
12. Institute of Bankers in Scotland
13. Royal Institution of Chartered Surveyors
14. Royal Town Planning Institute
15. Chartered Society of Physiotherapy
16. Royal Society of Chemistry
17. British Psychological Society
18. Library Association
19. Institute of Chartered Foresters
20. Chartered Institute of Building
21. Engineering Council
22. Institute of Energy
23. Institution of Structural Engineers
24. Institution of Civil Engineers
25. Institution of Mining Engineers
26. Institution of Mining and Metallurgy
27. Institution of Electrical Engineers
28. Institution of Gas Engineers
29. Institution of Mechanical Engineers
30. Institution of Chemical Engineers
31. Institution of Production Engineers
32. Institution of Marine Engineers
33. Royal Institution of Naval Architects
34. Royal Aeronautical Society
35. Institute of Metals
36. Chartered Institution of Building Services Engineers
37. Institute of Measurement and Control
38. British Computer Society

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<sup>(1)</sup> Irish nationals are also members of the following associations or organisations in the United Kingdom:

Institute of Chartered Accountants in England and Wales  
Institute of Chartered Accountants of Scotland  
Institute of Actuaries  
Faculty of Actuaries  
The Chartered Institute of Management Accountants  
Institute of Chartered Secretaries and Administrators  
Royal Town Planning Institute  
Royal Institution of Chartered Surveyors  
Chartered Institute of Building.

<sup>(2)</sup> Only for the activity of auditing accounts.

## ANNEX II

## LIST OF COURSES HAVING A SPECIAL STRUCTURE REFERRED TO IN POINT (a) OF THE SECOND SUBPARAGRAPH OF ARTICLE 11(4)

## 1. Paramedical and childcare training courses

Training for the following:

*in Germany:*

- paediatric nurse ('Kinderkrankenschwester/Kinderkrankenpfleger')
- physiotherapist ('Krankengymnast(in)/Physiotherapeut(in)') <sup>(1)</sup>
- occupational therapist ('Beschäftigungs- und Arbeitstherapeut(in)')
- speech therapist ('Logopäde/Logopädin')
- orthoptist ('Orthoptist(in)')
- State-recognised childcare worker ('Staatlich anerkannte(r) Erzieher(in)')
- State-recognised remedial teacher ('Staatlich anerkannte(r) Heilpädagoge(-in)')
- medical laboratory technician ('medizinisch-technische(r) Laboratoriums-Assistent(in)')
- medical X-ray technician ('medizinisch-technische(r) Radiologie-Assistent(in)')
- medical functional diagnostics technician ('medizinisch-technische(r) Assistent(in) für Funktionsdiagnostik')
- veterinary technician ('veterinärmedizinisch-technische(r) Assistent(in)')
- dietitian ('Diätassistent(in)')
- pharmacy technician ('Pharmazieingenieur') received prior to 31 March 1994 in the former German Democratic Republic or in the territory of the new Länder
- psychiatric nurse ('Psychiatrische(r) Krankenschwester/Krankenpfleger')
- speech therapist ('Sprachtherapeut(in)')

*in Italy:*

- dental technician ('odontotecnico')
- optician ('ottico')
- chiropodist ('podologo')

*in Luxembourg:*

- medical X-ray technician ('assistant(e) technique médical(e) en radiologie')
- medical laboratory technician ('assistant(e) technique médical(e) de laboratoire')
- psychiatric nurse ('infirmier/ière psychiatrique')
- medical technician — surgery ('assistant(e) technique médical(e) en chirurgie')
- paediatric nurse ('infirmier/ière puériculteur/trice')
- nurse — anaesthetics ('infirmier/ière anesthésiste')
- qualified masseur/masseuse ('masseur/euse diplômé(e)')
- childcare worker ('éducateur/trice')

*in the Netherlands:*

- veterinary assistant ('dierenartassistent')

<sup>(1)</sup> As from 1 June 1994, the professional title 'Krankengymnast(in)' will be replaced by that of 'Physiotherapeut(in)'. Nevertheless, the members of the profession who obtained their diplomas before this date may, if they wish, continue to use the former title of 'Krankengymnast(in)'.

which represent education and training courses of a total duration of at least thirteen years, comprising:

- (i) either at least three years of vocational training in a specialised school culminating in an examination, in some cases supplemented by a one or two-year specialisation course culminating in an examination
- (ii) or at least two and a half years of vocational training in a specialised school culminating in an examination and supplemented by work experience of at least six months or by a traineeship of at least six months in an approved establishment
- (iii) or at least two years of vocational training in a specialised school culminating in an examination and supplemented by work experience of at least one year or by a traineeship of at least one year in an approved establishment
- (iv) or in the case of the veterinary assistant ('dierenartassistent') in the Netherlands three years of vocational training in a specialised school ('MBO'-scheme) or alternatively three years of vocational training in the dual apprenticeship system ('LLW'), both of which culminate in an examination.

*in Austria:*

- special basic training for nurses specialising in the care of children and young people ('spezielle Grundausbildung in der Kinder- und Jugendlichenpflege')
- special basic training for psychiatric nurses ('spezielle Grundausbildung in der psychiatrischen Gesundheits- und Krankenpflege')
- contact lens optician ('Kontaktlinsenoptiker')
- pedicurist ('Fußpfleger')
- acoustic-aid technician ('Hörgeräteakustiker')
- druggist ('Drogist')

which represent education and training courses of a total duration of at least fourteen years, including at least five years' training followed within a structured training framework, divided into an apprenticeship of at least three years' duration, comprising training partly received in the workplace and partly provided by a vocational training establishment, and a period of professional practice and training, culminating in a professional examination conferring the right to exercise the profession and to train apprentices.

- masseur ('Masseur')

which represents education and training courses of a total duration of fourteen years, including five years' training within a structured training framework, comprising an apprenticeship of two years' duration, a period of professional practice and training of two years' duration and a training course of one year culminating in a professional examination conferring the rights to exercise the profession and to train apprentices.

- kindergarten worker ('Kindergärtner/in')
- child care worker ('Erzieher')

which represent education and training courses of a total duration of thirteen years, including five years of professional training in a specialised school, culminating in an examination.

## **2. Master craftsman sector ('Mester/Meister/Maître'), which represents education and training courses concerning skills not covered by the Directives listed in Annex A**

Training for the following:

*in Denmark:*

- optician ('optometrist')

this course is of a total duration of 14 years, including five years' vocational training divided into two and a half years' theoretical training provided by the vocational training establishment and two and a half years' practical training received in the workplace, and culminating in a recognised examination relating to the craft and conferring the right to use the title 'Mester'.

- orthopaedic technician ('ortopaedimekaniker')

this course is of a total duration of 12,5 years, including three and a half years' vocational training divided into six months' theoretical training provided by the vocational training establishment and three years' practical training received in the workplace, and culminating in a recognised examination relating to the craft and conferring the right to use the title 'Mester'.

— orthopaedic boot and shoemaker ('orthopaediskomager')

this course is of a total duration of 13,5 years, including four and a half years' vocational training divided into two years' theoretical training provided by the vocational training establishment and two and a half years' practical training received in the workplace, and culminating in a recognised examination relating to the craft and conferring the right to use the title 'Mester'.

*in Germany:*

- optician ('Augenoptiker')
- dental technician ('Zahntechniker')
- surgical truss maker ('Bandagist')
- hearing-aid maker ('Hörgeräteakustiker')
- orthopaedic technician ('Orthopädiemechaniker')
- orthopaedic bootmaker ('Orthopädienschuhmacher')

*in Luxembourg:*

- dispensing optician ('opticien')
- dental technician ('mécanicien dentaire')
- hearing-aid maker ('audioprothésiste')
- orthopaedic technician/surgical truss maker ('mécanicien orthopédiste/bandagiste')
- orthopaedic bootmaker ('orthopédiste-cordonnier')

these courses are of a total duration of 14 years, including at least five years' training followed within a structured training framework, partly received in the workplace and partly provided by the vocational training establishment, and culminating in an examination which must be passed in order to be able to practise any activity considered as skilled, either independently or as an employee with a comparable level of responsibility.

*in Austria:*

- surgical truss maker ('Bandagist')
- corset maker ('Miederwarenerzeuger')
- optician ('Optiker')
- orthopaedic shoemaker ('Orthopädienschuhmacher')
- orthopaedic technician ('Orthopädietechniker')
- dental technician ('Zahntechniker')
- gardener ('Gärtner')

which represent education and training of a total duration of at least fourteen years, including at least five years' training within a structured training framework, divided into apprenticeship of at least three years' duration, comprising training received partly in the workplace and partly provided by a vocational training establishment, and a period of professional practice and training of at least two years' duration culminating in mastership examination conferring the rights to exercise the profession, to train apprentices and to use the title 'Meister'.

training for master craftsmen in the field of agriculture and forestry, namely:

- master in agriculture ('Meister in der Landwirtschaft')
- master in rural home economics ('Meister in der ländlichen Hauswirtschaft')
- master in horticulture ('Meister im Gartenbau')
- master in market gardening ('Meister im Feldgemüsebau')
- master in pomology and fruit-processing ('Meister im Obstbau und in der Obstverwertung')
- master in viniculture and wine-production ('Meister im Weinbau und in der Kellerwirtschaft')
- master in dairy farming ('Meister in der Molkerei- und Käsereiwirtschaft')
- master in horse husbandry ('Meister in der Pferdewirtschaft')
- master in fishery ('Meister in der Fischereiwirtschaft')

- master in poultry farming ('Meister in der Geflügelwirtschaft')
- master in apiculture ('Meister in der Bienenwirtschaft')
- master in forestry ('Meister in der Forstwirtschaft')
- master in forestry plantation and forest management ('Meister in der Forstgarten- und Forstpflégewirtschaft')
- master in agricultural warehousing ('Meister in der landwirtschaftlichen Lagerhaltung')

which represent education and training of a total duration of at least fifteen years, including at least six years' training followed within a structured training framework divided into an apprenticeship of at least three years' duration, comprising training partly received in the workplace and partly provided by a vocational training establishment, and a period of three years of professional practice culminating in a mastership examination relating to the profession and conferring the rights to train apprentices and to use the title 'Meister'.

### 3. Seafaring sector

#### (a) *transport*

Training for the following:

*in Denmark:*

- ship's captain ('skibsfoerer')
- first mate ('overstyrmand')
- quartermaster, deck officer ('enestyrmand, vagthavende styrmand')
- deck officer ('vagthavende styrmand')
- engineer ('maskinchef')
- first engineer ('1. maskinmester')
- first engineer/duty engineer ('1. maskinmester/vagthavende maskinmester')

*in Germany:*

- captain, large coastal vessel ('Kapitän AM')
- captain, coastal vessel ('Kapitän AK')
- deck officer, large coastal vessel ('Nautischer Schiffsoffizier AMW')
- deck officer, coastal vessel ('Nautischer Schiffsoffizier AKW')
- chief engineer, grade C ('Schiffsbetriebstechniker CT — Leiter von Maschinenanlagen')
- ship's mechanic, grade C ('Schiffsmaschinist CMA — Leiter von Maschinenanlagen')
- ship's engineer, grade C ('Schiffsbetriebstechniker CTW')
- ship's mechanic, grade C — solo engineer officer ('Schiffsmaschinist CMaW — Technischer Alleinoffizier')

*in Italy:*

- deck officer ('ufficiale di coperta')
- engineer officer ('ufficiale di macchina')

*in the Netherlands:*

- first mate (coastal vessel) (with supplementary training) ('stuurman kleine handelsvaart (met aanvulling)')
- coaster engineer (with diploma) ('diploma motordrijver')
- VTS-official ('VTS-functionaris')

which represent training:

- in Denmark, of nine years' primary schooling followed by a course of basic training and/or service at sea of between 17 and 36 months, supplemented by:
  - (i) the deck officer, one year of specialised vocational training
  - (ii) for the others, three years of specialised vocational training.

- in Germany, of a total duration of between 14 and 18 years, including a three-year course of basic vocational training and one year's service at sea, followed by one or two years of specialised vocational training supplemented, where appropriate, by two year's work experience in navigation.
- in Italy, of a total duration of 13 years, of which at least five years consist of professional training culminating in an examination and are supplemented, where appropriate, by a traineeship.
- in the Netherlands:
  - (i) for first mate (coastal vessel) (with supplementary training) ('stuurman kleine handelsvaart (met aanvulling)'), and coaster engineer (with diploma) ('diploma motordrijver'), involving a course of 14 years, at least two years of which take place in a specialised vocational training establishment, supplemented by a twelve-month traineeship
  - (ii) for the VTS-official ('VTS-functionaris') of a total duration of at least 15 years, comprising at least three years of Higher Vocational Education ('HBO') or Intermediate Vocational Training ('MBO'), which are followed by national and regional specialisation courses, comprising at least 12 weeks of theoretical training each and culminating each in an examination

and which are recognised under the International STCW Convention (International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978).

(b) *sea fishing*

Training for the following:

*in Germany:*

- captain, deep-sea fishing ('Kapitän BG/Fischerei')
- captain, coastal fishing ('Kapitän BLK/Fischerei')
- deck officer, deep-sea vessel ('Nautischer Schiffsoffizier BGW/Fischerei')
- deck officer, coastal vessel ('Nautischer Schiffsoffizier BK/Fischerei')

*in the Netherlands:*

- first mate/engineer V ('stuurman werktuigkundige V')
- engineer IV (fishing vessel) ('werktuigkundige IV visvaart')
- first mate IV (fishing vessel) ('stuurman IV visvaart')
- first mate/engineer VI ('stuurman werktuigkundige VI')

which represent training:

- in Germany, of a total duration of between 14 and 18 years, including a three-year course of basic vocational training and one year's service at sea, followed by one or two years of specialised vocational training supplemented, where appropriate, by two years' work experience in navigation
- in the Netherlands, involving a course varying in duration between 13 and 15 years, at latest two years of which are provided in a specialised vocational school, supplemented by a 12-month period of work experience

and are recognised under the Torremolinos Convention (1977 International Convention for the Safety of Fishing Vessels).

#### 4. Technical sector

Training for the following:

*in Italy:*

- building surveyor ('geometra')
- land surveyor ('perito agrario')



which represent secondary technical courses of a total duration of at least 13 years, comprising eight years' compulsory schooling followed by five years' secondary study, including three years' vocational study, culminating in the Technical Baccalaureat examination, and supplemented:

(i) for building surveyors, by either a traineeship lasting at least two years in a professional office, or five years' work experience

(ii) for land surveyors, by the completion of a practical traineeship lasting at least two years

followed by the State Examination.

*in the Netherlands:*

— bailiff ('gerechtsdeurwaarder')

— dental-prosthesis maker ('tandprotheticus')

which represent a course of study and vocational training:

(i) in the case of the bailiff ('gerechtsdeurwaarder'), totalling 19 years, comprising eight years' compulsory schooling followed by eight years' secondary education including four years' technical education culminating in a State examination and supplemented by three years' theoretical and practical vocational training

(ii) in the case of the dental-prosthesis maker ('tandprotheticus') totalling at least 15 years of full time training and three years of part time training, comprising eight years of primary education, four years of general secondary education, completion of free years of vocational training, involving theoretical and practical training as a dental technician, supplemented by three years of part-time training as a dental prosthesis-maker, culminating in an examination.

*in Austria:*

— forester ('Förster')

— technical consulting ('Technisches Büro')

— labour leasing ('Überlassung von Arbeitskräften — Arbeitsleihe')

— employment agent ('Arbeitsvermittlung')

— investment adviser ('Vermögensberater')

— private investigator ('Berufsdetektiv')

— security guard ('Bewachungsgewerbe')

— real estate agent ('Immobilienmakler')

— real estate manager ('Immobilienverwalter')

— advertising and promotion agency ('Werbeagentur')

— building project organiser ('Bauträger, Bauorganisator, Baubetreuer')

— debt-collecting institute ('Inkassoinstitut')

which represent education and training of a total duration of at least 15 years, comprising eight years' compulsory schooling followed by a minimum of five years' secondary technical or commercial study, culminating in a technical or commercial matura examination, supplemented by at least two years' workplace education and training culminating in a professional examination.

— insurance consultant ('Berater in Versicherungsangelegenheiten')

which represents education and training of a total duration of 15 years, including six years' training followed within a structured training framework, divided into an apprenticeship of three years' duration and a three-year period of professional practice and training, culminating in an examination.

— master builder/planning and technical calculation ('Planender Baumeister')

— master woodbuilder/planning and technical calculation ('Planender Zimmermeister')

which represent education and training of a total duration of at least 18 years, including at least nine year's vocational training divided into four years' secondary technical study and five years' professional practice and training culminating in a professional examination conferring the rights to exercise the profession and to train apprentices, in so far as this training relates to the right to plan buildings, to make technical calculations and to supervise construction work (the Maria Theresian privilege).

**5. United Kingdom courses accredited as National Vocational Qualifications or Scottish Vocational Qualifications Training for:**

- mine electrical engineer
- mine mechanical engineer
- dental therapist
- dental hygienist
- dispensing optician
- mine deputy
- insolvency practitioner
- licensed conveyancer
- first mate — freight/passenger ships — unrestricted
- second mate — freight/passenger ships — unrestricted
- third mate — freight passenger ships unrestricted
- deck officer — freight/passenger ships — unrestricted
- engineer officer — freight/passenger ships — unlimited trading area
- certified technically competent person in waste management

leading to qualifications accredited as National Vocational Qualifications (NVQs) or, in Scotland, accredited as Scottish Vocational Qualifications, at levels 3 and 4 of the United Kingdom National Framework of Vocational Qualifications.

These levels are defined as follows:

- Level 3: competence in a broad range of varied work activities performed in a wide variety of contexts and most of which are complex and non-routine. There is considerable responsibility and autonomy, and control or guidance of others in often required.
  - Level 4: Competence in a broad range of complex technical or professional work activities performed in a wide variety of contexts and with a substantial degree of personal responsibility and autonomy. Responsibility for the work of others and the allocation of resources is often present.
-

## ANNEX III

**LIST OF REGULATED TRAINING REFERRED TO IN POINT (b) OF THE SECOND SUBPARAGRAPH OF ARTICLE 11(4)***In the United Kingdom:*

Regulated courses leading to qualifications accredited as National Vocational Qualifications (NVQs) or, in Scotland, accredited as Scottish Vocational Qualifications, at levels 3 and 4 of the United Kingdom National Framework of Vocational Qualifications.

These levels are defined as follows:

- Level 3: competence in a broad range of varied work activities performed in a wide variety of contexts and most of which are complex and non-routine. There is considerable responsibility and autonomy, and control or guidance of others is often required.
- Level 4: Competence in a broad range of complex technical or professional work activities performed in a wide variety of contexts and with a substantial degree of personal responsibility and autonomy. Responsibility for the work of others and the allocation of resources is often present.

*In Germany:*

The following regulated courses:

- Regulated courses preparatory to the pursuit of the professions of technical assistant ('technische(r) Assistent(in)'), commercial assistant ('kaufmännische(r) Assistent(in)'), social professions ('soziale Berufe') and the profession of state-certified respiration and elocution instructor ('staatlich geprüfte(r) Atem-, Sprech- und Stimmlehrer(in)'), of a total duration of at least 13 years, which require successful completion of the secondary course of education ('mittlerer Bildungsabschluss') and which comprise:
  - (i) at least three years<sup>(1)</sup> of vocational training at a specialised school ('Fachschule') culminating in an examination and, where applicable, supplemented by one-year or two-year specialisation course also culminating in an examination
  - (ii) or at least two and a half years at a specialised school ('Fachschule') culminating in an examination and supplemented by work experience of a duration of not less than six months or a traineeship of not less than six months in an approved establishment
  - (iii) or at least two years at a specialised school ('Fachschule') culminating in an examination and supplemented by work experience of a duration of not less than one year or a traineeship of not less than one year in an approved establishment.
- Regulated courses for the professions of state-certified ('staatlich geprüfte(r)') technician ('Techniker(in)'), business economist ('Betriebswirt(in)'), designer ('Gestalter(in)') and family assistant ('Familienpfleger(in)'), of a total duration of not less than 16 years, a prerequisite of which is successful completion of compulsory schooling or equivalent education and training (of a duration of not less than nine years) and successful completion of a course at a trade school ('Berufsschule') of a duration of not less than three years and comprising, upon completion of at least two years of work experience, full-time education and training of a duration of not less than two years or part-time education and training of equivalent duration.
- Regulated courses and regulated in-service training, of a total duration of not less than 15 years, a prerequisite of which is, generally speaking, successful completion of compulsory schooling (of a duration of not less than nine years) and of vocational training (normally three years) and which generally comprise at least two years of work experience (three years in most cases) and an examination in the context of in service training preparation for which generally comprises a training course which is either concurrent with the experience (at least 1 000 hours) or is attended on a full-time basis (at least one year).

The German authorities shall send to the Commission and to the other Member States a list of the training courses covered by this Annex.

<sup>(1)</sup> The minimum duration may be reduced from three years to two years if the person concerned has the qualification required to enter university ('Abitur'), i.e. thirteen years of prior education and training, of the qualification needed to enter a 'Fachhochschule' ('Fachhochschulreife'), i.e. 12 years of prior education and training.

*In the Netherlands:*

- Regulated training courses of a total duration of not less than 15 years, a prerequisite of which is successful completion of eight years of primary education plus four years of either intermediate general secondary education ('MAVO') or Preparatory Vocational Education ('VBO') or general secondary education of a higher level, and which require the completion of a three-year or four-year course at a college for intermediate vocational training ('MBO'), culminating in an examination.
- Regulated training courses of a total duration not less than 16 years, a prerequisite of which is successful completion of eight years of primary education plus four years of at least preparatory vocational education ('VBO') or a higher level of general secondary education, and which require the completion of at least four years of vocational training in the apprenticeship system, comprising at least one day of theoretical instruction at a college each week and on the other days practical training centre or in a firm, and culminating in a secondary or tertiary level examination.

The Dutch authorities shall send to the Commission and to the other Member States a list of the training courses covered by this Annex.

*In Austria:*

- Courses at higher vocational schools ('Berufsbildende Höhere Schulen') and higher education establishments for agriculture and forestry ('Höhere Land- und Forstwirtschaftliche Lehranstalten'), including special types ('einschließlich der Sonderformen'), the structure level of which are determined by law, regulations and administrative provisions.

These courses have a total length of not less than 13 years and comprise five years of vocational training, which culminate in a final examination, the passing of which is a proof of professional competence.

- Courses at master schools ('Meisterschulen'), master classes ('Meisterklassen'), industrial master schools ('Werkmeisterschulen') or building craftsmen schools ('Bauhandwerkerschulen'), the structure and level of which are determined by law, regulations and administrative provisions.

These courses have a total length of not less than 13 years, comprising nine years of compulsory education, followed by either at least three years of vocational training at a specialised school or at least three years of training in a firm and in parallel at a vocational training school ('Berufsschule'), both of which culminate in an examination, and are supplemented by successful completion of at least a one-year training course at a master school ('Meisterschule'), master classes ('Meisterklassen'), industrial master school ('Werkmeisterschule') or a building craftsmen school ('Bauhandwerkerschule'). In most cases the total duration is at least 15 years, comprising periods of work experience, which either precede the training courses at these establishments or are accompanied by part-time courses (at least 960 hours).

The Austrian authorities shall send to the Commission and to the other Member States a list of the training courses covered by this Annex.

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## ANNEX IV

**ACTIVITIES RELATED TO THE CATEGORIES OF PROFESSIONAL EXPERIENCE REFERRED TO IN ARTICLES 17 AND 18****List I**

*Classes covered by Directive 64/427/EEC, as amended by Directive 69/77/EEC, and by Directives 68/366/EEC, 75/368/EEC, 75/369/EEC, 82/470/EEC and 82/489/EEC*

## 1

Directive 64/427/EEC

(liberalisation Directive: 64/429/EEC)

NICE nomenclature (corresponding to ISIC classes 23-40)

Major group 23	manufacture of textiles
	232 manufacturing and processing of textile materials on woollen machinery
	233 manufacturing and processing of textile materials on cotton machinery
	234 manufacturing and processing of textile materials on silk machinery
	235 manufacturing and processing of textile materials on flax and hemp machinery
	236 other textile fibre industries (jute, hard fibres, etc.), cordage
	237 manufacture of knitted and crocheted goods
	238 textile finishing
	239 other textile industries
Major group 24	manufacture of footwear, other wearing apparel and bedding
	241 machine manufacture of footwear (except from rubber or wood)
	242 manufacture by hand and repair of footwear
	243 manufacture of wearing apparel (except furs)
	244 manufacture of mattresses and bedding
	245 skin and fur industries
Major group 25	manufactures of wood and cork, except manufacture of furniture
	251 sawing and industrial preparation of wood
	252 manufacture of semi-finished wood products
	253 series production of wooden building components including flooring
	254 manufacture of wooden containers
	255 manufacture of other wooden products (except furniture)
	259 manufacture of straw, cork, basketware, wicker-work and rattan products; brush-making
Major group 26	260 manufacture of wooden furniture
Major group 27	manufacture of paper and paper products
	271 manufacture of pulp, paper and paperboard
	272 processing of paper and paperboard, and manufacture of articles of pulp
Major group 28	280 printing, publishing and allied industries

Major group 29	leather industry
	291 tanneries and leather finishing plants
	292 manufacture of leather products
Ex major group 30	manufacture of rubber and plastic products, man-made fibres and starch products
	301 processing of rubber and asbestos
	302 processing of plastic materials
	303 production of man-made fibres
Ex major group 31	chemical industry
	311 manufacture of chemical base materials and further processing of such materials
	312 specialised manufacture of chemical products principally for industrial and agricultural purposes (including the manufacture for industrial use of fats and oils of vegetable or animal origin falling within ISIC group 312)
	313 specialised manufacture of chemical products principally for domestic or office use (excluding the manufacture of medicinal and pharmaceutical products (ex ISIC group 319))
Major group 32	320 petroleum industry
Major group 33	manufacture of non-metallic mineral products
	331 manufacture of structural clay products
	332 manufacture of glass and glass products
	333 manufacture of ceramic products, including refractory goods
	334 manufacture of cement, lime and plaster
	335 manufacture of structural material, in concrete, cement and plaster
	339 stone working and manufacture of other non-metallic mineral products
Major group 34	production and primary transformation of ferrous and non-ferrous metals
	341 iron and steel industry (as defined in the ECSC treaty, including integrated steelworks-owned coking plants)
	342 manufacture of steel tubes
	343 wire-drawing, cold-drawing, cold-rolling of strip, cold-forming
	344 production and primary transformation of non-ferrous metals
	345 ferrous and non-ferrous metal foundries
Major group 35	manufacture of metal products (except machinery and transport equipment)
	351 forging, heavy stamping and heavy pressing
	352 secondary transformation and surface-treatment
	353 metal structures
	354 boilermaking, manufacture of industrial hollow-ware
	355 manufacture of tools and implements and finished articles of metal (except electrical equipment)
	359 ancillary mechanical engineering activities
Major group 36	manufacture of machinery other than electrical machinery
	361 manufacture of agricultural machinery and tractors
	362 manufacture of office machinery

- 363 manufacture of metal-working and other machine-tools and fixtures and attachments for these and for other powered tools
- 364 manufacture of textile machinery and accessories, manufacture of sewing machines
- 365 manufacture of machinery and equipment for the food-manufacturing and beverage industries and for the chemical and allied industries
- 366 manufacture of plant and equipment for mines, iron and steel works foundries, and for the construction industry; manufacture of mechanical handling equipment
- 367 manufacture of transmission equipment
- 368 manufacture of machinery for other specific industrial purposes
- 369 manufacture of other non-electrical machinery and equipment
- Major group 37 electrical engineering
  - 371 manufacture of electric wiring and cables
  - 372 manufacture of motors, generators, transformers, switchgear, and other similar equipment for the provision of electric power
  - 373 manufacture of electrical equipment for direct commercial use
  - 374 manufacture of telecommunications equipment, meters, other measuring appliances and electromedical equipment
  - 375 manufacture of electronic equipment, radio and television receivers, audio equipment
  - 376 manufacture of electric appliances for domestic use
  - 377 manufacture of lamps and lighting equipment
  - 378 manufacture of batteries and accumulators
  - 379 repair, assembly, and specialist installation of electrical equipment
- Ex major group 38 manufacture of transport equipment
  - 383 manufacture of motor vehicles and parts thereof
  - 384 repair of motor vehicles, motorcycles and cycles
  - 385 manufacture of motorcycles, cycles and parts thereof
  - 389 manufacture of transport equipment not elsewhere classified
- Major group 39 miscellaneous manufacturing industries
  - 391 manufacture of precision instruments, and measuring and controlling instruments
  - 392 manufacture of medico-surgical instruments and equipment and orthopaedic appliances (except orthopaedic footwear)
  - 393 manufacture of photographic and optical equipment
  - 394 manufacture and repair of watches and clocks
  - 395 jewellery and precious metal manufacturing
  - 396 manufacture and repair of musical instruments
  - 397 manufacture of games, toys, sporting and athletic goods
  - 399 other manufacturing industries
- Major group 40 construction
  - 400 construction (non-specialised); demolition
  - 401 construction of buildings (dwellings or other)
  - 402 civil engineering; building of roads, bridges, railways, etc.
  - 403 installation work
  - 404 decorating and finishing

## 2

Directive 68/366/EEC

(liberalisation Directive: 68/365/EEC)

## NICE nomenclature

Major group	20A	200	industries producing animal and vegetable fats and oils
	20B		food manufacturing industries (excluding the beverage industry)
		201	slaughtering, preparation and preserving of meat
		202	milk and milk products industry
		203	canning and preserving of fruits and vegetables
		204	canning and preserving of fish and other sea foods
		205	manufacture of grain mill products
		206	manufacture of bakery products, including rusks and biscuits
		207	sugar industry
		208	manufacture of cocoa, chocolate and sugar confectionery
		209	manufacture of miscellaneous food products
Major group	21		beverage industry
		211	production of ethyl alcohol by fermentation, production of yeasts and spirits
		212	production of wine and other unmalted alcoholic beverages
		213	brewing and malting
		214	soft drinks and carbonated water industries
ex 30			manufacture of rubber products, plastic materials, artificial and synthetic fibres and starch products
		304	manufacture of starch products

## 3

Directive 75/368/EEC (activities referred to in Article 5(1))

## ISIC nomenclature

ex 04			fishing
		043	inland water fishing
ex 38			manufacture of transport equipment
		381	shipbuilding and repairing
		382	manufacture of railroad equipment
		386	manufacture of aircraft (including space equipment)
ex 71			activities allied to transport and activities other than transport coming under the following groups:
	ex 711		sleeping- and dining-car services; maintenance of railway stock in repair sheds; cleaning of carriages
	ex 712		maintenance of stock for urban, suburban and interurban passenger transport
	ex 713		maintenance of stock for other passenger land transport (such as motor cars, coaches, taxis)
	ex 714		operation and maintenance of services in support of road transport (such as roads, tunnels and toll-bridges, goods depots, car parks, bus and tram depots)
	ex 716		activities allied to inland water transport (such as operation and maintenance of waterways, ports and other installations for inland water transport; tug and piloting services in ports, setting of buoys, loading and unloading of vessels and other similar activities, such as salvaging of vessels, towing and the operation of boathouses)



- 73                    communications: postal services and telecommunications
- ex 85                personal services
  - 854                laundries and laundry services, dry-cleaning and dyeing
  - ex 856           photographic studios: portrait and commercial photography, except journalistic photographers
  - ex 859           personal services not elsewhere classified (only maintenance and cleaning of buildings or accommodation)

## 4

Directive 75/369/EEC (Article 6: where the activity is regarded as being of an industrial or small craft nature)

## ISIC nomenclature

The following itinerant activities:

- (a) — the buying and selling of goods by itinerant tradesmen, hawkers or pedlars (ex ISIC Group 612)
  - in covered markets other than from permanently fixed installations and in open-air markets.
- (b) activities covered by transitional measures already adopted that expressly exclude or do not mention the pursuit of such activities on an itinerant basis.

## 5

Directive 82/470/EEC (Article 6(1) and (3))

Groups 718 and 720 of the ISIC nomenclature

The activities comprise in particular:

- organising, offering for sale and selling, outright or on commission, single or collective items (transport, board, lodging, excursions, etc.) for a journey or stay, whatever the reasons for travelling (Article 2(B)(a))
- acting as an intermediary between contractors for various methods of transport and persons who dispatch or receive goods, and carrying out related activities:
  - (aa) by concluding contracts with transport contractors, on behalf of principals
  - (bb) by choosing the method of transport, the firm and the route considered most profitable for the principal
  - (cc) by arranging the technical aspects of the transport operation (e.g. packing required for transportation); by carrying out various operations incidental to transport (e.g. ensuring ice supplies for refrigerated wagons)
  - (dd) by completing the formalities connected with the transport such as the drafting of way bills; by assembling and dispersing shipments
  - (ee) by coordinating the various stages of transportation, by ensuring transit, reshipment, transshipment and other termination operations
  - (ff) by arranging both freight and carriers and means of transport for persons dispatching goods or receiving them:
    - assessing transport costs and checking the detailed accounts
    - taking certain temporary or permanent measures in the name of and on behalf of a shipowner or sea transport carrier (with the port authorities, ship's chandlers, etc.).

[The activities listed under Article 2(A)(a), (b) and (d)].

