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COUNCIL

COMMON POSITION (EC) No 49/2003

adopted by the Council on 16 June 2003

with a view to adopting Decision No .../2003/EC of the European Parliament and of the Council of ... establishing a programme for the enhancement of quality in higher education and the promotion of intercultural understanding through cooperation with third countries (Erasmus Mundus) (2004 to 2008)

(2003/C 240 E/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 149 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) The European Community should contribute to the development of quality education, *inter alia* through cooperation with third countries.

(2) The conclusions of the Lisbon European Council (23 to 24 March 2000) emphasised that if Europe is to meet the challenge of globalisation, Member States need to adapt their education and vocational training systems to the demands of the knowledge society.

(3) The Stockholm European Council (23 to 24 March 2001) indicated that work on the follow-up of the objectives of education and training systems should be assessed in the context of a worldwide perspective. The Barcelona European Council (15 to 16 March 2002) confirmed that opening up to the wider world is one of the three basic principles of the Work Programme for 2010 for education and training systems.

(4) The European Ministers of Education, meeting in Bologna (19 June 1999), stated in their Joint Declaration that it is necessary to ensure that the European higher education system acquires a worldwide degree of attractiveness appropriate to Europe's major cultural and scientific achievements.

(5) The European ministers in charge of higher education, meeting in Prague (19 May 2001), further emphasised, *inter alia*, the importance of enhancing the attractiveness of European higher education to students from Europe and other parts of the world.

(6) In its Communication on reinforcing cooperation with third countries in the field of higher education, the Commission argued that greater internationalisation of higher education is necessary to respond to the challenges of the process of globalisation, identified overall objectives for a third-country cooperation strategy in this field and suggested concrete measures for achieving these objectives.

(7) The Council Resolution of 14 February 2002 on the promotion of linguistic diversity and language learning in the framework of the implementation of the objectives of the European Year of Languages 2001 [5] underlines the need for the European Union to take into account the principle of linguistic diversity in its relations with third countries.

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[1] OJ C 331 E, 31.12.2002, p. 25.

[2] Opinion delivered on 26 February 2003 (OJ C 95, 23.4.2003, p. 35).

[3] Opinion delivered on 10 April 2003 (not yet published in the Official Journal).

[4] Opinion of the European Parliament of 8 April 2003 (not yet published in the Official Journal), Council Common Position of 16 June 2003 and Decision of the European Parliament of ... (not yet published in the Official Journal).

[5] OJ C 50, 23.2.2002, p. 1.

(8) The academic institutions in the European Union aim to increase the share of internationally mobile students. There is wide recognition of the great potential represented by the combined individual strengths of European higher education institutions, by their educational diversity and their wide experience in networking and in cooperation with third countries, which enable them to offer courses of great quality unique to Europe and allow the benefits of international mobility to be shared more widely within the Community and its partner countries.

(9) European higher education institutions must remain at the leading edge of developments. To this end they should encourage cooperation with third-country institutions that have achieved a level of development comparable to that of higher education institutions in the Community.

(10) The aim of this programme is to contribute to improving the quality of higher education in Europe and at the same time to have an impact on the visibility and perception of the European Union around the world, as well as building a capital of goodwill among those who have participated in the programme.

(11) The Community action should be managed in a way that is transparent, user-friendly, open and comprehensible.

(12) In promoting international mobility, the Community should be mindful of the phenomenon commonly known as 'the brain drain'.

(13) There is a need to step up Community efforts to promote dialogue and understanding between cultures worldwide, bearing in mind the social dimension of higher education as well as the ideals of democracy and respect for human rights, including gender equality, especially as mobility fosters the discovery of new cultural and social environments and facilitates understanding thereof, and in so doing to ensure that no group of citizens or of third-country nationals is excluded or disadvantaged, as mentioned in Article 21(1) of the Charter of Fundamental Rights of the European Union.

(14) In order to reinforce the added value of Community action it is necessary to ensure coherence and complementarity between the actions implemented in the framework of this Decision and other relevant Community policies, instruments and actions, in particular the sixth framework programme for research established by Decision No 1513/2002/EC [1] and external cooperation programmes in the higher education sector.

(15) The Agreement on the European Economic Area (EEA Agreement) provides for greater cooperation in the field of education, training and youth between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (EEA-EFTA States), on the other; the conditions and the detailed rules for the participation of the above countries in this programme should be established in accordance with the relevant provisions of the EEA Agreement.

(16) The conditions and the detailed rules for the participation of the associated central and eastern European countries (CEEC) in this programme should be established in accordance with the provisions laid down in the European agreements, in their additional Protocols and in the decisions of the respective Association Councils. With regard to Cyprus, participation should be funded by additional appropriations in accordance with the procedures to be agreed with that country. With regard to Malta and Turkey, participation should be funded by additional appropriations in accordance with the provisions of the Treaty.

(17) This programme should be regularly monitored and evaluated in cooperation between the Commission and the Member States in order to allow for readjustments, particularly as regards the priorities for implementing the measures; the evaluation should include an external and independent evaluation.

(18) Since the objectives of the proposed action concerning the contribution of European cooperation to quality education cannot be sufficiently achieved by the Member States, *inter alia*, because of the need for multilateral partnerships and multilateral mobility and exchanges of information between the Community and third countries, and can therefore be better achieved at Community level owing to the transnational dimension of Community actions and measures, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.

(19) This Decision lays down for the entire duration of the programme a financial framework constituting the prime reference, within the meaning of point 33 of the Inter-institutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure [2], for the budgetary authority during the annual budgetary procedure.

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[1] Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contribution to the creation of the European Research Area and to innovation (2002-2006), (OJ L 232, 29.8.2002, p. 1).

[2] OJ C 172, 18.6.1999, p. 1.

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

HAVE ADOPTED THIS DECISION:

Article 1

Establishment of the programme

1. This Decision establishes a programme — 'Erasmus Mundus' (hereinafter 'the programme') — for the enhancement of quality in higher education within the European Union and the promotion of intercultural understanding through cooperation with third countries.

2. The programme shall be implemented over a period starting on 1 January 2004 and ending on 31 December 2008.

3. The programme shall support and supplement action taken by and in the Member States while fully respecting their responsibility for the content of education and the organisation of education and training systems, and their cultural and linguistic diversity.

