COMMISSION OF THE EUROPEAN COMMUNITIES

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2002/0128 (COD)

C5-0066-04

OPINION OF THE COMMISSION

pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the 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, storage, and distribution of human tissues and cells

AMENDING THE PROPOSAL OF THE COMMISSION
pursuant to Article 250 (2) of the EC Treaty

2002/0128 (COD)

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1. INTRODUCTION

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the amendments proposed by Parliament.

2. BACKGROUND

Date of transmission of the proposal[1] to the European Parliament and the Council (2002/0128(COD))	20.06.2002
Date of the opinion of the European Economic and Social Committee[2]	11.12.2002
Date of the opinion of the European Parliament[3], first reading:	10.04.2003
Date of transmission of the amended proposal (10122/03 SAN 130 CODEC 779).	30.05.2003
Date of adoption of the common position[4]:	22.07.2003
Adoption by Parliament of the Resolution, second reading :	16.12.2003

3. PURPOSE OF THE PROPOSAL

The aims of this proposal are to establish European Community legislation setting standards for the quality and safety of tissues and cells of human origin used for application in the human body, in particular to strengthen suitability and screening of donors, and establish requirements for establishments and their accreditation.

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1 OJ C 227 E, 24.09.2002, p.505.
2 OJ C 85, 08.04.2003, p.44.
3 Not yet published in the OJ.
4 OJ C 240 E, 7.10.2003, p. 12.

The text also provides a mechanism for lay down provisions for a register of accredited establishments, quality system, training, traceability and regulation of imports and exports.

4. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

A compromise package concerning the proposed amendments of the European Parliament and which includes three draft declarations involving the Commission(in the attached annex), was submitted to the European Parliament for the Plenary session on 15 December 2003 with the endorsement of the Council.

The amendments approved by the Parliament reflect the compromise agreement reached between Parliament and Council, the compromise is acceptable to the Commission. These amendments are in line with the Common position of the Council, accepted by the Commission[5], and they respect all issues considered essential by the Commission to guarantee a high level of protection in the area of quality and safety of human tissues and cells.

The following amendments were accepted: 4, 6, 12, 23, 25, 27, 37, 45, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 and 77. They concern:

Amendment 4, recital on promotion of worldwide standards; Amendment 6, recital for clarification of the scope; Amendment 12, recital for clarification on accreditation of establishments; Amendments 23, 27, 67 and 73, on traceability; Amendment 25 on labelling; Amendment 37, 75 and 76 clarification on comitology; Amendment 45, clarification on the roles of third parties; Amendment 57, recital on promotion of donation, Amendment 58 clarification on specific risks of cells, Amendment 59, recital on equal access and transparency; Amendment 60, recital on reconstruction of the donor's body; Amendment 61 and 69 on voluntary and unpaid donations; Amendment 62, recital on access to tissues and cells for establishments; Amendment 63, mention of the chapter of human rights and the Convention; Amendments 64 and 72 on anonymity; Amendment 65, recital on comitology; Amendment 66, guidelines for inspection and training; Amendment 68 on import; Amendment 70 on non profit procurement; Amendment 71, editorial clarification; Amendment 74 on provisions in case of termination of activities in the tissue establishments and Amendment 77, new annex on information to the donor.

5. CONCLUSION

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal as set out above.

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[5] Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells /* SEC/2003/0906 final - COD 2002/0128.

ANNEX

Declarations of the commission within the framework of the second reading on the proposal setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells

Declaration on Organ Transplantation

"The important differences between organ transplantation and the use of other human substances such as blood, tissues and cells mean that a specific approach for organs in order to ensure safety and quality is necessary.

Such an approach in the current situation characterised by shortage of organs has to balance two factors: the need for organs' transplantation which is usually a matter of life and death with the need to ensure high standards of quality and safety.

The Commission believes that before considering any proposal it is necessary to conduct a thorough scientific evaluation of the situation regarding organ transplantation. The Commission will present a report on the conclusions of the analysis it undertakes as soon as possible."

Declaration on the future development of the relevant technical criteria

"In the absence of specific Community legislation on the processing, preservation, storage and distribution of tissues and cells intended for industrially manufactured products the Council and the Commission agree that the concerns raised by the Parliament in respect of the requirements to be determined for establishments operating in this field, such as the requirement to operate on a 24-hour basis, will be addressed in the development of the relevant technical requirements referred to in article 28 of the Directive".

Declaration on the future development of the relevant technical criteria

"The Council and the Commission agree that the concerns raised by the Parliament at first reading as regards the Annexes originally proposed by the Commission will be taken into account in the development of the relevant technical requirements referred to in article 28 of the Directive "