## 6

Directive 82/489/EEC

## ISIC nomenclature

- ex 855                hairdressing establishments (excluding chiropodists' activities and beauticians' training schools)

**List II**

*Directives 64/222/EEC, 68/364/EEC, 68/368/EEC, 75/368/EEC, 75/369/EEC, 70/523/EEC and 82/470/EEC*

**1**

Directive 64/222/EEC

(liberalisation Directives: 64/423/EEC and 64/224/EEC)

1. Activities of self-employed persons in wholesale trade, with the exception of wholesale trade in medicinal and pharmaceutical products, in toxic products and pathogens and in coal (ex Group 611).
2. Professional activities of an intermediary who is empowered and instructed by one or more persons to negotiate or enter into commercial transactions in the name of and on behalf of those persons.
3. Professional activities of an intermediary who, while not being permanently so instructed, brings together persons wishing to contract directly with one another or arranges their commercial transactions or assists in the completion thereof.
4. Professional activities of an intermediary who enters into commercial transactions in his own name on behalf of others.
5. Professional activities of an intermediary who carries out wholesale selling by auction on behalf of others.
6. Professional activities of an intermediary who goes from door to door seeking orders.
7. Provision of services, by way of professional activities, by an intermediary in the employment of one or more commercial, industrial or small craft undertakings.

**2**

Directive 68/364/EEC

(liberalisation Directive: 68/363/EEC)

Ex ISIC Group 612: Retail trade

Activities excluded:

- 012 Letting out for hire of farm machinery
- 640 Real estate, letting of property
- 713 Letting out for hire of automobiles, carriages and horses
- 718 Letting out for hire of railway carriages and wagons
- 839 Renting of machinery to commercial undertakings
- 841 Booking of cinema seats and renting of cinematograph films
- 842 Booking of theatre seats and renting of theatrical equipment
- 843 Letting out for hire of boats, bicycles, coin-operated machines for games of skill or chance
- 853 Letting of furnished rooms
- 854 Laundered linen hire
- 859 Garment hire

**3**

Directive 68/368/EEC

(liberalisation Directive: 68/367/EEC)

ISIC nomenclature

ISIC ex major Group 85

1. Restaurants, cafes, taverns and other drinking and eating places (ISIC Group 852).
2. Hotels, rooming houses, camps and other lodging places (ISIC Group 853).

## 4

## Directive 75/368/EEC (Article 7)

All the activities in the Annex to Directive 75/368/EEC, except the activities listed in Article 5(d) of this Directive (List 1, point 3, of this Annex)

## ISIC nomenclature

- ex 62 banks and other financial institutions
  - ex 620 patent buying and licensing companies
- ex 71 transport
  - ex 713 road passenger transport, excluding transportation by means of motor vehicles
  - ex 719 transportation by pipelines of liquid hydrocarbons and other liquid chemical products
- ex 82 community services
  - 827 libraries, museums, botanical and zoological gardens
- ex 84 recreation services
  - 843 recreation services nec:
    - sporting activities (sports grounds, organising sporting fixtures, etc.), except the activities of sports instructors
    - games (racing stables, areas for games, racecourses, etc.)
    - other recreation services (circuses, amusement parks and other entertainment)
- ex 85 personal services
  - ex 851 domestic services
  - ex 855 beauty parlours and services of manicurists, excluding services of chiropodists and professional beauticians' and hairdressers' training schools
  - ex 859 personal services not elsewhere classified, except sports and paramedical masseurs and mountain guides, divided into the following groups:
    - disinfecting and pest control
    - hiring of clothes and storage facilities
    - marriage bureaux and similar services
    - astrology, fortune telling and the like
    - sanitary services and associated activities
    - undertaking and cemetery maintenance
    - couriers and interpreter-guides

## 5

## Directive 75/369/EEC (Article 5)

The following itinerant activities:

- (a) the buying and selling of goods:
  - by itinerant tradesmen, hawkers or pedlars (ex ISIC Group 612)
  - in covered markets other than from permanently fixed installations and in open-air markets
- (b) activities covered by transitional measures already adopted that expressly exclude or do not mention the pursuit of such activities on an itinerant basis.

## 6

## Directive 70/523/EEC

Activities of self-employed persons in the wholesale coal trade and activities of intermediaries in the coal trade (ex Group 6112, ISIC nomenclature)

## 7

## Directive 82/470/EEC (Article 6(2))

(Activities listed in Article 2(A)(c) and (e), (B)(b), (C) and (D))

These activities comprise in particular:

- hiring railway cars or wagons for transporting persons or goods
- acting as an intermediary in the sale, purchase or hiring of ships
- arranging, negotiating and concluding contracts for the transport of emigrants
- receiving all objects and goods deposited, on behalf of the depositor, whether under customs control or not, in warehouses, general stores, furniture depots, coldstores, silos, etc.
- supplying the depositor with a receipt for the object or goods deposited
- providing pens, feed and sales rings for livestock being temporarily accommodated while awaiting sale or while in transit to or from the market
- carrying out inspection or technical valuation of motor vehicles
- measuring, weighing and gauging goods.

## ANNEX V

**RECOGNITION ON THE BASIS OF COORDINATION OF THE MINIMUM TRAINING CONDITIONS**

## ANNEX V.1: DOCTOR

**5.1.1. Knowledge and skills**

Basic training for doctors provides an assurance that the person in question has acquired the following knowledge and skills:

- adequate knowledge of the sciences on which medicine is based and a good understanding of the scientific methods including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data
- sufficient understanding of the structure, functions and behaviour of healthy and sick persons, as well as relations between the state of health and physical and social surroundings of the human being
- adequate knowledge of clinical disciplines and practices, providing him with a coherent picture of mental and physical diseases, of medicine from the points of view of prophylaxis, diagnosis and therapy and of human reproduction
- suitable clinical experience in hospitals under appropriate supervision.

## 5.1.2. Evidence of basic formal qualifications of doctors

Country	Evidence of formal qualifications	Body awarding the qualifications	Certificate accompanying the qualifications	Reference date
België/ Belgique/ Belgien	Diploma van arts/Diplôme de docteur en médecine	— Les universités/De universiteiten — Le Jury compétent d'enseignement de la Communauté française/De bevoegde Examencommissie van de Vlaamse Gemeenschap		20 December 1976
Danmark	Bevis for bestået lægevidenskabelig embedseksamen	Medicinsk universitetsfakultet	— Autorisation som læge, udstedt af Sundhedsstyrelsen og — Tilladelse til selvstændigt virke som læge (dokumentation for gennemført praktisk uddannelse), udstedt af Sundhedsstyrelsen	20 December 1976
Deutschland	— Zeugnis über die Ärztliche Prüfung — Zeugnis über die Ärztliche Staatsprüfung und Zeugnis über die Vorbereitungszeit als Medizinalassistent, soweit diese nach den deutschen Rechtsvorschriften noch für den Abschluss der ärztlichen Ausbildung vorgesehen war	Zuständige Behörden	Bescheinigung über die Ableistung der Tätigkeit als Arzt im Praktikum	20 December 1976
Ελλάς	Πτυχίο Ιατρικής	— Ιατρική Σολή Πανεπιστημίου — Σχολή Επιστημών Υγείας, Τμήμα Ιατρικής Πανεπιστημίου		1 January 1981
España	Título de Licenciado en Medicina y Cirugía	— Ministerio de Educación y Cultura — El rector de una Universidad		1 January 1986
France	Diplôme d'Etat de docteur en médecine	Universités		20 December 1976
Ireland	Primary qualification	Competent examining body	Certificate of experience	20 December 1976
Italia	Diploma di laurea in medicina e chirurgia	Università	Diploma di abilitazione all'esercizio della medicina e chirurgia	20 December 1976
Luxembourg	Diplôme d'Etat de docteur en médecine, chirurgie et accouchements,	Jury d'examen d'Etat	Certificat de stage	20 December 1976
Nederland	Getuigschrift van met goed gevolg afgelegd artsexamen	Faculteit Geneeskunde		20 December 1976
Österreich	1. Urkunde über die Verleihung des akademischen Grades Doktor der gesamten Heilkunde (bzw. Doctor medicinae universae, Dr.med.univ.) 2. Diplom über die spezifische Ausbildung zum Arzt für Allgemeinmedizin bzw. Facharzt Diplom	1. Medizinische Fakultät einer Universität 2. Österreichische Ärztekammer		1 January 1994
Portugal	Carta de Curso de licenciatura em medicina	Universidades	Diploma comprovativo da conclusão do internato geral emitido pelo Ministério da Saúde	1 January 1986
Suomi/ Finland	Lääketieteen lisensiaatin tutkinto/ Medicine licentiatexamen	— Helsingin yliopisto/Helsingfors universitet — Kuopion yliopisto — Oulun yliopisto — Tampereen yliopisto — Turun yliopisto	Todistus lääkäriin perusterveystieteiden lisäkoulutuksesta/ Examenbevis om tilläggsutbildning för läkare inom primärvården	1 January 1994

Country	Evidence of formal qualifications	Body awarding the qualifications	Certificate accompanying the qualifications	Reference date
Sverige	Läkarexamen	Universitet	Bevis om praktisk utbildning som utfärdas av Socialstyrelsen	1 January 1994
United Kingdom	Primary qualification	Competent examining body	Certificate of experience	20 December 1976

### 5.1.3. Evidence of formal qualifications of specialist doctors

Country	Evidence of formal qualifications	Body awarding the qualifications	Reference date
België/ Belgique/ Belgien	Bijzondere beroepstitel van geneesheer-specialist/Titre professionnel particulier de médecin spécialiste	Minister bevoegd voor Volksgezondheid/Ministre de la Santé publique	20 December 1976
Danmark	Bevis for tilladelse til at betegne sig som speciallæge	Sundhedsstyrelsen	20 December 1976
Deutschland	Fachärztliche Anerkennung	Landesärztekammer	20 December 1976
Ελλάς	Τίτλος Ιατρικής Ειδικότητας	1. Νομαρχιακή Αυτοδιοίκηση 2. Νομαρχία	1 January 1981
España	Título de Especialista	Ministerio de Educación y Cultura	1 January 1986
France	1. Certificat d'études spéciales de médecine 2. Attestation de médecin spécialiste qualifié 3. Certificat d'études spéciales de médecine 4. Diplôme d'études spécialisées ou spécialisation complémentaire qualifiante de médecine	1. Universités 2. Conseil de l'Ordre des médecins 3. Universités 4. Universités	20 December 1976
Ireland	Certificate of Specialist doctor	Competent authority	20 December 1976
Italia	Diploma di medico specialista	Università	20 December 1976
Luxembourg	Certificat de médecin spécialiste	Ministre de la Santé publique	20 December 1976
Nederland	Bewijs van inschrijving in een Specialistenregister	— Medisch Specialisten Registratie Commissie (MSRC) van de Koninklijke Nederlandsche Maatschappij tot Bevordering der Geneeskunst — Sociaal-Geneskundigen Registratie Commissie van de Koninklijke Nederlandsche Maatschappij tot Bevordering der Geneeskunst	20 December 1976
Österreich	Facharztdiplom	Österreichische Ärztekammer	1 January 1994
Portugal	1. Grau de assistente 2. Título de especialista	1. Ministério da Saúde 2. Ordem dos Médicos	1 January 1986
Suomi/ Finland	Erikoislääkärin tutkinto/Specialläkarexamen	1. Helsingin yliopisto/Helsingfors universitet 2. Kuopion yliopisto 3. Oulun yliopisto 4. Tampereen yliopisto 5. Turun yliopisto	1 January 1994
Sverige	Bevis om specialkompetens som läkare, utfärdat av Socialstyrelsen	Socialstyrelsen	1 January 1994
United Kingdom	Certificate of Completion of specialist training	Competent authority	20 December 1976

## 5.1.4. Titles of training courses in specialised medicine

Country	Anaesthetics Minimum period of training: 3 years	General surgery Minimum period of training: 5 years
	Title	Title
Belgique/België/Belgien	Anesthésie-réanimation/Anesthesie reanimatie	Chirurgie/Heelkunde
Danmark	Anæstesiologi	Kirurgi eller kirurgiske sygdomme
Deutschland	Anästhesiologie	Chirurgie
Ελλάς	Αναισθησιολογία	Χειρουργική
España	Anestesiología y Reanimación	Cirugía general y del aparato digestivo
France	Anesthésiologie-Réanimation chirurgicale	Chirurgie générale
Ireland	Anaesthesia	General surgery
Italia	Anestesia e rianimazione	Chirurgia generale
Luxembourg	Anesthésie-réanimation	Chirurgie générale
Nederland	Anesthesiologie	Heelkunde
Österreich	Anästhesiologie und Intensivmedizin	Chirurgie
Portugal	Anestesiologia	Cirurgia geral
Suomi/Finland	Anestesiologia ja tehohoito/Anestesiologi och intensivvård	Yleiskirurgia/Allmän kirurgi
Sverige	Anestesi och intensivvård	Kirurgi
United Kingdom	Anaesthetics	General surgery

Country	Neurological surgery Minimum period of training: 5 years	Gynaecology and obstetrics Minimum period of training: 4 years
	Title	Title
Belgique/België/Belgien	Neurochirurgie	Gynécologie — obstétrique/Gynaecologie — verloskunde
Danmark	Neurokirurgi eller kirurgiske nervesygdomme	Gynækologi og obstetrik eller kvindesygdomme og fødselshjælp
Deutschland	Neurochirurgie	Frauenheilkunde und Geburtshilfe
Ελλάς	Νευροχειρουργική	Μαιευτική-Γυναικολογία
España	Neurocirugía	Obstetricia y ginecología
France	Neurochirurgie	Gynécologie — obstétrique
Ireland	Neurological surgery	Obstetrics and gynaecology
Italia	Neurochirurgia	Ginecologia e ostetricia
Luxembourg	Neurochirurgie	Gynécologie — obstétrique
Nederland	Neurochirurgie	Verloskunde en gynaecologie
Österreich	Neurochirurgie	Frauenheilkunde und Geburtshilfe
Portugal	Neurocirurgia	Ginecologia e obstetricia
Suomi/Finland	Neurokirurgia/Neurokirurgi	Naistentaudit ja synnytykset/Kvinnosjukdomar och förlösningar
Sverige	Neurokirurgi	Obstetrik och gynekologi
United Kingdom	Neurosurgery	Obstetrics and gynaecology

	General medicine Minimum period of training: 5 years	Ophthalmology Minimum period of training: 3 years
Country	Title	Title
Belgique/België/Belgien	Médecine interne/Inwendige geneeskunde	Ophtalmologie/Oftalmologie
Danmark	Intern medicin	Oftalmologi eller øjensygdomme
Deutschland	Innere Medizin	Augenheilkunde
Ελλάς	Παθολογία	Οφθαλμολογία
España	Medicina interna	Oftalmología
France	Médecine interne	Ophtalmologie
Ireland	General medicine	Ophthalmology
Italia	Medicina interna	Oftalmologia
Luxembourg	Médecine interne	Ophtalmologie
Nederland	Inwendige geneeskunde	Oogheekunde
Österreich	Innere Medizin	Augenheilkunde und Optometrie
Portugal	Medicina interna	Oftalmologia
Suomi/Finland	Sisätaudit/Inre medicine	Silmätaudit/Ögonsjukdomar
Sverige	Internmedicin	Ögonsjukdomar (oftalmologi)
United Kingdom	General (internal) medicine	Ophthalmology

	Otolaryngology Minimum period of training: 3 years	Paediatrics Minimum period of training: 4 years
Country	Title	Title
Belgique/België/Belgien	Oto-rhino-laryngologie/Otorhinolaryngologie	Pédiatrie/Pediatric
Danmark	Oto-rhino-laryngologi eller øre-næse-halssygdomme	Pædiatri eller sygdomme hos børn
Deutschland	Hals-Nasen-Ohrenheilkunde	Kinderheilkunde
Ελλάς	Ωτορινολαρυγγολογία	Παιδιατρική
España	Otorrinolaringología	Pediatría y sus áreas específicas
France	Oto-rhino-laryngologie	Pédiatrie
Ireland	Otolaryngology	Paediatrics
Italia	Otorinolaringoiatria	Pédiatria
Luxembourg	Oto-rhino-laryngologie	Pédiatrie
Nederland	Keel-, neus- en oorheekunde	Kindergeneeskunde
Österreich	Hals-, Nasen- und Ohrenkrankheiten	Kinder- und Jugendheilkunde
Portugal	Otorrinolaringologia	Pediatría
Suomi/Finland	Korva-, nenä- ja kurkkutaudit/Öron-, näs- och hals-sjukdomar	Lastentaudit/Barnsjukdomar
Sverige	Öron-, näs- och halssjukdomar (oto-rhino-laryngologi)	Barn- och ungdomsmedicin
United Kingdom	Otolaryngology	Paediatrics



	Respiratory medicine Minimum period of training: 4 years	Urology Minimum period of training: 5 years
Country	Title	Title
Belgique/België/Belgien	Pneumologie	Urologie
Danmark	Medicinske lungesygdomme	Urologi eller urinvejenes kirurgiske sygdomme
Deutschland	Pneumologie	Urologie
Ελλάς	Φυματιολογία-Πνευμονολογία	Ουρολογία
España	Neumología	Urología
France	Pneumologie	Urologie
Ireland	Respiratory medicine	Urology
Italia	Malattie dell'apparato respiratorio	Urologia
Luxembourg	Pneumologie	Urologie
Nederland	Longziekten en tuberculose	Urologie
Österreich	Lungenkrankheiten	Urologie
Portugal	Pneumologia	Urologia
Suomi/Finland	Keuhkosairaudet ja allergologia/Lungsjukdomar och allergologi	Urologia/Urologi
Sverige	Lungsjukdomar (pneumologi)	Urologi
United Kingdom	Respiratory medicine	Urology

	Orthopaedic surgery Minimum period of training: 5 years	Morbid anatomy and histopathology Minimum period of training: 4 years
Country	Title	Title
Belgique/België/Belgien	Chirurgie orthopédique/Orthopedische heelkunde	Anatomie pathologique/Pathologische anatomie
Danmark	Ortopædisk kirurgi	Patologisk anatomi eller vævs- og celleundersøgelser
Deutschland	Orthopädie	Pathologie
Ελλάς	Ορθοπαιδική	Παθολογική Ανατομική
España	Traumatología y cirugía ortopédica	Anatomía patológica
France	Chirurgie orthopédique et traumatologie	Anatomie et cytologie pathologiques
Ireland	Orthopaedic surgery	Morbid anatomy and histopathology
Italia	Ortopedia e traumatologia	Anatomia patologica
Luxembourg	Orthopédie	Anatomie pathologique
Nederland	Orthopedie	Pathologie
Österreich	Orthopädie und Orthopädische Chirurgie	Pathologie
Portugal	Ortopedia	Anatomia patologica
Suomi/Finland	Ortopedia ja traumatologia/Ortopedi och traumatologi	Patologia/Patologi
Sverige	Ortopedi	Klinisk patologi
United Kingdom	Trauma and orthopaedic surgery	Histopathology

	Neurology Minimum period of training: 4 years	Psychiatry Minimum period of training: 4 years
Country	Title	Title
Belgique/België/Belgien	Neurologie	Psychiatrie
Danmark	Neurologi eller medicinske nervesygdomme	Psykiatri
Deutschland	Neurologie	Psychiatrie und Psychotherapie
Ελλάς	Νευρολογία	Ψυχιατρική
España	Neurología	Psiquiatría
France	Neurologie	Psychiatrie
Ireland	Neurology	Psychiatry
Italia	Neurologia	Psichiatria
Luxembourg	Neurologie	Psychiatrie
Nederland	Neurologie	Psychiatrie
Österreich	Neurologie	Psychiatrie
Portugal	Neurologia	Psiquiatria
Suomi/Finland	Neurologia/Neurologi	Psykiatria/Psykiatri
Sverige	Neurologi	Psykiatri
United Kingdom	Neurology	General psychiatry

	Diagnostic radiology Minimum period of training: 4 years	Radiotherapy Minimum period of training: 4 years
Country	Title	Title
Belgique/België/Belgien	Radiodiagnostic/Röntgendiagnose	Radiothérapie-oncologie/Radiotherapie-oncologie
Danmark	Diagnostik radiologi eller røntgenundersøgelse	Onkologi
Deutschland	Diagnostische Radiologie	Strahlentherapie
Ελλάς	Ακτινοδιαγνωστική	Ακτινοθεραπευτική — Ογκολογία
España	Radiodiagnóstico	Oncología radioterápica
France	Radiodiagnostic et imagerie médicale	Oncologie radiothérapique
Ireland	Diagnostic radiology	Radiotherapy
Italia	Radiodiagnostica	Radioterapia
Luxembourg	Radiodiagnostic	Radiothérapie
Nederland	Radiologie	Radiotherapie
Österreich	Medizinische Radiologie-Diagnostik	Strahlentherapie — Radioonkologie
Portugal	Radiodiagnóstico	Radioterapia
Suomi/Finland	Radiologia/Radiologi	Syöpätaudit/Cancersjukdomar
Sverige	Medicinsk radiologi	Tumörsjukdomar (allmän onkologi)
United Kingdom	Clinical radiology	Clinical oncology

Country	Plastic surgery Minimum period of training: 5 years
	Title
Belgique/België/Belgien	Chirurgie plastique, reconstructrice et esthétique/Plastische, reconstructieve en esthetische heekunde
Danmark	Plastikkirurgi
Deutschland	Plastische Chirurgie
Ελλάς	Πλαστική Χειρουργική
España	Cirugía plástica y reparadora
France	Chirurgie plastique, reconstructrice et esthétique
Ireland	Plastic surgery
Italia	Chirurgia plastica e ricostruttiva
Luxembourg	Chirurgie plastique
Nederland	Plastische chirurgie
Österreich	Plastische Chirurgie
Portugal	Cirurgia plástica e reconstrutiva
Suomi/Finland	Plastiikkakirurgia/Plastikkirurgi
Sverige	Plastikkirurgi
United Kingdom	Plastic surgery

#### 5.1.5. Evidence of formal qualifications of general practitioners

Country	Evidence of formal qualifications	Professional title	Reference date
België/ Belgique/ Belgien	Ministerieel erkenningsbesluit van huisarts/Arrêté ministériel d'agrément de médecin généraliste	Huisarts/Médecin généraliste	31 December 1994
Danmark	Speciallæge — I almen medicin	Speciallæge I almen medicin	31 December 1994
Deutschland	Zeugnis über die spezifische Ausbildung in der Allgemeinmedizin	— Praktischer Arzt — Ärztin	31 December 1994
Ελλάς	Τίτλος ιατρικής ειδικότητας γενικής ιατρικής	Ιατρός με ειδικότητα γενικής ιατρικής	31 December 1994
España	Titulo de especialista en medicina familiar y comunitaria	Especialista en medicina familiar y comunitaria	31 December 1994
France	Diplôme d'Etat de docteur en médecine (avec document annexé attestant la formation spécifique en médecine générale)	Médecin qualifié en médecine générale	31 December 1994
Ireland	Certificate of specific qualifications in general medical practice	General medical practitioner	31 December 1994
Italia	Attestato di formazione specifica in medicina generale	Medico di medicina generale	31 December 1994
Luxembourg	Il n'existe pas de titre, parce qu'il n'y a pas de formation au Luxembourg	Médecin généraliste	31 December 1994
Nederland	Certificaat van inschrijving in het register van erkende huisartsen van de Koninklijke Nederlandsche Maatschappij tot bevordering der geneeskunst	Huisarts	31 December 1994
Österreich	Arzt für Allgemeinmedizin	Arzt für Allgemeinmedizin	31 December 1994
Portugal	Diploma do internato complementar de clínica geral	Assistente de clínica geral	31 December 1994
Suomi/ Finland	Todistus lääkärin perusterveydenhuollon lisäkoulutuksesta/Bevis om tilläggsutbildning av läkare I primärvård	Yleislääkäri/Allmänläkare	31 December 1994
Sverige	Bevis om kompetens som allmänpraktiserande läkare (Europaläkare) utfärdad av Socialstyrelsen	Allmänpraktiserande läkare (Europaläkare)	31 December 1994
United Kingdom	Certificate of prescribed/equivalent experience	General medical practitioner	31 December 1994

## ANNEX V.2: NURSE RESPONSIBLE FOR GENERAL CARE

## 5.2.1. Knowledge and skills

Training for nurses responsible for general care provides an assurance that the person in question has acquired the following knowledge and skills:

- adequate knowledge of the sciences on which general nursing is based, including sufficient understanding of the structure, physiological functions and behaviour of healthy and sick persons, and of the relationship between the state of health and the physical and social environment of the human being
- sufficient knowledge of the nature and ethics of the profession and of the general principles of health and nursing
- adequate clinical experience; such experience, which should be selected for its training value, should be gained under the supervision of qualified nursing staff and in places where the number of qualified staff and equipment are appropriate for the nursing care of the patient
- the ability to participate in the practical training of health personnel and experience of working with such personnel
- experience of working with members of other professions in the health sector.

## 5.2.2. Training programme for nurses responsible for general care

The training leading to the award of a formal qualification of nurses responsible for general care shall consist of the following two parts.

## A. Theoretical instruction

- |  |   |                                 |
|--|---|---------------------------------|
| (a) Nursing:                               | (b) Basic sciences:                       | (c) Social sciences:            |
| — Nature and ethics of the profession      | — Anatomy and physiology                  | — Sociology                     |
| — General principles of health and nursing | — Pathology                               | — Psychology                    |
| — Nursing principles in relation to:       | — Bacteriology, virology and parasitology | — Principles of administration  |
| — general and specialist medicine          | — Biophysics, biochemistry and radiology  | — Principles of teaching        |
| — general and specialist surgery           | — Dietetics                               | — Social and health legislation |
| — child care and paediatrics               | — Hygiene:                                | — Legal aspects of nursing      |
| — maternity care                           | — preventive medicine                     |                                 |
| — mental health and psychiatry             | — health education                        |                                 |
| — care of the old and geriatrics           | — Pharmacology                            |                                 |

## B. Clinical instruction

- Nursing in relation to:
  - general and specialist medicine
  - general and specialist surgery
  - child care and paediatrics

- maternity care
- mental health and psychiatry
- care of the old and geriatrics
- home nursing

One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.

The theoretical instruction must be weighted and coordinated with the clinical instruction in such a way that the knowledge and skills referred to in this Annex can be acquired in an adequate fashion.

### 5.2.3. Evidence of formal qualifications of nurses responsible for general care

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Professional title	Reference date
België/ Belgique/ Belgien	<ul style="list-style-type: none"> <li>— Diploma gegradueerde verpleger/verpleegster/Diplôme d'infirmier(ère) gradué(e)/Diplom eines (einer) graduierten Krankenpflegers (-pflegerin)</li> <li>— Diploma in de ziekenhuisverpleegkunde/Brevet d'infirmier(ère) hospitalier(ère)/Brevet eines (einer) Krankenpflegers (-pflegerin)</li> <li>— Brevet van verpleeg-assistent(e)/Brevet d'hospitalier(ère)/Brevet einer Pflege-Assistentin</li> </ul>	<ul style="list-style-type: none"> <li>— De erkende opleidingsinstututen/Les établissements d'enseignement reconnus/Die anerkannten Ausbildungsanstalten</li> <li>— De bevoegde Examencommissie van de Vlaamse Gemeenschap/Le Jury compétent d'enseignement de la Communauté française/Der zuständige Prüfungsausschuss der Deutschsprachigen Gemeinschaft</li> </ul>	<ul style="list-style-type: none"> <li>— Hospitalier(ère)/Verpleegassistent(e)</li> <li>— Infirmier(ère) hospitalier(ère)/Ziekenhuisverpleger (-verpleegster)</li> </ul>	29 June 1979
Danmark	Eksamensbevis efter gennemført sygeplejerskeuddannelse	Sygeplejeskole godkendt af Undervisningsministeriet	Sygeplejerske	29 June 1979
Deutschland	Zeugnis über die staatliche Prüfung in der Krankenpflege	Staatlicher Prüfungsausschuss	<ul style="list-style-type: none"> <li>— Krankenschwester</li> <li>— Krankenpfleger</li> </ul>	29 June 1979
Ελλάς	<ol style="list-style-type: none"> <li>1. Πτυχίο Νοσηλευτικής Παν/μίου Αθηνών</li> <li>2. Πτυχίο Νοσηλευτικής Τεχνολογικών Εκπαιδευτικών Ιδρυμάτων</li> <li>3. Πτυχίο Αξιωματικών Νοσηλευτικής</li> <li>4. Πτυχίο Αδελφών Νοσοκόμων πρώην Ανωτέρων Σχολών Υπουργείου Υγείας και Πρόνοιας</li> <li>5. Πτυχίο Αδελφών Νοσοκόμων και Επισκεπτριών πρώην Ανωτέρων Σχολών Υπουργείου Υγείας και Πρόνοιας</li> <li>6. Πτυχίο Τμήματος Νοσηλευτικής</li> </ol>	<ol style="list-style-type: none"> <li>1. Πανεπιστήμιο Αθηνών</li> <li>2. Τεχνολογικά Εκπαιδευτικά Ιδρύματα Υπουργείο Εθνικής Παιδείας και Θρησκευμάτων</li> <li>3. Υπουργείο Εθνικής Άμυνας</li> <li>4. Υπουργείο Υγείας και Πρόνοιας</li> <li>5. Υπουργείο Υγείας και Πρόνοιας</li> <li>6. ΚΑΤΕΕ Υπουργείου Εθνικής Παιδείας και Θρησκευμάτων</li> </ol>	Διπλωματούχος ή πτυχιούχος, νοσοκόμος, νοσηλεύτης ή νοσηλεύτρια	1 January 1981
España	Titulo de Diplomado universitario en Enfermería	<ul style="list-style-type: none"> <li>— Ministerio de Educación y Cultura</li> <li>— El rector de una Universidad</li> </ul>	Enfermero/a diplomado/a	1 January 1986
France	<ul style="list-style-type: none"> <li>— Diplôme d'État d'infirmier(ère)</li> <li>— Diplôme d'État d'infirmier(ère) délivré en vertu du décret n° 99-1147 du 29 décembre 1999</li> </ul>	Le ministère de la santé	Infirmier(ère)	29 June 1979

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Professional title	Reference date
Ireland	Certificate of Registered General Nurse	An Bord Altranais (The Nursing Board)	Registered General Nurse	29 June 1979
Italia	Diploma di infermiere professionale	Scuole riconosciute dallo Stato	Infermiere professionale	29 June 1979
Luxembourg	— Diplôme d'État d'infirmier — Diplôme d'État d'infirmier hospitalier gradué	Ministère de l'éducation nationale, de la formation professionnelle et des sports	Infirmier	29 June 1979
Nederland	1. Diploma's verpleger A, verpleegster A, verpleegkundige A 2. Diploma verpleegkundige MBOV (Middelbare Beroepsopleiding Verpleegkundige) 3. Diploma verpleegkundige HBOV (Hogere Beroepsopleiding Verpleegkundige) 4. Diploma beroepsonderwijs verpleegkundige — Kwalificatieniveau 4 5. Diploma hogere beroepsopleiding verpleegkundige — Kwalificatieniveau 5	1. Door een van overheidswege benoemde examencommissie 2. Door een van overheidswege benoemde examencommissie 3. Door een van overheidswege benoemde examencommissie 4. Door een van overheidswege aangewezen opleidingsinstelling 5. Door een van overheidswege aangewezen opleidingsinstelling	Verpleegkundige	29 June 1979
Österreich	1. Diplom als 'Diplomierte Gesundheits- und Krankenschwester, Diplomierter Gesundheits- und Krankenpfleger' 2. Diplom als 'Diplomierte Krankenschwester, Diplomierter Krankenpfleger'	1. Schule für allgemeine Gesundheits- und Krankenpflege 2. Allgemeine Krankenpflegeschule	— Diplomierte Krankenschwester — Diplomierter Krankenpfleger	1 January 1994
Portugal	1. Diploma do curso de enfermagem geral 2. Diploma/carta de curso de bacharelato em enfermagem 3. Carta de curso de licenciatura em enfermagem	1. Escolas de Enfermagem 2. Escolas Superiores de Enfermagem 3. Escolas Superiores de Enfermagem; Escolas Superiores de Saúde	Enfermeiro	1 January 1986
Suomi/ Finland	1. Sairaanhoitajan tutkinto/Sjukskötarexamen 2. Sosiaali- ja terveystieteiden ammattikorkeakoulututkinto, sairaanhoitaja (AMK)/Yrkes-högskole-examen inom hälsovård och det sociala området, sjukskötare (YH)	1. Terveystieteiden tutkimuskeskus/Hälsöförhållningsanstalt 2. Ammattikorkeakoulut/Yrkes-högskolor	Sairaanhoitaja/Sjukskötare	1 January 1994
Sverige	Sjukskötarskeexamen	Universitet eller högskola	Sjukskötarska	1 January 1994
United Kingdom	Statement of Registration as a Registered General Nurse in part 1 or part 12 of the register kept by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting	Various	— State Registered Nurse — Registered General Nurse	29 June 1979

## ANNEX V.3: DENTAL PRACTITIONER

5.3.1. **Knowledge and skills**

Training for dental practitioners provides an assurance that the person in question has acquired the following knowledge and skills:

- adequate knowledge of the sciences on which dentistry is based and a good understanding of scientific methods, including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data
- adequate knowledge of the constitution, physiology and behaviour of healthy and sick persons as well as the influence of the natural and social environment on the state of health of the human being, in so far as these factors affect dentistry
- adequate knowledge of the structure and function of the teeth, mouth, jaws and associated tissues, both healthy and diseased, and their relationship to the general state of health and to the physical and social well-being of the patient
- adequate knowledge of clinical disciplines and methods, providing the dentist with a coherent picture of anomalies, lesions and diseases of the teeth, mouth, jaws and associated tissues and of preventive, diagnostic and therapeutic dentistry
- suitable clinical experience under appropriate supervision

This training shall provide him with the skills necessary for carrying out all activities involving the prevention, diagnosis and treatment of anomalies and diseases of the teeth, mouth, jaws and associated tissues.