Article 2

Definitions

For the purpose of this Decision:

1. 'higher education institution' means any institution which according to national legislation or practice offers qualifications or degrees at that level, whatever such establishments may be called;

2. 'third-country graduate student' means a national of a third country other than those from EEA-EFTA States and candidate countries for accession to the European Union who has already obtained a first higher education degree, who is not a resident of any of the Member States or the participating countries as provided for in Article 11, who has not carried out his or her main activity (studies, work, etc.) for more than a total of 12 months over the last five years in any of the Member States or the participating countries and who has been accepted to register or is registered in an Erasmus Mundus Masters course as described in the Annex;

3. 'third-country scholar' means a national of a third country other than those from EEA-EFTA States and candidate countries for accession to the European Community who is not a resident of any of the Member States or the participating countries as provided for in Article 11, who has not carried out his or her main activity (studies, work, etc.) for more than a total of 12 months over the last five years in any of the Member States or the participating countries and who has outstanding academic and/or professional experience;

4. 'graduate or postgraduate studies' means courses of higher education study that follow a first degree lasting a minimum of three years and lead to a second or further degree.

Article 3

Objectives of the programme

1. The programme's overall aim is to enhance the quality of European higher education by fostering cooperation with third countries in order to improve the development of human resources and to promote dialogue and understanding between peoples and cultures.

2. The programme's specific objectives are:

(a) to promote a quality offer in higher education with a distinct European added value, attractive both within the European Union and beyond its borders;

(b) to encourage and enable highly qualified graduates and scholars from all over the world to obtain qualifications and/or experience in the European Union;

(c) to develop more structured cooperation between European Union and third-country institutions and greater European Union outgoing mobility as part of European study programmes;

(d) to improve accessibility and enhance the profile and visibility of higher education in the European Union.

3. The Commission shall, when pursuing the objectives of the programme, observe the Community's general policy on equal opportunities for men and women. The Commission shall also ensure that no group of citizens or third-country nationals is excluded or disadvantaged.

Article 4

Programme actions

1. The objectives of the programme as set out in Article 3 shall be pursued by means of the following actions:

(a) Erasmus Mundus Masters courses;

(b) a scholarship scheme;

(c) partnerships with third-country higher education institutions;

(d) measures enhancing the attractiveness of Europe as an educational destination;

(e) technical support measures.

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

2. These actions shall be realised using the procedures described in the Annex, and through the following types of approaches, which may be combined where appropriate:

(a) support for the development of joint educational programmes and cooperation networks facilitating the exchange of experience and good practice;

(b) enhanced support for mobility, between the Community and third countries, of people in the field of higher education;

(c) promotion of language skills and the understanding of different cultures;

(d) support for pilot projects based on transnational partnerships designed to develop innovation and quality in higher education;

(e) support for the analysis and follow-up of trends in, and evolution of, higher education in an international perspective.

Article 5

Access to the programme

Under the conditions and arrangements for implementation specified in the Annex and bearing in mind the definitions in Article 2, the programme is aimed in particular at:

(a) higher education institutions;

(b) students having obtained a first degree awarded by a higher education institution;

(c) scholars or professionals who lecture or conduct research;

(d) staff directly involved in higher education;

(e) other public or private bodies active in the field of higher education which may take part only in actions 4 and 5 in the Annex.

Article 6

Implementation of the programme and cooperation with the Member States

1. The Commission shall:

(a) ensure the effective implementation of the Community actions covered by the programme in conformity with the Annex;

(b) take account of bilateral cooperation with third countries undertaken by Member States;

(c) consult the relevant associations and organisations in the field of higher education at European level and inform the Committee referred to in Article 8 of their opinions;

(d) seek synergies and develop joint actions with other Community programmes and actions in the field of higher education and research.

2. The Member States shall:

(a) take the necessary steps to ensure the efficient running of the programme at Member State level, involving all the parties concerned in education in accordance with national practice, including endeavours to adopt such measures as may be deemed appropriate to remove legal and administrative barriers;

(b) designate appropriate structures to cooperate closely with the Commission;

(c) encourage potential synergies with other Community programmes and possible similar national initiatives taken at Member State level.

3. The Commission, in cooperation with the Member States, shall ensure:

(a) appropriate information, publicity and follow-up with regard to actions supported by the programme;

(b) the dissemination of the results of the actions undertaken within the framework of the programme.

Article 7

Implementing measures

1. The following measures necessary for the implementation of this Decision shall be adopted in accordance with the management procedure referred to in Article 8(2):

(a) the annual plan of work, including priorities;

(b) the selection criteria and procedures, including the composition and internal rules of procedure of the Selection Board, and the results of selections for action 1, with due regard to the provisions set out in the Annex;

(c) the general guidelines for implementing the programme;

(d) the annual budget, the breakdown of funds among the different actions of the programme and indicative grant amounts;

(e) the arrangements for monitoring and evaluating the programme and for the dissemination and transfer of results.

2. Proposals for decisions concerning the results of selections, except selections for action 1, and all other measures necessary for the implementation of this Decision shall be adopted in accordance with the advisory procedure referred to in Article 8(3).

Article 8

Committee

1. The Commission shall be assisted by a Committee.

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

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

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

4. The Committee shall adopt its rules of procedure.

Article 9

Funding

1. The financial framework for the implementation of the programme for the period specified in Article 1 is hereby set at EUR 180 million. For the period following 31 December 2006, this amount shall be deemed to be confirmed if it is consistent for this phase with the financial perspectives in force for the period commencing in 2007.

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

Article 10

Consistency and complementarity

1. The Commission shall, in cooperation with the Member States, ensure overall consistency and complementarity with other relevant Community policies, instruments and actions, in particular with the sixth framework programme for research and with external cooperation programmes in the field of higher education.

2. The Commission shall keep the Committee regularly informed about Community initiatives taken in relevant fields, ensure efficient linkage and, where appropriate, joint actions between the programme and the programmes and actions in the area of education undertaken within the framework of the Community's cooperation with third countries, including bilateral agreements, and the competent international organisations.

Article 11

Participation of EEA-EFTA States, and candidate countries for accession to the European Union

The conditions and detailed rules on the participation of EEA-EFTA States and candidate countries for accession to the European Union in the programme shall be established in accordance with the relevant provisions of the instruments governing the relations between the European Community and these countries.

Article 12

Monitoring and evaluation

1. The Commission shall regularly monitor the programme in cooperation with the Member States. The results of the monitoring and evaluation process shall be utilised when implementing the programme.