5.3.2. **Study programme for dental practitioners**

The programme of studies leading to evidence of formal qualifications in dentistry shall include at least the following subjects. One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.

A. Basic subjects	B. Medico-biological subjects and general medical subjects	C. Subjects directly related to dentistry
— Chemistry	— Anatomy	— Prosthodontics
— Physics	— Embryology	— Dental materials and equipment
— Biology	— Histology, including cytology	— Conservative dentistry
	— Physiology	— Preventive dentistry
	— Biochemistry (or physiological chemistry)	— Anaesthetics and sedation
	— Pathological anatomy	— Special surgery
	— General pathology	— Special pathology
	— Pharmacology	— Clinical practice
	— Microbiology	— Paedodontics
	— Hygiene	— Orthodontics
	— Preventive medicine and epidemiology	— Periodontics
	— Radiology	— Dental radiology
	— Physiotherapy	— Dental occlusion and function of the jaw
	— General surgery	— Professional organisation, ethics and legislation
	— General medicine, including paediatrics	— Social aspects of dental practice
	— Oto-rhino-laryngology	
	— Dermato-venereology	
	— General psychology — psychopathology	
	— neuropathology	
	— Anaesthetics	

## 5.3.3. Evidence of formal qualifications of dental practitioners

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Professional title	Reference date
België/ Belgique/ Belgien	Diploma van tandarts/ Diplôme licencié en science dentaire	— De universiteiten/Les universités — De bevoegde Examen- commissie van de Vlaamse Gemeenschap/ Le Jury compétent d'enseignement de la Communauté française		Licentiaat in de tand- heelkunde/Licencié en science dentaire	28 January 1980
Danmark	Bevis for tandlægeeksamen (odontologisk kandidat- eksamen)	Tandlægehøjskolerne, Sund- hedsvidenskabeligt universi- tetsfakultet	Autorisation som tandlæge, udstedt af Sundhedssty- relsen	Tandlæge	28 January 1980
Deutschland	Zeugnis über die Zahnärztliche Prüfung	Zuständige Behörden		Zahnarzt	28 January 1980
Ελλάς	Πτυχίο Οδοντιατρικής	Πανεπιστήμιο		Οδοντίαρος ή χειρουργός όδοντίαρος	1 January 1981
España	Título de Licenciado en Odontología	El rector de una universidad		Licenciado en odon- tología	1 January 1986
France	Diplôme d'État de docteur en chirurgie dentaire	Universités		Chirurgien-dentiste	28 January 1980
Ireland	— Bachelor in Dental Science (B.Dent.Sc.) — Bachelor of Dental Surgery (BDS) — Licentiate in Dental Surgery (LDS)	— Universities — Royal College of Surgeons in Ireland		— Dentist — Dental practitio- ner — Dental surgeon	28 January 1980
Italia	Diploma di laurea in Odontoiatria e Protesi Dentaria	Università	Diploma di abilitazione all'esercizio dell'odontoi- atria e protesi dentaria	Odontoiatra	28 January 1980
Luxembourg	Diplôme d'État de docteur en médecine dentaire	Jury d'examen d'Etat		Médecin-dentiste	28 January 1980
Nederland	Universitair getuigschrift van een met goed gevolg afgelegd tandartsexamen	Faculteit Tandheelkunde		Tandarts	28 January 1980
Österreich	Bescheid über die Verleihung des akade- mischen Grades 'Doktor der Zahnheilkunde'	Medizinische Fakultät der Universität		Zahnarzt	1 January 1994
Portugal	Carta de curso de licen- ciatura em medicina dentária	— Faculdades — Institutos Superiores		Médico dentista	1 January 1986
Suomi/ Finland	Hammaslääketieteen lisen- siaatin tutkinto/Odon- tologie licentiatexamen	— Helsingin yliopisto/Hel- singfors universitet — Oulun yliopisto — Turun yliopisto	Terveysturvakeskuksen oikeus- turvakeskuksen päätös käytännön palvelun hyväk- symisestä/Beslut av Rätts- kyddscentralen för hälso- vården om godkännande av praktisk tjänstgöring	Hammaslääkäri/Tand- läkare	1 January 1994
Sverige	Tandläkareexamen	Universitetet i Umeå Universitetet i Göteborg Karolinska Institutet Malmö Högskola	Endast för examensbevis som erhållits före den 1 juli 1995, ett utbild- ningsbevis som utfärdats av Socialstyrelsen	Tandläkare	1 January 1994
United Kingdom	— Bachelor of Dental Surgery (BDS or B.Ch.D.) — Licentiate in Dental Surgery	— Universities — Royal Colleges		— Dentist — Dental practitio- ner — Dental surgeon	28 January 1980



## ANNEX V.4: VETERINARY SURGEON

**5.4.1. Knowledge and skills**

Training as a veterinary surgeon provides an assurance that the person in question has acquired the following knowledge and skills:

- adequate knowledge of the sciences on which the activities of the veterinary surgeon are based
- adequate knowledge of the structure and functions of healthy animals, of their husbandry, reproduction and hygiene in general, as well as their feeding, including the technology involved in the manufacture and preservation of foods corresponding to their needs
- adequate knowledge of the behaviour and protection of animals
- adequate knowledge of the causes, nature, course, effects, diagnosis and treatment of the diseases of animals, whether considered individually or in groups, including a special knowledge of the diseases which may be transmitted to humans
- adequate knowledge of preventive medicine
- adequate knowledge of the hygiene and technology involved in the production, manufacture and putting into circulation of animal foodstuffs or foodstuffs of animal origin intended for human consumption
- adequate knowledge of the laws, regulations and administrative provisions relating to the subjects listed above
- adequate clinical and other practical experience under appropriate supervision.

**5.4.2. Study programme for veterinary surgeons**

The programme of studies leading to the evidence of formal qualifications in veterinary medicine shall include at least the subjects listed below.

Instruction in one or more of these subjects may be given as part of, or in association with, other courses.

*A. Basic subjects*

- Physics
- Chemistry
- Animal biology
- Plant biology
- Biomathematics

*B. Specific subjects*

- |  |   |   |
|--|---|---|
| (a) Basic sciences:                            | (b) Clinical sciences:  | (c) Animal production   |
| — Anatomy (including histology and embryology) | — Obstetrics  | — Animal production   |
| — Physiology                                   | — Pathology (including pathological anatomy)  | — Animal nutrition  |
| — Biochemistry                                 | — Parasitology  | — Agronomy  |
| — Genetics                                     | — Clinical medicine and surgery (including anaesthetics)                              | — Rural economics   |
| — Pharmacology                                 | — Clinical lectures on the various domestic animals, poultry and other animal species | — Animal husbandry  |
| — Pharmacy                                     |   | — Veterinary hygiene  |
| — Toxicology                                   | — Preventive medicine   | — Animal ethology and protection  |
| — Microbiology                                 | — Radiology   |   |
| — Immunology                                   | — Reproduction and reproductive disorders   | (d) Food hygiene  |
| — Epidemiology                                 | — Veterinary state medicine and public health   | — Inspection and control of animal foodstuffs or foodstuffs of animal origin                                      |
| — Professional ethics                          | — Veterinary legislation and forensic medicine  | — Food hygiene and technology   |
|  | — Therapeutics  | — Practical work (including practical work in places where slaughtering and processing of foodstuffs takes place) |
|  | — Propaedeutics   |   |

Practical training may be in the form of a training period, provided that such training is full-time and under the direct control of the competent authority, and does not exceed six months within the aggregate training period of five years study.

The distribution of the theoretical and practical training among the various groups of subjects shall be balanced and coordinated in such a way that the knowledge and experience may be acquired in a manner which will enable veterinary surgeons to perform all their duties.

#### 5.4.3. Evidence of formal qualifications of veterinary surgeons

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference date
België/ Belgique/ Belgien	Diploma van dierenarts/Diplôme de docteur en médecine vétérinaire	— De universiteiten/Les universités  — De bevoegde Examencommissie van de Vlaamse Gemeenschap/Le Jury compétent d'enseignement de la Communauté française		21 December 1980
Danmark	Bevis for bestået kandidat-eksamen I veterinærvidenskab	Kongelige Veterinær- og Landbohøjskole		21 December 1980
Deutschland	Zeugnis über das Ergebnis des Dritten Abschnitts der Tierärztlichen Prüfung und das Gesamtergebnis der Tierärztlichen Prüfung	Der Vorsitzende des Prüfungsausschusses für die Tierärztliche Prüfung einer Universität oder Hochschule		21 December 1980
Ελλάς	Πτυχίο Κτηνιατρικής	Πανεπιστήμιο Θεσσαλονίκης και Θεσσαλίας		1 January 1981
España	Titulo de Licenciado en Veterinaria	— Ministerio de Educación y Cultura  — El rector de una Universidad		1 January 1986
France	Diplôme d'État de docteur vétérinaire			21 December 1980
Ireland	— Diploma of Bachelor in/of Veterinary Medicine (MVB)  — Diploma of Membership of the Royal College of Veterinary Surgeons (MRCVS)			21 December 1980
Italia	Diploma di laurea in medicina veterinaria	Università	Diploma di abilitazione all'esercizio della medicina veterinaria	1 January 1985
Luxembourg	Diplôme d'État de docteur en médecine vétérinaire	Jury d'examen d'État		21 December 1980
Nederland	Getuigschrift van met goed gevolg afgelegd diergeneeskundig/veeartse-nijkundig examen			21 December 1980

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference date
Österreich	— Diplom-Tierarzt — Magister medicinae veterinariae	Universität	— Doktor der Veterinärmedizin — Doctor medicinae veterinariae — Fachtierarzt	1 January 1994
Portugal	Carta de curso de licenciatura em medicina veterinária	Universidade		1 January 1986
Suomi/ Finland	Eläinlääketieteen lisensiaatin tutkinto/Veterinärmedicine licentiatexamen	Helsingin yliopisto/Helsingfors universitet		1 January 1994
Sverige	Veterinärexamen	Sveriges Lantbruksuniversitet		1 January 1994
United Kingdom	1. Bachelor of Veterinary Science (BVSc) 2. Bachelor of Veterinary Science (BVSc) 3. Bachelor of Veterinary Medicine (BvetMB) 4. Bachelor of Veterinary Medicine and Surgery (BVM&S) 5. Bachelor of Veterinary Medicine and Surgery (BVM&S) 6. Bachelor of Veterinary Medicine (BvetMed)	1. University of Bristol 2. University of Liverpool 3. University of Cambridge 4. University of Edinburgh 5. University of Glasgow 6. University of London		21 December 1980

## ANNEX V.5: MIDWIFE

## 5.5.1. Knowledge and skills (Training types I and II)

Training as a midwife provides an assurance that the person in question has acquired the following knowledge and skills:

- adequate knowledge of the sciences on which the activities of midwives are based, particularly obstetrics and gynaecology
- adequate knowledge of the ethics of the profession and the professional legislation
- detailed knowledge of biological functions, anatomy and physiology in the field of obstetrics and of the newly born, and also a knowledge of the relationship between the state of health and the physical and social environment of the human being, and of his behaviour
- adequate clinical experience gained in approved institutions under the supervision of staff qualified in midwifery and obstetrics
- adequate understanding of the training of health personnel and experience of working with such.

## 5.5.2. Training programme for midwives (Training types I and II)

The training programme for obtaining evidence of formal qualifications in midwifery consists of the following two parts:

A. *Theoretical and technical instruction*

(a) General subjects

- Basic anatomy and physiology
- Basic pathology
- Basic bacteriology, virology and parasitology
- Basic biophysics, biochemistry and radiology
- Paediatrics, with particular reference to new-born infants
- Hygiene, health education, preventive medicine, early diagnosis of diseases
- Nutrition and dietetics, with particular reference to women, new-born and young babies
- Basic sociology and socio-medical questions
- Basic pharmacology
- Psychology
- Principles and methods of teaching
- Health and social legislation and health organisation
- Professional ethics and professional legislation
- Sex education and family planning
- Legal protection of mother and infant

(b) Subjects specific to the activities of midwives

- Anatomy and physiology
- Embryology and development of the foetus
- Pregnancy, childbirth and puerperium
- Gynaecological and obstetrical pathology
- Preparation for childbirth and parenthood, including psychological aspects
- Preparation for delivery (including knowledge and use of technical equipment in obstetrics)
- Analgesia, anaesthesia and resuscitation
- Physiology and pathology of the new-born infant
- Care and supervision of the new-born infant
- Psychological and social factors

B. *Practical and clinical training*

This training is to be dispensed under appropriate supervision:

- Advising of pregnant women, involving at least 100 pre-natal examinations.
- Supervision and care of at least 40 pregnant women.
- Conduct by the student of at least 40 deliveries; where this number cannot be reached owing to the lack of available women in labour, it may be reduced to a minimum of 30, provided that the student assists with 20 further deliveries.
- Active participation with breech deliveries. Where this is not possible because of lack of breech deliveries, practice may be in a simulated situation.
- Performance of episiotomy and initiation into suturing. Initiation shall include theoretical instruction and clinical practice. The practice of suturing includes suturing of the wound following an episiotomy and a simple perineal laceration. This may be in a simulated situation if absolutely necessary.
- Supervision and care of 40 women at risk in pregnancy, or labour or post-natal period.
- Supervision and care (including examination) of at least 100 post-natal women and healthy new-born infants.
- Observation and care of the new-born requiring special care, including those born pre-term, post-term, underweight or ill.
- Care of women with pathological conditions in the fields of gynaecology and obstetrics.
- Initiation into care in the field of medicine and surgery. Initiation shall include theoretical instruction and clinical practice.

The theoretical and technical training (Part A of the training programme) shall be balanced and coordinated with the clinical training (Part B of the same programme) in such a way that the knowledge and experience listed in this Annex may be acquired in an adequate manner.

Clinical instruction shall take the form of supervised in-service training in hospital departments or other health services approved by the competent authorities or bodies. As part of this training, student midwives shall participate in the activities of the departments concerned in so far as those activities contribute to their training. They shall be taught the responsibilities involved in the activities of midwives.

#### 5.5.3. Activities of midwives within the meaning of Article 38(2)

- to provide sound family planning information and advice
- to diagnose pregnancies and monitor normal pregnancies; to carry out the examinations necessary for the monitoring of the development of normal pregnancies
- to prescribe or advise on the examinations necessary for the earliest possible diagnosis of pregnancies at risk
- to provide a programme of parenthood preparation and a complete preparation for childbirth including advice on hygiene and nutrition
- to care for and assist the mother during labour and to monitor the condition of the foetus in utero by the appropriate clinical and technical means
- to conduct spontaneous deliveries including where required an episiotomy and in urgent cases a breech delivery
- to recognise the warning signs of abnormality in the mother or infant which necessitate referral to a doctor and to assist the latter where appropriate; to take the necessary emergency measures in the doctor's absence, in particular the manual removal of the placenta, possibly followed by manual examination of the uterus
- to examine and care for the new-born infant; to take all initiatives which are necessary in case of need and to carry out where necessary immediate resuscitation
- to care for and monitor the progress of the mother in the post-natal period and to give all necessary advice to the mother on infant care to enable her to ensure the optimum progress of the new-born infant
- to carry out the treatment prescribed by a doctor
- to maintain all necessary records.

#### 5.5.4. Evidence of formal qualifications of midwives

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Professional title	Reference date
België/ Belgique/ Belgien	Diploma van vroedvrouw/ Diplôme d'accoucheuse	— De erkende opleidingsinstututen/Les établissements d'enseignement  — De bevoegde Examencommissie van de Vlaamse Gemeenschap/Le Jury compétent d'enseignement de la Communauté française	Vroedvrouw/Accoucheuse	23 January 1983
Danmark	Bevis for bestået jordemoder-eksamen	Danmarks jordemoderskole	Jordemoder	23 January 1983
Deutschland	Zeugnis über die staatliche Prüfung für Hebammen und Entbindungspfleger	Staatlicher Prüfungsausschuss	— Hebamme — Entbindungspfleger	23 January 1983

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Professional title	Reference date
Ελλάς	<ol style="list-style-type: none"> <li>1. Πτυχίο Τμήματος Μαιευτικής Τεχνολογικών Εκπαιδευτικών Ιδρυμάτων (Τ.Ε.Ι.)</li> <li>2. Πτυχίο του Τμήματος Μαιών της Ανωτέρας Σχολής Στελεχών Υγείας και Κοινων. Πρόνοιας (ΚΑΤΕΕ)</li> <li>3. Πτυχίο Μαίας Ανωτέρας Σχολής Μαιών</li> </ol>	<ol style="list-style-type: none"> <li>1. Τεχνολογικά Εκπαιδευτικά Ιδρύματα (Τ.Ε.Ι.)</li> <li>2. ΚΑΤΕΕ Υπουργείου Εθνικής Παιδείας και Θρησκευμάτων</li> <li>3. Υπουργείο Υγείας και Πρόνοιας</li> </ol>	<ul style="list-style-type: none"> <li>— Μαλα</li> <li>— Μαιευτής</li> </ul>	23 January 1983
España	<ul style="list-style-type: none"> <li>— Título de matrona</li> <li>— Título de asistente obstétrico (matrona)</li> <li>— Título de enfermería obstétrica-ginecológica</li> </ul>	Ministerio de Educación y Cultura	<ul style="list-style-type: none"> <li>— Matrona</li> <li>— Asistente obstétrico</li> </ul>	1 January 1986
France	Diplôme de sage-femme	L'Etat	Sage-femme	23 January 1983
Ireland	Certificate in Midwifery	An Board Altranais	Midwife	23 January 1983
Italia	Diploma d'ostetrica	Scuole riconosciute dallo Stato	Ostetrica	23 January 1983
Luxembourg	Diplôme de sage-femme	Ministère de l'éducation nationale, de la formation professionnelle et des sports	Sage-femme	23 January 1983
Nederland	Diploma van verloskundige	Door het Ministerie van Volksgezondheid, Welzijn en Sport erkende opleidings-instellingen	Verloskundige	23 January 1983
Österreich	Hebammen-Diplom	<ul style="list-style-type: none"> <li>— Hebammenakademie</li> <li>— Bundeshebammenlehranstalt</li> </ul>	Hebamme	1 January 1994
Portugal	<ol style="list-style-type: none"> <li>1. Diploma de enfermeiro especialista em enfermagem de saúde materna e obstétrica</li> <li>2. Diploma/carta de curso de estudos superiores especializados em enfermagem de saúde materna e obstétrica</li> <li>3. Diploma (do curso de pós-licenciatura) de especialização em enfermagem de saúde materna e obstétrica</li> </ol>	<ol style="list-style-type: none"> <li>1. Ecolas de Enfermagem</li> <li>2. Escolas Superiores de Enfermagem</li> <li>3. — Escolas Superiores de Enfermagem — Escolas Superiores de Saúde</li> </ol>	Enfermeiro especialista em enfermagem de saúde materna e obstétrica	1 January 1986
Suomi/ Finland	<ol style="list-style-type: none"> <li>1. Kättilön tutkinto/barnmorske-examen</li> <li>2. Sosiaali- ja terveystieteiden ammattikorkeakoulututkinto, kättilö (AMK)/yrkeshögskoleexamen inom hälsovård och det sociala området, barnmorska (YH)</li> </ol>	<ol style="list-style-type: none"> <li>1. Terveystieteiden tutkimuslaitokset/hälsövärdsläroanstalter</li> <li>2. Ammattikorkeakoulut/Yrkes-högskolor</li> </ol>	Kättilö/Barnmorska	1 January 1994
Sverige	Barnmorskeexamen	Universitet eller högskola	Barnmorska	1 January 1994
United Kingdom	Statement of registration as a Midwife on part 10 of the register kept by the United Kingdom Central Council for Nursing, Midwifery and Health visiting	Various	Midwife	23 January 1983

## ANNEX V.6: PHARMACIST

**5.6.1. Knowledge and skills**

Training of pharmacists provides an assurance that the person concerned has acquired the following knowledge and skills:

- adequate knowledge of medicines and the substances used in the manufacture of medicines
- adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products
- adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products
- adequate knowledge to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge
- adequate knowledge of the legal and other requirements associated with the practice of pharmacy.

**5.6.2. Course of training for pharmacists**

- Plant and animal biology
- Physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Anatomy and physiology; medical terminology
- Microbiology
- Pharmacology and pharmacotherapy
- Pharmaceutical technology
- Toxicology
- Pharmacognosy
- Legislation and, where appropriate, professional ethics.

The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.

**5.6.3. Activities of pharmacists within the meaning of Article 41(2)**

- the preparation of the pharmaceutical form of medicinal products
- the manufacture and testing of medicinal products
- the testing of medicinal products in a laboratory for the testing of medicinal products
- the storage, preservation and distribution of medicinal products at the wholesale stage
- the preparation, testing, storage and supply of medicinal products in pharmacies open to the public
- the preparation, testing, storage and dispensing of medicinal products in hospitals
- the provision of information and advice on medicinal products.

## 5.6.4. Evidence of formal qualifications of pharmacists

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Reference date
België/ Belgique/ Belgien	Diploma van apoteker/Diplôme de pharmacien	— De universiteiten/Les universités — De bevoegde Examencommissie van de Vlaamse Gemeenschap/Le Jury compétent d'enseignement de la Communauté française	1 October 1987
Danmark	Bevis for bestået farmaceutisk kandidateksamen	Danmarks Farmaceutiske Højskole	1 October 1987
Deutschland	Zeugnis über die Staatliche Pharmazeutische Prüfung	Zuständige Behörden	1 October 1987
Ελλάς	Άδεια άσκησης φαρμακευτικού επαγγέλματος	Νομαρχιακή Αυτοδιοίκηση	1 October 1987
España	Título de licenciado en farmacia	— Ministerio de Educación y Cultura — El rector de una Universidad	1 October 1987
France	— Diplôme d'État de pharmacien — Diplôme d'État de docteur en pharmacie	Universités	1 October 1987
Ireland	Certificate of Registered Pharmaceutical Chemist		1 October 1987
Italia	Diploma o certificato di abilitazione all'esercizio della professione di farmacista ottenuto in seguito ad un esame di Stato	Università	1 November 1993
Luxembourg	Diplôme d'État de pharmacien	Jury d'examen d'État + visa du ministre de l'éducation nationale	1 October 1987
Nederland	Getuigschrift van met goed gevolg afgelegd apothekersexamen	Faculteit Pharmacie	1 October 1987
Österreich	Staatliches Apothekerdiplom	Bundesministerium für Arbeit, Gesundheit und Soziales	1 October 1994
Portugal	Carta de curso de licenciatura em Ciências Farmacêuticas	Universidades	1 October 1987
Suomi/ Finland	Proviisorin tutkinto/Provisorexamen	— Helsingin yliopisto/Helsingfors universitet — Kuopion yliopisto	1 October 1994
Sverige	Aptekarexamen	Uppsala universitet	1 October 1994
United Kingdom	Certificate of Registered Pharmaceutical Chemist		1 October 1987



## ANNEX V.7: ARCHITECT

## 5.7.1. Knowledge and skills

Training of architects provides an assurance that the person concerned has acquired the following knowledge and skills:

1. An ability to create architectural designs that satisfy both aesthetic and technical requirements.
2. An adequate knowledge of the history and theories of architecture and the related arts, technologies and human sciences.
3. A knowledge of the fine arts as an influence on the quality of architectural design.
4. An adequate knowledge of urban design, planning and the skills involved in the planning process.
5. An understanding of the relationship between people and buildings, and between buildings and their environment, and of the need to relate buildings and the spaces between them to human needs and scale.
6. An understanding of the profession of architecture and the role of the architect in society, in particular in preparing briefs that take account of social factors.
7. An understanding of the methods of investigation and preparation of the brief for a design project.
8. An understanding of the structural design, constructional and engineering problems associated with building design.
9. An adequate knowledge of physical problems and technologies and of the function of buildings so as to provide them with internal conditions of comfort and protection against the climate.
10. The necessary design skills to meet building users' requirements within the constraints imposed by cost factors and building regulations.
11. An adequate knowledge of the industries, organisations, regulations and procedures involved in translating design concepts into buildings and integrating plans into overall planning.

## 5.7.2. Evidence of formal qualifications of architects recognised pursuant to Article 20(1)

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference academic year
België/ Belgique/ Belgien	1. Architect/Architecte 2. Architect/Architecte 3. Architect 4. Architect/Architecte 5. Architect/Architecte 6. Burgelijke ingenieur-architect  1. Architecte/Architect 2. Architecte/Architect 3. Architect 4. Architecte/Architect 5. Architecte/Architect 6. Ingénieur-civil-architecte	1. Nationale hogescholen voor architectuur 2. Hogere-architectuur-instituten 3. Provinciaal Hoger Instituut voor Architectuur te Hasselt 4. Koninklijke Academies voor Schone Kunsten 5. Sint-Lucasscholen 6. Faculteiten Toegepaste Wetenschappen van de Universiteiten 6. 'Faculté Polytechnique' van Mons  1. Écoles nationales supérieures d'architecture 2. Instituts supérieurs d'architecture 3. École provinciale supérieure d'architecture de Hasselt 4. Académies royales des Beaux-Arts 5. Écoles Saint-Luc 6. Facultés des sciences appliquées des universités 6. Faculté polytechnique de Mons		1988/1989
Danmark	Arkitekt cand. arch.	— Kunstakademiets Arkitektskole i København — Arkitektskolen i Århus		1988/1989

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference academic year
Deutschland	Diplom-Ingenieur, Diplom-Ingenieur Univ.          Diplom-Ingenieur, Diplom-Ingenieur FH	<ul style="list-style-type: none"> <li>— Universitäten (Architektur/Hochbau)</li> <li>— Technischen Hochschulen (Architektur/Hochbau)</li> <li>— Technischen Universitäten (Architektur/Hochbau)</li> <li>— Universitäten-Gesamthochschulen (Architektur/Hochbau)</li> <li>— Hochschulen für bildende Künste</li> <li>— Hochschulen für Künste</li> <li>— Fachhochschulen (Architektur/Hochbau) <sup>(1)</sup></li> <li>— Universitäten-Gesamthochschulen (Architektur/Hochbau) bei entsprechenden Fachhochschulstudiengängen</li> </ul> <p><sup>(1)</sup> Diese Diplome sind je nach Dauer der durch sie abgeschlossenen Ausbildung gemäß Artikel 43 Absatz 1 anzuerkennen.</p>		1988/1989
Ελλάς	Δίπλωμα αρχιτέκτονα — μηχανικού	<ul style="list-style-type: none"> <li>— Εθνικό Μετσόβιο Πολυτεχνείο (ΕΜΠ), τμήμα αρχιτεκτόνων — μηχανικών</li> <li>— Αριστοτέλειο Πανεπιστήμιο Θεσσαλονίκης (ΑΠΘ), τμήμα αρχιτεκτόνων — μηχανικών της Πολυτεχνικής σχολής</li> </ul>	Βεβαίωση που χορηγεί το Τεχνικό Επιμελητήριο Ελλάδας (ΤΕΕ) και η οποία επιτρέπει την άσκηση δραστηριοτήτων στον τομέα της αρχιτεκτονικής	1988/1989
España	Título oficial de arquitecto	<p>Rectores de las universidades enumeradas a continuación:</p> <ul style="list-style-type: none"> <li>— Universidad politécnica de Cataluña, escuelas técnicas superiores de arquitectura de Barcelona o del Vallès;</li> <li>— Universidad politécnica de Madrid, escuela técnica superior de arquitectura de Madrid;</li> <li>— Universidad politécnica de Las Palmas, escuela técnica superior de arquitectura de Las Palmas;</li> <li>— Universidad politécnica de Valencia, escuela técnica superior de arquitectura de Valencia;</li> <li>— Universidad de Sevilla, escuela técnica superior de arquitectura de Sevilla;</li> <li>— Universidad de Valladolid, escuela técnica superior de arquitectura de Valladolid;</li> <li>— Universidad de Santiago de Compostela, escuela técnica superior de arquitectura de La Coruña;</li> <li>— Universidad del País Vasco, escuela técnica superior de arquitectura de San Sebastián;</li> <li>— Universidad de Navarra, escuela técnica superior de arquitectura de Pamplona.</li> </ul>		1988/1989

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference academic year
France	<ol style="list-style-type: none"> <li>1. Diplôme d'architecte DPLG, y compris dans le cadre de la formation professionnelle continue et de la promotion sociale.</li> <li>2. Diplôme d'architecte ESA</li> <li>3. Diplôme d'architecte ENSAIS</li> </ol>	<ol style="list-style-type: none"> <li>1. Le ministre chargé de l'architecture</li> <li>2. École spéciale d'architecture de Paris</li> <li>3. École nationale supérieure des arts et industries de Strasbourg, section architecture</li> </ol>		1988/1989
Ireland	<ol style="list-style-type: none"> <li>1. Degree of Bachelor of Architecture (B.Arch.NUI)</li> <li>2. Degree standard diploma in architecture (Dip. Arch)</li> <li>3. Certificate of associateship (ARIAI)</li> <li>4. Certificate of membership (MRIA)</li> </ol>	<ol style="list-style-type: none"> <li>1. National University of Ireland to architecture graduates of University College Dublin</li> <li>2. College of Technology, Bolton Street, Dublin</li> <li>3. Royal Institute of Architects of Ireland</li> <li>4. Royal Institute of Architects of Ireland</li> </ol>		1988/1989
Italia	<p>Laurea in architettura</p> <p>Laurea in ingegneria edile — architettura</p>	<ul style="list-style-type: none"> <li>— Università di Camerino</li> <li>— Università di Catania — Sede di Siracusa</li> <li>— Università di Chieti</li> <li>— Università di Ferrara</li> <li>— Università di Firenze</li> <li>— Università di Genova</li> <li>— Università di Napoli Federico II</li> <li>— Università di Napoli II</li> <li>— Università di Palermo</li> <li>— Università di Parma</li> <li>— Università di Reggio Calabria</li> <li>— Università di Roma 'La Sapienza'</li> <li>— Università di Roma II</li> <li>— Università di Trieste</li> <li>— Politecnico di Bari</li> <li>— Politecnico di Milano</li> <li>— Politecnico di Torino</li> <li>— Istituto universitario di architettura di Venezia</li> <li>— Università dell'Aquila</li> <li>— Università di Pavia</li> <li>— Università di Roma 'La Sapienza'</li> </ul>	<p>Diploma di abilitazione all'esercizio indipendente della professione che viene rilasciato dal ministero della pubblica istruzione dopo che il candidato ha sostenuto con esito positivo l'esame di Stato davanti ad una commissione competente</p>	<p>1988/1989</p> <p>1998/1999</p>

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference academic year
Nederland	<ol style="list-style-type: none"> <li>1. Het getuigschrift van het met goed gevolg afgelegde doctoraal examen van de studierichting bouwkunde, afstudeerrichting architectuur</li> <li>2. Het getuigschrift van het met goed gevolg afgelegde doctoraal examen van de studierichting bouwkunde, differentiatie architectuur en urbanistiek</li> <li>3. Het getuigschrift hoger beroepsonderwijs, op grond van het met goed gevolg afgelegde examen verbonden aan de opleiding van de tweede fase voor beroepen op het terrein van de architectuur, afgegeven door de betrokken examencommissies van respectievelijk: <ul style="list-style-type: none"> <li>— de Amsterdamse Hogeschool voor de Kunsten te Amsterdam</li> <li>— de Hogeschool Rotterdam en omstreken te Rotterdam</li> <li>— de Hogeschool Katholieke Leer- gangen te Tilburg</li> <li>— de Hogeschool voor de Kunsten te Arnhem</li> <li>— de Rijkshogeschool Groningen te Groningen</li> <li>— de Hogeschool Maastricht te Maastricht</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Technische Universiteit te Delft</li> <li>2. Technische Universiteit te Eindhoven</li> </ol>	Verklaring van de Stichting Bureau Architectenregister die bevestigt dat de opleiding voldoet aan de normen van artikel 42	1988/1989
Österreich	<ol style="list-style-type: none"> <li>1. Diplom.-Ingenieur, Dipl.-Ing.</li> <li>2. Diplom. Ingenieur, Dipl.-Ing.</li> <li>3. Diplom Ingenieur, Dipl.-Ing.</li> <li>4. Magister der Architektur, Magister architectura, Mag. Arch.</li> <li>5. Magister der Architektur, Magister architecturae, Mag. Arch.</li> <li>6. Magister der Architektur, Magister architecturae, Mag. Arch.</li> </ol>	<ol style="list-style-type: none"> <li>1. Technische Universität, Graz (Erzherzog-Johann-Universität Graz)</li> <li>2. Technische Universität Wien</li> <li>3. Universität Innsbruck (Leopold-Franzens-Universität Innsbruck)</li> <li>4. Hochschule für Angewandte Kunst in Wien</li> <li>5. Akademie der Bildenden Künste in Wien</li> <li>6. Hochschule für künstlerische und industrielle Gestaltung in Linz</li> </ol>		1998/1999
Portugal	Carta de curso de Licenciatura em Arquitectura	<ul style="list-style-type: none"> <li>— Faculdade de arquitectura da Universidade técnica de Lisboa</li> <li>— Faculdade de arquitectura da Universidade do Porto</li> <li>— Escola Superior Artística do Porto</li> </ul>		1988/1989

Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Certificate accompanying the evidence of qualifications	Reference academic year
Sverige	Arkitektexamen	Chalmers Tekniska Högskola AB Kungliga Tekniska Högskolan Lunds Universitet		1998/1999
United Kingdom	1. Diplomas in architecture 2. Degrees in architecture 3. Final examination 4. Examination in architecture 5. Examination Part II	1. — Universities — Colleges of Art — Schools of Art 2. Universities 3. Architectural Association 4. Royal College of Art 5. Royal Institute of British Architects	Certificate of architectural education, issued by the Architects Registration Board  The diploma and degree courses in architecture of the universities, schools and colleges of art should have met the requisite threshold standards as laid down in Article 42 of this Directive and in Criteria for validation published by the Validation Panel of the Royal Institute of British Architects and the Architects Registration Board  EU nationals who possess the Royal Institute of British Architects Part I and Part II certificates, which are recognised by ARB as the competent authority, are eligible. Also EU nationals who do not possess the ARB-recognised Part I and Part II certificates will be eligible for the Certificate of Architectural Education if they can satisfy the Board that their standard and length of education has met the requisite threshold standards of Article 42 of this Directive and of the Criteria for validation	1988/1989

## ANNEX VI

# ESTABLISHED RIGHTS APPLICABLE TO THE PROFESSIONS SUBJECT TO RECOGNITION ON THE BASIS OF COORDINATION OF THE MINIMUM TRAINING CONDITIONS

## 6.1. Established rights of specialised doctors

Clinical biology Minimum period of training: 4 years	
Country	Title
Belgique/België/Belgien	Biologie clinique/Klinische biologie
España	Análisis clínicos
France	Biologie médicale
Italia	Patologia clinica
Luxembourg	Biologie clinique
Österreich	Medizinische Biologie
Portugal	Patologia clinica

Microbiology-bacteriology Minimum period of training: 4 years	
Country	Title
Danmark	Klinisk mikrobiologi
Deutschland	Mikrobiologie und Infektionsepidemiologie
Ελλάς	— Ιατρική Βιοπαθολογία — Μικροβιολογία
España	Microbiología y parasitología
Ireland	Microbiology
Italia	Microbiologia e virologia
Luxembourg	Microbiologie
Nederland	Medische microbiologie
Österreich	Hygiene und Mikrobiologie
Suomi/Finland	Kliininen mikrobiologia/Klinisk mikrobiologi
Sverige	Klinisk bakteriologi
United Kingdom	Medical microbiology and virology

Biological haematology Minimum period of training: 4 years	
Country	Title
Danmark (*)	Klinisk blodtypeserologi
France	Hématologie
Luxembourg	Hématologie biologique
Portugal	Hematologia clinica

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1983, except for persons having commenced training before that date and completing it before the end of 1988.

Biological chemistry Minimum period of training: 4 years	
Country	Title
Danmark	Klinisk biokemi
España	Bioquímica clínica
Ireland	Chemical pathology
Italia	Biochimica clinica
Luxembourg	Chimie biologique
Nederland	Klinische chemie
Österreich	Medizinische und Chemische Labor-diagnostik
Suomi/Finland	Kliininen kemia/Klinisk kemi
Sverige	Klinisk kemi
United Kingdom	Chemical pathology

Immunology Minimum period of training: 4 years	
Country	Title
Danmark	Klinisk immunologi
España	Immunología
Ireland	Clinical immunology
Österreich	Immunologie
Sverige	Klinisk immunologi
United Kingdom	Immunology

Paediatric surgery Minimum period of training: 5 years	
Country	Title
Deutschland	Kinderchirurgie
Ελλάς	Χειρουργική Παιδών
España	Cirugía pediátrica
France	Chirurgie infantile
Ireland	Paediatric surgery
Italia	Chirurgia pediatrica
Luxembourg	Chirurgie pédiatrique
Österreich	Kinderchirurgie
Portugal	Cirurgia pediátrica
Suomi/Finland	Lastenkirurgia/Barnkirurgi
Sverige	Barn- och ungdomskirurgi
United Kingdom	Paediatric surgery

Thoracic surgery  
Minimum period of training: 5 years

Country	Title
Belgique/België/Belgien (*)	Chirurgie thoracique/Heelkunde op de thorax
Danmark	Thoraxkirurgi eller brysthulens kirurgiske sygdomme
Deutschland	Herzchirurgie
Ελλάς	Χειρουργική Θώρακος
España	Cirugía torácica
France	Chirurgie thoracique et cardiovasculaire
Ireland	Thoracic surgery
Italia	Chirurgia toracica
Luxembourg	Chirurgie thoracique
Nederland	Cardio-thoracale chirurgie
Portugal	Cirurgia cardiotorácica
Suomi/Finland	Sydän- ja rintaelinkirurgia/Hjärt- och thoraxkirurgi
Sverige	Thoraxkirurgi
United Kingdom	Cardo-thoracic surgery

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1983

Vascular surgery  
Minimum period of training: 5 years

Country	Title
Belgique/België/Belgien (*)	Chirurgie des vaisseaux/Bloedvaten-heelkunde
Danmark	Karkirurgi eller kirurgiske blodkar-sygdomme
Ελλάς	Αγγειοχειρουργική
España	Angiología y cirugía vascular
France	Chirurgie vasculaire
Italia	Chirurgia vascolare
Luxembourg	Chirurgie vasculaire
Portugal	Cirurgia vascular
Suomi/Finland	Verisuonikirurgia/Kärlkirurgi

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1983

Cardiology  
Minimum period of training: 4 years

Country	Title
Belgique/België/Belgien	Cardiologie/Kardiologie
Danmark	Kardiologi
Ελλάς	Καρδιολογία
España	Cardiología
France	Pathologie cardio-vasculaire
Ireland	Cardiology
Italia	Cardiologia
Luxembourg	Cardiologie et angiologie
Nederland	Cardiologie
Portugal	Cardiologia
Suomi/Finland	Kardiologia/Kardiologi
Sverige	Kardiologi
United Kingdom	Cardiology

Rheumatology  
Minimum period of training: 4 years

Country	Title
Belgique/België/Belgien	Rhumathologie/Reumatologie
Danmark	Reumatologi
Ελλάς	Ρευματολογία
España	Reumatología
France	Rhumathologie
Ireland	Rheumatology
Italia	Reumatologia
Luxembourg	Rhumathologie
Nederland	Reumatologie
Portugal	Reumatologia
Suomi/Finland	Reumatologia/Reumatologi
Sverige	Reumatologi
United Kingdom	Rheumatology

Gastro-enterology Minimum period of training: 4 years	
Country	Title
Belgique/België/Belgien	Gastro-entérologie/Gastroenterologie
Danmark	Medicinsk gastroenterologi eller medicinske mave-tarmsygdomme
Ελλάς	Γαστρεντερολογία
España	Aparato digestivo
France	Gastro-entérologie et hépatologie
Ireland	Gastro-enterology
Italia	Gastroenterologia
Luxembourg	Gastro-enterologie
Nederland	Gastro-enterologie
Portugal	Gastrenterologia
Suomi/Finland	Gastroenterologia/Gastroenterologi
Sverige	Medicinsk gastroenterologi och hepatologi
United Kingdom	Gastro-enterology

Haematology Minimum period of training: 3 years	
Country	Title
Danmark	Hæmatologi eller blodsygdomme
Ελλάς	Αιματολογία
España	Hematología y hemoterapia
Ireland	Haematology
Italia	Ematologia
Luxembourg	Hématologie
Portugal	Imuno-hemoterapia
Suomi/Finland	Kliininen hematologia/Klinisk hematologi
Sverige	Hematologi

Endocrinology Minimum period of training: 3 years	
Country	Title
Danmark	Medicinsk endokrinologi eller medicinske hormonsygdomme
Ελλάς	Ενδοκρινολογία
España	Endocrinología y nutrición
France	Endocrinologie, maladies métaboliques
Ireland	Endocrinology and diabetes mellitus
Italia	Endocrinologia e malattie del ricambio
Luxembourg	Endocrinologie, maladies du métabolisme et de la nutrition
Portugal	Endocrinologia
Suomi/Finland	Endokrinologia/Endokrinologi
Sverige	Endokrina sjukdomar
United Kingdom	Endocrinology and diabetes mellitus

Stomatology Minimum period of training: 3 years	
Country	Title
España	Estomatología
France	Stomatologie
Italia	Odontostomatologia
Luxembourg	Stomatologie
Portugal	Estomatologia

Physical and rehabilitative medicine Minimum period of training: 3 years	
Country	Title
Belgique/België/Belgien	Médecine physique et réadaptation/ Fysische geneeskunde en revalidatie
Danmark (*)	Fysiurgi og rehabilitering
Deutschland	Physikalische und Rehabilitative Medizin
Ελλάς	Φυσική Ιατρική και Αποκατάσταση
España	Rehabilitación
France	Rééducation et réadaptation fonctionnelles
Italia	Medicina fisica e riabilitazione
Luxembourg	Rééducation et réadaptation fonctionnelles
Nederland	Revalidatiegeneeskunde
Österreich	Physikalische Medizin
Portugal	Fisiatria ou Medicina física e de reabilitação
Suomi/Finland	Fysiatria/Fysiatri
Sverige	Rehabiliteringsmedicin

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1983, except for persons having commenced training before that date and completing it before the end of 1988

Neuropsychiatry Minimum period of training: 5 years	
Country	Title
Belgique/België/Belgien (*)	Neuropsychiatrie
Deutschland	Nervenheilkunde (Neurologie und Psychiatrie)
Ελλάς	Νευρολογία — Ψυχιατρική
France (**)	Neuropsychiatrie
Italia	Neuropsichiatria
Luxembourg (***)	Neuropsychiatrie
Nederland (****)	Zenuw — en zielsziekten
Österreich	Neurologie und Psychiatrie

Dates of repeal within the meaning of Article 25(5):

(\*) 1 August, except for persons having commenced training before that date

(\*\*) 31 December 1971

(\*\*\*) Evidence of qualifications is no longer awarded for training commenced after 5 March 1982

(\*\*\*\*) 9 July 1984



Dermato-venereology Minimum period of training: 3 years	
Country	Title
Belgique/België/Belgien	Dermato-vénérologie/Dermato-venereologie
Danmark	Dermato-venerologi eller hud- og køns-sygdomme
Deutschland	Haut- und Geschlechtskrankheiten
Ελλάς	Δερματολογία — Αφροδισιολογία
España	Dermatología médico-quirúrgica y venereología
France	Dermatologie et vénéréologie
Italia	Dermatologia e venerologia
Luxembourg	Dermato-vénérologie
Nederland	Dermatologie en venerologie
Österreich	Haut- und Geschlechtskrankheiten
Portugal	Dermatovenereologia
Suomi/Finland	Ihotaudit ja allergologia/Hudsjukdomar och allergologi
Sverige	Hud- och könssjukdomar

Venereology Minimum period of training: 4 years	
Country	Title
Ireland	Venereology
United Kingdom	Genito-urinary medicine

Dermatology Minimum period of training: 4 years	
Country	Title
Ireland	Dermatology
United Kingdom	Dermatology

Radiology Minimum period of training: 4 years	
Country	Title
Deutschland	Radiologie
Ελλάς	Ακτινολογία — Ραδιολογία
España	Electroradiologia
France (*)	Electro-radiologie
Italia	Radiologia
Luxembourg (**)	Électroradiologie
Nederland (***)	Radiologie
Österreich	Radiologie
Portugal	Radiologia

Dates of repeal within the meaning of Article 25(5):

(\*) 3 December 1971

(\*\*) Evidence of qualifications is no longer awarded for training commenced after 5 March 1982

(\*\*\*) 8 July 1984

Tropical medicine Minimum period of training: 4 years	
Country	Title
Danmark (*)	Tropemedicin
Ireland	Tropical medicine
Italia	Medicina tropicale
Österreich	Spezifische Prophylaxe und Tropenhygiene
Portugal	Medicina tropical
United Kingdom	Tropical medicine

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1987, except for persons having commenced training before that date and completing it before the end of 1988

Geriatrics Minimum period of training: 4 years	
Country	Title
Danmark	Geriatrí eller alderdommens sygdomme
España	Geriatría
Ireland	Geriatrics
Italia	Geriatría
Nederland	Klinische geriatrie
Suomi/Finland	Geriatría/Geriatri
Sverige	Geriatrík
United Kingdom	Geriatrics

Child and adolescent psychiatry Minimum period of training: 4 years	
Country	Title
Danmark	Børne- og ungdomspsykiatri
Deutschland	Kinder- und Jugendpsychiatrie und -psychotherapie
Ελλάς	Παιδοψυχιατρική
France	Pédo-psychiatrie
Ireland	Child and adolescent psychiatry
Italia	Neuropsichiatria infantile
Luxembourg	Psychiatrie infantile
Portugal	Pedopsiquiatria
Suomi/Finland	Lastenpsykiatria/Barnpsykiatri
Sverige	Barn- och ungdomspsykiatri
United Kingdom	Child and adolescent psychiatry

Renal medicine  
Minimum period of training: 4 years

Country	Title
Danmark	Nefrologi eller medicinske nyresygdomme
Ελλάς	Νεφρολογία
España	Nefrología
France	Néphrologie
Ireland	Nephrology
Italia	Nefrologia
Luxembourg	Néphrologie
Portugal	Nefrologia
Suomi/Finland	Nefrologia/Nefrologi
Sverige	Medicinska njursjukdomar (nefrologi)
United Kingdom	Renal medicine

Infectious diseases  
Minimum period of training: 4 years

Country	Title
Danmark	Infektionsmedicin
Ireland	Communicable diseases
Italia	Malattie infettive
Suomi/Finland	Infektiosairaudet/Infektionssjukdomar
Sverige	Infektionssjukdomar
United Kingdom	Infectious diseases

Pharmacology  
Minimum period of training: 4 years

Country	Title
Danmark	Klinisk farmakologi
Deutschland	Pharmakologie und Toxikologie
España	Farmacología clínica
Ireland	Clinical pharmacology and therapeutics
Österreich	Pharmakologie und Toxikologie
Suomi/Finland	Kliininen farmakologia ja lääkehoito/ Klinisk farmakologi och läkemedels- behandling
Sverige	Klinisk farmakologi
United Kingdom	Clinical pharmacology and therapeutics

Public health and social medicine  
Minimum period of training: 4 years

Country	Title
Danmark	Samfundsmedicin
Deutschland	Öffentliches Gesundheitswesen
Ελλάς	Κοινωνική Ιατρική
España	Medicina preventiva y salud pública
France	Santé publique et médecine sociale
Ireland	Community medicine
Italia	Igiene e medicina sociale
Luxembourg	Santé publique
Nederland	Maatschappij en gezondheid
Österreich	Sozialmedizin
Suomi/Finland	Terveystieteiden tutkimus/Hälsöförskning
Sverige	Socialmedicin
United Kingdom	Public health medicine

Occupational medicine  
Minimum period of training: 4 years

Country	Title
Belgique/België/Belgien	Médecine du travail/Arbeidsgeneeskunde
Danmark	Arbejdsmedicin
Deutschland	Arbeitsmedizin
Ελλάς	Ιατρική της Εργασίας
France	Médecine du travail
Ireland	Occupational medicine
Italia	Medicina del lavoro
Luxembourg	Médecine du travail
Nederland	— Arbeid en gezondheid, bedrijfs- geneeskunde — Arbeid en gezondheid, verzeker- ingsgeneeskunde
Österreich	Arbeits- und Betriebsmedizin
Portugal	Medicina do trabalho
Suomi/Finland	Työterveyshuolto/Företagshälsöförskning
Sverige	Yrkes- och miljömedicin
United Kingdom	Occupational medicine

Allergology  
Minimum period of training: 3 years

Country	Title
Danmark	Medicinsk allergologi eller medicinske overfølsomhedssygdomme
Ελλάς	Αλλεργιολογία
España	Alergología
Italia	Allergologia ed immunologia clinica
Nederland	Allergologie en inwendige geneeskunde
Portugal	Imuno-alergologia
Sverige	Allergisjukdomar

Nuclear medicine  
Minimum period of training: 4 years

Country	Title
Belgique/België/Belgien	Médecine nucléaire/Nucleaire geneeskunde
Danmark	Klinisk fysiologi og nuklearmedicin
Deutschland	Nuklearmedizin
Ελλάς	Πυρηνική Ιατρική
España	Medicina nuclear
France	Médecine nucléaire
Italia	Medicina nucleare
Luxembourg	Médecine nucléaire
Nederland	Nucleaire geneeskunde
Österreich	Nuklearmedizin
Portugal	Medicina nuclear
Suomi/Finland	Kliininen Fysiologia ja isotooppi-lääketiede/Klinisk Fysiologi och nukleärmedicin
United Kingdom	Nuclear medicine

Gastro-enterological surgery  
Minimum period of training: 5 years

Country	Title
Belgique/België/Belgien (*)	Chirurgie abdominale/Heelkunde op het abdomen
Danmark	Kirurgisk gastroenterologi eller kirurgiske mave-tarmsygdomme
España	Cirugía del aparato digestivo
France	Chirurgie viscérale et digestive
Italia	Chirurgia dell'apparato digestivo
Luxembourg	Chirurgie gastro-entérologique
Suomi/Finland	Gastroenterologinen kirurgia/Gastroenterologisk kirurgi

Dates of repeal within the meaning of Article 25(5):

(\*) 1 January 1983

Accident and emergency medicine  
Minimum period of training: 5 years

Country	Title
Ireland	Accident and emergency medicine
United Kingdom	Accident and emergency medicine

Clinical neurophysiology  
Minimum period of training: 4 years

Country	Title
Danmark	Klinisk neurofysiologi
España	Neurofisiología clínica
Ireland	Neurophysiology
Suomi/Finland	Kliininen neurofysiologia/Klinisk neurofysiologi
Sverige	Klinisk neurofysiologi
United Kingdom	Clinical neurophysiology

Dental, oral and maxillo-facial surgery (basic medical and dental training) <sup>(1)</sup>  
Minimum period of training: 4 years

Country	Title
Belgique/België/Belgien	Stomatologie et chirurgie orale et maxillo-faciale/Stomatologie en mond-, kaak- en aangezichtschirurgie
Deutschland	Mund-, Kiefer- und Gesichtschirurgie
Ireland	Oral and maxillo-facial surgery
Luxembourg	Chirurgie dentaire, orale et maxillo-faciale
Suomi/Finland	Suu- ja leukakirurgia/Oral och maxillo-facial kirurgi
United Kingdom	Oral and maxillo-facial surgery

<sup>(1)</sup> Training leading to the award of evidence of formal qualifications as a specialist in dental, oral and maxillo-facial surgery (basic medical and dental training) assumes completion and validation of basic medical studies (Article 19) and, in addition, completion and validation of dental studies (Article 29).

Maxillo-facial surgery (basic medical training)  
Minimum period of training: 5 years

Country	Title
España	Cirugía oral y maxilofacial
France	Chirurgie maxillo-faciale et stomatologie
Italia	Chirurgia maxillo-facciale
Luxembourg	Chirurgie maxillo-faciale
Österreich	Mund-, Kiefer- und Gesichtschirurgie

## 6.2. Established rights of specialised dentists

Orthodontics			
Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Reference date
Danmark	Bevis for tilladelse til at betegne sig som specialt-andlæge i ortodonti	Sundhedsstyrelsen	28 January 1980
Deutschland	Fachzahnärztliche Anerkennung für Kieferorthopädie	Landeszahnärztekammer	28 January 1980
Ελλάς	Τίτλος Οδοντιατρικής ειδικότητας της Ορθοδοντικής	— Νομαρχιακή Αυτοδιοίκηση — Νομαρχία	1 January 1981
France	Titre de spécialiste en orthodontie	Conseil National de l'Ordre des chirurgiens dentistes	28 January 1980
Ireland	Certificate of specialist dentist in orthodontics	Competent authority recognised for this purpose by the competent minister	28 January 1980
Nederland	Bewijs van inschrijving als orthodontist in het Specialistenregister	Specialisten Registratie Commissie (SRC) van de Nederlandse Maatschappij tot bevordering der Tandheelkunde	28 January 1980
Suomi/Finland	Erikoishammaslääkärin tutkinto, hampaiston oikomishoito/Specialtand-läkarexamen, tandreglering	— Helsingin yliopisto/Helsingfors universitet — Oulun yliopisto — Turun yliopisto	1 January 1994
Sverige	Bevis om specialistkompetens i tandreglering	Socialstyrelsen	1 January 1994
United Kingdom	Certificate of Completion of specialist training in orthodontics	Competent authority recognised for this purpose	28 January 1980

Oral surgery			
Country	Evidence of formal qualifications	Body awarding the evidence of qualifications	Reference date
Danmark	Bevis for tilladelse til at betegne sig som specialt-andlæge i hospitalsodontologi	Sundhedsstyrelsen	28 January 1980
Deutschland	Fachzahnärztliche Anerkennung für Oralchirurgie/Mundchirurgie	Landeszahnärztekammer	28 January 1980
Ελλάς	Τίτλος Οδοντιατρικής ειδικότητας της Γναθοχειρουργικής	— Νομαρχιακή Αυτοδιοίκηση — Νομαρχία	1 January 1981
Ireland	Certificate of specialist dentist in oral surgery	Competent authority recognised for this purpose by the competent minister	28 January 1980
Nederland	Bewijs van inschrijving als kaakchirurg in het Specialistenregister	Specialisten Registratie Commissie (SRC) van de Nederlandse Maatschappij tot bevordering der Tandheelkunde	28 January 1980
Suomi/Finland	Erikoishammaslääkärin tutkinto, suu- ja leukakirurgia/Specialtandläkar-examen, oral och maxillo-facial kirurgi	— Helsingin yliopisto/Helsingfors universitet — Oulun yliopisto — Turun yliopisto	1 January 1994
Sverige	Bevis om specialist-kompetens i tandsystemets kirurgiska sjukdomar	Socialstyrelsen	1 January 1994
United Kingdom	Certificate of completion of specialist training in oral surgery	Competent authority recognised for this purpose	28 January 1980

**6.3. Evidence of formal qualifications of architects benefiting from the established rights acquired pursuant to the first paragraph of Article 45(1)**

Country	Evidence of formal qualifications	Reference academic year
België/ Belgique/ Belgien	<ul style="list-style-type: none"> <li>— the diplomas awarded by the higher national schools of architecture or the higher national institutes of architecture (architecte-architect)</li> <li>— the diplomas awarded by the higher provincial school of architecture of Hasselt (architect)</li> <li>— the diplomas awarded by the Royal Academies of Fine Arts (architecte — architect)</li> <li>— the diplomas awarded by the 'écoles Saint-Luc' (architecte — architect)</li> <li>— university diplomas in civil engineering, accompanied by a traineeship certificate awarded by the association of architects entitling the holder to hold the professional title of architect (architecte — architect)</li> <li>— the diplomas in architecture awarded by the central or State examining board for architecture (architecte — architect)</li> <li>— the civil engineering/architecture diplomas and architecture/engineering diplomas awarded by the faculties of applied sciences of the universities and by the Polytechnical Faculty of Mons (ingénieur-architecte, ingénieur-architect)</li> </ul>	1987/1988
Danmark	<ul style="list-style-type: none"> <li>— the diplomas awarded by the National Schools of Architecture in Copenhagen and Aarhus (arkitekt)</li> <li>— the certificate of registration issued by the Board of Architects pursuant to Law No 202 of 28 May 1975 (registreret arkitekt)</li> <li>— diplomas awarded by the Higher Schools of Civil Engineering (bygningskonstruktoer), accompanied by a certificate from the competent authorities to the effect that the person concerned has passed a test of his formal qualifications, comprising an appreciation of plans drawn up and executed by the candidate during at least six years' effective practice of the activities referred to in Article 44 of this Directive</li> </ul>	1987/1988
Deutschland	<ul style="list-style-type: none"> <li>— the diplomas awarded by higher institutes of fine arts (Dipl.-Ing., Architekt (HfbK))</li> <li>— the diplomas awarded by the departments of architecture (Architektur/Hochbau) of 'Technische Hochschulen', of technical universities, of universities and, in so far as these institutions have been merged into 'Gesamthochschulen', of 'Gesamthochschulen' (Dipl.-Ing. and any other title which may be laid down later for holders of these diplomas)</li> <li>— the diplomas awarded by the departments of architecture (Architektur/Hochbau) of 'Fachhochschulen' and, in so far as these institutions have been merged into 'Gesamthochschulen', by the departments of architecture (Architektur/Hochbau) of 'Gesamthochschulen', accompanied, where the period of study is less than four years but at least three years, by a certificate attesting to a four-year period of professional experience in the Federal Republic of Germany issued by the professional body in accordance with Article 43(1) (Ingenieur grad. and any other title which may be laid down later for holders of these diplomas)</li> <li>— the diplomas (Prüfungszeugnisse) awarded before 1 January 1973 by the departments of architecture of 'Ingenieurschulen' and of 'Werkkunstschulen', accompanied by a certificate from the competent authorities to the effect that the person concerned has passed a test of his formal qualifications, comprising an appreciation of plans drawn up and executed by the candidate during at least six years' effective practice of the activities referred to in Article 44 of this Directive</li> </ul>	1987/1988
Ελλάς	<ul style="list-style-type: none"> <li>— the engineering/architecture diplomas awarded by the Metsovion Polytechnion of Athens, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> <li>— the engineering/architecture diplomas awarded by the Aristotelion Panepistimion of Thessaloniki, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> <li>— the engineering/civil engineering diplomas awarded by the Metsovion Polytechnion of Athens, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> <li>— the engineering/civil engineering diplomas awarded by the Aristotelion Panepistimion of Thessaloniki, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> <li>— the engineering/civil engineering diplomas awarded by the Panepistimion Thrakis, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> <li>— the engineering/civil engineering diplomas awarded by the Panepistimion Patron, together with a certificate issued by Greece's Technical Chamber conferring the right to pursue activities in the field of architecture</li> </ul>	1987/1988

Country	Evidence of formal qualifications	Reference academic year
España	the official formal qualification of an architect (título oficial de arquitecto) awarded by the Ministry of Education and Science or by the universities	1987/1988
France	<ul style="list-style-type: none"> <li>— the Government architect's diploma awarded by the Ministry of Education until 1959, and subsequently by the Ministry of Cultural Affairs (architecte DPLG)</li> <li>— the diplomas awarded by the 'Ecole spéciale d'architecture' (architecte DESA)</li> <li>— the diplomas awarded by the 'Ecole nationale supérieure des arts et industries de Strasbourg' (former 'Ecole nationale d'ingénieurs de Strasbourg'), department of architecture (architecte ENSAIS)</li> </ul>	1987/1988
Ireland	<ul style="list-style-type: none"> <li>— the degree of Bachelor of Architecture awarded by the National University of Ireland (B Arch. (NUI)) to architecture graduates of University College, Dublin</li> <li>— the diploma of degree standard in architecture awarded by the College of Technology, Bolton Street, Dublin (Dipl. Arch.)</li> <li>— the Certificate of Associateship of the Royal Institute of Architects of Ireland (ARIAI)</li> <li>— the Certificate of Membership of the Royal Institute of Architects of Ireland (MRIAI)</li> </ul>	1987/1988
Italia	<ul style="list-style-type: none"> <li>— 'laurea in architettura' diplomas awarded by universities, polytechnic institutes and the higher institutes of architecture of Venice and Reggio Calabria, accompanied by the diploma entitling the holder to pursue independently the profession of architect, awarded by the Minister for Education after the candidate has passed, before a competent board, the State examination entitling him to pursue independently the profession of architect (dott. Architetto)</li> <li>— 'laurea in ingegneria' diplomas in building construction awarded by universities and polytechnic institutes, accompanied by the diploma entitling the holder to pursue independently a profession in the field of architecture, awarded by the Minister for Education after the candidate has passed, before a competent board, the State examination entitling him to pursue the profession independently (dott. Ing. Architetto or dott. Ing. In ingegneria civile)</li> </ul>	1987/1988
Nederland	<ul style="list-style-type: none"> <li>— the certificate stating that its holder has passed the degree examination in architecture awarded by the departments of architecture of the technical colleges of Delft or Eindhoven (bouwkundig ingenieur)</li> <li>— the diplomas awarded by State-recognised architectural academies (architect)</li> <li>— the diplomas awarded until 1971 by the former architectural colleges (Hoger Bouwkunstondericht) (architect HBO)</li> <li>— the diplomas awarded until 1970 by the former architectural colleges (voortgezet Bouwkunstondericht) (architect VBO)</li> <li>— the certificate stating that the person concerned has passed an examination organised by the Architects Council of the 'Bond van Nederlandse Architecten' (Order of Dutch Architects, BNA) (architect)</li> <li>— the diploma of the 'Stichting Instituut voor Architectuur' ('Institute of Architecture' Foundation) (IVA) awarded on completion of a course organised by this foundation and extending over a minimum period of four years (architect), accompanied by a certificate from the competent authorities to the effect that the person concerned has passed a test of his formal qualifications, comprising an appreciation of plans drawn up and executed by the candidate during at least six years' effective practice of the activities referred to in Article 44 of this Directive</li> <li>— a certificate issued by the competent authorities to the effect that, before the date of 5 August 1985, the person concerned passed the degree examination of 'Kandidaat in de bouwkunde' organised by the technical colleges of Delft or Eindhoven and that, over a period of at least five years immediately prior to that date, he pursued architectural activities the nature and importance of which, in accordance with Netherlands requirements, guarantee that he is competent to pursue those activities (architect)</li> <li>— a certificate issued by the competent authorities only to persons who had reached the age of 40 years before the date of 5 August 1985, certifying that, over a period of at least five years immediately prior to that date, the person concerned had pursued architectural activities the nature and importance of which, in accordance with Netherlands requirements, guarantee that he is competent to pursue those activities (architect)</li> <li>— the certificates referred to in the seventh and eighth indents need no longer be recognised as from the date of entry into force of laws and regulations in the Netherlands governing the taking up and pursuit of architectural activities under the professional title of architect, in so far as under such provisions those certificates do not authorise the taking up of such activities under that professional title</li> </ul>	1987/1988

Country	Evidence of formal qualifications	Reference academic year
Österreich	<ul style="list-style-type: none"> <li>— the diplomas awarded by the Universities of Technology of Vienna and Graz and by the University of Innsbruck, Faculty for Building-Engineering ('Bauingenieurwesen') and Architecture ('Architektur'), in the fields of study of architecture, building-engineering ('Bauingenieurwesen'), building ('Hochbau') and ('Wirtschaftsingenieurwesen — Bauwesen')</li> <li>— the diplomas awarded by the University for 'Bodenkultur' in the fields of study of 'Kulturtechnik und Wasserwirtschaft'</li> <li>— the diplomas awarded by the University College of Applied Arts in Vienna in architectural studies</li> <li>— the diplomas awarded by the Academy of Fine Arts in Vienna in architectural studies</li> <li>— the diplomas of certified engineers (Ing.) awarded by higher technical colleges or technical colleges for building, plus the licence of 'Baumeister' attesting a minimum of six years of professional experience in Austria, sanctioned by an examination</li> <li>— the diplomas awarded by the University College for artistic and industrial training in Linz, in architectural studies</li> <li>— the certificates of qualification for Civil Engineers or Engineering Consultants in the field of construction ('Hochbau', 'Bauwesen', 'Wirtschaftsingenieurwesen — Bauwesen', 'Kulturtechnik und Wasserwirtschaft') according to the Civil Technician Act (Ziviltechnikergesetz, BGBl. No 156/1994)</li> </ul>	1997/1998
Portugal	<ul style="list-style-type: none"> <li>— the Diploma 'diploma do curso especial de arquitectura' awarded by the Schools of Fine Arts of Lisbon and of Porto</li> <li>— the Architects Diploma 'diploma de arquitecto' awarded by the Schools of Fine Arts of Lisbon and of Porto</li> <li>— the Diploma 'diploma do curso de arquitectura' awarded by the Higher Schools of Fine Arts of Lisbon and Porto</li> <li>— the Diploma 'diploma de licenciatura em arquitectura' awarded by the Higher School of Fine Arts of Lisbon</li> <li>— the Diploma 'carta de curso de licenciatura em arquitectura' awarded by the Technical University of Lisbon and the University of Porto</li> <li>— the university diploma in civil engineering (licenciatura em engenharia civil) awarded by the Higher Technical Institute of the Technical University of Lisbon</li> <li>— the university diploma in civil engineering (licenciatura em engenharia civil) awarded by the Faculty of Engineering (de Engenharia) of the University of Porto</li> <li>— the university diploma in civil engineering (licenciatura em engenharia civil) awarded by the Faculty of Science and Technology of the University of Coimbra</li> <li>— the university diploma in civil engineering, production (licenciatura em engenharia civil, produção) awarded by the University of Minho</li> </ul>	1987/1988
Suomi/Finland	<ul style="list-style-type: none"> <li>— the diplomas awarded by the architecture departments of Universities of Technology and the University of Oulu (arkkitehti/arkitekt)</li> <li>— the diplomas awarded by the Institutes of Technology (rakennusarkkitehti/byggnadsarkitekt)</li> </ul>	1997/1998
Sverige	<ul style="list-style-type: none"> <li>— the diplomas awarded by the School of Architecture at the Royal Institute of Technology, the Chalmers Institute of Technology and the Institute of Technology at Lund University (arkitekt, university diploma in architecture)</li> <li>— the certificates of membership of the 'Svenska Arkitekters Riksförbund' (SAR) if the persons concerned have received their training in a State to which this Directive applies</li> </ul>	1997/1998
United Kingdom	<ul style="list-style-type: none"> <li>— the qualifications awarded following the passing of examinations of: <ul style="list-style-type: none"> <li>— the Royal Institute of British Architects</li> <li>— schools of architecture at universities, polytechnics, colleges, academies, schools of technology and art which, as of 10 June 1985, were recognised by the Architects Registration Council of the United Kingdom for the purpose of admission to the Register (Architect)</li> </ul> </li> <li>— a certificate stating that its holder has an established right to hold the professional title of architect by virtue of section 6(1) a, 6(1) b or 6(1) d of the Architects Registration Act 1931 (Architect)</li> <li>— a certificate stating that its holder has an established right to hold the professional title of architect by virtue of section 2 of the Architects Registration Act 1938 (Architect)</li> </ul>	1987/1988

## ANNEX VII

**DOCUMENTS AND CERTIFICATES WHICH MAY BE REQUIRED IN ACCORDANCE WITH ARTICLE 46(1)****1. Documents**

- (a) Proof of the nationality of the person concerned.
- (b) Copies of the attestations of professional competence or of the evidence of formal qualifications giving access to the profession in question, and an attestation of the professional experience of the person concerned where applicable.
- (c) For the cases referred to in Article 16, a certificate concerning the nature and duration of the activity issued by the competent authority or body in the Member State of origin.
- (d) Where the competent authority of a host Member State requires of persons wishing to take up a regulated profession proof that they are of good character or repute or that they have not been declared bankrupt, or suspends or prohibits the pursuit of that profession in the event of serious professional misconduct or a criminal offence, that State shall accept as sufficient evidence, in respect of nationals of Member States wishing to pursue that profession in its territory, the production of documents issued by competent authorities in the Member State of origin or the Member State from which the foreign national comes, showing that those requirements are met. Those authorities must provide the documents required within a period of two months.