This monitoring shall include the reports referred to in paragraph 3 and specific activities.

2. The programme shall be evaluated regularly by the Commission with regard to the objectives referred to in Article 3, the impact of the programme as a whole and the complementarity between action under the programme and that pursued under other relevant Community policies, instruments and actions.

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

(a) on the accession of new Member States, a report on the financial repercussions of these accessions on the programme, followed, if appropriate, by proposals to deal with those repercussions. The European Parliament and the Council will take a decision on such proposals as soon as possible;

(b) an interim evaluation report on the results achieved and on the qualitative aspects of the implementation of the programme by 30 June 2007;

(c) a communication on the continuation of the programme by 31 December 2007;

(d) an *ex post* evaluation report by 31 December 2009.

Article 13

Entry into force

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

. . .

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

ANNEX

COMMUNITY ACTIONS AND SELECTION PROCEDURES

ACTION 1: ERASMUS MUNDUS MASTERS COURSES

ACTION 2: SCHOLARSHIPS

ACTION 3: PARTNERSHIPS WITH THIRD-COUNTRY HIGHER EDUCATION INSTITUTIONS

ACTION 4: ENHANCING ATTRACTIVENESS

ACTION 5: TECHNICAL SUPPORT MEASURES

SELECTION PROCEDURES

ACTION 1: ERASMUS MUNDUS MASTERS COURSES

1. The Community will select European postgraduate courses which for the purposes of the programme will be called 'Erasmus Mundus Masters courses', as provided for under 'Selection Procedures' in the second part of this Annex.

2. For the purpose of the programme, Erasmus Mundus Masters courses shall:

   (a) involve a minimum of three higher education institutions from three different Member States;

   (b) implement a study programme which involves a period of study in at least two of the three institutions under (a);

   (c) have built-in mechanisms for the recognition of periods of study undertaken in partner institutions based on, or compatible with, the European credit transfer system;

   (d) result in the awarding of joint, double or multiple degrees, recognised or accredited by the Member States, from the participating institutions;

   (e) reserve a minimum of places for, and host, third-country students who have been granted financial support under the programme;

   (f) establish transparent conditions for admissions which pay due regard, *inter alia*, to gender issues and equity issues;

   (g) agree to respect the rules applicable to the selection procedure of grantees (students and scholars);

   (h) put in place appropriate arrangements to facilitate access for, and hosting of, third-country students (information facilities, accommodation, etc.);

   (i) without prejudice to the language of instruction, provide for the use of at least two European languages spoken in the Member States where the higher education institutions involved in the Erasmus Mundus Masters course are situated and, as appropriate, for language preparation and assistance for students.

3. Erasmus Mundus Masters courses will be selected for a five-year period, subject to a light-weight annual renewal procedure based on progress reporting, which period could include a year's preparatory activities before the actual course begins to run. Balanced representation of different fields of study will be sought over the duration of the programme. The Community may provide financial support for Erasmus Mundus Masters courses and funding would be subject to the annual renewal procedure.

ACTION 2: SCHOLARSHIPS

1. The Community will establish a single, global scholarship scheme targeted at the third-country graduate students and scholars.

   (a) The Community may provide financial support to third-country students who have been admitted, through a competitive process, to Erasmus Mundus Masters courses.

   (b) The Community may provide financial support to third-country scholars visiting the Erasmus Mundus Masters courses, with a view to carrying out teaching and research assignments and scholarly work in the institutions participating in Erasmus Mundus Masters courses.

2. Scholarships will be open to third-country students and scholars as defined in Article 2, without any precondition for participation other than the existence of relations between the European Union and the country of origin of the students and scholars in question.

3. The Commission shall take steps to ensure that no student or scholar receives financial support for the same purpose under more than one Community programme.

ACTION 3: PARTNERSHIPS WITH THIRD-COUNTRY HIGHER EDUCATION INSTITUTIONS

1. The Community may support structured relations between Erasmus Mundus Masters courses and third-country higher education institutions. While having regard to the overarching criteria of quality, a varied geographical distribution among the third-country institutions participating in the programme should also be taken into consideration. Partnerships will provide the framework for outgoing mobility of European Union students and scholars involved in the Erasmus Mundus Masters courses.

2. Partnerships will:

— involve an Erasmus Mundus Masters course and at least one higher education institution from a third country,

— be supported for periods of up to three years,

— provide a framework for outgoing mobility for students enrolled in the Erasmus Mundus Masters courses and the courses' teachers; eligible students and scholars must be citizens of the European Union or third-country nationals who had been legal residents in the European Union for at least three years (and for purposes other than study) before the start of the outgoing mobility,

— ensure recognition of study periods at the host (i.e., non-European) institution.

3. Partnership project activities may also include:

— teaching assignments at a partner institution supporting the project's curriculum development,

— exchanges of teachers, trainers, administrators, and other relevant specialists,

— development and dissemination of new methodologies in higher education, including the use of information and communication technologies, e-learning and open and distance learning,

— development of cooperation schemes with third-country higher education institutions with a view to offering a course in the country in question.

ACTION 4: ENHANCING ATTRACTIVENESS

1. Through this action, the Community may support activities aimed at enhancing the profile and visibility of and accessibility to European education. The Community shall also support complementary activities that contribute to the objectives of the programme including activities dealing with the international dimension of quality assurance, credit recognition, recognition of European qualifications abroad and mutual recognition of qualifications with third countries, curriculum development and mobility.

2. Eligible institutions may include public or private organisations active in the field of higher education domestically or at international level. Activities shall be conducted within networks involving a minimum of three organisations from three different Member States and may involve organisations from third countries. Activities (which may include seminars, conferences, workshops, development of ICT tools, production of material for publication, etc.) may take place in the Member States or in third countries.

3. Promotional activities shall seek to establish links between higher education and research, and exploit whenever possible potential synergies.

4. Through this action the Community may support international thematic networks to deal with these issues.

5. The Community may support as appropriate pilot projects with third countries with a view to developing further cooperation in the field of higher education with the countries in question.

6. The Community shall support an alumni association of all students (third-country and Europeans) graduating from Erasmus Mundus Masters courses.

ACTION 5: TECHNICAL SUPPORT MEASURES

In carrying out the programme, the Commission may have recourse to experts, to an executive agency, to existing competent agencies in Member States and, if necessary, to other forms of technical assistance, the financing of which may be provided from within the overall financial framework of the programme.

SELECTION PROCEDURES

The selection procedures will be laid down as provided for in Article 7(1). These procedures should respect the following provisions:

(a) the selection of proposals under action 1 and under action 3 shall be carried out by a Selection Board presided over by a person whom it elects, composed of personalities of high standing from the academic world who are representative of the diversity of higher education in the European Union. The Selection Board shall ensure that Erasmus Mundus Masters courses and partnerships correspond to the highest academic quality;

(b) each Erasmus Mundus Masters course will be allocated a specific number of grants under action 2. The selection of third-country students will be carried out by the institutions participating in the Erasmus Mundus Masters courses. Selection procedures shall provide for a clearing mechanism at European level, in order to prevent serious imbalances across fields of study and students' and scholars' regions of provenance and Member State of destination;

(c) proposals under action 4 will be selected by the Commission;

(d) selection procedures shall involve consultation with the structures designated in accordance with Article 6(2)(b).

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 19 July 2002 the Commission submitted to the European Parliament and to the Council a proposal for a decision, based on Article 149 of the EC Treaty, establishing a programme for the enhancement of the quality of higher education through cooperation with third countries (Erasmus World).

2. The European Economic and Social Committee and the Committee of the Regions delivered their opinions on 26 February 2003 and 10 April 2003 respectively.

3. The European Parliament delivered its opinion on 8 April 2003.

4. In the light of the European Parliament's opinion, the Commission submitted an amended proposal for decision on 29 April 2003.

5. On 16 June 2003, the Council adopted its common position in accordance with Article 251(2) of the EC Treaty.

II. AIM OF THE PROPOSAL

The proposal aims to enhance the quality of European higher education by fostering cooperation with third countries in order to improve the development of human resources and to promote dialogue and understanding between peoples and cultures.

1. GENERAL COMMENTS

In its common position the Council has approved the Commission's proposal in principle, while making certain amendments which it thought desirable, and which are in many cases similar or identical to the Parliament's opinion as well as the Commission's amended proposal.

2. SPECIFIC COMMENTS

2.1. ***Amendments made by the Council to the Commission's proposal*** [1]

2.1.1. **Name of the programme**

The Council has agreed that the programme should be designated 'Erasmus Mundus'.

2.1.2. **Funding and review clause** (Article 9)

The Council believes that a financial framework of EUR 180 million is sufficient to attain the objectives of the programme, while bearing in mind the need to exercise budgetary restraint. Furthermore, in view of the fact that the programme includes the first two years of the next financial perspectives, a review clause has been introduced into paragraph 1.

2.1.3. **Implementation of the programme and cooperation with Member States** (Article 6)

Paragraph 2 has been reworded so that point (a) now makes the link between the efficient running of the programme and the removal of legal and administrative barriers. A new paragraph 3 has been added concerning, *inter alia*, information and the dissemination of results of actions whose wording is based on Article 5(3) of the Socrates programme.

2.1.4. **Implementing measures** (Article 7)

The Council considers that the results of selections under action 1 should be subject to the management procedure, and has adapted paragraphs 1(b) and 2 accordingly.

[1] References in this section are to the text of the common position.

2.1.5. **Linguistic aspects** (recital 7 and action 1(2)(i))

The Council has sought to recall both the importance of the linguistic diversity of the Union and the desirability for third-country students to have the use of at least two EU languages.

2.1.6. **Selection procedures** (Annex, second part)

In the interests of greater clarity and consistency, a specific section on selection procedures as applied to actions 1 to 4 has been added to the Annex.

2.1.7. **Erasmus Mundus Masters courses** (Annex, action 1)

The wording of the introductory paragraph now makes it clear that these courses are selected but not managed at EU level. They have been designated Erasmus Mundus Masters courses in line with the programme's name.

2.1.8. **Scholarships** (action 2)

Greater concision has been brought to this action without loss of content. The Council considers moreover that certain considerations should be dealt with elsewhere, as for instance the question of braindrain (recital 12), or the balance across fields of study (Selection Procedures). Reference to equal opportunities is already made in Article 3.

2.1.9. **Enhancing attractiveness** (action 4)

The Council has simplified the structure of this action without any essential loss of content.

2.1.10. **Other questions**

The Council has also introduced other additions, modifications or clarifications to the text, concerning, *inter alia*:

— *references to the Stockholm and Barcelona European Councils* (recital 3),

— *principles of management of the Community action* (recital 11),

— *dialogue and understanding between cultures* (recital 13),

— *subsidiarity* (Article 1(3)),

— *objectives of the Programme* (Article 3(1) and recital 9),

— *consistency and complementarity* (Article 10; formerly Articles 9 and 11).

2.2. ***European Parliament amendments***

2.2.1. **Parliament amendments adopted by the Commission**

The Commission adopted in full, in part or in essence 38 of the 65 amendments adopted by the Parliament.

2.2.2. **Parliament amendments adopted by the Council**

The Council adopted in full, in part or in essence 33 of the amendments proposed by the Parliament and adopted by the Commission. Those amendments are: 1, 4, 5, 9, 10, 11, 14, 17, 18, 20, 21, 23, 24, 26, 28, 31, 32, 34, 36, 37, 38, 39, 41, 43, 46, 47, 48, 49, 50, 51, 53, 69, 70.

2.2.3. **Parliament amendments not adopted by the Council**

In addition to the amendments not adopted by the Commission, and which were not accepted by the Council, the Council did not accept the following amendments ([1]) for the reasons stated:

— *Amendment 35*

Information on the programme (Article 6(2)(b))

The Council considers that questions relating to information are sufficiently covered by paragraph 3 of this Article, and that it is not therefore necessary to specify an information role for the structures designated by the Member States.

— *Amendment 59*

Partnerships with undertakings (Annex, action 3(5))

The Council has not accepted this amendment introducing the involvement of the business world, which is not provided for elsewhere in the programme.

— *Amendments 62 and 63* (Annex, action 4(2))

Establishment of an Internet gateway

The Council has decided that examples of eligible activities (former actions 4(1) and 4(2)) do not need to be specified, with the exception of a few general references in 4(2), since these are considered indicative and could be dealt with by the programme committee.

— *Amendment 66* (Annex, action 4(1))

Surveys and studies

The Council considers that it is not necessary to promote surveys and studies within the context of this programme and has deleted this reference.

III. **CONCLUSIONS**

The Council considers that its common position constitutes a balanced text, providing a good basis for launching this programme, thereby promoting the attractiveness of European higher education to students and scholars from third countries and enhancing cooperation in general between EU and third-country higher education institutions.