Where the competent authorities of the Member State of origin or of the Member State from which the foreign national comes do not issue the documents referred to in the first subparagraph, such documents shall be replaced by a declaration on oath — or, in States where there is no provision for declaration on oath, by a solemn declaration — made by the person concerned before a competent judicial or administrative authority or, where appropriate, a notary or qualified professional body of the Member State of origin or the Member State from which the person comes; such authority or notary shall issue a certificate attesting the authenticity of the declaration on oath or solemn declaration.

- (e) Where a host Member State requires of its own nationals wishing to take up a regulated profession, a document relating to the physical or mental health of the applicant, that State shall accept as sufficient evidence thereof the presentation of the document required in the Member State of origin. Where the Member State of origin does not issue such a document, the host Member State shall accept a certificate issued by a competent authority in that State. In that case, the competent authorities of the Member State of origin must provide the document required within a period of two months.
- (f) Where a host Member State requires its own nationals wishing to take up a regulated profession to furnish:
  - proof of the applicant's financial standing
  - proof that the applicant is insured against the financial risks arising from their professional liability in accordance with the laws and regulations in force in the host Member State regarding the terms and extent of cover

that Member State shall accept as sufficient evidence an attestation to that effect issued by the banks and insurance undertakings of another Member State.

**2. Certificates**

- (a) To facilitate the application of Title III, Chapter III, of this Directive, Member States may prescribe that, in addition to formal certificates of training, the person who satisfies the conditions of training required must provide a certificate from the competent authorities of his country of origin stating that these certificates of training are those covered by this Directive.
  - (b) In the event of justified doubts, the host Member State may require from the competent authorities of a Member State confirmation of the authenticity of the attestations and evidence of formal qualifications awarded in that other Member State, as well as, where applicable, confirmation of the fact that the beneficiary fulfils, for the professions referred to in Title III, Chapter III, of this Directive, the minimum training conditions set out respectively in Articles 22, 23, 26, 29, 32, 35, 36, 40 and 42.
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**Proposal for a Council Decision concerning the conclusion, on behalf of the Community, of the  
Cartagena Protocol on Biosafety**

(2002/C 181 E/10)

COM(2002) 127 final — 2002/0062(CNS)

*(Submitted by the Commission on 13 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1), in conjunction with the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Whereas:

- (1) The promotion of measures at international level to deal with regional or worldwide environmental problems, including the conservation and sustainable use of biological diversity, is one of the objectives of the Community's policy on the environment, in accordance with Article 174 of the Treaty;
- (2) By Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity <sup>(1)</sup> the Community concluded the Convention on Biological Diversity under the auspices of the United Nations Environment Programme;
- (3) In 1995 the Council authorised the Commission <sup>(2)</sup> to participate, on behalf of the Community, in the negotiations on a Protocol on Biosafety, under Article 19(3) of the Convention on Biological Diversity. The Commission participated in those negotiations, together with the Member States;
- (4) The Cartagena Protocol on Biosafety was adopted in Montreal on 29 January 2000;
- (5) The Protocol provides a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity,

taking also into account risks to human health and specifically focussing on transboundary movements;

- (6) The Community and fourteen Members States signed the Protocol on 24 May 2000, during the fifth meeting of the Parties to the Convention on Biological Diversity held in Nairobi. Luxembourg signed the Protocol on 11 July 2000;
- (7) According to Article 34 of the Convention on Biological Diversity, any protocol to that Convention is subject to ratification, acceptance or approval by States and by regional economic integration organisations;
- (8) The Cartagena Protocol on Biosafety contributes to the achievement of the objectives of the environmental policy of the Community. It is therefore appropriate that this Protocol be concluded on behalf of the Community as soon as possible,

HAS DECIDED AS FOLLOWS:

*Article 1*

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is hereby approved on behalf of the Community.

The text of the Protocol is attached to this Decision.

*Article 2*

1. The President of the Council is authorised to designate the person or persons empowered to deposit the instrument of approval on behalf of the Community with the Secretary General of the United Nations, in accordance with Articles 34 and 41 of the Convention on Biological Diversity.
2. The President of the Council is authorised to designate the person or persons empowered to deposit, on behalf of the Community, the declaration of competence set out in the Annex to this Decision, in accordance with Article 34(3) of the Convention on Biological Diversity.

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<sup>(1)</sup> OJ L 309, 13.12.1993, p. 1.

<sup>(2)</sup> Council Document 10887/95 ENV 265.

**PROTOCOL****Cartagena on biosafety to the Convention on Biological Diversity**

THE PARTIES TO THIS PROTOCOL,

BEING Parties to the Convention on Biological Diversity, hereinafter referred to as 'the Convention',

RECALLING Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention,

RECALLING also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

REAFFIRMING the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

AWARE OF the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

RECOGNISING that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

RECOGNISING ALSO the crucial importance to humankind of centres of origin and centres of genetic diversity,

TAKING INTO ACCOUNT the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

RECOGNISING that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

EMPHASISING that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

UNDERSTANDING that the above recital is not intended to subordinate this Protocol to other international agreements,

HAVE AGREED AS FOLLOWS:

*Article 1***Objective**

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

*Article 2***General provisions**

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

### Article 3

#### Use of terms

For the purposes of this Protocol:

- (a) 'Conference of the Parties' means the Conference of the Parties to the Convention;
- (b) 'Contained use' means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
- (c) 'Export' means intentional transboundary movement from one Party to another Party;
- (d) 'Exporter' means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;
- (e) 'Import' means intentional transboundary movement into one Party from another Party;
- (f) 'Importer' means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;
- (g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) 'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) 'Modern biotechnology' means the application of:

(a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(b) Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

(j) 'Regional economic integration organisation' means an organisation constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorised, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) 'Transboundary movement' means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

### Article 4

#### Scope

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

### Article 5

#### Pharmaceuticals

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

*Article 6***Transit and contained use**

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

*Article 7***Application of the advance informed agreement procedure**

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. 'Intentional introduction into the environment' in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

*Article 8***Notification**

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national

authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex 1.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

*Article 9***Acknowledgement of receipt of notification**

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, *prima facie*, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2(c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

*Article 10***Decision procedure**

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2(a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex 1; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimise such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

#### Article 11

##### **Procedure for living modified organisms intended for direct use as food or feed, or for processing**

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified

organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex 2. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex 2.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Article 15; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimise such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

#### Article 12

##### Review of decisions

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

- (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
- (b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

#### Article 13

##### Simplified procedure

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

- (a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and
- (b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1(a) above shall be the information specified in Annex I.

#### Article 14

##### Bilateral, regional and multilateral agreements and arrangements

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

*Article 15***Risk assessment**

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

*Article 16***Risk management**

1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring risk assessments to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

*Article 17***Unintentional transboundary movements and emergency measures**

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organisations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimise any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

#### Article 18

##### **Handling, transport, packaging and identification**

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

- (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;
- (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and
- (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of

the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

#### Article 19

##### **Competent national authorities and national focal points**

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorised to act on its behalf with respect to those functions. A Party may designate a single entity to fulfill the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

#### Article 20

##### **Information sharing and the Biosafety Clearing-House**

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

- (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and



(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

## Article 21

### Confidential information

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

*Article 22***Capacity-building**

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

*Article 23***Public awareness and participation**

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make

the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

*Article 24***Non-parties**

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

*Article 25***Illegal transboundary movements**

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalising transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

*Article 26***Socio-economic considerations**

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

#### Article 27

##### Liability and redress

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

#### Article 28

##### Financial mechanism and resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in

transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

#### Article 29

##### Conference of the parties serving as the meeting of the parties to this protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

- (a) Make recommendations on any matters necessary for the implementation of this Protocol;
- (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;
- (c) Seek and utilise, where appropriate, the services and cooperation of, and information provided by, competent international organisations and intergovernmental and non-governmental bodies;
- (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
- (e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
- (f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialised agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

#### Article 30

##### **Subsidiary bodies**

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

#### Article 31

##### **Secretariat**

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

#### Article 32

##### **Relationship with the convention**

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

#### Article 33

##### **Monitoring and reporting**

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

#### Article 34

##### **Compliance**

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

*Article 35***Assessment and review**

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

*Article 36***Signature**

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organisations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

*Article 37***Entry into force**

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organisations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organisation that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organisation deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organisation, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organisation shall not be counted as additional to those deposited by member States of such organisation

*Article 38***Reservations**

No reservations may be made to this Protocol.

*Article 39***Withdrawal**

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

*Article 40***Authentic texts**

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

In witness whereof the undersigned, being duly authorised to that effect, have signed this Protocol.

Done at Montreal on this twenty-ninth day of January, two thousand.

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*Annex 1***Information required in notifications under Articles 8, 10 and 13**

- (a) Name, address and contact details of the exporter.
  - (b) Name, address and contact details of the importer.
  - (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
  - (d) Intended date or dates of the transboundary movement, if known.
  - (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
  - (f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
  - (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
  - (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
  - (i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
  - (j) Quantity or volume of the living modified organism to be transferred.
  - (k) A previous and existing risk assessment report consistent with Annex 3.
  - (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
  - (m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
  - (n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
  - (o) A declaration that the abovementioned information is factually correct.
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*Annex 2***Information required concerning living modified organisms intended for direct use as food or feed, or for processing under Article 11**

- (a) The name and contact details of the applicant for a decision for domestic use.
- (b) The name and contact details of the authority responsible for the decision.
- (c) Name and identity of the living modified organism.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
- (e) Any unique identification of the living modified organism.
- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (i) Approved uses of the living modified organism.
- (j) A risk assessment report consistent with Annex 3.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

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*Annex 3***Risk assessment under Article 15****Objective**

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

**Use of risk assessment**

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

**General principles**

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organisations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

### Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.
8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
  - (b) An evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
  - (c) An evaluation of the consequences should these adverse effects be realised;
  - (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;
  - (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
  - (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

### Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:
- (a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
  - (b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
  - (c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
  - (d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
  - (e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
  - (f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;
  - (g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
  - (h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.
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**DECLARATION BY THE EUROPEAN COMMUNITY IN ACCORDANCE WITH ARTICLE 34  
(PARAGRAPH 3) OF THE CONVENTION ON BIOLOGICAL DIVERSITY**

The European Community declares that, in accordance with the Treaty establishing the European Community, and in particular Article 175 thereof, it is competent for entering into international agreements, and for implementing the obligations resulting therefrom, which contribute to the pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment;
- protecting human health;
- prudent and rational utilisation of natural resources;
- promoting measures at international level to deal with regional or worldwide environmental problems.

Moreover, the European Community declares that it has already adopted legal instruments, binding on its Member States, covering all matters governed by this Protocol'.

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**Proposal for a Council Regulation amending Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs**

(2002/C 181 E/11)

COM(2002) 139 final — 2002/0066(CNS)

*(Submitted by the Commission on 15 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Having regard to the opinion of the Committee of the Regions,

Whereas:

(1) Annex I to the Treaty establishing the European Community<sup>(1)</sup> lists the products covered by Title II of the Treaty.

(2) Council Regulation (EEC) No 2081/92<sup>(2)</sup> covers neither viticultural products nor spirit drinks but to plug a gap in the Community's protection provisions wine vinegar should be included in the scope defined in its Article 1.

(3) Annex I to Regulation (EEC) No 2081/92 listing the types of foodstuff that may be registered includes natural mineral and spring waters. Examination of registration applications for these has revealed several difficulties: the use of identical names for different waters and of invented names not covered by the Regulation's provisions, and a general finding that these products are not suitable for registration under the Regulation, notably in view of the implications of Article 13. These difficulties have led to many clashes of interest in the course of work on implementation of the Regulation.

(4) Mineral and spring waters are already the subject of Council Directive 80/777/EEC of 15 July 1980 on approximation of the laws of the Member States relating to exploitation and marketing of natural mineral waters<sup>(3)</sup>. This does not have exactly the same purpose as Regulation (EEC) No 2081/92 but does provide adequate

regulation at Community level. Names of mineral and spring waters should not therefore be registered and this product category should be deleted from Annex I to the Regulation. Some names have already been registered in Commission Regulation (EEC) No 1107/96 of 12 June 1996 on registration of geographical indications and designations of origin under the procedure set in Article 17 of Council Regulation (EEC) No 2081/92<sup>(4)</sup>, and to avoid any injury there should be a five-year transition period after which these names will no longer be on the register specified in Article 6(3) of the latter.

(5) To protect the traditional heritage of Member States' producers, provision should be made for regulating cases of total or partial identity of geographical names. These provisions should cover both names meeting the registration requirements and those not doing so but meeting certain precisely established utilisation requirements.

(6) Article 10 should be amended to refer to standard EN 45011 in such a way that its most recent version is always applicable.

(7) If after showing good reason a group or a natural or legal entity wishes to give up the registration of a geographical indication or denomination of origin it should be deleted from the Community register.

(8) The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement 1994, contained in Annex 1C to the Agreement establishing the World Trade Organisation) contains detailed provisions on the existence, acquisition, scope, maintenance and enforcement of intellectual property rights.

(9) The protection provided by registration under Regulation (EEC) No 2081/92 is open to third countries' names by reciprocity and under equivalence conditions as provided for in Article 12 of that Regulation. That Article should be supplemented so as to guarantee that the Community registration procedure is available to the countries meeting those conditions.

<sup>(1)</sup> OJ C 340, 10.11.1997, p. 303.

<sup>(2)</sup> OJ L 208, 24.7.1992, p. 1. Regulation last amended by Commission Regulation (EC) No 2796/2000 (OJ L 324, 21.12.2000, p. 26).

<sup>(3)</sup> OJ L 229, 30.8.1980, p. 1. Directive last amended by Directive 96/70/EC (OJ L 299, 23.11.1996, p. 26).

<sup>(4)</sup> OJ L 148, 21.6.1996, p. 1. Regulation last amended by Regulation (EC) No 2703/2000 (OJ L 311, 12.12.2000, p. 25).

(10) Article 7 of Regulation (EEC) No 2081/92 specifies how objections are to be made and dealt with. To satisfy the obligation resulting from Article 22 of the TRIPS Agreement it should be made clear that in this matter nationals of WTO member countries are covered by these arrangements and that the provisions in question apply without prejudice to international agreements, as already specified in Article 12. The right of objection should be granted to WTO member countries' nationals with a legitimate interest on the same terms as laid down in Article 7(4). Compliance with these terms must be demonstrated in relation to the territory of the Community, this being the territory in which protection granted under the Regulation applies.

(11) Article 24(5) of the TRIPS Agreement applies not only to trademarks registered or applied for but also those to which rights have been acquired through use before a specified date, notably that of protection of the name in the country of origin. Article 14(2) of Regulation (EEC) No 2081/92 should therefore be amended: the reference date now specified should be changed to the date of protection in the country of origin or of submission of the application for registration of the geographical indication or designation of origin, depending on whether the name falls under the Article 17 or the Article 5 procedure; also in Article 14(1) the reference date should become the date of application instead of the date of first publication.

(12) Since the measures required for implementation of Regulation (EEC) No 2081/92 are measures of general scope as specified in Article 2 of Council Decision 1999/468/EC of 28 June 1999 on procedures for the exercise of implementing powers conferred on the Commission<sup>(1)</sup>, they should be adopted using the regulatory procedure specified in Article 5 of that Decision.

(13) The simplified procedure provided for in Article 17 of Regulation (EEC) No 2081/92 for the registration of names already protected or established by usage in Member States does not provide for any right of objection. For reasons of legal security and transparency, it should be deleted. By the same logic so also should the five-year transition period provided for in Article 13(2) in the case of names registered under Article 17 but without prejudice to exhaustion of that period in regard to the names already registered.

(14) Regulation (EEC) No 2081/92 should therefore be amended as indicated above,

HAS ADOPTED THIS REGULATION:

#### Article 1

Regulation (EEC) No 2081/92 is amended as follows:

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

1. Article 1(1) is replaced by:

'1. This Regulation sets rules on protection of designations of origin and geographical indications for agricultural products intended for human consumption listed in Annex I to the Treaty and for foodstuffs and agricultural products listed in Annexes I and II respectively to this Regulation.

It shall not however apply to wine-sector products, except wine vinegars, or to spirit drinks. This paragraph shall be without prejudice to the application of Regulation (EC) No 1493/1999 on the common organisation of the market in wine.

From the date of entry into force of this Regulation, mineral waters shall no longer be covered by Regulation (EEC) No 2081/92. As a result, at the end of a transitional period of five years from the date of entry into force of this Regulation, names relating to mineral waters already registered shall be removed from the register provided for in Article 6(3) of Regulation (EEC) No 2081/92.

Annexes I and II may be amended using the procedure specified in Article 15.'

2. The last subparagraph of Article 5(5) is deleted.

3. The following Article 5a is added after Article 5:

#### 'Article 5a

If the application concerns a name that also designates a geographical area in another Member State or in a third country recognised under the procedure provided for in Article 12(3), the country in question shall be consulted before any decision is taken.

Homonymous names meeting the requirements of this Regulation may be registered subject to proper account being taken of local and traditional usage and the actual risk of confusion.

Use of such names shall be subject to clear indication of the country of origin on the labelling.'

4. The last subparagraph of Article 10(3) is replaced by:

'To be approved by a Member State for the purposes of this Regulation, private bodies must meet the requirements set in the latest version of standard EN 45011 in force.'

5. The following is added to Article 11(4):

*'The action taken shall be notified in the Official Journal of the European Communities.'*

6. The following Article 11a is added after Article 11:

*'Article 11a*

The Commission may cancel registration of a name in response to a duly substantiated application by the group concerned transmitted by the country that submitted the original application for registration.

Notice of cancellation shall be given in the *Official Journal of the European Communities*.'

7. In Article 12, the second indent of paragraph 1 is replaced by the following:

— the third country concerned has inspection arrangements and a right to objection equivalent to those laid down in this Regulation,'.

8. In Article 12, the following paragraph is added:

'3. The Commission may examine, in accordance with the procedure laid down in Article 15 and at the request of the country concerned, whether a third country satisfies the equivalence conditions within the meaning of paragraph 1 above as a result of its national legislation. Where the Commission decision is in the affirmative, the procedure set in Article 12a shall apply.'

9. The following Articles 12a to 12d are added after Article 12:

*'Article 12a*

1. In the case provided for in Article 12(3), if a group or a physical or legal entity as referred to in Article 5(1) and (2) in a third country wishes to have a name registered under this Regulation it shall send a registration application to the authorities in the country in which the geographical area is located. Applications must be accompanied by the specification referred to in Article 4 for each name.

2. If that third country deems the requirements of this Regulation to be satisfied it shall transmit the registration application to the Commission accompanied by:

- (a) a description of the legal provisions and the usage on the basis of which the designation of origin or the geographical indication is protected or established in the country,
- (b) a declaration that the structures provided for in Article 10 are established on its territory, and

(c) other documents on which it has based its assessment.

3. The application and all documents forwarded to the Commission shall be in one of the official Community languages or accompanied by a translation into one of the official Community languages.

*Article 12b*

1. The Commission shall verify within six months whether the registration request sent by the third country contains all the necessary elements and shall inform the country concerned of its conclusions.

If the Commission:

- (a) concludes that the name satisfies the conditions for protection, it shall publish the application in accordance with Article 6(2). Prior to publication the Commission may ask the Committee provided for in Article 15 for its opinion;
- (b) concludes that the name does not satisfy the conditions for protection, it shall decide, after consulting the country having transmitted the application, in accordance with the procedure provided for in Article 15, not to proceed with publication as provided for in (a) above.

2. Within six months of the date of publication as provided for in paragraph 1(a), any person with a legitimate concern may object to the application published in accordance with paragraph 1(a) on the following terms: Where the objection comes from a Member State of the European Union or a WTO member, Article 7(1), (2) and (3) or Article 12d respectively shall apply. Where it comes from a third-country national meeting the equivalence conditions of Article 12(3), a duly substantiated statement of objection shall be addressed to the country in which he or she resides or is established, which shall forward it to the Commission.

The statement of objection and all documents forwarded to the Commission shall be in one of the official Community languages or accompanied by a translation into one of the official Community languages.

3. The Commission shall examine admissibility in accordance with the criteria set out in Article 7(4). Those criteria must be demonstrated in regard to the territory of the Community. Where one or more objections are admissible the Commission shall adopt a decision in accordance with the procedure laid down in Article 15 after consulting the country which transmitted the application, taking account of traditional fair usage and the actual risk of confusion on Community territory. If the decision is to proceed with registration the name shall be entered in the register provided for in Article 6(3) and published in accordance with Article 6(4).

4. If the Commission receives no statement of objection it shall enter the name(s) in question in the register provided for in Article 6(3) and publish the name(s) as provided for in Article 6(4).

#### Article 12c

The group or physical or legal entity referred to in Article 5(1) and (2) may request amendment of the specification for a name registered under Article 12a, in particular to take account of the development of scientific and technical knowledge or to revise the geographical zone.

The procedure in accordance with Articles 12a and 12b shall apply.

However, the Commission may decide, in accordance with the Article 15 procedure, not to apply the procedure provided for in Articles 12a and 12b if the amendment is of a minor nature.

#### Article 12d

1. Within six months of the date of the notice in the *Official Journal of the European Communities* specified in Article 6(2) relating to a registration application submitted by a Member State, any legitimately concerned natural or legal entity that is a national of a WTO member country or of a third country recognised under the procedure provided for in Article 12(3) may object to the proposed registration by sending a duly substantiated statement to the member country in which they reside or are established, which shall transmit it, made out or translated into a Community language, to the Commission. Member States shall ensure that all persons belonging to WTO member countries or a third country recognised under the procedure provided for in Article 12(3) who can demonstrate a legitimate economic interest are authorised to consult the application.

2. The Commission shall examine the admissibility of objections on the terms of Article 7(4). Admissibility must be demonstrated in regard to the territory of the Community.

3. If an objection is admissible the Commission shall, after consulting the country that transmitted the objection, adopt a decision using the procedure specified in Article 15 that takes account of traditional fair usage and the actual risk of confusion. If the decision is to proceed with registration, publication shall be made in line with Article 6(4).'

10. Article 13 is amended as follows:

(a) Paragraph 2 is deleted.

(b) Paragraph 4 is replaced by the following:

'4. In the case of names for which registration has been applied for under Article 5 or Article 12a, provision may be made for a maximum transitional period of five years under Article 7(5)(b) or under Articles 12b(3) or 12d(3), solely where a statement of objection has been declared admissible on the ground that the registration of the proposed name would jeopardise the existence of an entirely or partly homonymous name or the existence of products which have been legally on the market for at least five years preceding the date of the publication provided for in Article 6(2).

Such transitional period may be provided for only where undertakings have legally marketed the products in question by using the names in question continuously for at least five years preceding the date of the publication provided for in Article 6(2).'

(c) The following paragraph 5 is added:

'5. The Commission may decide to allow, under the procedure provided for in Article 15, the co-existence of a registered name and a name designating a place in a Member State of the European Union or in a third country recognised under the procedure provided for in Article 12(3) where that name is identical to the registered name, provided that the following conditions are met:

- the identical name has been in legal use on Community territory consistently and equitably for at least 25 years prior to the entry into force of Regulation (EEC) No 2081/92, and
- it is shown that the purpose of its use has not at any time been to profit from the reputation of the registered name and that the public has not been nor could be misled as to the true origin of the product, and
- the problem resulting from the identical names was raised before registration of the name.

The registered name and the identical name concerned may co-exist for a period not exceeding 15 years.

Use of the geographical name concerned shall be authorised only where the country of origin is clearly and visibly indicated on the label.'

11. Article 14 is amended as follows:

(a) Paragraph 1 is replaced by:

'1. Where a designation of origin or geographical indication is registered under this Regulation, any application for registration of a trademark that is for a product of the same type and use of which will engender one of the situations indicated in Article 13 shall be refused if made after the date of submission to the Commission of the application for registration of the designation of origin or geographical indication.

Trademarks registered in breach of the first subparagraph shall be invalidated.'

(b) Paragraph 2 is replaced by:

'2. With due regard to Community law, a trademark the use of which engenders one of the situations indicated in Article 13 and which has been registered, or established by use if that possibility is provided for by the legislation concerned, in good faith within the territory of the Community, before either the date of protection in the country of origin or the date of submission to the Commission of the application for registration of the designation of origin or geographical indication, may continue to be used notwithstanding the registration of a designation of origin or geographical indication, provided that no grounds for its invalidity or revocation exist as specified by Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks <sup>(1)</sup> and/or

Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark <sup>(2)</sup>.

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 1.

<sup>(2)</sup> OJ L 11, 14.1.1994, p. 1.'

12. Article 15 is replaced by:

*'Article 15*

1. The Commission shall be assisted by the Committee on Designations of Origin and Geographical Indications composed of Member States' representatives and chaired by a Commission representative.

2. In cases where this paragraph applies, the regulatory procedure set out in Article 5 of Decision 1999/468/EC shall be used. Article 7(3) of the latter shall apply.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

4. The Committee may examine any other matter put to it by its Chairman on his own initiative or at the request of a Member State's representative.'

13. Article 17 is deleted.

*Article 2*

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

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

**Proposal for a Council Decision authorising the United Kingdom to apply a differentiated rate of excise duty to fuels containing biodiesel in accordance with Article 8(4) of Directive 92/81/EEC**

(2002/C 181 E/12)

COM(2002) 144 final

*(Submitted by the Commission on 18 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/81/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on mineral oils <sup>(1)</sup>, and in particular Article 8(4) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) The United Kingdom has applied for a differentiated rate of excise duty to be authorised on biodiesel used as road fuel either as pure fuel or blended into diesel fuels up to 5 per cent volume in accordance with EN590.
- (2) The other Member States have been notified of this request.
- (3) The development of renewable energies and biofuels in particular has been encouraged in the Community since 1985. Lastly, on 7 November 2001 <sup>(2)</sup>, the Commission adopted an action plan and two proposals for directives on encouraging the use of substitute fuels in the transport sector, starting with regulatory and tax measures designed to promote biofuels.
- (4) The derogation requested by the British authorities is therefore in line with the Community's policy of developing the biofuel sector, in the interests of protecting the environment and ensuring security of energy supply.
- (5) The rate for biodiesel would be set at 20 pence per litre below that for ultra-low sulphur diesel (ULSD). This equates to an excise duty of 25.82 pence (41.4 eurocents) per litre of biodiesel at current rates. Furthermore, the reduction in excise duty proposed by the United Kingdom is proportional to the percentage of biofuel contained in the final product.

- (6) The effective rates of excise duty are higher than the applicable Community minimum rates, in accordance with Council Directive 92/82/EEC of 19 October 1992 on the approximation of the rates of excise duties on mineral oils <sup>(3)</sup>:

Community minimum (per 1 000 l)	ULSD	Pure biodiesel
245 euros	734,3 euros (*)	413,8 euros
	458,2 GBP	258,2 GBP

(\*) Average exchange rate in December 2001 is 0.624 GBP for one euro.

- (7) The requested reduction should concern biodiesel, a fuel made from biomass within the meaning of Article 2(b) of Directive 2001/77/EC of the European Parliament and of the Council of 27 September 2001 on the promotion of electricity produced from renewable energy sources in the internal electricity market <sup>(4)</sup>, or made from used fried oils, to be used as a road fuel.
- (8) The differentiated rate would apply to pure biodiesel at the point of production or import. The biodiesel can then be used either as pure fuel or be blended into diesel fuels. Duty on imported blends would be payable at the appropriate rates for the constituent parts in the relevant proportion.
- (9) Production costs of biodiesel exceed those of conventional diesel, and its retail price would therefore be uncompetitive without the duty reduction. The duty reduction is intended to offset the additional production costs. It will enable biodiesel to be sold at a similar pump price to conventional diesel.
- (10) The government of the United Kingdom should annually review the production cost of biodiesel and thus monitor that no overcompensation takes place.

<sup>(1)</sup> OJ L 316, 31.10.1992, p. 12. Directive as last amended by Directive 94/74/EC (OJ L 365, 31.12.1994, p. 46).

<sup>(2)</sup> COM(2001) 547 final, 7.11.2001.

<sup>(3)</sup> OJ L 316, 31.10.1992, p. 19. Directive as last amended by Directive 94/74/EC.

<sup>(4)</sup> OJ L 283, 27.10.2001, p. 33.

(11) The accorded authorisation should apply for a period of five years.

(12) The Commission regularly reviews reductions and exemptions to check that they do not distort competition or hinder the operation of the internal market and are not incompatible with Community policy on protection of the environment, energy and transport,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The United Kingdom is authorised to apply differentiated rates of excise duty to road fuel containing biodiesel and on biodiesel used as pure road fuel.

Biodiesel is a fuel made from biomass, within the meaning of Article 2(b) of Directive 2001/77/EC, or made from used fried oils to be used as a road fuel.

2. The reduction in excise duty shall not be greater than the amount of excise duty payable on the volume of biodiesel

present in the products referred to in paragraph 1 eligible for the reduction.

3. The rates of duty applicable to the products referred to in paragraph 1 must comply with the terms of Directive 92/82/EEC, and in particular the minimum rate laid down in Article 5 thereof.

*Article 2*

Based on an annual review by the United Kingdom, the reduction in excise duty shall be adjusted to avoid over-compensating for the extra costs involved in the manufacture of biofuels.

*Article 3*

This Decision shall expire on 31 March 2007.

*Article 4*

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

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**Proposal for a Council Regulation imposing a definitive anti-dumping duty on imports of ammonium nitrate originating in Russia**

(2002/C 181 E/13)

COM(2002) 148 final

*(Submitted by the Commission on 18 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community<sup>(1)</sup>, and in particular Article 11(2) and 11(3) thereof,

Having regard to the proposal submitted by the Commission after consulting the Advisory Committee,

Whereas:

**A. PROCEDURE**

**1. Previous investigations**

- (1) In May 1994, by Decision 94/293/EC<sup>(2)</sup>, the Commission accepted undertakings with regard to imports of ammonium nitrate originating in Lithuania and Russia, following a regional anti-dumping proceeding concerning imports into the United Kingdom. The undertaking accepted from the Russian authorities was, however, breached within the first year of operation.
- (2) In June 1994, a Community-wide anti-dumping investigation concerning ammonium nitrate originating in Lithuania and Russia was initiated subsequent to a complaint lodged by the European Fertiliser Manufacturers Association (EFMA). The proceeding was terminated in respect of imports from Lithuania<sup>(3)</sup> and in August 1995, the Council, by Regulation (EC) No 2022/95<sup>(4)</sup>, imposed a definitive anti-dumping duty on imports of ammonium nitrate originating in Russia. The measures applying to imports originating in Russia consisted of a variable duty equal to the difference between ECU 102.9 per tonne net of product ('minimum import price' or 'MIP') and the net cif price, Community frontier before customs clearance, in all cases where the latter was lower.

- (3) Pursuant to a further investigation which established that these measures were being absorbed, the measures were changed, in March 1998, by Council Regulation (EC) No 663/98<sup>(5)</sup>, to a specific duty of ECU 26.3 per tonne.

**2. Investigations concerning other countries**

- (4) In October 1999, an anti-dumping investigation was initiated concerning imports into the Community of ammonium nitrate originating in Lithuania, Poland and Ukraine<sup>(6)</sup>. It showed that imports of ammonium nitrate originating in Poland and Ukraine were dumped and caused material injury to the Community industry, whereas imports originating in Lithuania were found not to be dumped. Consequently, by Council Regulation (EC) No 132/2001<sup>(7)</sup>, definitive anti-dumping measures were imposed on imports of ammonium nitrate originating in Poland and Ukraine, while the proceeding was terminated in respect of imports originating in Lithuania. Duties were imposed in the form of a specific duty per tonne, in order to ensure the efficiency of the measures and to discourage any price manipulation.

**3. Present investigation**

**3.1. Request for review**

- (5) Following the publication, on 24 February 2000, of the notice of the impending expiry of the anti-dumping measures in force on imports of ammonium nitrate originating in Russia<sup>(8)</sup>, the Commission received a request for an expiry and an interim review pursuant to Article 11(2) and 11(3) of Council Regulation (EC) No 384/96 of 22 December 1995<sup>(9)</sup> ('the basic Regulation'), lodged by the European Fertiliser Manufacturers Association (EFMA) on behalf of producers representing a major proportion of Community production of ammonium nitrate ('applicant Community producers'). The request for an expiry review alleged that injurious dumping of imports originating in Russia would be likely to continue or to recur if measures were allowed to expire. The applicant's request for an interim review was based on the grounds that the current measures did not appear to be sufficient to counteract the injurious effects of dumping.

<sup>(1)</sup> OJ L 56, 6.3.1996, p. 1. as last amended by Council Regulation (EC) No 2238/2000 (OJ L 257, 11.10.2000, p. 2).

<sup>(2)</sup> OJ L 129, 21.5.1994, p. 24.

<sup>(3)</sup> Commission Decision 95/344/EC (OJ L 198, 23.8.1995, p. 27).

<sup>(4)</sup> OJ L 198, 23.8.1995, p. 1.

<sup>(5)</sup> OJ L 93, 26.3.1998, p. 1.

<sup>(6)</sup> OJ C 311, 29.10.1999, p. 3.

<sup>(7)</sup> OJ L 23, 25.1.2001, p. 1.

<sup>(8)</sup> OJ C 52, 24.2.2000, p. 3.

<sup>(9)</sup> OJ L 56, 6.3.1996, p. 1. Regulation as last amended by Council Regulation (EC) No 2238/2000 (OJ L 257, 11.10.2000, p. 2).

### 3.2. Notice of initiation

- (6) Having determined, after consultation of the Advisory Committee, that sufficient evidence existed for the initiation of a review, the Commission initiated an investigation pursuant to Article 11(2) and 11(3) of the basic Regulation by a notice published in the *Official Journal of the European Communities* <sup>(1)</sup>.

### 3.3. Period of investigation

- (7) The investigation period ('IP') for the examination of continuation and recurrence of dumping and injury covered the period from 1 July 1999 to 30 June 2000. The examination of trends relevant for the assessment of continuation and/or recurrence of injury covered the period from 1 January 1996 up to the end of the IP ('period under review').

### 3.4. Parties concerned by the investigation

- (8) The Commission officially advised the applicant Community producers, the exporting producers in Russia, the importers, users and associations known to be concerned, and the representatives of the exporting country concerned of the initiation of the review. The Commission sent questionnaires to the exporting producers, Community producers, importers, users and associations known to be concerned and to those who made themselves known within the time limit set in the notice of initiation.
- (9) In order to allow Russian exporting producers to submit a claim for market economy treatment ('MET') or individual treatment ('IT'), if they so wished, the Commission sent claim forms to the exporting producers known to be concerned.
- (10) Nine Community producers, one analogue country producer, two importers, one importers' association, and two users' associations replied to the questionnaires. With respect to the exporting country concerned, only one reply to the questionnaire was received.

### 3.5. Verification of information received

- (11) The Commission sought and verified all information it deemed necessary for the purpose of a determination of the continuation or recurrence of dumping and injury and of the Community interest. The Commission also gave the parties directly concerned the opportunity to make their

views known in writing and to request and hold a hearing.

- (12) Verification visits were carried out at the premises of the following companies:

Community producers:

— Grande Paroisse SA, France

— Hydro Agri France, France

— Kemira Ince Ltd, United Kingdom

— Terra Nitrogen, United Kingdom

Analogue country producer:

— Mississippi Chemical Corporation, Yazoo City, USA

## B. PRODUCT CONCERNED AND LIKE PRODUCT

### 1. Product concerned

- (13) The product under consideration is the same as in the previous investigation, i.e. ammonium nitrate ('AN' or 'product under consideration'), a solid nitrogen fertiliser commonly used in agriculture. It is manufactured from ammonia and nitric acid and the nitrogen content exceeds 28 % by weight in prilled or granular form.
- (14) The product concerned currently falls within CN codes 3102 30 90 (ammonium nitrate other than in aqueous solutions) and 3102 40 90 (mixtures of ammonium nitrate with calcium carbonate or other inorganic non-fertilising substances, with a nitrogen content exceeding 28 % by weight).

### 2. Like product

- (15) As both the previous investigation and the investigation concerning other countries have shown, AN is a pure commodity product and its basic chemical characteristics are comparable whatever the country of origin. There are two different types of AN: granular and prilled. Granular AN has a larger diameter and therefore has better spreading characteristics. The investigation has shown that imports of AN originating in Russia are prilled and that the majority of AN produced by the Community industry is granular. However, since granular and prilled AN have the same chemical characteristics and end use and are perceived by users as being interchangeable, they are to be regarded as two different types of the same product.

<sup>(1)</sup> OJ C 239, 23.8.2000, p. 10.

- (16) Therefore, the product produced and sold in the Community by the applicant Community producers is considered to be a like product to that produced in Russia and sold domestically or exported to the Community. The same is true with regard to AN sold on the domestic market of the analogue country.

### C. DUMPING AND LIKELIHOOD OF A CONTINUATION OF DUMPING

- (17) In accordance with Article 11(2) of the basic Regulation, it is necessary to examine whether the expiry of the measures would be likely to lead to a continuation or recurrence of dumping.
- (18) In examining whether there is a likelihood of a continuation of dumping, it is necessary to verify whether dumping exists at present and whether any such dumping is likely to continue.

#### 1. Dumping during the IP

##### 1.1. Volume of exports to the Community during the IP

- (19) Exports of AN from Russia amounted to 282 Ktonnes during the IP i.e. about 20 % of total Community imports of AN and about 5 % of Community AN consumption. These imports are only slightly below the level found in the previous investigation period i.e. 340 Ktonnes between April 1993 and March 1994.

##### 1.2. Market Economy Treatment (MET) and Individual Treatment (IT)

- (20) Claims for MET and/or IT were received from three exporting producers. As two of these companies later failed to submit their reply to the Commission's questionnaire within a reasonable period of time, it was considered appropriate not to further process their MET/IT claim forms. Indeed, in the absence of the necessary data for carrying out a dumping calculation, the claims for MET and IT could not be considered. These companies were therefore considered as non-cooperating with the investigation and were subsequently informed that the findings would be based on the facts available, in accordance with Article 18 of the basic Regulation.
- (21) The third company having submitted a MET/IT claim form was found to have no exports of the product concerned to the Community during the IP. In the absence of any actual export sales data for the IP, no dumping calculation was possible in the context of

either the expiry review or the interim review. Consequently, neither MET nor IT could be considered.

#### 1.3. Analogue country

- (22) Since imports from Russia fall under Article 2(7)(a) of the basic Regulation except where MET is granted, normal value has to be based on information obtained in an appropriate market economy third country. In the Notice of initiation, the Commission suggested Poland as an appropriate analogue country because it was used as an analogue country in other investigations concerning the same product, and the production processes and access to raw materials are comparable to those prevailing in Russia.
- (23) Comments were received by the European Fertiliser Import Association (EFIA) objecting to this choice. Their main objection was that Poland has very high domestic fertiliser prices due to its high level of protection against fertiliser imports and also it has the highest gas prices in central Europe because of its monopolistic State-owned gas distribution system. As an alternative, EFIA proposed Lithuania on the grounds of its close proximity and similar manufacturing conditions to Russia, its absence of barter trade and the fact that the sole Lithuanian producer purchases gas from a Russian supplier, which also supplies the Russian producers, at prices which vary in accordance with the published cif northern Europe price for ammonia.
- (24) However, neither the known Polish producers nor the sole Lithuanian producer were willing to co-operate.
- (25) The Commission then approached producers in Australia and the USA as suggested by EFMA. As only one producer from each of these countries was willing to co-operate, a further analysis was carried out into the importance of their respective domestic sales in terms of domestic market share, and into the representativeness of their domestic sales volume compared to Russian exports to the Community. This analysis showed that, whereas both producers had representative domestic sales, the Australian producer did not face any significant competition in its domestic market. Although the USA producer also had significant domestic sales, it faced price competition from both domestic and foreign companies. Consequently, the USA was selected as the most appropriate analogue country.
- (26) The sales of AN by the USA producer on its domestic market were examined and found to be representative in comparison with Russian export sales of AN to the Community.

(27) Following disclosure, EFIA argued that the lack of co-operation from the sole Lithuanian producer should not have prevented the Commission from using Lithuania as the analogue country, as it had relevant information from its recent anti-dumping proceeding concerning imports of ammonium nitrate from Lithuania, Ukraine and Poland <sup>(1)</sup>. There was indeed an overlap of the IPs in the two proceedings. However, this overlapping period was limited to the first three months of the IP for the current proceeding. In accordance with Article 6(1) of the basic Regulation, for a representative finding, the IP should normally cover a period of six months immediately prior to the initiation of the proceeding. In these circumstances it was considered that data from the first three months of the IP would not be sufficiently representative for the seasonal and volatile AN market. In addition, it should be stressed that using information received in the context of a given proceeding for a precise purpose, in another proceeding for a different purpose, where the party concerned has moreover expressed its unwillingness to co-operate with the second investigation, would be contrary to the provisions of Article 19(6) of the basic Regulation. The argument was, therefore, rejected.

#### 1.4. Normal value

(28) As stated above, normal value was calculated on the basis of the data verified at the premises of the USA company which co-operated fully with the investigation.

(29) In order to establish whether sales in the USA market of the like product were made in the ordinary course of trade, the domestic selling price at an ex-works level was compared to the full cost of production (i.e. the cost of manufacturing plus SG&A expenses). As the weighted average sales price was higher than the weighted average unit cost, normal value was established on the basis of the weighted average domestic selling price for the IP.

(30) Both EFIA and the co-operating Russian exporter argued that a downward adjustment to constructed normal value should have been made due to high gas prices paid by USA producers. Firstly, it should be noted that normal value was not constructed, but was established on the basis of profitable sales prices in the USA domestic market. Secondly, although gas is an important cost element in the production of AN, it was noted that the domestic AN market in the USA is driven by competition and that there are significant imports. As such, the domestic prices of AN are to a significant extent market driven rather than cost driven. No evidence was obtained with regard to the extent to which higher gas prices in the USA market would have affected the domestic sales prices of AN during the IP. Finally, even if high gas prices were

deemed to have affected the domestic sales prices of AN to a quantifiable extent, this would have had no impact on the definitive duty, since the dumping margin found would not have fallen below the injury margin. In these circumstances, the argument was rejected.

#### 1.5. Export price

(31) As the sole co-operating exporting producer had no exports of the product concerned to the Community during the IP, the export price was established on the basis of the available data, in this case, Eurostat statistics of Community frontier cif prices, in accordance with Article 18 of the basic Regulation.

#### 1.6. Comparison

(32) The normal value was compared to the export price on an ex-works basis. This method was used in order to take into account the differences in internal transport costs in market and non-market economy countries incurred in particular for a bulk product such as the product under consideration, for which transport costs account for a very high proportion of the selling price. The appropriate adjustments were made, therefore, to the cif export price in respect of the costs for transport from ex-works to port, port services, insurance and freight costs.

(33) The transport costs for AN in the USA were found to be market driven and there is competition between transport companies. Since the USA is a competitive market, rail fares established during the investigation for the product under consideration in the USA were applied proportionately to the Community frontier export price of Russian exporting producers, on the basis of the weighted average distance to the Community border estimated for all 'export-oriented' (see recital (37)) Russian producers.

#### 1.7. Dumping margin

(34) In accordance with Article 2(11) and (12) of the basic Regulation, the country-wide dumping margin was established on the basis of a comparison of the weighted average normal value with the weighted average export price at an ex-works level. The countrywide dumping margin expressed as a percentage of the 'cif-Community-border' price is 115.8 %.

### 2. Likelihood of a continuation of dumping

(35) As indicated in recital (34) above, exports to the Community were found to be made at dumped prices during the IP. Moreover, the dumping margin found was much higher than that of the previous investigation.

<sup>(1)</sup> OJ L 23, 25.1.2001, p. 1.

- (36) In examining whether dumping was likely to continue at substantial levels and in significant quantities, a number of sources of information were analysed. First, information submitted by the only co-operating Russian producer was used. However, this producer, although exporting to third countries did not have any export sales to the EC. Second, in the absence of any co-operating company with exports to the Community market, in accordance with Article 18(1) of the basic Regulation, the analysis was also based on Eurostat data as well as information provided in the review request which permitted projections to be made of likely future export volumes to the Community.
- (37) The total capacity for AN production in Russia is estimated about 8 900 Ktonnes (i.e. 1.6 times the Community consumption for the IP), of which the production capacity of the 'export-oriented' producers, (i.e. generally those with reasonable access to a port), is estimated at a minimum of 4 500 Ktonnes. Although capacity utilisation rates vary significantly between different companies and from year to year, local consumption is estimated at only about 2 200 Ktonnes. Taking into account the current level of Russian exports to other third countries (i.e. 2 189 Ktonnes in 1999), this means that there is still significant capacity available for production for export and this could potentially be used to increase further the existing exports to the Community, in the event of expiry of the measures.
- (38) Furthermore, it is recalled that as recently as 1996, Russian exports to the EC accounted for 40 % of total Russian exports<sup>(1)</sup> of the product under consideration. This, in conjunction with the fact that a number of third countries (USA, Australia, Poland and Hungary) adopted commercial defence measures against imports from Russia, that China, since 1997, actively pursued a strategy of replacement of imports by domestic production, and that domestic consumption in Russia is likely to stay at relatively low levels in the near future, means that Russian producers would be more likely to direct any additional production to the Community market.
- (39) Having regard to the current price levels on the Community market, it is likely that the Russian exporting producers would continue to adopt a policy of dumped prices in order to regain their lost market shares. This is also confirmed by the Russian exporters' price behaviour on their other most important export markets besides the Community and the USA.
- (40) In addition, even though the world fertilizer consumption is forecast to increase by 2004, the bulk of the increase is expected to take place in Asia, mostly China and India. However, China and India have developed massive capacities for fertilizer production in order to reduce the level of imports. More particularly, China imposed a ban on nitrogenous fertilizer imports, including AN.
- (41) As mentioned in recital (21) above, the one exporting producer which co-operated with the investigation had no exports to the Community during the IP. Although this producer had significant production capacity during the IP, it had limited unused capacity and therefore, any substantial production for export to the Community in the event of expiry of the measures would have necessitated a reduction in sales to other markets. Given the substantial volume of exports and margin of dumping during the IP from other exporters, even if this exporter might sell to the Community at non-dumped prices following any expiry of the measures, this would not have altered the finding with regard to the likelihood of a continuation of dumping for the country as a whole.
- (42) EFIA argued that since the recent terrorist attacks in the USA all related costs, such as insurance, transport, unloading, storage and handling, are increasing and that this will be reflected in higher prices of imported fertiliser, as importers have to recover these costs as well. However, this argument was unsubstantiated, as no evidence was provided to show that this would have a greater impact on export prices from Russia than domestic prices in the USA. In addition, developments after the IP can only be taken into consideration if it can be demonstrated that these developments would make the results of the investigation unsuitable and the planned imposition of an anti-dumping duty manifestly inappropriate. This was not found to be the case and therefore, the argument was rejected.

### 3. Conclusion

- (43) Nothing was found during the investigation to suggest that the dumping margin or volume of dumped exports determined for the investigation period would disappear or even decrease should the measures be allowed to expire. Moreover, it was found that Russian producers had substantial spare capacities and that the removal of measures would likely result in further dumped exports to the Community. It was therefore concluded that, should the measures expire, there is a likelihood of continuation of dumping at a substantial level and in increased volumes.

<sup>(1)</sup> Source: Eurostat — Comext 'Russian exports'.

#### D. DEFINITION OF THE COMMUNITY INDUSTRY

- (44) Out of the 11 applicant Community producers, one did not reply to the questionnaire (Sefanitro) and one did not submit sufficient information (Chemical Industries of Northern Greece). Consequently, these latter were considered to be non-co-operating and therefore were not regarded as being part of the Community industry. The investigation established that the remaining nine co-operating producers represented more than 85 % of the Community production of AN during the IP. Therefore they constitute the Community industry within the meaning of Article 4(1) and Article 5(4) of the Basic Regulation.

#### E. ANALYSIS OF THE SITUATION IN THE COMMUNITY MARKET

##### 1. Preliminary remark

- (45) The introduction of the anti-dumping measures on imports of AN originating in Russia in 1995 in a first stage considerably improved the economic situation of the applicant Community producers, in particular in terms of better financial results, due to the increase in prices between 1995 and 1996.

##### 2. Consumption

- (46) Community consumption was established on the basis of the sales volumes of the Community industry on the Community market, as reported in the questionnaire replies, the sales volume on the Community market of the other Community producers (both non-co-operating and non-applicants), as reported in the complaint and the import volumes into the Community from the country concerned and all other third countries, on the basis of Eurostat.

On this basis, Community consumption decreased by 13 % between 1996 and the IP i.e. from 6 328 Ktonnes in 1996 to 5 525 Ktonnes in the IP. Consumption decreased particularly between 1996 and 1997, and then remained relatively stable until the end of the IP.

##### 3. Imports from the country concerned

###### 3.1. Volume and market share

- (47) Total imports of AN in the Community followed a downward trend during the period under review (- 28 %) even though they increased slightly between 1999 and the IP.

With respect to the volume of the Russian imports, it decreased significantly over the period under review, in particular as from 1997. This trend seems to be the result of the reopening of the investigation published in 1997

and whose conclusions published in 1998 led to the amendment of the anti-dumping measures in that year, and of the significant increase of the imports from certain other third countries, which have benefited from the imposition of anti-dumping duties on Russian imports. Between 1996 and the end of the IP, Russian imports went down by 74 %, while other imports increased by 30 %.

- (48) The market share of the imports from Russia decreased by 12 percentage points during the period under review. However, during the IP, it still represented 5 % of Community consumption and a significant part of overall imports, i.e. 20 %.

###### 3.2. Prices

- (49) After the imposition of the measures in 1995, the average prices of the imports concerned, as reported by Eurostat, fell by 45 %, between 1996 and the IP.

###### 3.3. Price comparison

- (50) The Commission has examined whether the exporting producers in the country concerned undercut the prices of the Community industry during the IP. For this analysis, the cif prices of the exporting producers have been duly adjusted to a Community frontier ex quay custom duty paid level (DEQ) and compared, at the same level of trade, to Community producers' ex-works prices both for bagged products. This was done as imports are always bagged, whereas the Community industry sold its products both in bagged and in bulk form. Thus, adjustments were made where appropriate. In addition, the investigation has shown that granular products were on average sold at a higher price than prilled products. Therefore, an allowance of EUR 3.1 per tonne was made for the price comparison. This amount is the average price difference between granular and prilled AN sold by the Community industry during the investigation period.

- (51) EFIA argued that an adjustment should have been made for the lower quality of the product imported from Russia. However, the investigation established that the quality of the product concerned originating in Russia has improved in recent years and has been upgraded to the higher European standards. Therefore, the argument has been rejected.

- (52) The countrywide price difference found on this basis, expressed as a percentage of the Community producers' prices, is 27.7 %. This difference still amounts to 3.2 % when the anti-dumping duty is added to the export price. Furthermore, prices of the Community industry were depressed, as the industry incurred losses of 18 %.

#### 4. Economic situation of the Community industry

##### 4.1. Production

- (53) The Community industry's production decreased by 17 % between 1996 and the IP, i.e. from 4 713 Ktonnes to 3 903 Ktonnes. A slight increase took place between 1997 and 1998, but the production fell back again in 1999.

##### 4.2. Capacity and capacity utilisation

- (54) It should be noted that capacity and capacity utilisation were not found to be meaningful indicators for this type of production and industry since they are affected by the fact that also other products are produced on the same production equipment. Indeed, based on natural gas transformed into ammonia, various different products are produced using the same production lines. The total production capacity of the Community industry was relatively stable over the period under consideration. Capacity utilisation decreased from 56 % in 1996 to 46 % in 1997 and subsequently remained stable.

##### 4.3. Sales in the Community

- (55) The sales volume of the Community industry decreased from 4 238 Ktonnes in 1996 to 3 766 Ktonnes in the IP i.e. by 11 %. The decrease was most notable between 1996 and 1997 when the sales decreased by 15 %.

##### 4.4. Stocks

- (56) The level of stocks is not considered to be a relevant injury indicator owing to the seasonal nature of the sales and the fact that AN is partly stored by the producers themselves and partly by the co-operatives of farmers.

##### 4.5. Market share

- (57) The market share of the Community industry decreased between 1996 and 1997 and then increased to gain finally 1.2 percentage points between 1996 and the IP. In the IP, it was 68.2 % compared to 67 % in 1996.

##### 4.6. Prices and factors affecting prices

- (58) The Community producer's average net sales price decreased from ECU 133/tonne in 1996 to ECU 99/tonne in the IP i.e. by 25 %. The fall was particularly marked between 1996 and 1999, i.e. (– 28 %). Besides the price depressive effect of the imports concerned, other factors that may have contributed to the fall in prices were the decrease in demand on the Community market between 1996 and 1997, imports from countries covered by Council Regulation (EC) No 132/2001 and the Chinese ban in nitrogen fertiliser imports imposed in 1997.

##### 4.7. Profitability and return on investment

- (59) The weighted average profitability of the Community industry deteriorated by 37 percentage points between 1996 and the IP from 18.6 % to (– 18.0 %). This trend has to be seen in the light of the price evolution, which showed a similar pattern, and of the natural gas price which increased as from the third quarter of 1999.

During the period under review, the return on investment followed a trend similar to the one of profitability.

##### 4.8. Cash flow

- (60) The cash flow generated by the Community industry in relation to sales of ammonium nitrate followed very closely the profitability trend.

##### 4.9. Ability to raise capital

- (61) Due to the structure of the complainant companies, i.e. the fact that the fertiliser producers are a part of large chemical groups also dealing with other products, it was not possible to establish the ability to raise capital for the product under consideration only, and it was therefore considered as not being a meaningful indicator to measure injury.

##### 4.10. Employment, and wages

- (62) Employment of the Community industry decreased, between 1996 and the IP, from 1 986 to 1 608 employees, i.e. a decrease of (– 19 %). With respect to overall wages, they followed a similar decline as compared to the decrease of the number of persons employed.

##### 4.11. Investments

- (63) Investment figures remained relatively stable over the period under consideration. These investment figures include investments relating to production steps preceding the production of AN. The most important investments between 1996 and the IP were investments in production facilities for nitric acid, which is a raw material for the production of AN, but which may also be used for other purposes such as the production of UAN solutions.

##### 4.12. Magnitude of the dumping margin

- (64) As concerns the impact on the Community industry of the magnitude of the actual margin of dumping, given the volume and the prices of the imports from the countries concerned, this impact cannot be considered to be negligible.

## 5. Conclusion

- (65) As explained under recital (45) the introduction of the anti-dumping measures on imports of AN originating in Russia in 1995 in a first stage considerably improved the economic situation of the applicant Community producers. However, starting from the year 1997, the situation deteriorated again. Except market shares, which slightly increased on account of price decreases, all other injury indicators, i.e. production, sales volumes, prices, profitability, return on investment, cash flow and employment developed negatively. In particular the sharp decrease in the sales prices of the Community industry had a negative effect on its profitability. As confirmed by Council Regulation (EC) No 132/2001 imposing definitive duties on imports of AN originating in Poland and Ukraine, this development should be seen in the light of the increased presence in the Community market of imports from these third countries, which have gained more than half of Russian market shares and significantly undercut the prices of the Community industry.
- (66) In this respect it should be noted that Russian prices, on the basis of Eurostat and excluding the specific duty imposed in 1998, were below the sales price of Poland and Ukraine during the whole period under review (27 % below during the IP), with the exception of the year 1997, when they were at the same level.

## F. LIKELIHOOD OF RECURRENCE OF INJURY

### 1. Changes with respect to dumping and the situation of the Community industry

#### 1.1. Change in circumstances with respect to dumping

- (67) The investigation has shown that the dumping margin has increased significantly compared to the dumping margin calculated in the previous investigation which led to the measures in force. In fact, the dumping margin calculated in the previous investigation was 41.9 % which is substantially lower than that calculated in the current investigation (115.8 %).

#### 1.2. Change in circumstances with respect to the situation of the Community industry

- (68) The investigation has shown that significant losses have been suffered by the Community industry between 1998 and the IP. The situation is even worse than it was during the investigation which led to the measures in place, since for instance, the level of losses was almost three times higher during the IP of the current investigation than it was in the investigation period of the previous investigation <sup>(1)</sup>.
- (69) Nearly throughout the entire period of the existence of the duty on imports from Russia, substantial price undercutting took place. In March 1998 the variable duty had to be replaced by a specific duty because measures proved

not to be effective. Moreover, as from July 1998, the export prices at duty paid level (i.e. including the specific duty) were below the non-injurious price of the Community industry which was established in the original investigation and which determined the level of the duty.

## 2. Likelihood of recurrence of injury

- (70) In order to assess the likely effect of the expiry of the measures in force, the following elements were considered.
- (71) A pricing behaviour by Russian exporting producers, as evidenced by low prices on third country markets and on the Community market, coupled with their ability to deliver additional significant quantities of AN, would in all likelihood have a general price depressing impact on what is a very price-sensitive commodity market should measures be repealed. Russian exporting producers would in all likelihood take over from the Community industry significant additional market shares. This in turn would lead to a recurrence of injury from imports originating in Russia in terms of decreasing sales prices of the Community industry, sales volumes and market shares as well as the consequent impact in terms of profitability.
- (72) The Community industry is in a difficult situation having regard in particular to its profitability. Indeed, although the situation of the Community industry, following the imposition of the measures under consideration, markedly improved in the first year of application of the measures, it deteriorated again, in particular as from 1997, due to the injurious dumping of other countries' imports, as established in Council Regulation (EC) No 132/2001 and is now even worse. In this regard, should the measures against Russia be repealed, not only would the situation of the Community industry again be put at risk, but also the benefit which the Community industry should derive from the measures imposed against other countries could be weakened or even nullified.
- (73) EFIA argued that the price decrease experienced in the Community market as from 1997 is due to a number of factors amongst which the Chinese import ban on nitrogen fertilisers and that it cannot be attributed to the Russian price behaviour. However, even if other factors such as the decrease in demand on the Community market between 1996 and 1997 and the Chinese strategy may be at the origin of a price decrease, the Russian prices decreased far more than the prices of all other exporters, and were far below other prevailing non-dumped import prices from countries such as Lithuania, Egypt and Bulgaria. This may be explained by the fact that Russia lost one of its most important export markets given that Russian exports to China amounted to more than 1 000 Ktonnes, i.e. 90 % of the Chinese AN imports in 1996, i.e. the year before the ban was imposed.

<sup>(1)</sup> OJ L 198, 23.8.1995, p. 1.



(74) It was also claimed by the same importers' association that, since the deterioration of the situation of the Community industry has already been attributed to Poland and Ukraine in the context of another investigation, leading to the imposition of anti-dumping measures, it cannot be considered in relation to the imports of AN originating in Russia as well. In this respect, it should be recalled that the scope of an expiry review is to analyse the situation of the Community market in the perspective of the likelihood of continuation or recurrence of dumping and injury should the measures in force be removed. Consequently, with regard to the current expiry investigation, the fact that the deterioration of the Community industry has been attributed during a certain period to the presence of other third countries, namely Poland and Ukraine, in the context of another anti-dumping proceeding, does not affect the analysis of the future behaviour in the Community market of Russian exporters and its likely effect on the situation of the Community industry.

(75) EFIA finally claimed that the decrease of the Community industry's profitability is mainly due to the price increase of natural gas, and that an adjustment should have been made to the non-injurious price to take this into account.

As mentioned under recital (59), it was considered that this gas price increase may have had an influence on profitability. However, profitability is only part of the analysis of the situation of the Community industry and as explained under recital (65), many other indicators developed negatively over the period under review. It was therefore considered that the gas price evolution should be seen rather as an aggravating factor than as a cause of the injury, given that the price pressure found did not allow the Community industry to pass on the increase via its sales prices.

Finally, the analysis of the gas price evolution in the Community over recent years shows it to be very volatile and no conclusions can be drawn with respect to future development. Consequently, it was concluded that there are no special circumstances on the Community market that justify an adjustment.

(76) On the basis of the above, it is concluded that, should the measures be repealed, there is a likelihood of recurrence of injury.

## G. COMMUNITY INTEREST

### 1. Introduction

(77) According to Article 21 of the basic Regulation, the Commission examined whether a prolongation and

amendment of the existing anti-dumping measures would be against the interest of the Community as a whole. The determination of the Community interest was based on an appreciation of all the various interests involved, i.e. those of the Community industry, the importers/traders as well as the users of the product under consideration. In order to assess the likely impact of maintaining or not maintaining the measures, the Commission requested information from all interested parties mentioned above.

(78) It should be recalled that, in the previous investigation, the adoption of measures was considered not to be against the interest of the Community. Furthermore, the fact that the present investigation is a review, thus analysing a situation in which anti-dumping measures have already been in place, would allow the assessment of any undue negative impact on the parties concerned by the current anti-dumping measures.

(79) On this basis it was examined whether, despite the conclusions on the likelihood of a recurrence of injurious dumping, compelling reasons existed which would lead to the conclusion that it is not in the Community interest to maintain measures in this particular case.

### 2. Interest of the Community industry

(80) It is considered that if anti-dumping duties are not maintained, injurious dumping is likely to recur and that the situation of the Community industry, which worsened during the period under review, would further deteriorate.

(81) The Community industry has proven to be a structurally viable industry, able to adapt to the changing conditions on the market. This has been shown in particular by the industry's profits achieved until 1997 and its investment in state of the art production capacity. The success of these efforts strongly depends on existence of a fair competition on the Community market.

(82) It can reasonably be expected that the Community industry will benefit from the measures imposed by Council Regulation (EC) No 132/2001 provided that no other source of injurious dumping will undermine these measures. As outlined above, since there is a likelihood of a recurrence of injurious dumping from Russia, it is in the interest of the Community industry to maintain the anti-dumping measures on imports of AN originating in Russia.

### 3. Interest of importers

(83) Questionnaires and information were received from the European Fertiliser Import Association (EFIA — representing 24 importers) and two importers (out of the 48 questionnaires sent).

(84) The replies received from the two co-operating importers confirmed the price decrease as from 1998 and the fact that the Community producers had to follow this trend in order to ensure competitiveness. One of them also underlined the necessity to maintain the European infrastructure in order to guarantee good conditions for the supply of the European market, whereas the association was against the continuation of the measures.

(85) In view of the low level of co-operation and the fact that importers generally deal with a wide range of fertilisers, of which ammonium nitrate is only one, it was concluded that any negative impact of the continuation of measures on importers would not be a compelling reason not to impose the continuation of measures.

### 4. Interest of users

(86) The users of the product concerned are farmers. The Commission sent questionnaires to six users' associations at the European and national levels. Two of them replied to the questionnaire. Both are, as a matter of principle, against the continuation of the measures.

(87) One users' association argued that the analysis of the interest of the users should be closely linked to the British users' interest, on the grounds that the highest level of consumption of AN in the Community is in the United Kingdom. However, the investigation established that, during the IP, the United Kingdom accounted for only 16 % (in volume) of the imports from Russia into the Community of the product concerned, whereas France accounted for 47 % of the Russian imports of AN into the Community. On this basis, the argument has to be rejected.

(88) In addition, the same association argued that maintaining the anti-dumping measures in force would decrease the incomes of British farmers, thus putting them in a much more difficult economic situation. In this respect, as stated in Council Regulation (EC) No 132/2001, fertilisers represented on average 6 % of the total production costs for farmers. Given that imports from the country concerned represented, during the IP, 5 % of AN consumption in the Community market, and given that only part of any resulting import price increase is likely to be passed on to the users, any increase in farmers' production costs is likely to be minor. Moreover, were the Community industry to increase not only the volume of sales but also the prices, any such price increase would be limited given the existence of other sources of supply. Indeed, 37 % of all imports of AN into the Community are not subject to anti-dumping measures.

(89) EFIA and one users' association argued that the anti-dumping measures restrict competitively priced alternative sources of AN for the farmers since only 37 % of all imports of AN into the Community are not subject to anti-dumping measures.

On the one hand it is recalled that the purpose of the anti-dumping measures is not to restrict supply, but to re-establish fair competition on the Community market.

On the other hand, it should be noted that percentage of 37 % is partly underestimated due to the fact that the supply of AN to the EC market by non-dumping countries became less attractive owing to the strong price pressure exerted by Russia, Poland and Ukraine. It is therefore highly likely that, should fair competition be re-established, non-dumping countries will increase their presence on the Community market.

(90) On the basis of the above, the likely impact on farmers was considered not to constitute a compelling reason against the continuation of the measures, as a possible negative effect on farmers is unlikely to offset the positive effect on the Community industry.

### 5. Conclusion on the Community interest

(91) Given the above, it was concluded that there are no compelling reasons of Community interest against the continuation of the measures.

### H. ANTI-DUMPING MEASURES

(92) The complainant submitted that there were indications of the emergence of new forms of ammonium nitrate, i.e. mixtures of ammonium nitrate with other products, whose only purpose is to circumvent possible anti-dumping measures concerning ammonium nitrate. The attention of the customs authorities is drawn to this issue.