([1]) The references in this section are to the original proposal.

COMMON POSITION (EC) No 50/2003

adopted by the Council on 22 July 2003

with a view to the adoption of a Directive 2003/. . ./EC of the European Parliament and of the Council of . . . on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

(2003/C 240 E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Following consultation of the Committee of the Regions,

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

Whereas:

(1) The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.

(2) The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.

(3) It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'. The aim of these campaigns should be to help European citizens decide to become donors during their lifetime and let their families or legal representatives know their wishes.

(4) There is an urgent need for a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of tissues and cells across the Community and to facilitate exchanges thereof for patients receiving this type of therapy each year. It is essential, therefore, that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State, nonetheless, carry the same guarantees as those in their own country.

(5) As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards.

(6) Tissues and cells intended to be used for industrially manufactured products, including medical devices, should be covered by this Directive only as far as donation, procurement and testing are concerned, where the processing, preservation, storage and distribution are regulated by other Community legislation. The further manufacturing steps are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [4].

(7) This Directive excludes blood and blood products (other than haematopoietic progenitor cells), human organs, as well as organs, tissues, or cells of animal origin. Blood and blood products are currently regulated by Directive 2001/83/EC, Directive 2000/70/EC [5], Recommendation 98/463/EC [6] and Directive 2002/98/EC [7]. Tissues and cells used as an autologous graft (tissues removed and transplanted back to the same individual), within the same surgical procedure and without being subjected to any banking process, are also excluded from this Directive. The quality and safety considerations associated with this process are completely different.

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[1] OJ C 227 E, 24.9.2002, p. 505.

[2] OJ C 85, 8.4.2003, p. 44.

[3] Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council Common Position of 22 July 2003 and Decision of the European Parliament . . . (not yet published in the Official Journal).

[4] OJ L 311, 28.11.2001, p. 67. Directive as amended by Directive 2002/98/EC (OJ L 33, 8.2.2003, p. 30).

[5] Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13.12.2000, p. 22).

[6] Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community (OJ L 203, 21.7.1998, p. 14).

[7] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Directive 2001/83/EC.

(8) The use of organs to some extent raises the same issues as the use of tissues and cells, though there are serious differences, and the two subjects should therefore not be covered by one directive.

(9) This Directive covers tissues and cells intended for human applications, including human tissues and cells used for the preparation of cosmetic products. However, in view of the risk of transmission of communicable diseases, the use of human cells, tissues and products in cosmetic products is prohibited by Commission Directive 95/34/EC of 10 July 1995 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products ([1]).

(10) This Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body, e.g. *in vitro* research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.

(11) This Directive should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health and guarantee respect for fundamental rights. Moreover, this Directive should not interfere with provisions of Member States defining the legal term 'person' or 'individual'.

(12) The donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications should comply with high standards of quality and safety in order to ensure a high level of health protection in the Community. This Directive should establish standards for each one of the steps in the human tissues and cells application process.

(13) It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors, and in the safety of the application process.

(14) Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination should be required. The dignity of the deceased donor should be respected.

(15) The use of tissues and cells for application in the human body can cause diseases and unwanted effects. Most of these can be prevented by careful donor evaluation and the testing of each donation in accordance with rules established and updated according to the best available scientific advice.

(16) As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development.

(17) The procurement of human tissues and cells must take into account the general principles of the Charter of Fundamental Rights of the European Union ([2]) and of the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine, in particular in relation to donor consent.

(18) All necessary measures need to be taken in order to provide prospective donors of tissues and cells with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of tests on their donations, as well as any future traceability of their donation.

(19) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data ([3]), applies to personal data processed in application of this Directive. Article 8 of that Directive prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC provides also for the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.

(20) An accreditation system for tissue establishments and a system for notification of adverse events and reactions linked to the procurement, testing, processing, preservation, storage, and distribution of human tissues and cells should be established in the Member States.

([1]) OJ L 167, 18.7.1995, p. 19.

([2]) OJ C 364, 18.12.2000, p. 1.

([3]) OJ L 281, 23.11.1995, p. 31.

(21) Member States should organise inspections and control measures, to be carried out by officials representing the competent authority, to ensure that tissue establishments comply with the provisions of this Directive. Member States should ensure that the officials involved in inspections and control measures are appropriately qualified and receive adequate training.

(22) Personnel directly involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be appropriately qualified and provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications.

(23) An adequate system to ensure the traceability of human tissues and cells should be established. This would also make it possible to verify compliance with quality and safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures as well as record maintenance and an appropriate labelling system.

(24) As a general principle, the identity of the recipient(s) should not be disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions of disclosure, which could authorise in particular cases the lifting of donor anonymity.

(25) In order to increase the effective implementation of the provisions adopted under this Directive, it is appropriate to provide for penalties to be applied by Member States.

(26) Since the objective of this Directive, namely to set high standards of quality and safety for human tissues and cells throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of scale and effects, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(27) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of tissues and cells; in particular in order to assist the Commission in adapting the provisions of this Directive to scientific and technical progress.

(28) The opinions of the Scientific Committee for Medicinal Products and Medical Devices and that of the European Group on Ethics in Science and New Technologies have been taken into account, as well as international experience in this field, and will be sought in the future whenever necessary.

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

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Objective

This Directive lays down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.

Article 2

Scope

1. This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.

Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing.

2. This Directive shall not apply to:

(a) tissues and cells used as an autologous graft within the same surgical procedure;

(b) blood and blood components as defined by Directive 2002/98/EC;

(c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.

Article 3

Definitions

For the purposes of this Directive:

(a) 'cells' means individual human cells or a collection of human cells when not bound by any form of connective tissue;

(b) 'tissue' means all constituent parts of the human body formed by cells;

(c) 'donor' means every human source, whether living or deceased, of human cells or tissues;

(d) 'donation' means donating human tissues or cells intended for human applications;

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

(e) 'organ' means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

(f) 'procurement' means a process by which tissue or cells are made available;

(g) 'processing' means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

(h) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

(i) 'quarantine' means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

(j) 'storage' means maintaining the product under appropriate controlled conditions until distribution;

(k) 'distribution' means transportation and delivery of tissues or cells intended for human applications;

(l) 'human application' means the use of tissues or cells on or in a human recipient and extracorporal applications;

(m) 'serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling, or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

(n) 'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

(o) 'tissue establishment' means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

(p) 'allogeneic use' means cells or tissues removed from one person and applied to another;

(q) 'autologous use' means cells or tissues removed from and applied in the same person.