(93) In view of the conclusions reached with regard to dumping and injury, and taking into consideration that it could be established that existing measures are not achieving the intended results in removing the injury previously established, it is concluded that anti-dumping measures should be maintained in order to prevent further injury, and that the level of the measures should be modified.

(94) For establishing the level of duty, account has been taken of the level of the dumping margin found and the amount of duty necessary to eliminate the injury suffered by the Community industry. On the basis of the lesser duty rule, the injury margin was used for determining the amount of duty to be imposed.

(95) EFMA argued that a double mechanism (specific duty coupled with a minimum import price) would be more appropriate given the extremely low State-fixed gas prices paid by the Russian producers. It is however considered, that the specific duty is sufficient as it is based on the findings of the review investigation and that the form of the measure, i.e. a specific duty, discourages price manipulation and absorption of the duties. EFMA's request was therefore rejected.

(96) In order to establish the level of duty needed to remove the injury caused by dumping, injury margins have been calculated. The necessary price increase was determined on the basis of a comparison, at the same level of trade, of the weighted average import price, with the non-injurious price of AN sold by the Community industry on the Community market.

(97) The non-injurious price has been obtained by adding to the full unit cost of production a profit margin that may reasonably be reached in the absence of injurious dumping, taking account of the allowance with respect to the difference between granular and prilled AN already made for the undercutting calculations. The profit margin used for this calculation is 8 %. The difference resulting from the comparison between the weighted average import price and the non-injurious price of the Community industry was then expressed as a percentage of the total cif import value.

(98) The applicant submitted that a profit margin of 15 % return on capital employed (ROCE) would be appropriate. It argued that this level of return was necessary to re-invest for the long term and to achieve an adequate return on equity for shareholders. In the current context, however, the relevant concept is a reasonable profit the Community industry could have reached in the absence of injurious dumping, which does not coincide with the concept of the profit sought by shareholders. Given the findings in recital (56) of Regulation (EC) No 132/2001, and in the absence of any other comments, 8 % of turnover seems to be a reasonable profit. In order to ensure the efficiency of the measures and to discourage the price manipulation which has been observed previously, it is considered appropriate to impose the duty in the form of a specific amount per tonne.

(99) On the basis of the above, the amount of the duty shall be equal to the fixed amount per tonne of AN as shown below:

Country	Fixed amount of duty EUR per tonne
Russia	47.07

HAS ADOPTED THIS REGULATION:

#### Article 1

1. A definitive anti-dumping duty is hereby imposed on imports of ammonium nitrate, falling within CN code 3102 30 90 and 3102 40 90, originating in Russia.

2. The amount of the applicable duty per tonne of product shall be a fixed amount per tonne of ammonium nitrate as shown below:

Country	Fixed amount of duty EUR per tonne
Russia	47.07

3. In cases where goods have been damaged before entry into free circulation and, therefore, the price actually paid or payable is apportioned for the determination of the customs value pursuant to Article 145 of Commission Regulation (EEC) No 2454/93 <sup>(1)</sup> the amount of anti-dumping duty mentioned above, shall be reduced by a percentage which corresponds to the apportioning of the price actually paid or payable.

4. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

#### Article 2

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

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

<sup>(1)</sup> OJ L 253, 11.10.1993, p. 40.

**Proposal for a Council Regulation temporarily suspending the autonomous Common Customs  
Tariff duties on certain goods imported with airworthiness certificates**

(2002/C 181 E/14)

COM(2002) 147 final

*(Submitted by the Commission on 18 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 26 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Customs procedures for duty-free imports of parts, components and other goods used for the manufacture, repair, maintenance, rebuilding, modification or conversion of aircraft should be simplified.

(2) In order to achieve that aim, it is appropriate to suspend autonomous customs duties on imports of such goods imported with airworthiness certificates issued by a party authorised by aviation authorities within the Community or in a third country.

(3) In view of the fact that the prices for parts and components used in the aircraft sector are usually at least three times higher than the prices for similar goods used for other purposes, the risk that the goods imported duty free might be used in other industrial areas is very small.

(4) Suspension would alleviate the administrative burden for the economic operators in the aircraft sector since it would reduce the need for these companies to use suspensive customs regimes like favourable tariff treatment for goods by reason of their end-use, inward processing relief or customs warehousing. Furthermore, it would enable small and medium-sized enterprises, which have hitherto been unable to use suspensive customs regimes, to become more competitive with regard to the bigger operators in this area.

(5) Since airworthiness certificates do not always accompany the goods during transport, a procedure should be laid down under which customs authorities would be able to identify the certificates during on-spot checks after the product has been released for free circulation.

(6) In view of the complexity of the rules in the aviation sector, customs authorities should be able, at the expense of the importer, to call upon the expertise of a representative of the national aviation authorities where they have

good reason to believe that airworthiness certificates have been falsified and where the matter cannot be resolved otherwise. However, before taking such action, customs authorities should weigh the costs entailed against the import volume and the amount of duty at risk, so as to avoid a situation where it transpires that no infringement has been committed, but the benefit to the importer of the duty suspension has been nullified by the cost of procuring the expert opinion.

(7) The Commission should prepare a report on the basis of the information received from Member States about their experience in applying this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The autonomous Common Customs Tariff duties shall be suspended for parts, components and other goods of a kind to be incorporated in or used for civil aircraft and falling within Chapters 25 to 97 of the Common Customs Tariff and in respect of which an airworthiness certificate has been issued by a party authorised by European aviation authorities or the aviation authorities of a third country.

*Article 2*

1. The suspension laid down in Article 1 shall be conditional on submission of the original airworthiness certificate to the customs authorities when the goods are declared for release into free circulation.

Where the original airworthiness certificate cannot be submitted at the time when the goods are released for free circulation, suspension shall be conditional on the inclusion of a declaration, signed by the seller of the goods in question, on the commercial invoice or a document annexed thereto. A model of the required declaration is set out in Section A of the Annex.

2. In field 44 of the Single Administrative Document ("SAD") the text set out in Section B of the Annex shall be inserted by the importer.

3. Where goods are released for free circulation under simplified procedures in accordance with Council Regulation (EEC) No 2913/92 <sup>(1)</sup>, the importer shall insert in the SAD (field 44) or in any authorised document replacing the SAD the text set out in Section B of the Annex.

In such cases suspension shall be conditional on the submission of the documents referred to in paragraph 1 in accordance with the terms of the authorisation of the simplified procedure at the time when the supplementary declaration is submitted to the competent customs office.

#### Article 3

Where the customs authorities have good reason to suspect that airworthiness certificates have been falsified and where the matter cannot be resolved otherwise, they may request an expert opinion from a representative of the national aviation authorities at the expense of the importer.

<sup>(1)</sup> OJ L 302, 19.10.1992, p. 1.

In such cases, customs authorities shall take into account the import volume and the amount of duty at risk, in order to prevent the benefit to the importer of the duty suspension being nullified by the cost of procuring the expert opinion, if the investigation shows that the rules for the issuing of those certificates have not been infringed.

#### Article 4

No later than three years after the entry into force of this Regulation the Commission shall submit to the Council a report on the application of that Regulation based on the information received from Member States.

#### Article 5

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

It shall apply from 1 April 2002.

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

### ANNEX

A. Declaration on the commercial invoice or a document annexed to such invoice (Article 2(1)):

'For the following goods of [this invoice]/[invoice No ... of ...] <sup>(1)</sup> the following airworthiness certificates (see column 2) have been issued by the company shown in column 3 authorised by the aviation authority shown in column 4 of the country shown in column 5.

Position No on the invoice	No of the airworthiness certificate	Issuer of the certificate	Name of the authorising aviation authority	Name of the country
(1)	(2)	(3)	(4)	(5)

<sup>(1)</sup> When the declaration is annexed on a separate page, the number and date of the invoice should be inserted.'

B. Text to be inserted in field 44 of the Single Administrative Document (Article 2(2) and (3)):

'Import with airworthiness certificate'

**Proposal for a Council Decision on the signing of the agreement for scientific and technological cooperation between the European Community and the Republic of Chile**

(2002/C 181 E/15)

COM(2002) 151 final

*(Submitted by the Commission on 19 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 170(2) thereof, in conjunction with the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) A Framework Cooperation Agreement between the European Community and its Member States, on the one part, and the Republic of Chile, of the other part entered into force on 1 February 1999 <sup>(1)</sup>.
- (2) In its resolution of 14 March 1997 on the Commission communication entitled 'Promoting RTD cooperation with the world's emerging economies' — COM(96) 344 final — the European Parliament 'calls on the Commission to negotiate, with due regard for the circumstances in each country, bilateral agreements establishing a legal framework for the promotion of RTD cooperation' <sup>(2)</sup>.
- (3) The European Community and the Republic of Chile are pursuing specific RTD programmes in areas of common interest.
- (4) On the basis of past experience, both sides have expressed a desire to establish a deeper and broader framework for the conduct of collaboration in science and technology.
- (5) This cooperation agreement in the field of science and technology forms part of the global cooperation between the European Community and the Republic of Chile.
- (6) By its decision of 10 July 2001, the Council authorised the Commission to negotiate an agreement for scientific and technological cooperation between the European Community and the Republic of Chile. The negotiations, conducted in line with the negotiating directives, resulted in the attached draft agreement and its annex on intellectual property rights.
- (7) Subject to its possible conclusion at a later date, the agreement initialled on 11 December 2001 should be signed,

HAS DECIDED AS FOLLOWS:

*Sole Article*

Subject to a possible conclusion at a later date, the President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the European Community, the Agreement for scientific and technological co-operation between the European Community and the Republic of Chile.

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<sup>(1)</sup> OJ L 42, 16.2.1999, p. 46.

<sup>(2)</sup> OJ C 115, 14.4.1997, p. 236.

**AGREEMENT****for scientific and technological cooperation between the European Community and the Republic of Chile**

THE EUROPEAN COMMUNITY (hereinafter referred to as 'the Community'),

on the one part,

and

THE REPUBLIC OF CHILE (hereinafter referred to as 'Chile') on the other part,

hereinafter referred to as the 'Parties';

CONSIDERING the Framework Agreement of Cooperation between the Government of the Republic of Chile and the European Economic Community concluded on 20 December 1990;

CONSIDERING the importance of science and technology for their economic and social development and article 16 of the Framework Agreement signed in Florence on 21 June 1996;

CONSIDERING the present scientific and technological cooperation between the Community and Chile;

CONSIDERING that the Community and Chile are carrying out research and technological development activities, including demonstration projects referred to as letter d) of Article 2, in a number of areas of common interest, and that mutual benefits may be derived from the participation of one Party in the research and development of the other based on the reciprocity criteria;

DESIRING to create a formal cooperation basis in scientific and technological research with a view to extend and intensify the conduct of cooperative activities in areas of common interest and to encourage the application of the results of such cooperation to the economic and social benefit of both Parties;

CONSIDERING that the present Scientific and Technological Cooperation Agreement between Chile and the Community is part of the general cooperation between Chile and the Community,

HAVE AGREED AS FOLLOWS:

**Article 1****Purpose**

The Parties shall encourage, develop and facilitate cooperative research and development activities in science and technology fields of common interest between the Community and Chile.

**Article 2****Definitions**

For the purpose of this Agreement:

- (a) 'cooperative activity' means any activity which the Parties undertake or support, pursuant to this Agreement, and includes joint research;
- (b) 'information' means scientific or technical data, results or methods of research and development stemming from joint

research carried out under this agreement and any other data deemed necessary by the participants to cooperative activities, including, as necessary, by the Parties themselves;

- (c) 'intellectual property' shall have the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, done at Stockholm, 14 July 1967 and the TRIPS Agreement;
- (d) 'joint research' means research, technological development or demonstration project that is implemented with financial support from one or both Parties and that involves collaboration between participants from both the Community and Chile;
- (e) 'demonstration project' means the project aimed at demonstrating the viability of new technologies, processes, services or products that offer a potential economic advantage, but that cannot be directly commercialised;

- (f) 'research and Development' (R & D) means creative work carried out in a systematic way so as to increase the human, cultural, social and technological knowledge volume and the use of this knowledge to stem new applications;
- (g) 'participant' or 'research entities' means any physical or legal person, research institute, firms, or any other legal entity or undertaking established in the Community or in Chile involved in cooperative activities, including the Parties themselves.

### Article 3

#### Principles

Cooperative activities shall be conducted on the basis of the following principles:

- (a) mutual benefit based on an overall balance of advantages;
- (b) reciprocal access to the activities of research and technological development undertaken by each Party;
- (c) timely exchange of information which may affect cooperative activities;
- (d) appropriate protection of intellectual property rights.

### Article 4

#### Scope of cooperation

1. Cooperation under this Agreement may cover all the activities of research, technological development and demonstration, hereinafter referred to as 'RTD', included in the first activity of the framework programme under Article 164 of the Treaty establishing the European Community and all similar RTD activities in Chile in the corresponding scientific and technological fields.

2. This Agreement does not affect the participation of Chile, as a developing country, in Community activities in the field of research for development.

### Article 5

#### Modalities of cooperation

The Parties will foster the participation of the research and technological development bodies in the cooperation activities under this Agreement in compliance with their internal dispositions and politics, so as to offer similar opportunities in their own research and scientific development and technological activities.

Cooperative activities may take the following forms:

- 1. Participation of Chilean research and technological development entities to RTD projects of the framework programme and reciprocal participation of research and technological development entities established in the Community to Chilean projects in similar sectors of RTD. Such a participation is subject to the rules and procedures applicable in each Party;
- 2. Pooling of RTD projects already implemented according to the procedures applicable in the RTD programmes of each Party;
- 3. Joint RTD Projects under the framework of their scientific and technological policies, especially those relating to scientific and technological prospective activities;
- 4. Visits and exchanges of scientists and technical experts, as well as public, university and private specialists in the field of design and application of scientific and technological policies;
- 5. Joint organisation of seminars, conferences, symposia and workshops, as well as participation of experts to those activities;
- 6. Scientific networks and researchers training;
- 7. Concerted actions for dissemination of results, exchange of experience on joint RTD projects that have been funded or for their coordination;
- 8. Exchanges and sharing of equipment and materials including shared use of advanced research facilities;
- 9. Exchanges of information on practices, laws, regulations and programmes relevant to cooperation under this Agreement;
- 10. Any other modality that would be recommended by the Steering Committee and deemed in conformity with the policies and procedures applicable in both Parties.

### Article 6

#### Coordination and facilitation of cooperative activities

- (a) The coordination and facilitation of cooperative activities under this Agreement shall be accomplished on behalf of Chile, by the National Scientific and Technological Research Commission (CONICYT), decentralised body of the Ministry of Education, with its own juridical personality, or other organisms which Chile could notify at any moment with previous written notice and, on behalf of the Community, by the services of the European Commission, in charge of Community RTD policies and activities, acting as executives agents.



(b) The executive agents shall establish a Steering Committee on S & T Cooperation, hereinafter referred to as the 'Steering Committee' for the management of this Agreement; this Committee shall consist of a similar number of official representatives of each Party and shall have co-chairpersons from Parties; it shall establish its own rules of procedure.

(c) The functions of the Steering Committee shall include:

1. Promoting and overseeing the different cooperative activities as mentioned in Articles 2 and 4 of this Agreement, as well as those that will be implemented in the framework of RTD for development;
2. Indicating, for the following year, pursuant to Article 5, first and second indents, among the potential sectors for RTD cooperation, those priority sectors or sub sectors of mutual interest in which cooperation is sought;
3. Proposing, pursuant to Article 5, second indent, to the scientists of both Parties the pooling of their projects which would be of mutual benefit and complementary;
4. Making recommendations pursuant to Article 5, tenth indent;
5. Advising the Parties on ways to enhance and improve cooperation consistent with the principles set out in this Agreement;
6. Reviewing the efficient functioning and implementation of this Agreement including evaluation of on-going cooperative projects involving Chile as a developing country under Community's activities in the field of research for development;
7. Providing an annual report to the Parties on the status, the level reached and the effectiveness of cooperation undertaken under this Agreement. This report will be transmitted to the Joint Commission established within the Framework Cooperation Agreement between the European Community and Chile of June 1996.

(d) The Steering Committee shall, as a general rule, meet annually, preferably before the meeting of the Joint Committee established within the Framework Cooperation Agreement of 1996, according to a jointly agreed schedule, and will refer to it. The meetings should be held alternatively in the Community and in Chile. Extraordinary meetings may be organised at the request of either Party.

(e) Decisions of the Steering Committee shall be reached by consensus. Minutes, comprising of a record of decisions and principal points discussed, shall be taken at each

meeting. These minutes shall be agreed upon by the co-chairpersons of the Steering Committee.

(f) Each Party will support the cost of its participation to the Steering Committee meetings. For the Steering Committee Meeting, the expenses, travel and accommodation, of the participants, will be borne by the Parties to whom they relate. Any other cost associated with the Steering Committee Meeting will be borne by the host Party.

#### Article 7

##### Funding

- (a) Cooperative activities shall be subject to the availability of appropriated funds and to the laws, regulations, policies and programmes applicable in territories of each Party. Costs incurred on selected cooperative activities will be shared by the participants without any transfer of funds from one Party to the other.
- (b) When a specific cooperative mechanism of one Party confers economic support to the participants of the other, such subventions, financial or other contributions of one Party to the participants of the other, in support to those activities, will be granted free of charges and customs duties, pursuant to the laws and dispositions applicable in territories of each Party.
- (c) RTD projects, involving Chile as developing country, sponsored under Community's activities in the field of research for development will be excluded from the provisions specified under Article 7 letter (a).

#### Article 8

##### Entry of personnel and equipment

Each Party shall take all appropriate steps and use its best efforts, within the laws and regulations applicable in the territories of each Party, to facilitate entry to, sojourn and exit from its territory of persons, material, data and equipment related to or used in cooperative activities developed by the Parties under the provisions of this Agreement.

#### Article 9

##### Diffusion and utilisation of information

1. The dissemination and utilisation of information, and the management, allocation and exercise of intellectual property rights resulting from joint research under this Agreement shall be subject to the requirements of Annex to this Agreement.

2. This Annex called 'Intellectual Property Rights' is an integral part of this Agreement.

*Article 10***Territorial application**

This Agreement shall apply, on the one hand to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty, and on the other hand to the territory of the Republic of Chile. This shall not exclude cooperative activities on the high seas, outer space, or the territory of third countries, in accordance with international law.

*Article 11***Entry into force, termination and dispute settlement**

- (a) This Agreement shall enter into force on the date on which both parties have notified each other in writing that their respective necessary internal procedures have been completed.
- (b) This Agreement shall be concluded for an initial period of five years and may be tacitly renewed after evaluation during the next to last year of each successive period.
- (c) This Agreement may be amended by decision of the Parties. Amendments shall enter into force within the same conditions as the mentioned in letter (a).
- (d) This Agreement may be terminated at any time by either Party upon six months' written notice to the other Party

through diplomatic channels. The expiration of this Agreement shall not affect the validity or duration of any arrangements made under it, or any specific rights and obligations that have accrued in compliance with the Annex.

- (e) All questions or disputes related to the interpretation or implementation of this Agreement shall be settled by mutual agreement between the Parties.

*Article 12*

This Agreement is drawn up in duplicate in the German, Danish, Spanish, French, Finnish, Greek, English, Italian, Dutch, Portuguese and Swedish languages, each of these texts being equally authentic.

In witness whereof, the undersigned, being duly authorised thereto, have signed this Agreement.

Done at . . . on the day of . . . in the year . . . , in two copies, in the German, Danish, Spanish, Finnish, French, Greek, English, Italian, Dutch, Portuguese and Swedish languages, with each text being equally authentic.

*For the European Community*

*For the Republic of Chile*

## ANNEX

**INTELLECTUAL PROPERTY RIGHTS**

This Annex is part of the 'Agreement for Scientific and Technological Cooperation between the European Community and the Republic of Chile', hereinafter referred to as 'the Agreement'.

Rights to intellectual property created or furnished under the Agreement shall be allocated as provided in this Annex.

**I. APPLICATION**

This Annex is applicable to joint research undertaken pursuant to the Agreement, except as otherwise agreed by the Parties.

**II. OWNERSHIP, ALLOCATION AND EXERCISE OF RIGHTS**

1. For purpose of this Annex 'intellectual property' is defined in Article 2 (c) of the Agreement.
2. This Annex addresses the allocation of rights and interests of the Parties and their participants. Each Party and its participants shall ensure that the other Party and its participants may obtain the rights to intellectual property allocated to it in accordance with this Annex. This Annex does not otherwise alter or prejudice the allocation of rights, interests and intellectual property between a Party and its nationals or participants, and the rules of diffusion and utilisation of information, which will be determined by the laws and practices of each Party.
3. The Parties will also be guided by, and contractual arrangements should provide for, the following principles:
  - (a) effective protection of intellectual property. The Parties and their participants shall ensure that they notify one another within a reasonable time of the creation of any intellectual property arising under the Agreement or implementation arrangements and to seek protection for such intellectual property in a timely fashion;
  - (b) effective exploitation of results, taking into account the contributions of the Parties and their participants;
  - (c) non-discriminatory treatment of participants from the other Party as compared with the treatment given to its own participants;
  - (d) protection of business-confidential information.
4. The participants shall jointly develop a Technology Management Plan (TMP). TMP is a specific agreement to be concluded between the participants in joint research defining their respective rights and obligations, including those in respect of the ownership and use, including publication, of information and intellectual property to be created in the course of joint research.

The TMP will be approved by the responsible funding agency of the Party involved in financing the research, before the conclusion of the corresponding specific research and development cooperation contracts. The TMP shall be developed within the rules and regulations in force in each Party taking into account the aims of the joint research, the relative financial or other contributions of the Parties and participants, the advantages and disadvantages of licensing by territory or for fields of use, transfers of data, goods or services submitted to export controls, requirements imposed by applicable laws, and other factors deemed appropriate by the participants. The rights and obligations concerning the research and information generated by invited researchers (i.e. researchers not coming from a Party or a participant) in respect of IP shall also be addressed in the joint technology management plans.

With respect to IP, the TMP will normally address, among other things, ownership, protection, user rights for research and development purposes, exploitation and dissemination, including arrangements for joint publication, the rights and obligations of visiting researchers and dispute settlement procedures. The TMP shall also address foreground and background information, licensing and deliverables.

5. Information or intellectual property created in the course of joint research and not regulated in the TMP will be allocated, with the agreement of the Parties, according to the principles set out in the TMP. In case of disagreement, such information or IP shall be owned jointly by all the participants involved in the joint research from which the information or IP results. Each participant to whom this provision applies shall have the right to use such information or IP for his own commercial exploitation with no geographical limitation.

6. Each Party will ensure that the other Party and its participants may have the rights to IP allocated to them in accordance with the present principles.
7. While maintaining the conditions of competition in areas affected by the Agreement, each Party shall endeavour to ensure that rights acquired pursuant to the Agreement, are exercised in such a way as to encourage, in particular
  - (i) the dissemination and use of information created, disclosed or otherwise made available, under the Agreement and
  - (ii) the adoption and implementation of international standards.
8. Termination or expiry of the Agreement will not affect rights or obligations of participants in accordance with this Annex.

### III. COPYRIGHT WORKS AND SCIENTIFIC LITERARY WORKS

Copyright belonging to the Parties or to their participants shall be accorded treatment consistent with the Berne Convention (Paris Act 1971) and the TRIPS Agreement. The IP rights will protect the expression but not the ideas, procedures, methods or mathematical concepts as such. Only limitations or exceptions may be introduced to exclusive rights in specific special cases that do not obstruct the normal exploitation of results nor unduly endanger the legitimate interests of the right titular.

Without prejudice to Section IV and V, and unless otherwise agreed in the TMP, publication of results of research shall be made jointly by the Parties or participants. Subject to the foregoing general rule, the following procedures shall apply:

1. In the case of publication by a Party or public bodies of that Party of journals, articles, reports, books, including video and software arising from joint research pursuant to the Agreement, the other Party will be entitled to a worldwide, non-exclusive, irrevocable, royalty-free license to translate, reproduce, adapt, transmit and publicly distribute such works.
2. The Parties shall endeavour to disseminate literary works of a scientific character arising from joint research pursuant to the Agreement and published by independent publishers will be disseminated as widely as possible.
3. All copies of a copyright work to be publicly distributed and prepared under this provision shall indicate the names of the author(s) of the work unless an author explicitly declines to be named. Copies shall also bear a clearly visible acknowledgement of the cooperative support of the Parties.

### IV. INVENTIONS AND OTHER SCIENTIFIC AND TECHNOLOGICAL RESULTS

The inventions and other scientific and technological results arising from cooperative activities between Parties will be owned by them, unless otherwise agreed by them.

### V. UNDISCLOSED INFORMATION

#### A. *Documentary undisclosed information*

1. Each Party, its agencies or its participants, as appropriate, shall identify at the earliest possible moment and preferably in the TMP the information that they wish to remain undisclosed in relation to the Agreement, taking into account inter-alia the following criteria:
  - (a) secrecy of the information in the sense that it is not, as a body or in the precise configuration or assembly of its components, generally known among or readily accessible by lawful means to experts in the fields;
  - (b) the actual or potential commercial value of the information by virtue of its secrecy;
  - (c) previous protection of the information in the sense that it has been subject to steps that were reasonable under the circumstances by the person lawfully in control, to maintain its secrecy.

The Parties and their participants may in certain cases agree that, unless otherwise indicated, parts or all of the information provided, exchanged or created in the course of joint research pursuant to the Agreement may not be disclosed.

2. Each Party shall ensure that it and its participants clearly identify undisclosed information, for example by means of an appropriate marking or restrictive legend. This also applies to any reproduction of the said information, in whole or in part.

A Party receiving undisclosed information pursuant to the Agreement will respect the privileged nature thereof. These limitations shall automatically terminate when this information is disclosed by the owner into the public domain.

3. Undisclosed information communicated under this Agreement may be disseminated by the receiving Party to persons within or employed by the receiving Party and other governmental departments or concerned agencies of the receiving Party authorised for the specific purposes of the joint research under way, provided that any undisclosed information so disseminated shall be pursuant to a written agreement of confidentiality and shall be readily recognisable as such, as set out above.
4. With the prior written consent of the Party providing undisclosed information, the receiving Party may disseminate such undisclosed information more widely than otherwise permitted in paragraph 3 above. The Parties shall cooperate in developing procedures for requesting and obtaining prior written consent for such wider dissemination, and each Party will grant such approval to the extent permitted by its domestic policies, regulations and laws.

*B. Non-documentary undisclosed information*

Non-documentary undisclosed or other confidential or privileged information provided in seminars and other meetings arranged under this Agreement, or information arising from the attachment of staff, use of facilities, or joint projects, shall be treated by the Parties or their participants according to the principles specified for documentary information in the Agreement; provided, however, that the recipient of such undisclosed or other confidential or privileged information has been made aware in advance and in written form of the confidential character of the information at the moment of its communication.

*C. Control*

Each Party shall endeavour to ensure that undisclosed information received by it under this Agreement shall be controlled as provided herein. If one of the Parties becomes aware that it will be, or may be reasonably expected to become, unable to meet the non-dissemination provisions of sections A and B, it shall immediately inform the other Party. The Parties will thereafter consult to define the most appropriate course of action.

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**Amended proposal for a Council Regulation introducing special measures to terminate the service of officials of the Commission of the European Communities as part of the reform of the Commission**

(2002/C 181 E/16)

COM(2002) 136 final — 2001/0027(CNS)

*(Submitted by the Commission on 20 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 283 thereof,

Having regard to the proposal made by the Commission after consulting the Staff Regulations Committee in accordance with Article 10a of the Staff Regulations of Officials of the European Communities <sup>(1)</sup>,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Court of Justice,

Having regard to the opinion of the Court of Auditors,

Whereas:

- (1) A reform is now under way in the Commission designed in particular to refocus the use of resources on priority activities.
- (2) A communication from the Commission <sup>(2)</sup> has indicated, despite the successes already achieved in 1999 and 2000, some shortfalls in the staff assigned to certain priority activities.
- (3) The Commission intends to meet a significant part of those needs through internal rationalisation and redeployments.
- (4) The Commission intends to take steps, mainly through training, to help redeployed staff to adjust in the most satisfactory and effective way possible.
- (5) However, the skills of some officials, particularly older members of staff, are deemed not to be in line with the duties to be performed.
- (6) The Commission needs new skill profiles and a rebalancing of its establishment plan, but the number of officials retiring in the normal way will not be sufficient to allow the necessary skills to be acquired through recruiting new staff within a satisfactory timescale.
- (7) Special measures should accordingly be adopted with regard to termination of service together with internal administrative arrangements for effective monitoring of the implementation of this Regulation.

(8) These measures must be applied as far as possible with due regard for geographical balance, in compliance with the principles governing this Regulation.

(9) These measures must be budget neutral.

(10) The measures contained in this Regulation must be implemented as a matter of urgency in order to ensure the proper functioning of the Commission departments. While the measures are now ready in so far as the Commission is concerned, that is not the case with regard to the other institutions.

(11) Other specific one-off measures of the type contained in this Regulation must not be used by the Commission in the context of the reform, including where the measures proposed in this Regulation fail to produce the desired result,

HAS ADOPTED THIS REGULATION:

*Article 1*

The European Commission is hereby authorised, in the interests of the service and in order to take account of the need to renew skills arising from the refocusing of the use of its resources on priority activities, to adopt measures up to 31 December 2004 for terminating the service within the meaning of Article 47 of the Staff Regulations of officials who have reached the age of 55 and have completed at least 15 years' service, regardless of the budget (operating or research) from which they are paid, with the exception of those in Grades A1 and A2, under the conditions specified below.

*Article 2*

The total number of officials to be covered by the measures referred to in Article 1 shall be 600.

This measure shall be without prejudice to decisions to be taken under the annual budget procedures.

*Article 3*

Within the ceilings laid down in Article 2, and with due regard to the interests of the service, the Commission, after having consulted its Joint Committee, shall select from among the officials applying for termination of their service under Article 1 those to whom it wishes to apply this measure.

<sup>(1)</sup> Hereinafter called the 'Staff Regulations'.

<sup>(2)</sup> Doc. No 6343/00 INST 4.

It shall consider as a priority officials affected by the reorganisation measures and measures for refocusing the use of its resources on priority activities, in particular redeployment, whose skills are deemed not to be in line with the duties to be performed. It shall take account of the amount of training necessary for them to undertake new tasks, their age, ability, performance, conduct in the service, family circumstances and length of service.

#### Article 4

1. Former officials whose service is terminated under Article 1 shall be entitled to a monthly allowance set as a percentage of the last basic salary received according to age and length of service at the time of departure as shown in the table in the Annex to this Regulation. The last basic salary shall be that for the grade and step held by the official or member of the temporary staff concerned at the time of departure, determined by reference to the table in Article 66 of the Staff Regulations in force on the first day of the month for which the allowance is payable.

2. Such former officials may at any time, at their own request, receive a retirement pension on the terms and conditions laid down in the Staff Regulations. Entitlement to the allowance shall then cease. It shall cease in any event not later than the last day of the month in which the former official or member of the temporary staff concerned reaches the age of 65 years or as soon as he or she is eligible before that age for the maximum retirement pension of 70 % (Article 77 of the Staff Regulations).

At that point the former official shall automatically receive a retirement pension, which shall take effect on the first day of the calendar month following the month in which the allowance was paid for the last time.

3. The allowance provided for in paragraph 1 shall be adjusted by the weighting fixed for the country situated inside the Community in which the recipient proves that he is resident. Recipients shall provide evidence each year of their place of residence.

If the recipient resides in a country situated outside the Community, the weighting to be applied to the allowance shall be 100.

The allowance shall be expressed in euro. It shall be paid in the currency of the country of residence of the recipient. However, if it is subject to the weighting of 100 under the second subparagraph, it shall be paid in euro.

An allowance paid in a currency other than euro shall be calculated on the basis of the exchange rates referred to in the second paragraph of Article 63 of the Staff Regulations.

4. Where gross income accruing to the former official from any new employment, when combined with the allowance provided for in paragraph 1, exceeds the total gross remuneration last received by the official or member of the temporary staff concerned, determined by reference to the salary scales in force on the first day of the month for which the allowance is payable, the amount of the excess shall be deducted from that allowance. That remuneration shall be weighted as provided for in paragraph 3.

Gross income and total gross remuneration last received, as referred to above, mean sums paid after deduction of social security contributions but before deduction of tax.

The former official shall give a formal undertaking to provide any written proof which may be required, including an annual statement of income in the form of a salary statement or audited accounts, as appropriate, and a sworn or authenticated declaration that he or she is not in receipt of any other income from any new employment, and shall notify the institution of any other factor which may affect his or her right to the allowance, failing which he or she shall be liable to disciplinary action as provided for in Article 86 of the Staff Regulations.

5. As set out in Article 67 of the Staff Regulations and Articles 1, 2 and 3 of Annex VII thereto, the household allowance, dependent child allowance and education allowance shall be payable either to the recipient of the allowance provided for in paragraph 1 or to the person or persons to whom custody of the child or children has been entrusted by law or by an order of court or of the competent administrative authority; the household allowance shall be calculated by reference to the allowance provided for in paragraph 1.

6. Provided they do not receive income from gainful employment, recipients of the allowance shall be entitled, in respect of themselves and persons covered by their insurance, to benefits under the sickness insurance scheme provided for in Article 72 of the Staff Regulations provided they pay the relevant contribution, calculated on the basis of the allowance provided for in paragraph 1.