Article 4

Implementation

1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

2. This Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary unpaid donation, which include the prohibition or restriction of imports of human tissues and cells, to ensure a high level of health protection, provided that the conditions of the Treaty are met.

3. This Directive does not affect the decisions of the Member States prohibiting the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells or cells from any specified source, including where those decisions also concern imports of the same type of human tissues or cells.

4. In carrying out the activities covered by this Directive, the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 5

Supervision of human tissue and cell procurement

1. Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.

2. The competent authority or authorities shall take all necessary measures to ensure that tissue and cell procurement complies with the requirements referred to in Article 28(b), (f) and (g). The tests required for donors shall be carried out by a qualified laboratory accredited, designated, authorised or licensed by the competent authority or authorities.

Article 6

Accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes

1. Member States shall ensure that all tissue establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

2. The competent authority or authorities, having verified that the tissue establishment complies with the requirements referred to in Article 28(a), shall accredit, designate, authorise or license the tissue establishment and indicate which activities it may undertake and which conditions apply. It or they shall authorise the tissue and cell preparation processes which the tissue establishment may carry out in accordance with the requirements referred to in Article 28(h). Agreements between tissue establishments and third parties, as referred to in Article 24, shall be examined within the framework of this procedure.

3. The tissue establishment shall not undertake any substantial changes to its activities without the prior written approval of the competent authority or authorities.

4. The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation or licensing of a tissue establishment or of a tissue or cell preparation process if inspections or control measures demonstrate that such establishment or process does not comply with the requirements of this Directive.

5. Some specified tissues and cells, which will be determined in accordance with the requirements referred to in Article 28(k), may, with the agreement of the competent authority or authorities, be distributed directly for immediate transplantation to the recipient as long as the supplier is provided with an accreditation, designation, authorisation or license for this activity.

Article 7

Inspections and control measures

1. Member States shall ensure that the competent authority or authorities organise inspections and that tissue establishments carry out appropriate control measures in order to ensure compliance with the requirements of this Directive.

2. Member States shall also ensure that appropriate control measures are in place for the procurement of human tissues and cells.

3. Inspections shall be organised and control measures shall be carried out by the competent authority or authorities on a regular basis. The interval between two inspections shall not exceed two years.

4. Such inspections and control measures shall be carried out by officials, representing the competent authority, who shall be empowered to:

(a) inspect tissue establishments and the facilities of any third parties as specified in Article 24;

(b) evaluate and verify the procedures and the activities carried out in tissue establishments and the facilities of third parties that are relevant to the requirements of this Directive;

(c) examine any documents or other records relating to the requirements of this Directive.

5. The competent authority or authorities shall organise inspections and carry out control measures as appropriate whenever there is any serious adverse reaction or serious adverse event. In addition, such an inspection shall be organised and control measures shall be carried out at the duly justified request of the competent authority or authorities in another Member State in any such case.

6. Member States shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out in relation to the requirements of this Directive.

Article 8

Traceability

1. Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa.

2. Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

3. All tissues and cells must be identified with a label that contains the information referred to in Article 28(g) and (i).

4. The procedures for ensuring traceability at Community level shall be established by the Commission in accordance with the procedure referred to in Article 29(2).

Article 9

Import/export of human tissues and cells

1. Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those Member States that receive such imports from third countries shall ensure that they meet standards of quality and safety equivalent to the ones laid down in this Directive.

2. Member States shall take all necessary measures to ensure that all exports of tissues and cells to third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those Member States that send such exports to third countries shall ensure that the exports comply with the requirements of this Directive.

3. (a) The import or export of tissues and cells referred to in Article 6(5) may be authorised directly by the competent authority or authorities.

(b) In case of emergency, the import or export of certain tissues and cells may be authorised directly by the competent authority or authorities.

(c) The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive.

4. The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission in accordance with the procedure referred to in Article 29(2).

Article 10

Register of tissue establishments and reporting obligations

1. Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and of the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(g). They shall submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible.

2. The competent authority or authorities shall establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been accredited, designated, authorised or licensed.

3. Member States and the Commission shall establish a network linking the national tissue establishment registers.

Article 11

Notification of serious adverse events and reactions

1. Member States shall ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

2. All persons or establishments using human tissues and cells regulated by this Directive shall report any relevant information to establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety control.

3. The responsible person referred to in Article 17 shall ensure that the competent authority or authorities is or are notified of any serious adverse events and reactions referred to in paragraph 1 and is or are provided with a report analysing the cause and the ensuing outcome.

4. The procedure for notifying serious adverse events and reactions shall be established by the Commission in accordance with the procedure referred to in Article 29(2).

5. Each tissue establishment shall ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any product which may be related to an adverse event or reaction.

CHAPTER III

DONOR SELECTION AND EVALUATION

Article 12

Principles governing tissue and cell donation

1. Member States shall take the necessary measures to encourage voluntary and unpaid donations of human tissues and cells with a view to ensuring that, insofar as is possible, they are obtained from such donations.

Member States shall report to the Commission on these measures before . . . (*) and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take at Community level.

2. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage.

3. Member States shall encourage the procurement of tissues and cells to be carried out on a non-profit basis.

Article 13

Consent

1. The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.

2. Member States shall, in keeping with their national legislation, take all necessary measures to ensure that donors, their relatives or any persons granting authorisation on behalf of the donors are provided with all appropriate information as referred to in Article 28(d).

Article 14

Data protection and confidentiality

1. Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive and to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.

(*) Two years after the entry into force of this Directive.

2. For that purpose, they shall ensure that:

(a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) procedures are in place to resolve data discrepancies;

(c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.

3. Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions for disclosure.

Article 15

Selection, evaluation and procurement

1. The activities related to tissue procurement shall be carried out in such a way as to ensure that donor evaluation and selection is carried out in accordance with the requirements referred to in Article 28(e) and (f) and that the tissues and cells are procured, packaged and transported in accordance with the requirements referred to in Article 28(g).

2. In the case of an autologous donation, the suitability criteria shall be established in accordance with the requirements referred to in Article 28(e).

3. The results of the donor evaluation and testing procedures shall be documented and any major anomalies shall be reported in accordance with the requirements referred to in Article 28(d).

4. The competent authority or authorities shall ensure that all activities related to tissue procurement are carried out in accordance with the requirements referred to in Article 28(g).

5. In the case of cells used for reproduction purposes, the conditions for donor selection, evaluation and procurement shall be laid down in accordance with the requirements referred to in Article 28(j).

CHAPTER IV

PROVISIONS ON THE QUALITY AND SAFETY OF TISSUES AND CELLS

Article 16

Quality management

1. Member States shall take all necessary measures to ensure that each tissue establishment puts in place and updates a quality system based on the principles of good practice.

2. The Commission shall establish the Community standards and specifications referred to in Article 28(c) for activities relating to a quality system.

3. Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:

— standard operating procedures,

— guidelines,

— training and reference manuals,

— reporting forms,

— donor records,

— information on the final destination of tissues or cells.

4. Tissue establishments shall take all necessary measures to ensure that this documentation is available for inspection by the competent authority or authorities.

5. Tissue establishments shall keep the data required for full traceability for a minimum of 30 years. Data storage may also be in electronic form.

Article 17

Responsible person

1. Every tissue establishment shall designate a responsible person who shall at least fulfil the following conditions and have the following qualifications:

(a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

(b) at least two years' practical experience in the relevant fields.

2. The person designated under paragraph 1 shall be responsible for:

(a) ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with this Directive and with the laws in force in the Member State;

(b) providing information to the competent authority or authorities as required in Article 6;

(c) implementing the requirements of Articles 7, 10, 11, 15, 16 and 18 to 24 within the tissue establishment.

3. Tissue establishments shall inform the competent authority or authorities of the name of the responsible person referred to in paragraph 1. Where the responsible person is permanently or temporarily replaced, the tissue establishment shall immediately inform the competent authority of the name of the new responsible person and the date on which the duties of that person commence.

Article 18

Personnel

Personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells in a tissue establishment shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28(c).

Article 19

Tissue and cell reception

1. Tissue establishments shall ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to Article 28(f) and that the selection and acceptance of tissues and cells comply with the requirements referred to in Article 28(g).

2. Tissue establishments shall ensure that human tissue and cells and associated documentation comply with the requirements referred to in Article 28(g).

3. Tissue establishments shall verify and record the fact that the packaging of human tissue and cells received complies with the requirements referred to in Article 28(g). All tissues and cells that do not comply with those provisions shall be discarded.

4. The acceptance or rejection of received tissues/cells shall be documented.

5. Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with Article 8.

6. Tissue and cells shall be held in quarantine until such time as the requirements relating to donor testing and information have been met in accordance with Article 15.

Article 20

Tissue and cell processing

1. Tissue establishments shall include in their standard operating procedures all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions. Tissue establishments shall ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in Article 28(i).

2. Any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in paragraph 1.

3. Tissue establishments shall include in their standard operating procedures special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel.

Article 21

Tissue and cell storage conditions

1. Tissue establishments shall ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in Article 28(i).

2. Tissue establishments shall ensure that all storage processes are carried out under controlled conditions.

3. Tissue establishments shall establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells.

4. Processed tissues or cells shall not be distributed until all the requirements laid down in this Directive have been met.

Article 22

Labelling, documentation and packaging

Tissue establishments shall ensure that labelling, documentation and packaging conform to the requirements referred to in Article 28(g).

Article 23

Distribution

Tissue establishments shall ensure the quality of tissues and cells during distribution. Distribution conditions shall comply with the requirements referred to in Article 28(i).

Article 24

Relations between tissue establishments and third parties

1. Tissue establishments shall establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances:

(a) where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party;

(b) where a third party provides goods and services that affect tissue or cell quality and safety assurance;

(c) where a tissue establishment provides services to a tissue establishment which is not accredited;

(d) where a tissue establishment distributes tissue or cells processed by third parties.

2. Tissue establishments shall evaluate and select third parties on the basis of their ability to meet the standards laid down in this Directive.

3. Tissue establishments shall keep a complete list of the agreements referred to in paragraph 1 that they have established with third parties.

4. Agreements between tissue establishments and third parties shall specify the responsibilities of the third parties and detailed procedures.

5. Tissue establishments shall provide copies of agreements with third parties at the request of the competent authority or authorities.

CHAPTER V

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 25

Coding of information

1. Member States shall establish a system for the identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8.

2. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells.

Article 26

Reports

1. Member States shall send the Commission, before . . . (*) and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

2. The Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions the reports submitted by the Member States on experience gained in implementing this Directive.

3. Before . . . (**) and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of the requirements of this Directive, in particular as regards inspection and monitoring.

Article 27

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by . . . (***) and shall notify it without delay of any subsequent amendments affecting them.

CHAPTER VI

CONSULTATION OF COMMITTEES

Article 28

Technical requirements and their adaptation to scientific and technical progress

The following technical requirements and their adaptation to scientific and technical progress shall be decided in accordance with the procedure referred to in Article 29(2):

(a) requirements for the accreditation, designation, authorisation or licensing of tissue establishments;

(b) requirements for the procurement of human tissues and cells;

(c) quality system, including training;

(d) information to be provided on the donation of cells and/or tissues;

(e) selection criteria for the donor of tissues and/or cells;

(f) laboratory tests required for donors;

(g) cell and/or tissue procurement procedures and reception at the tissue establishment;

(h) requirements for the tissue and cell preparation process;

(i) tissue and cell processing, storage and distribution;

(j) determination of conditions for the selection, evaluation and procurement of cells used for reproduction purposes;

(k) requirements for the direct distribution to the recipient of specific tissues and cells.

Article 29

Committee

1. The Commission shall be assisted by a Committee.

(*) Five years after the entry into force of this Directive.

(**) Four years after the entry into force of this Directive.

(***) Two years after the entry into force of this Directive.

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

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

3. The Committee shall adopt its rules of procedure.

Article 30

Consultation of one or more Scientific Committees

The Commission may consult the relevant Scientific Committee(s) when defining or adapting the technical requirements referred to in Article 28 to scientific and technical progress.

CHAPTER VII

FINAL PROVISIONS

Article 31

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than . . . (*). They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States may decide for one year after the date laid down in the first subparagraph of paragraph 1 not to apply the requirements of this Directive to tissue establishments bound by national provisions before the entry into force of this Directive.

3. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 32

Entry into force

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

Article 33

Addressees

This Directive is addressed to the Member States.