7. During the period for which they are entitled to receive the allowance, but for not more than 65 months, former officials shall continue to acquire further rights to retirement pension based on the salary carried by their grade and step, provided that the contribution provided for in the Staff Regulations by reference to that salary is paid during that period and provided that the total pension does not exceed the maximum specified in the second paragraph of Article 77 of the Staff Regulations. For the purposes of Article 5 of Annex VIII to the Staff Regulations, such period shall be considered to be a period of service.

8. Subject to Articles 1(1) and 22 of Annex VIII to the Staff Regulations, the surviving spouse of a former official who dies while in receipt of the allowance provided for in paragraph 1 shall be entitled, provided that they have been the spouse of the former official for at least one year when he or she left the service of the Commission, to a survivor's pension equal to 60 % of the retirement pension which, irrespective of length of service or age, would have been payable to the former official if he or she had qualified for it at the time of death.

The survivor's pension referred to in the previous subparagraph shall not be less than the amounts specified in the second paragraph of Article 79 of the Staff Regulations. However, in no case may it exceed the amount of the retirement pension to which the former official would have been entitled had he or she survived and been granted a retirement pension when ceasing to be eligible for the allowance referred to above.

The minimum duration of the marriage as referred to in the first subparagraph shall not be taken into account if there are one or more children of a marriage contracted by the official before he or she left the service provided that the surviving spouse maintains or has maintained those children.

Nor shall the duration of the marriage be taken into account if the death of the former official resulted from one of the circumstances referred to at the end of the second paragraph of Article 17 of Annex VIII to the Staff Regulations.

9. On the death of a former official in receipt of the allowance provided for paragraph 1, dependent children within the meaning of Article 2 of Annex VII to the Staff Regulations shall be entitled to an orphan's pension on the conditions set out in the first, second and third paragraphs of Article 80 of the Staff Regulations and in Article 21 of Annex VIII to the Staff Regulations.

#### Article 5

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

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

### ANNEX

#### ALLOWANCE PERCENTAGE

The allowance percentage referred to in Article 4(1) of this Regulation will be determined on the basis of the age and length of service of officials at the time of departure as shown in the table below:

*Level of allowance depending on age and length of service*

Length of service \ Age	Age				
	From 55 to 56 years	From 57 to 58 years	From 59 to 60 years	From 61 to 62 years	Over 63 years
From 15 to 19 years	60,0 %	60,0 %	60,0 %	62,0 %	64,0 %
From 20 to 24 years	60,0 %	60,0 %	62,0 %	64,0 %	66,0 %
From 25 to 29 years	62,0 %	64,0 %	66,0 %	68,0 %	70,0 %
30 years and over	64,0 %	66,0 %	68,0 %	70,0 %	70,0 %

Age and length of service will be considered in relation to the actual date of departure of the official concerned.

Applying these conditions to the target group of officials on a weighted basis gives a maximum average allowance of 62,5 %.



**Proposal for a Council Regulation introducing special measures to terminate the service of officials  
of the General Secretariat of the Council of the European Union**

(2002/C 181 E/17)

COM(2002) 136 final — 2002/0069(CNS)

(Submitted by the Commission on 20 March 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 283 thereof,

Having regard to the proposal made by the Commission after consulting the Staff Regulations Committee in accordance with Article 10a of the Staff Regulations of Officials of the European Communities <sup>(1)</sup>,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Court of Justice,

Having regard to the opinion of the Court of Auditors,

Whereas:

- (1) The development of the European Union since the Treaty of Maastricht has extended the scope of the Council's activities. These changes have increased and reinforced the General Secretariat's tasks, which go beyond those of a Conference Secretariat.
- (2) The General Secretariat of the Council intends to meet a significant part of those needs through internal rationalisation and redeployments.
- (3) The General Secretariat of the Council intends to take steps, mainly through training, to help redeployed staff to adjust in the most satisfactory and effective way possible.
- (4) However, the skills of some officials, particularly older members of staff, are deemed not to be in line with the duties to be performed.
- (5) The General Secretariat of the Council needs new skill profiles and a rebalancing of its establishment plan, but the number of officials retiring in the normal way will not be sufficient to allow the necessary skills to be acquired through recruiting new staff within a satisfactory timescale.

(6) Special measures should accordingly be adopted with regard to termination of service together with internal administrative arrangements for effective monitoring of the implementation of this Regulation.

(7) These measures must be applied as far as possible with due regard for geographical balance, in compliance with the principles governing this Regulation.

(8) These measures must be budget-neutral,

HAS ADOPTED THIS REGULATION:

*Article 1*

The General Secretariat of the Council is hereby authorised, in the interests of the service and in order to take account of the need to renew skills arising from the refocusing of the use of its resources on priority activities, to adopt measures up to 31 December 2004 for terminating the service within the meaning of Article 47 of the Staff Regulations of officials who have reached the age of 55 and have completed at least 15 years' service, with the exception of those in Grades A1 and A2, under the conditions specified below.

*Article 2*

The total number of officials to be covered by the measures referred to in Article 1 shall be 94 (12 As, 22 LAs, 8 Bs, 44 Cs, and 8 Ds).

This measure shall be without prejudice to decisions to be taken under the annual budget procedures.

*Article 3*

Within the ceilings laid down in Article 2, and with due regard to the interests of the service, the General Secretariat of the Council, after having consulted its Joint Committee, shall select from among the officials applying for termination of their service under Article 1 those to whom it wishes to apply this measure.

<sup>(1)</sup> Hereinafter called the 'Staff Regulations'.

It shall consider as a priority officials affected by the reorganisation measures and measures for refocusing the use of its resources on priority activities, in particular redeployment, whose skills are deemed not to be in line with the duties to be performed. It shall take account of the amount of training necessary for them to undertake new tasks, their age, ability, performance, conduct in the service, family circumstances and length of service.

#### Article 4

1. Former officials whose service is terminated under Article 1 shall be entitled to a monthly allowance set as a percentage of the last basic salary received according to age and length of service at the time of departure as shown in the table in the Annex to this Regulation. The last basic salary shall be that for the grade and step held by the official concerned at the time of departure, determined by reference to the table in Article 66 of the Staff Regulations in force on the first day of the month for which the allowance is payable.

2. Such former officials may at any time, at their own request, receive a retirement pension on the terms and conditions laid down in the Staff Regulations. Entitlement to the allowance shall then cease. It shall cease in any event not later than the last day of the month in which the former official concerned reaches the age of 65 years or as soon as he or she is eligible before that age for the maximum retirement pension of 70 % (Article 77 of the Staff Regulations).

At that point the former official shall automatically receive a retirement pension, which shall take effect on the first day of the calendar month following the month in which the allowance was paid for the last time.

3. The allowance provided for in paragraph 1 shall be adjusted by the weighting fixed for the country situated inside the Community in which the recipient proves that he is resident. Recipients shall provide evidence each year of their place of residence.

If the recipient resides in a country situated outside the Community, the weighting to be applied to the allowance shall be 100.

The allowance shall be expressed in euro. It shall be paid in the currency of the country of residence of the recipient. However, if it is subject to the weighting of 100 under the second subparagraph, it shall be paid in euro.

An allowance paid in a currency other than euro shall be calculated on the basis of the exchange rates referred to in the second paragraph of Article 63 of the Staff Regulations.

4. Where gross income accruing to the former official from any new employment, when combined with the allowance provided for in paragraph 1, exceeds the total gross remuneration last received by the official or member of the temporary staff concerned, determined by reference to the salary scales in force on the first day of the month for which the allowance is payable, the amount of the excess shall be deducted from that allowance. That remuneration shall be weighted as provided for in paragraph 3.

Gross income and total gross remuneration last received, as referred to above, mean sums paid after deduction of social security contributions but before deduction of tax.

The former official shall give a formal undertaking to provide any written proof which may be required, including an annual statement of income in the form of a salary statement or audited accounts, as appropriate, and a sworn or authenticated declaration that he or she is not in receipt of any other income from any new employment, and shall notify the institution of any other factor which may affect his or her right to the allowance, failing which he or she shall be liable to disciplinary action as provided for in Article 86 of the Staff Regulations.

5. As set out in Article 67 of the Staff Regulations and Articles 1, 2 and 3 of Annex VII thereto, the household allowance, dependent child allowance and education allowance shall be payable either to the recipient of the allowance provided for in paragraph 1 or to the person or persons to whom custody of the child or children has been entrusted by law or by an order of court or of the competent administrative authority; the household allowance shall be calculated by reference to the allowance provided for in paragraph 1.

6. Provided that they are not receiving income from any gainful employment, recipients of the allowance shall be entitled, in respect of themselves and persons covered by their insurance, to benefits under the sickness insurance scheme provided for in Article 72 of the Staff Regulations provided they pay the relevant contribution, calculated on the basis of the allowance provided for in paragraph 1, and are not covered by another sickness insurance scheme by virtue of legal or statutory provisions.

7. During the period for which they are entitled to receive the allowance, but for not more than 65 months, former officials shall continue to acquire further rights to retirement pension based on the salary carried by their grade and step, provided that the contribution provided for in the Staff Regulations by reference to that salary is paid during that period and provided that the total pension does not exceed the maximum specified in the second paragraph of Article 77 of the Staff Regulations. For the purposes of Article 5 of Annex VIII to the Staff Regulations, such period shall be considered to be a period of service.

8. Subject to Articles 1(1) and 22 of Annex VIII to the Staff Regulations, the surviving spouse of a former official who dies while in receipt of the allowance provided for in paragraph 1 shall be entitled, provided that the marriage was contracted at least one year before the former official left the service of the Council, to a survivor's pension equal to 60 % of the retirement pension which, irrespective of length of service or age, would have been payable to the former official if he or she had qualified for it at the time of death.

The survivor's pension referred to in the previous subparagraph shall not be less than the amounts specified in the second paragraph of Article 79 of the Staff Regulations. However, in no case may it exceed the amount of the retirement pension to which the former official would have been entitled had he or she survived and been granted a retirement pension when ceasing to be eligible for the allowance referred to above.

The minimum duration of the marriage as referred to in the first subparagraph shall not be taken into account if there are one or more children of a marriage contracted by the official before he or she left the service provided that the surviving spouse maintains or has maintained those children.

Nor shall the duration of the marriage be taken into account if the death of the former official resulted from one of the circumstances referred to at the end of the second paragraph of Article 17 of Annex VIII to the Staff Regulations.

9. On the death of a former official in receipt of the allowance provided for in paragraph 1, dependent children within the meaning of Article 2 of Annex VII to the Staff Regulations shall be entitled to an orphan's pension on the conditions set out in the first, second and third paragraphs of Article 80 of the Staff Regulations and in Article 21 of Annex VIII to the Staff Regulations.

#### Article 5

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

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

### ANNEX

#### ALLOWANCE PERCENTAGE

The allowance percentage referred to in Article 4(1) of this Regulation will be determined on the basis of the age and length of service of officials at the time of departure as shown in the table below:

*Level of allowance depending on age and length of service*

Length of service \ Age	From 55 to 56 years	From 57 to 58 years	From 59 to 60 years	From 61 to 62 years	Over 63 years
From 15 to 19 years	60,0 %	60,0 %	60,0 %	62,0 %	64,0 %
From 20 to 24 years	60,0 %	60,0 %	62,0 %	64,0 %	66,0 %
From 25 to 29 years	62,0 %	64,0 %	66,0 %	68,0 %	70,0 %
30 years and over	64,0 %	66,0 %	68,0 %	70,0 %	70,0 %

Age and length of service will be considered in relation to the actual date of termination of service of the official concerned.

Applying these conditions to the target group of officials on a weighted basis gives a maximum average allowance of 62,5 %.

**Proposal for a Council Regulation introducing special measures to terminate the service of European Parliament officials and temporary staff working in the Political Groups**

(2002/C 181 E/18)

COM(2002) 136 final — 2002/0070(CNS)

*(Submitted by the Commission on 20 March 2002)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 283 thereof,

Having regard to the proposal made by the Commission after consulting the Staff Regulations Committee in accordance with Article 10a of the Staff Regulations of Officials of the European Communities <sup>(1)</sup>,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Court of Justice,

Having regard to the opinion of the Court of Auditors,

Whereas:

- (1) The European Parliament has been engaged in a thorough restructuring of its way of operating since 1997, when the Bureau adopted the new staff policy.
- (2) In the light of four years' experience of implementing this new policy, and with a view to establishing a longer term policy for recruitment and appointments, based on foreseeable requirements for specific skills, Parliament has been studying its human resource requirements for the years to come, as part of an exercise to draw up an operational list of duties.
- (3) Parliament intends to take steps, mainly through training, to help redeployed staff to adjust in the most satisfactory and effective way possible.
- (4) However, the skills of some officials and temporary staff working in the Political Groups, particularly older members of staff, are deemed not to be in line with the duties to be performed.
- (5) Parliament needs new skill profiles and a rebalancing of its establishment plan, but the number of officials retiring in the normal way will not be sufficient to allow the necessary skills to be acquired through recruiting new staff within a satisfactory timescale.

(6) Special measures should accordingly be adopted with regard to termination of service together with internal administrative arrangements for effective monitoring of the implementation of this Regulation.

(7) These measures must be applied as far as possible with due regard for geographical balance, in compliance with the principles governing this Regulation.

(8) These measures must be budget-neutral,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Parliament is hereby authorised, in the interests of the service and in order to take account of the need to renew skills arising from the process of adjusting its resources to its activities, to adopt measures up to 31 December 2004 for terminating the service within the meaning of Article 47 of the Staff Regulations of officials and temporary staff working in the Political Groups who have reached the age of 55 and have completed at least 15 years' service, with the exception of those in Grades A1 and A2, under the conditions specified below.

*Article 2*

The total number of officials to be covered by the measures referred to in Article 1 shall be 100. The total number of temporary staff working in the Political Groups to be covered by the measures referred to in Article 1 shall be 24.

This measure shall be without prejudice to decisions to be taken under the annual budget procedures.

*Article 3*

Within the ceilings laid down in Article 2, and with due regard to the interests of the service, the European Parliament, after having consulted its Joint Committee, shall select from among the officials and temporary staff working in the Political Groups applying for termination of their service under Article 1 those to whom it wishes to apply this measure.

<sup>(1)</sup> Hereinafter called the 'Staff Regulations'.

It shall consider as a priority officials and temporary staff affected by the reorganisation measures and measures for adjusting its resources to its activities, in particular redeployment, whose skills are deemed not to be in line with the duties to be performed. It shall take account of the amount of training necessary for them to undertake new tasks, their age, ability, performance, conduct in the service, family circumstances and length of service.

#### Article 4

1. Former officials and temporary staff whose service is terminated under Article 1 shall be entitled to a monthly allowance set as a percentage of the last basic salary received according to age and length of service at the time of departure as shown in the table in the Annex to this Regulation. The last basic salary shall be that for the grade and step held by the official or member of the temporary staff concerned at the time of departure, determined by reference to the table in Article 66 of the Staff Regulations in force on the first day of the month for which the allowance is payable.

2. Such former officials and temporary staff may at any time, at their own request, receive a retirement pension on the terms and conditions laid down in the Staff Regulations. Entitlement to the allowance shall then cease. It shall cease in any event not later than the last day of the month in which the former official or member of the temporary staff concerned reaches the age of 65 years or as soon as he or she is eligible before that age for the maximum retirement pension of 70 % (Article 77 of the Staff Regulations).

At that point the former official or member of the temporary staff shall automatically receive a retirement pension, which shall take effect on the first day of the calendar month following the month in which the allowance was paid for the last time.

3. The allowance provided for in paragraph 1 shall be adjusted by the weighting fixed for the country situated inside the Community in which the recipient proves that he is resident. Recipients shall provide evidence each year of their place of residence.

If the recipient resides in a country situated outside the Community, the weighting to be applied to the allowance shall be 100.

The allowance shall be expressed in euro. It shall be paid in the currency of the country of residence of the recipient. However, if it is subject to the weighting of 100 under the second subparagraph, it shall be paid in euro.

An allowance paid in a currency other than euro shall be calculated on the basis of the exchange rates referred to in the second paragraph of Article 63 of the Staff Regulations.

4. Where gross income accruing to the former official or member of the temporary staff from any new employment, when combined with the allowance provided for in paragraph 1, exceeds the total gross remuneration last received by the official or member of the temporary staff concerned, determined by reference to the salary scales in force on the first day of the month for which the allowance is payable, the amount of the excess shall be deducted from that allowance. That remuneration shall be weighted as provided for in paragraph 3.

Gross income and total gross remuneration last received, as referred to above, mean sums paid after deduction of social security contributions but before deduction of tax.

The former official or member of the temporary staff shall give a formal undertaking to provide any written proof which may be required, including an annual statement of income in the form of a salary statement or audited accounts, as appropriate, and a sworn or authenticated declaration that he or she is not in receipt of any other income from any new employment, and shall notify the institution of any other factor which may affect his or her right to the allowance, failing which he or she shall be liable to disciplinary action as provided for in Article 86 of the Staff Regulations.

5. As set out in Article 67 of the Staff Regulations and Articles 1, 2 and 3 of Annex VII thereto, the household allowance, dependent child allowance and education allowance shall be payable either to the recipient of the allowance provided for in paragraph 1 or to the person or persons to whom custody of the child or children has been entrusted by law or by an order of court or of the competent administrative authority; the household allowance shall be calculated by reference to the allowance provided for in paragraph 1.

6. Provided that they are not receiving income from any gainful employment, recipients of the allowance shall be entitled, in respect of themselves and persons covered by their insurance, to benefits under the sickness insurance scheme provided for in Article 72 of the Staff Regulations provided they pay the relevant contribution, calculated on the basis of the allowance provided for in paragraph 1, and are not covered by another sickness insurance scheme by virtue of legal or statutory provisions.

7. During the period for which they are entitled to receive the allowance, but for not more than 65 months, former officials and temporary staff shall continue to acquire further rights to retirement pension based on the salary carried by their grade and step, provided that the contribution provided for in the Staff Regulations by reference to that salary is paid during that period and provided that the total pension does not exceed the maximum specified in the second paragraph of Article 77 of the Staff Regulations. For the purposes of Article 5 of Annex VIII to the Staff Regulations, such period shall be considered to be a period of service.

8. Subject to Articles 1(1) and 22 of Annex VIII to the Staff Regulations, the surviving spouse of a former official who dies while in receipt of the allowance provided for in paragraph 1 shall be entitled, provided that the marriage was contracted at least one year before the former official or member of the temporary staff left the service of the Council, to a survivor's pension equal to 60 % of the retirement pension which, irrespective of length of service or age, would have been payable to the former official if he or she had qualified for it at the time of death.

The survivor's pension referred to in the previous subparagraph shall not be less than the amounts specified in the second paragraph of Article 79 of the Staff Regulations. However, in no case may it exceed the amount of the retirement pension to which the former official or member of the temporary staff would have been entitled had he or she survived and been granted a retirement pension when ceasing to be eligible for the allowance referred to above.

The minimum duration of the marriage as referred to in the first subparagraph shall not be taken into account if there are one or more children of a marriage contracted by the official or member of the temporary staff before he or she left the service provided that the surviving spouse maintains or has maintained those children.

Nor shall the duration of the marriage be taken into account if the death of the former official or member of the temporary staff resulted from one of the circumstances referred to at the end of the second paragraph of Article 17 of Annex VIII to the Staff Regulations.

9. On the death of a former official or member of the temporary staff in receipt of the allowance provided for in paragraph 1, dependent children within the meaning of Article 2 of Annex VII to the Staff Regulations shall be entitled to an orphan's pension on the conditions set out in the first, second and third paragraphs of Article 80 of the Staff Regulations and in Article 21 of Annex VIII to the Staff Regulations.

#### Article 5

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

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

### ANNEX

#### ALLOWANCE PERCENTAGE

The allowance percentage referred to in Article 4(1) of this Regulation will be determined on the basis of the age and length of service of officials or temporary staff at the time of departure as shown in the table below:

*Level of allowance depending on age and length of service*

Age Length of service	From 55 to 56 years	From 57 to 58 years	From 59 to 60 years	From 61 to 62 years	Over 63 years
From 15 to 19 years	60,0 %	60,0 %	60,0 %	62,0 %	64,0 %
From 20 to 24 years	60,0 %	60,0 %	62,0 %	64,0 %	66,0 %
From 25 to 29 years	62,0 %	64,0 %	66,0 %	68,0 %	70,0 %
30 years and over	64,0 %	66,0 %	68,0 %	70,0 %	70,0 %

Age and length of service will be considered in relation to the actual date of termination of service of the official or member of the temporary staff concerned.

Applying these conditions to the target group of officials and temporary staff on a weighted basis gives a maximum average allowance of 62,5 %.

**Amended proposal for a Council Regulation amending Regulation (EEC, Euratom, ECSC) No 260/68 laying down the conditions and procedure for applying the tax for the benefit of the European Communities**

(2002/C 181 E/19)

COM(2002) 136 final

(Submitted by the Commission on 20 March 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 283 thereof,

Having regard to the Protocol on the Privileges and Immunities of the European Communities, and in particular Article 13 thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) Regulation (EEC, Euratom, ECSC) No 260/68 <sup>(1)</sup>, as last amended by Regulation (EC, ECSC, Euratom) No 2804/00 <sup>(2)</sup>, should be amended to take account of Council Regulation [xxx] No [xxx] of ... introducing special measures to terminate the service of officials of the Commission of the European Communities as part of the reform of the Commission.
- (2) Regulation (EEC, Euratom, ECSC) No 260/68, as last amended by Regulation (EC, ECSC, Euratom) No 2804/2000, should be amended to take account of Council Regulation [yyy] No [yyy] of ... introducing special measures to terminate the service of officials of the General Secretariat of the Council of the European Union.
- (3) Regulation (EEC, Euratom, ECSC) No 260/68, as last amended by Regulation (EC, ECSC, Euratom) No 2804/2000, should be amended to take account of Council Regulation [zzz] No [zzz] of ... introducing special measures to terminate the service of European

Parliament officials and temporary staff working in the Political Groups,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 2 of Regulation (EEC, Euratom, ECSC) No 260/68, the following 16th, 17th, and 18th indents are added:

- ‘ — those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [xxx] No [xxx]
- those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [yyy] No [yyy]
- those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [zzz] No [zzz].’

*Article 2*

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

This Regulation shall apply from the date of entry into force of the Regulation referred to in Article 1.

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

<sup>(1)</sup> OJ L 56, 4.3.1968, p. 8.

<sup>(2)</sup> OJ L 326, 22.12.2000, p. 3.

**Amended proposal for a Council Regulation amending Regulation (Euratom, ECSC, EEC) No 549/69 determining the categories of officials and other servants of the European Communities to whom the provisions of Article 12, the second paragraph of Article 13 and Article 14 of the Protocol on the Privileges and Immunities of the Communities apply**

(2002/C 181 E/20)

COM(2002) 136 final — 2001/0028(CNS)

(Submitted by the Commission on 20 March 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 283 thereof,

Having regard to the Protocol on the Privileges and Immunities of the European Communities, and in particular Articles 16 and 22 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Court of Justice,

Having regard to the opinion of the Court of Auditors,

Whereas:

- (1) Regulation (Euratom, ECSC, EEC) No 549/69 <sup>(1)</sup>, as last amended by Regulation (EC, ECSC, Euratom) No 1198/98 <sup>(2)</sup>, should be amended to take account of Council Regulation [xxx] No [xxx] of ... introducing special measures to terminate the service of officials of the Commission of the European Communities as part of the reform of the Commission.
- (2) Regulation (EEC, Euratom, ECSC) No 549/69, as last amended by Regulation (EC, ECSC, Euratom) No 1198/98, should be amended to take account of Council Regulation [yyy] No [yyy] of ... introducing special measures to terminate the service of officials of the General Secretariat of the Council of the European Union.
- (3) Regulation (EEC, Euratom, ECSC) No 549/69, as last amended by Regulation (EC, ECSC, Euratom) No 1198/2000, should be amended to take account of

Council Regulation [zzz] No [zzz] of ... introducing special measures to terminate the service of European Parliament officials and temporary staff working in the Political Groups,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 2 of Regulation (Euratom, ECSC, EEC) No 549/69, the following points (p), (q) and (r) are added:

- ‘(p) those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [xxx] No [xxx]
- (q) those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [yyy] No [yyy]
- (r) those entitled to the allowance provided for in the event of termination of service under Article 4 of Regulation [zzz] No [zzz].’

*Article 2*

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

This Regulation shall apply from the date of entry into force of the Regulation referred to in Article 1.

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

<sup>(1)</sup> OJ L 74, 27.3.1969, p. 1.

<sup>(2)</sup> OJ L 166, 11.6.1998, p. 3.



**Proposal for a Council Regulation amending Regulation (EC) No 517/94 on common rules for imports of textile products from certain third countries not covered by bilateral agreements, protocols or other arrangements, or by other specific Community import rules**

(2002/C 181 E/21)

COM(2002) 167 final — 2002/0081(ACC)

(Submitted by the Commission on 8 April 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) In the interest of more efficient administrative management, the surveillance document in Annex VII of Council Regulation (EC) No 517/94 <sup>(1)</sup> should be updated to align it on the common Community surveillance document provided for in Council Regulations (EC) No 3285/94 <sup>(2)</sup> and (EC) No 519/94 <sup>(3)</sup>, as they were amended by Regulation (EC) No 139/96 <sup>(4)</sup>. In the interest of clarity, the provisions of Article 14 of Regulation (EC) No 517/94 should be redrafted accordingly.
- (2) The possibility to apply for and issue the surveillance document electronically should be introduced. In that context, it is necessary to amend Article 21 of Regulation (EC) No 517/94 in order to allow the electronic submission of the request concerning that document.
- (3) The provisions of Regulation (EC) No 517/94 concerning the committee procedure should be adapted to take account of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(5)</sup>.
- (4) The procedure under Article 25(4) of Regulation (EC) No 517/94 relating to the introduction of emergency safeguard measures under Article 13 of that Regulation is a variant of the former 'IIIB' procedure which is no longer valid. It is appropriate to apply, for the application of emergency safeguard measures, the procedure for the application of safeguards foreseen by Article 6(c), first alternative, of Decision 1999/468/EC.
- (5) The procedure for the application of standard safeguard measures contained in Article 25(5) of Regulation (EC) No 517/94 corresponds to the procedure set out in Article 6(c), second alternative, of Decision 1999/468/EC, which is appropriate for the application of such safeguard measures.

(6) The procedure for the application of surveillance measures under Title III of Regulation (EC) No 517/94 should therefore be the same as that for the application of normal safeguard measures, namely that foreseen in Article 6(c), second alternative, of Decision 1999/468/EC, since the two types of measure are closely linked.

(7) For reasons of clarity it is appropriate to replace the whole provisions of Regulation (EC) No 517/94 relating to the Committee procedure.

(8) In the implementation of Regulation (EC) No 517/94, the Federal Republic of Yugoslavia includes Kosovo, as defined by the United Nations Security Council Resolution 1244 of 10 June 1999. In Kosovo, the international civil administration (UNMIK) has established a separate customs administration. The Annexes to that Regulation should be adapted in order to take account of this situation.

(9) Regulation (EC) No 517/94 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 517/94 is amended as follows:

1. In Article 14, paragraphs 1 and 2 are replaced by the following:

'1. Products subject to prior Community surveillance or safeguard measures may be put into free circulation only on production of an import document.

In the case of prior Community surveillance measures, the import document shall be issued free of charge by the competent authority designated by Member States within a maximum of five working days following receipt of an application to the national competent authority by any Community importer, regardless of his place of business in the Community, for any quantity requested. Such an application shall be deemed to be received by the national competent authority no later than three working days after submission, unless it is proven otherwise. The import document shall be made out on a form corresponding to the model in Annex VII. The provisions of Article 21 shall apply *mutatis mutandis*.

<sup>(1)</sup> OJ L 67, 10.3.1994, p. 1. Regulation as last amended by Commission Regulation (EC) No 2878/2000 (OJ L 333, 29.12.2000, p. 60).

<sup>(2)</sup> OJ L 349, 31.12.1994, p. 53. Regulation as last amended by Regulation (EC) No 2474/2000 (OJ L 286, 11.11.2000, p. 1).

<sup>(3)</sup> OJ L 67, 10.3.1994, p. 89. Regulation as last amended by Regulation (EC) No 1138/98 (OJ L 159, 3.6.1998, p. 1).

<sup>(4)</sup> OJ L 21, 27.1.1996, p. 7.

<sup>(5)</sup> OJ L 184, 28.6.1999, p. 23.

In the case of safeguard measures, the import document shall be issued in accordance with the provisions of Title IV.

2. Information other than that provided for in paragraph 1 may be required when the decision to impose surveillance or safeguard measures is taken.'

2. Article 21 is amended as follows:

(a) Paragraph 3 is replaced by the following:

'3. Applications for import authorisations shall be drawn up on forms conforming to a specimen the characteristics of which shall be established in accordance with the procedure provided for in Article 25(2). The competent authorities may, under the conditions fixed by them, allow declarations to be submitted or requests to be transmitted or printed by electronic means. However, all documents and evidence must be available to the competent authorities.'

(b) In paragraph 4, the second subparagraph is replaced by the following:

'Any measure necessary to implement this paragraph may be adopted in accordance with the procedure provided for in Article 25(2).'

3. Article 25 is replaced by the following:

'Article 25

#### **The textile committee**

1. The Commission shall be assisted by a committee called the "textile committee", hereinafter "the committee", composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof. The period provided for in Article 5(6) of Decision 1999/468/EC shall be one month.

3. For matters falling within Title III of this Regulation except for Article 13 thereof, the safeguard procedure in accordance with Article 6 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof. The time limit provided for in Article 6(b) shall be one month from the adoption of the decision of the Commission concerning safeguard measures. The Council, acting by a qualified majority, may confirm, amend or revoke the decision

adopted by the Commission within a period of three months from the referral of the Commission's decision to the Council, failing which the decision of the Commission is deemed to be revoked.

4. In the case of emergency safeguard measures pursuant to Article 13 of this Regulation the procedure in accordance with Article 6 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof. The time limit provided for in Article 6(b) shall be one month from the adoption of the decision of the Commission concerning safeguard measures. The Council, acting by a qualified majority, may take a different decision within a period of three months from the referral of the Commission's decision to the Council.

5. The chairman may, on his own initiative or at the request of one of the Member States' representatives, consult the committee about any other matter relating to the operation or application of this Regulation.

6. The Committee shall adopt its rules of procedure.'

4. In Articles 3(3), 5(2), 6(2), 6(3), 7(1), 8(2), 17(3), 17(6), 20, 21(2), 22, 23 and 28 the words 'in accordance with the appropriate procedure provided for in Article 25' shall be replaced by the words 'in accordance with the procedure provided for in Article 25(2).'

5. The Annexes are amended as follows:

(a) In Annexes IIIb and VI 'Federal Republic of Yugoslavia (Serbia and Montenegro)' is replaced by 'Federal Republic of Yugoslavia (\*)';

(\*) Including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999.'

(b) Annex VII is replaced by the text in Annex I to this Regulation.

#### *Article 2*

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

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

## ANNEX I

## \*ANNEX VII

**LIST OF PARTICULARS TO BE GIVEN IN THE BOXES OF THE SURVEILLANCE DOCUMENT**

## SURVEILLANCE DOCUMENT

1. Consignee (name, full address, country, VAT number)
2. Issue Number
3. Proposed place & date of import
4. Authority responsible for issue (name, address & telephone No)
5. Declarant/representative as applicable (name & full address)
6. Country of origin/Code
7. Country of consignment/Code
8. Last day of validity
9. Description of goods
10. CN code & textile category
11. Quantity of kilograms (net mass) or in additional units
12. Customs value in euro, cif at Community frontier
13. Additional remarks, including:

Certification by the applicant:

I, the undersigned, certify that the information provided in this application is true and given in good faith

Date and place

(signature) (stamp)

14. Competent authority's endorsement

Date and place

(signature) (stamp)

Original for the applicant

Copy for the competent authorities



## EUROPEAN COMMUNITY

## SURVEILLANCE DOCUMENT

<b>COPY FOR THE COMPETENT AUTHORITY</b>	<b>2</b>	<b>1 Consignee</b> (name, full address, country, VAT number) <input type="checkbox"/>		<b>2</b> Issue number	
				<b>3</b> Proposed place and date of import	
				<b>4</b> Authority responsible for issue (name, address and telephone No)	
		<b>5</b> Declarant/representative as applicable (name and full address)		<b>6</b> Country of origin <span style="float: right;">Code</span>	
				<b>7</b> Country of consignment <span style="float: right;">Code</span>	
				<b>8</b> Last day of validity	
		<b>9</b> Description of goods		<b>10</b> CN code and textile category	
				<b>11</b> Quantity of kilograms (net mass) or in additional units	
				<b>12</b> Customs value in euro, cif at Community frontier	
<b>13</b> Additional remarks  <p>I the undersigned, certify that the information provided in this application is true and given in good faith.</p> <p>Date:</p> <p>Place:</p> <p style="text-align: right;">Signature <span style="float: right;">Stamp</span></p>					
<b>14</b> Competent authority's endorsement  <p>Date:</p> <p>Place:</p> <p style="text-align: right;">Signature <span style="float: right;">Stamp</span></p>					

<b>15 ATTRIBUTIONS</b> Indicate the quantity available in part 1 of column 17 and the quantity attributed in part 2 thereof			
<b>16</b> Net quantity (net mass or other unit of measure stating the unit)		<b>19</b> Customs document (form and number) or extract form and date of attribution	<b>20</b> Name, Member State, stamp and signature of the attributing authority
<b>17</b> In figures	<b>18</b> In words for the quantity attributed		
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			

Extension pages to be attached hereto.'