. . .

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

(*) 24 months after the date of entry into force of this Directive.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 20 June 2002 the Commission forwarded to the Council a proposal for a directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ([1]).

   The European Economic and Social Committee delivered its opinion ([2]) on the proposal on 11 December 2002.

   The European Parliament delivered its opinion ([3]) on 10 April 2003.

2. Following delivery of the European Parliament's opinion, the Commission forwarded to the Council an amended proposal (see document 10122/03 SAN 130 CODEC 779).

3. On 22 July 2003 the Council adopted its common position in accordance with Article 251(2) of the Treaty.

II. OBJECTIVES

The Commission's proposed Directive is intended to set detailed quality and safety standards for human tissues and cells for human applications, with respect to the activities ranging from their procurement up to their distribution.

In particular the proposed Directive:

— sets requirements for the accreditation of the establishments involved in these activities, inspections, control measures, etc.;

— provides for the traceability of donated tissues and cells, as well as the regulation of imports and exports of these substances;

— provides for principles, minimum standards and obligatory procedures for the whole chain (donation, procurement, testing, processing, storage and distribution);

— sets minimum applicable quality and safety standards, including professional qualifications and required training.

III. ANALYSIS OF THE COMMON POSITION ([4])

A. AMENDED COMMISSION PROPOSAL

The Council's common position is to a great extent in line with the Commission's amended proposal.

In particular, the Council shares the Commission's argument that amendments of an ethical nature are not acceptable, since they fall outside the scope of Article 152 of the Treaty. The Council has however agreed to insert a general reference in the preamble to the need for altruism and non-profit procurement (recital 16). The Council further notes that the Commission in its amended proposal introduced the clarification of provisions, as a result of their examination of the proposed Directive by the Council.

The Council adopted — wholly, partly, or retaining only the substance — 15 of the 35 amendments adopted by the European Parliament, which were taken up, either wholly or in part, in the Commission's proposal.

([1]) OJ C 227 E, 24.9.2002, p. 505.

([2]) OJ C 85, 8.4.2003, p. 44.

([3]) Not yet published in the Official Journal.

([4]) The numbering of the recitals and Articles follows that adopted in the common position.

B. AMENDMENTS ACCEPTED BY THE COMMISSION BUT NOT TAKEN UP IN THE COMMON POSITION

These were *amendments 78, 12, 13, 20, 80, 32, 38, 55, 56, 57, 58, 63, 64, 66, 69, 85, 72, 74, 75 and 76*.

Amendment 78

The Council considers that, given the Directive's legal basis, this amendment falls outside the scope of the Directive. Moreover, the Council considers that the initial Commission's text is more appropriate, whereas the essence of the Parliament's amendment is covered by the current text of Article 4(3).

Amendment 12

The Council considers that this amendment falls outside the scope of the Directive.

Amendment 13

The Council considers that the text adopted in the common position reflects in the best way the current situation, with respect to the international texts concerned.

Amendment 20

The proposed insertion of an explicit reference to those specific categories of cells and tissues is not needed, since they are covered by the current text of the proposal.

Amendment 80

The aim pursued with this amendment is adequately covered, according to the Council, both by recital 11 and Article 4(3) of the Directive.

Amendment 32

The essence of the amendment is reflected in Article 10(1) of the common position.

Amendment 38

The proposed additional text is rather vague and may result in legal uncertainty. This amendment would be unworkable in practice, since it would mean applying traceability requirements to everything (including gloves, test tubes, etc.) that could come into contact with tissues and cells.

Amendment 55

The Council considers that two years of experience in the relevant fields are sufficient.

Amendment 56

The Council considers that the aim pursued with this amendment is reflected in recital 14, which provides for the respect of the dignity of the deceased donor. Moreover, such an issue could be examined in the context of the requirements for procurement, through the comitology procedure.

Amendment 57

The Council considers that the aim of the amendment is sufficiently covered by the text in the first sentence of Article 24(1) of the common position.

Amendment 58

Refers to text which has been deleted.

Amendments 63, 64, 66, 69, 85, 72, 74, 75 and 76

Refer to the Annexes of the initial Commission's proposal, which, according to the common position, are referred in their entirety to the comitology procedure (cf. part D).

C. AMENDMENTS REJECTED BY THE COMMISSION BUT TAKEN UP IN THE COMMON POSITION

Amendments 4, 5 and 6 were accepted wholly or in part.

D. PRINCIPAL CHANGES INTRODUCED BY THE COUNCIL

The Council introduced a series of amendments to the amended Commission's proposal, particularly in order to clarify the provisions and ensure a more efficient implementation of the Directive, while safeguarding the Member States' competence.

The Council introduced the following main changes:

The Member States' competence in implementing the Directive

The necessary margin of manoeuvre left to the Member States with respect to various aspects of the Directive, given the scope of Article 152 of the Treaty, has been further reaffirmed in certain cases, such as the matter of publicity or promotion activities in this field (Article 12(2)) or as regards access to the donated tissues and cells (deletion of Article 25 of the Commission's proposal).

Enhancement of the accreditation requirements (Article 6)

An accreditation requirement not only for the establishments dealing with tissues and cells in their activities, but also for the procedures that they perform has been introduced, in order to guarantee the efficient application of the Directive.

Reference of the Annexes to the comitology procedure (Article 28)

The Council considers appropriate to refer the matters treated by the Annexes in the Commission's proposal to the regulatory committee procedure, given the advantages of the latter for regulating very detailed and technical requirements in connection with the application of the Directive.

The list of the technical requirements (Article 28) is made more complete, with the introduction in the list of provisions concerning the elaboration of requirements for the accreditation, designation, authorisation or licensing of tissue establishments, for the tissue and cell preparation process, for the determination of conditions for the selection, evaluation and procurement of cells used for reproduction purposes, as well as of requirements for the direct distribution to the recipient of specific tissues and cells (Article 28(a), (h), (j) and (k)).

Other changes

— The requirement for the notification of serious adverse events and reactions (Article 11(2)) is extended to all personnel involved in the process.

— A new recital was adopted (recital 9) clarifying the legal status of cosmetic products. Some definitions were deleted whenever deemed to be unnecessary (tissue bank and tissue procurement team) or replaced by a comprehensive definition. New definitions have been inserted to the text (donation and storage).

— Certain terms and provisions throughout the text have been differentiated in comparison to the Commission's amended text, without nevertheless any substantial change to their actual content.